Recordati S.P.A

"Acquisition of Global Rights to Enjaymo Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati Acquisition of Global Rights of Enjaymo 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. Eugenia Litz, Vice President of Investor Relations of Recordati. Please go ahead, Madam.

EUGENIA LITZ: Thank you, and good afternoon, everyone. I'm very pleased to introduce Rob Koremans, our CEO and Scott Pescatore, Executive Vice President of Rare Diseases. Together, they will provide an update on our agreement to acquire the Global Rights to Enjaymo. Also joining for the Q&A session will be Luigi La Corte, our CFO. As always, the presentation is available in the investor section of our website.

It is now my pleasure to pass the call over to Rob. Please go ahead.

ROBERT KOREMANS: Thank you, Eugenia, and good morning, good afternoon, and thank you for joining us. We are extremely pleased to update you today on our agreement with Sanofi to acquire the Global Rights to Enjaymo. The transaction reaffirms our commitment to addressing serious unmet needs in rare diseases and is a perfect strategic fit with an attractive product and a great financial profile.

Enjaymo provides patients with cold agglutinin disease a novel treatment option as the only approved targeted product launched in 2022, in the US, Europe, and Japan, it has a broad geographic footprint and fast uptake with last 12 month sales of approximately €100 million.

Enjaymo complements our current rare disease portfolio in an area of high unmet medical need and is synergistic with Sylvant, with hematologists as the key target physicians. We aim to retain all Sanofi employees in scope to continue enhancing the global support for Enjaymo.

On the financial side, we expect the 2025 revenue of greater than €150 million and peak sales in the range of €250 million to €300 million. After a successful closing of the deal, we anticipate an immediate positive EBITDA contribution with margins expected to be accretive to our current rare disease business from 2025 onwards.

Lastly, I would really like to highlight the de-risked deal structure, with commercial milestones subject to achievements of net sales at or above the top end of our peak year sales expectations.

Now, I would like to turn the call over to Scott to provide more details on Enjaymo and on the CAD market. Scott.

SCOTT PESCATORE: Thanks, Rob. It's my great pleasure to provide some more insights into Enjaymo and the CAD market. Starting with the market, CAD is a rare B-cell lymphoproliferative disorder and is caused by autoantibodies from B-cells binding to erythrocytes, leading to their aggregation and destruction through the classical complement system.

This condition is seriously debilitating for patients, causing severe fatigue, risk of thrombosis, and cold-induced circulatory symptoms, all of which significantly impact their quality of life. In the US, Japan, and Europe, there are approximately 11,000 to 12,000 patients, and the median onset of age is about 66 years, and unfortunately, there are very limited current treatment options available. The dynamics of the CAD market highlight

the significant unmet medical need and emphasize the importance of Enjaymo as a treatment option for patients.

Now, turning a bit to Enjaymo and as you recall, it's the only approved product for CAD. It's administered as an IV, Enjaymo is indicated for patients, who do not respond to first-line treatment or who are experiencing severe anemia.

Enjaymo is a biologic with IP exclusivity in the US and Japan until 2036, and in Europe until 2037. We anticipate limited competition in the mid-term. As for the mechanism of action, the classical complement pathway activation in CAD results in red blood cell destruction. Enjaymo intervenes by binding to C1s, which is a part of this pathway.

Enjaymo was approved based on very compelling results from the Phase 3 CADENZA trial, where 73% of patients met all 3 key indicators, significant hemoglobin increase, transfusion dependence, and no need for additional treatment. Finally, on the right side of the slide, you'll find some additional financial highlights that Rob just covered.

With that, I'd like to turn the call back over to Rob for the financial summary of the transaction. Rob.

ROBERT KOREMANS: Thanks, Scott. Yes, as already indicated, we anticipate 2025 revenue to exceed €150 million, with peak sales between €250 million and €300 million.

EBITDA margin should positively impact our rare disease business starting in 2025, and we expect non-recurring cost of around €10 million. Depending on the closing date, we expect minimal financial contributions in 2024. The agreement includes an upfront payment of $825 million and

potential additional commercial milestones up to $250 million if net sales meets or exceeds the highest expectations for peak year sales.

