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Euroapi
Conference Call

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Euroapi Conference Call

Operator: Hello, and welcome to the Euroapi Conference Call. My name is Caroline, and I'll be your coordinator for today's event. Please note this call is being recorded, and for the duration of the call, your lines will be on listen-only mode. However, you will have the opportunity to ask questions at the end of the call. This can be done by pressing star one on your telephone keypad to register your questions. If you require assistance at any point, please press star zero and you will be connected to an operator.

I will now hand over the call to your host, Mr Guillaume Rosso, the Head of Investor Relations to begin today's conference. Thank you.

Guillaume Rosso: Good morning, everyone. And thank you for joining this call on a short notice. I am Guillaume Rosso, the Head of Investor Relations at Euroapi. As you are aware, we have issued earlier this morning a press release to provide an update on our guidance following the temporary and proactive suspension of prostaglandin production activities at our Budapest site.

I am today with Karl Rotthier, our CEO, and Antoine Delcour, our CFO, who will come back on the main element of this update, and then answer all the questions that you may have. A replay of this call will be available on Euroapi's Investor Relations webpage.

With that, I hand over to Karl.

Karl Rotthier: Thank you very much, Guillaume. Good morning, everybody. Let me start with a few words on the current situation at our Budapest site. And then I will let Antoine elaborate on the financial impact of our guidance.

With respect, in regard to our Budapest site, during a routine internal assessment, we identified some Good Manufacturing Practices documentation management deficiencies. These deficiencies were related to the production records of certain prostaglandin products, which are manufactured in a segregated production unit at this site. Based on our assessment, we consider that the prostaglandin products on the market are within specification and are, of course, suitable for their intended use.

Nevertheless, once we have identified these documentation management deficiencies, we proactively decided to pause batch releases, and, as a second step, to temporarily suspend our prostaglandin production. Of course, we also proactively informed the relevant health authorities in Hungary, and are in the process of informing the concerned customers as well.

At this stage, we estimate that prostaglandin production could remain suspended for a few weeks.

We are still finalising our assessments and we are building a robust action plan to remedy this situation, which will be shared with the relevant health authorities in due course. Nonetheless, I want to emphasise that we do not anticipate any impacts on the other activities of our Budapest site, including our CDMO activities.

As stated in the press release, the temporary and targeted pause of production will have some consequences also on our financial performance.

That's why I now hand over to Antoine, who will further elaborate on this point.

Antoine Delcour: Thank you, Karl. And good morning, everyone. Based on the information we have today, we expect this targeted suspension to have an impact on our 2022 full year guidance. We now anticipate net sales at circa €980 million versus around €1 billion previously and a core EBITDA margin between 12% and 13% in 2022 versus 14% of above previously.

The main factors behind this update are a combination of a loss of sales for those products, related provision, and remediation costs, which will be necessary to restart production and to ensure right oversight is in place.

I would like now to hand it back to Karl.

Karl Rotthier: Thanks, Antoine. Before we take your questions, let me reaffirm Euroapi's commitment to offering quality products in compliance with the highest level of standards and regulatory requirements. Because we stand at the heart of the pharmaceutical value chain from research to patient, we make transparency, reactiveness, and quality of our highest priorities.

We are currently building a remediation action plan to further strengthen our document management oversight for prostaglandins, which will allow us to resume our prostaglandin production activities as soon as possible.

With this, I would like to thank you for your attention. And Antoine and I will now be more than happy to take whatever questions that you might have. Thank you very much.

Questions and Answers

Operator: Thank you. As a reminder, if you would like to ask a question or make a contribution on today's call, please press star one on your telephone keypad. We can take the first question from line Falko from Deutsche Bank. The line is open now. Please go ahead.

Falko Friedrichs (Deutsche Bank): Thank you very much. Good morning, everyone. So I think my first question is an obvious one. Thanks for providing the impact for 2022. Will there also be any impact to your midterm guidance targets?

Then the second question is, what we've seen in the past when these situations happened is that companies often really turn every stone in other facilities as well. So do you intend to do that as well? And is there sort of the risk that these documentation problems could also arise in other facilities?

And then the third question is, do you think that this could set you back from a competitive standpoint in the prostaglandin's market? Thank you.

Karl Rotthier: Thank you very much for your questions. I will give the floor to Antoine in a second on the midterm guidance.

Regarding the other facilities, I think the production of prostaglandins is done in a very meticulous way, which is a bit different from the others. It is semi-automated, so also still manual sometimes, because of the huge complexity to produce prostaglandins. So that is why, I think, this particular incident where we reactive, proactive, where we saw some deficiencies, is different from the automated ones.