We are financing the transaction with existing cash and committed debt facilities. This will result in a leverage between 2.4 and 2.5 times EBITDA pro forma by year end and decreasing to below 2 times in 2025 if there is no additional BD.

Our dividend and capital allocation policy remain unchanged. The transaction is expected to close by the end of 2024, and is subject to regulatory clearances, of course.

Before concluding, I would like to sincerely thank Gabriele Finzi, our Executive VP of BD, his team and many others throughout the organization who have worked diligently on this transaction. I would also like to thank Sanofi for the very constructive discussions and the results we achieved together.

Now, together with Scott and Luigi, we are ready and happy to open the call for questions.

Q&A

OPERATOR: Thank you. This is the Chorus Call conference operator. We will now begin the question and answer session. Anyone who wishes to ask a question may press "*" and "1" on their touchtone telephone. To remove yourself from the question queue, please press "*" and "2." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Brian Balchin with Jefferies. Please go ahead.

ANALYST: Hey guys, Brian here. So, just on the peak sales guide of up to €300 million, I believe that's only for CAD, isn't it, so it'd be great to get your thoughts on potential label expansion, for instance, to warm autoimmune hemolytic anemia?

And then just on the manufacturing, would it be correct to assume similar to what you currently have with GSK on Avodart/Combodart and that you book transfer price to COGS?

ROBERT KOREMANS: Hi, Brian. Thanks. The peak sales do relate to the labeled indication. I don't want to speculate before the deal is closed on anything potentially beyond that. So, as I said, we expect this closing by the end of this year, but it's obviously subject to the authorities' approval of this, and I don't think we should do anything that speculates on what is there beyond what we have communicated at the moment.

We have cost of goods that are very favorable in terms of EBITDA contribution for our business, and the production is at the moment with Biogen and Vetter, and the combination of that is actually very favorable for us and we'll continue with that supply chain. So, it's different from the GSK deal where really they make all of the finished products and get a fairly high margin. So, we have a much more attractive margin construct here with Enjaymo.

LUIGI LA CORTE: We do not share the economics through the supply price as we did on the GSK deal. This is upfront and milestones only.

ANALYST: Got it. Super. Thank you, guys.

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

ISACCO BRAMBILLA: Hi, good afternoon, everybody. Thanks for the presentation. Congratulations for the deal, which looks a compelling one, both financially and strategically. A couple of questions on my side. The first one is on the performance recorded so far by Enjaymo based on data reported by Sanofi in the first half of 2024 revenues in Europe are already almost doubling the results posted in 2023 in the full-year. Could you elaborate a bit more on the timing of launches in Europe so far for Enjaymo and just tell us if there is any relevant market still missing. Also, fair to see growth in Europe as the main driver of the acceleration from last month's sales to your indication for 2025?

Second question is on net financial position. Are you going to include the earn out in your net financial position and the clarification on your pro forma leverage for 2024? Is it including the last 12-month EBITDA by Enjaymo?

ROBERT KOREMANS: Luigi, you want to take the second question, first?

LUIGI LA CORTE: Yes, we always put a pro forma for trading last 12 months as if we've done the benefit of the economics from you know, the 12 month basis. It's quite customary to do that.

And in terms of…do we already recognize now the liability? No, under accounting standards, this is subject to regulatory approval, once we have the regulatory approval and the deal closes, we would be recognizing the liability for the payment at that stage.

SCOTT PESCATORE: Thanks, Luigi. This is Scott. Perhaps I can circle back to your first question. And basically I can tell you, we don't have all of the details and we don't provide the split by country or by region in terms of the sales. But what we know so far for 2024 is that sales are progressing quite positively. They've done more than €100 million for the last 12 months. And moving into next year with regards to the regional rollout, it really comes down to increased diagnosis, increased penetration. And as we all know, when we have an approved product and indication, the increased disease awareness allows us to treat more patients. So we'll be focusing in those 3 areas as we continue to integrate the product and drive the sales into next year.

ISACCO BRAMBILLA: Okay, thanks both.

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

NICCOLO STORER: Good afternoon, gents and thanks for taking my few questions. The first one is on peak sales. I see that in the presentation, you write about patent expiry, et cetera, but considering the fast uptake, when do you think you will reach the €250 million, €300 million or at least get close to those numbers?

The second one is on further geographical expansion. Do you think that you might have the possibility to bring this enzyme also beyond the 3 markets in which it is today?

And the last one may be a clarification on milestones to be paid. How does it work, the mechanism, because it's not clear to me, are you getting…are you paying some money if you get to the peak sales and additional money if you're getting to more than peak sales? And is the timing related to this payment linked to when actually you're reaching

peak sales or is maybe more linked to the time when patents are expiring? Can you clarify a little bit more? Thank you.

ROBERT KOREMANS: Hi, Niccolo. So at this point, as we haven't closed the deal and still really subject to the approval and from the regulatory authorities, I am very uncomfortable to give any detail on this product that we don't own. It's currently owned by Sanofi. We gave peak sales of €250 million to €300 million. I don't want to get into details as to when we expect it and what the plans are for geographic expansion at this point in time. The moment this is closed, we are more than happy to give more details on our plans with this product going forward. At this moment, it would just not be the right thing to do.

We will pay commercial milestones when certain net revenues are achieved, which is typically what you do with commercial milestones. And beyond that, there's no meaningful royalty. We have a down payment and the commercial milestones, and it's basically a very straightforward, lean and simple deal structure.

LUIGI LA CORTE: And maybe, Rob, I'll just add on that, because I think it was maybe part of the question that I had earlier. I mean, as we said, the threshold for these are at or above the peak sales guidance that we've provided. So when we get to it, you know, we'll discuss with auditors, under IFRS3 to what extent any or part of those milestones need to be recognized at that time as mobility. But again, given where the thresholds are, we'll have to have that discussion.

NICCOLO STORER: Thank you. Maybe a quick follow-up for Luigi. How much new debt are you taking on to finance this deal? Which is the mix between new and available finances?

LUIGI LA CORTE: Yes, most is new Niccolo. We always like to keep balance of cash on hand. Of course, it's a cash generating business. As you know, we were back below 1.8 times leverage at the end of Q2. Q3 is usually a quarter where we generate cash and we reduce that further ahead of the interim dividend. So I assume most of it will be new facilities. You may recall we said when we did the GSK deal, we took down one facility which also had a further piece that we could draw down as needed. So it'll be a mixture of those, but you should assume mostly new debt and mostly at rates which are consistent with our current financing arrangements. And it's nice to see interest rates coming down around the world.

NICCOLO STORER: Thank you.

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

GIORGIO TAVOLINI: Hi, good morning, gentlemen. Thank you for taking my 3 questions, please. I may have missed this detail. I don't know if you are in the position to disclose it. What is the duration of the Enjaymo licensing agreement with Sanofi, and if it extends beyond the expiration of the patent?

The second one is regarding the synergies with Sylvant in oncology, as you mentioned in the press release. So what is the expected magnitude, or if you can provide more color on the commercial synergies?

And the third one is on the non-recurring costs of approximately €10 million. I was wondering if they are related to the R&D activity. Thank you.

LUIGI LA CORTE: Maybe I can take the last one first, if that's okay. So the non-recurring costs are, as customary in the case of an acquisition, as is this deal, a number of transaction-related costs which IFRS3 does not allow to add to intangibles. So those will go through the P&L. The cash component of this, we estimate below €10 million. It's mostly customary insurances that we'll take out. There'll be some transition costs and small advisory costs that we've incurred. Some of the €10 million have been incurred already in Q2…Q3, and to the tune of €3 million or thereabouts, and the balance most likely by the end of the year. We obviously have to go to a purchase price allocation, similar to when we did the EUSA deal, some non-cash adjustments that we'll have to do to the reported financials, particularly around the initial inventory that we purchased, but we'll provide more details on those when the deal closes. Hopefully that addresses that one question.

GIORGIO TAVOLINI: Thank you.

ROBERT KOREMANS: And, Giorgio, maybe the other part to address as we have acquired the global rights, the ownership of Enjaymo, so there's no license and there is no end to it. This is our product. It needs to be approved by the authorities, and after the authorities have approved it, this is going be in our hands. The IP position is quite strong and it's until 2036 in the US and Japan, and the end of 2037 in Europe. And this is a monoclonal antibody, so expensive and difficult to produce. And with our peak sales expectations, this typically is not an attractive target for any generic to try and copy. But we're well beyond that at the moment. So with the IP exclusivity, we have a really good and fantastic protection.

And I'll pass to Scott for the synergies with Sylvant.

SCOTT PESCATORE: Thanks, Rob. Thanks, Giorgio, for the question. I think with regards to the synergies with Sylvant, maybe I'd take a step back and I'd look at really what the synergies are with our existing organization. As you know, we've had Sylvant available in both the US and Europe for quite some time now, so we have a very strong relationship with the hematologists in those markets, and we're excited to bring Enjaymo on board to further those relationships with this new opportunity. It's a little early right now to talk about structure, but one of our key priorities for the early days of the deal is to retain and integrate as many of the Sanofi colleagues as possible, and to really anticipate harnessing their background know-how to continue to optimally serve the patients with CAD in those markets.

GIORGIO TAVOLINI: Thank you very much.

OPERATOR: The next question is from Charles Pitman-King with Barclays. Please go ahead.

ANALYST: Hi, guys. Thank you very much for taking my questions, and congrats on the deal. Maybe just speaking a little bit more about your IP protection. Obviously, this has got a great run rate on it, and I understand you're not going give us more details on the milestones until the deal is closed. But maybe if you could just speak a little bit more about your commentary around the kind of competition for the midterm, just kind of what assets, I know that some assets have been terminated from development, and it looks like you're going to be alone for a while. Just how are you thinking about that competition over the longer term, and what are your kind of plans to mitigate that? And then just in terms of the fact that this is taking you up to kind of 2.5 times leverage for next year, but you're looking to de-lever, what sort of potential further M&A could we expect to see next year, given you seem to be kind of pushing with the standard one deal a

year strategy, which, you know, it looks great. So just further detail on that would be great. Thank you.

ROBERT KOREMANS: Thanks, Charles. A number of questions. First, thanks for the congratulations on the deal. We're also super happy with it. And more details on the IP, there really isn't, right? So the patents look strong, very, very healthy, and both in the US and Japan, last until 2036. In Europe, to 2037, and this being a monoclonal antibody gives additional protection. And then, as you know, rare disease products and patients and the entire market generics work a bit different anyway, but you're looking fairly far into the future. So we feel very secure with the patent protection and the IP on this as we speak.

To answer your question on further deals, we've always stressed that, and traditionally, Recordati has been not only been good at doing deals, but doing deals that bring a fantastic return on capital employed. We're good at integrating, and I'm very optimistic that once this is approved by the authorities, we'll do a good business on this as well and serving patients in need. We continue to be active in both rare disease and on our traditional SPC business to look at the right deal for us to continue our growth path. And of course, immediately after this, we're not going to do something immediately sizable. I really want to focus on making sure that we land and integrate and continue to serve patients with CAD to our best ability and as good as we can, but we'll continue to be active in this field. So Gabriele and his team have a weekend of rest and then the journey continues.

The competitive landscape, I'll pass to Scott to give a little bit more of a background to that, if that's okay.

ANALYST: I was just clarifying that I'm talking about the kind of competition from other assets as opposed to the IP of your asset, but you're about to speak about that, so that's great. Thank you.

SCOTT PESCATORE: Yes, no problem. So just to reiterate, as I said before, Enjaymo is the only approved product for CAD at the moment. There are a number of off-label treatments that are currently available that people are using to treat CAD, but again, this is only on-label treatment for CAD.

With regards to future competition, we know that there are a couple that are being developed now that have CAD as part of their development portfolio. There's the ANX1502, the Annexon compound, which is also a C1 inhibitor. That's in Phase 2, but from our understanding they're considering going after other indications with that molecule. And then there's a follow-up compound from Sanofi, the Riliprubart C1 inhibitor, and they made a statement not too long ago that they will cease development for the CAD indication for that molecule. So while there are some things in development, we have to obviously keep an eye on, for the time being, we're the only approved treatment and we'll continue in that direction.

ROBERT KOREMANS: And maybe to add to that, also in a very effective treatment, right? So there's an incredibly good response rate for CAD. And what we've seen is that, whereas many have tried to develop in this indication, everyone basically had to stop this, and this is really the only product, Enjaymo is the only product that made it to market and has been successfully developed with an incredibly good efficacy and safety profile. So we're very confident on the ability of Enjaymo to continue to help patients address this serious situation and disease, and confident about the possibility to achieve our targets there.

ANALYST: That's great, thank you very much.

OPERATOR: The next question is from Niall Alexander with Deutsche Bank. Please go ahead.

NIALL ALEXANDER: Hi, how's it going? It's Niall from Deutsche Bank. Thanks for taking my question. So first one, just on M&A, just to push a little bit, I know typically you'll switch your focus between the segments, so potentially, is it fair to say that the next deal you would go for could be an SPC, or do you feel you perhaps keep pursuing something in rare diseases? That's the first question.

And then the second is on just the rare disease margins. Now, obviously we've seen a decline in recent quarters in that margin, but I'm just wondering if with this deal, how the rare disease margin will play out now. Do you feel it will somewhat stabilize? It'd be helpful just to get your view on the outlook for the rare disease margin there. Thank you.

ROBERT KOREMANS: Thanks, Niall for the question. This deal has a margin that is above the average of our rare disease, so we'll improve the margins once it gets approved. I think one of the reasons why you've seen some pressure, on the still very, very attractive margins for our rare disease, is because there were also royalties, which in this deal we do not have. So we're very optimistic about the opportunity to really also help and push the already high margins for rare disease up a bit further when this product is available to us and further progresses.

On the nature of the next M&A, it's always very difficult to predict what's happened when. Like I said before, both businesses are equally important to us. The rare disease space offers beautiful opportunities, but so does SPC, and we'll keep the discipline after doing this, but also before this, we

were in no pressure to do a deal. This is just what we think a really good opportunity to, and strategic, fantastic fit, so we're very happy with the agreement with Sanofi. And we'll continue to pursue anything that makes sense for us and helps us to further strengthen our company and serve patients.

NIALL ALEXANDER: Great. Thank you very much.

OPERATOR: The next question is from Alistair Campbell with Royal Bank of Canada. Please go ahead.

ALISTAIR CAMPBELL: Well, hi, everyone. Not really a lot left to ask, but just a couple of ones, please. In terms of retaining Sanofi employees, I wonder if you can give us an indication of broadly how many people you think that might be, or at least which specific geographies you think might be strengthened through that. And then obviously, you're saying the synergy here in terms of adding it into an existing hematology franchise, but with Sanofi employees coming on board and this product coming on board, do you think this will increase your appetite to look for other hematology assets going forward from here? Thank you.

SCOTT PESCATORE: Thanks, Alistair, for the question. So your first question around the Sanofi employees, you know, like I mentioned, absolutely, we're looking forward to welcoming them on board. They're primarily coming mostly from the US, but we also have many colleagues that are joining us in the Japanese market and a couple that are coming in Europe, specifically in Germany. So like I said, it's early days now, but we're looking forward to our first interaction with them and beginning the transition to welcome them to Recordati.

And then with regards to your second question, yes, absolutely. I mean, oncology, since we acquired the EUSA portfolio a couple of years ago, it's been a key strategic growth driver for us. You've seen the phenomenal results that we've had with Qarziba and with Sylvant over the past couple of years. We anticipate, you know, obviously, similar success with Enjaymo and whatever else we can do in that space. It's up to Rob and Gabriele and the team to continue to drive new products in hematology and oncology in the future.

ROBERT KOREMANS: Now, I understand there's no more further questions. This is all very new and thank you for joining. Wishing you a wonderful Friday. And if there are questions further, we're very happy to engage with you. You can always reach out to Eugenia and her team. And as always, we'll be happy to try and answer what we can at this point in time. It's going to be easier for us to answer questions specifically on the future and the outlook on Enjaymo once the authorities have approved. And we're hopeful that they will do this by the end of this year, but that's always their choice. So thank you for joining and looking forward to engage with you in the future.