So, of course, we also discovered it via our routine quality batch records reviews after each production. That is also done in all the other sites, of course, where we release products. So in that respect, we really do think that this particular issue is really related to this particular prostaglandin production.

It will also require, of course – now that we have this internal assessment, the remediation action plan, we do not expect that this will put us in a less competitive way versus our competitors.

And then I think your first question, Antoine, a logic one, can you please respond to this?

Antoine Delcour: Yes. So on the 2025 guidance, it is really part of our process to review it on a regular basis. And at this stage, we have no update on this – on the midterm guidance.

Falko Friedrichs: Okay, thank you. And if I may ask a follow up. Can you share with us when we look at your total production or facilities, how much is roughly semi-automatic and how much is fully automatic?

Karl Rotthier: Well, I think we really put here, this prostaglandin production as the only one which is really not automated. That's why, also the quality review is done in a very, very, very meticulous way. And that's why we proactively, of course, also act upon it when we see that there are deficiencies. Rest is all automated.

Falko Friedrichs: Okay. And do you plan to proactively update us once the situation is resolved or will we only hear from you again when you report your full year results?

Karl Rotthier: We are, first of all, in continuous dialogue with the health authorities. I think that is the first and foremost. We also need to have the full remediation action plan ready. And then we will, of course, in full dialogue with the health authorities also decide on the restart of the production facilities.

Now, I think, it's logic that we, of course, also communicate further on that.

Falko Friedrichs: Okay, thank you.

Karl Rotthier: Thank you.

Operator: Thank you. We will take the next question from line Gary Steventon from BNP Paribas Exane. The line is open now. Please go ahead.

Karl Rotthier: Hi, Gary.

Operator: Apologise. Gary's line has been disconnected. Hi, Gary, can you please raise up question again? Thank you?

Karl Rotthier: Perhaps first another question.

Operator: Hi, Gary's line, yes, has been opened for question and answer. Thank you.

Gary Steventon (Exane BNP Paribas): Hi, can you hear me?

Karl Rotthier: Yes. Hi, Gary.

Gary Steventon: Perfect. Sorry, not sure what happened there. First question is just on the updated guidance, please. You're taking 20 million off the top line, which is quite explicit, but then giving that 1 to 2 percentage point range for the margin. And so I was really just wondering if you could share your thoughts over kind of what gets you towards the top end

versus the bottom end, and really where the uncertainty lies there and whether that's just related to the timeframe for restarting production?

And then secondly, if we look at the revenue impact, I'd assume that relates to the batch that has been paused, but you do use the language that it's been paused rather than it's been cancelled or could not be used. So is there an option to kind of subsequently release the batch to the customer once the remediation – given the remediation is related to documentation that has been completed? And then therefore, that €20 million or so of revenues can be booked, say, in 2023? So is that revenue now lost or is that something that's just going to be deferred into 2023? Thank you.

Karl Rotthier: Thank you very much, Gary, for your question. Now, there are a couple of elements which are important in this one. When you also discover these document deficiencies, also on a batch, that means that you, from a quality perspective, also need to immediately pause the release. You cannot release those batches anymore, because actually, when the documentation is wrong, the batch doesn't exist. Let me be very clear. So that's why that was the first step that we took.

And the second step that we took is to, indeed, also put the production on hold, because we really need to go, during an internal assessment, to the bottom to really find the root cause and to repair all these things.

We are here in the middle of the process to indeed see whether – depending on the restart of the production, whether we could pick this up in 2023. But this is too early to tell right now. On the turnover points, Antoine, and also the – perhaps more important question on the EBITDA points, can you elaborate a bit further?

Antoine Delcour: So on the top line impact, it's coming from a loss of prostaglandin sales, meaning, since – for the month of December, and then regarding the uncertainty, meaning, whatever range we are providing on core EBITDA margin, it encompass loss of margin of sales, which had been paused for the time being, and then also impact-related to destruction of inventories, potential destruction of the inventory, I would say, and remediation costs, that we are still assessing. And this is the reason why we provided a range for the core EBITDA at this stage.

Gary Steventon: Okay, perfect. Can I just follow up on that second point there. Can you give or can you help us at all with the split between the margin impact on those three elements you just mentioned?

Antoine Delcour: No, we do not – I mean, I guess, we mentioned a few times, we do not provide the level of margin we're making on our products. So I cannot comment on this aspect.

Gary Steventon: Okay, thank you.

Operator: Thank you. As a reminder, if you would like to ask a question, please signal by pressing star one on your telephone keypad. We will take the next question from line Richard Vosser from JP Morgan. The line is open now. Please go ahead.

Richard Vosser (JP Morgan): Hi, thanks for taking my questions. Just to follow up on '23 and prostaglandin sales. If we – I think you mentioned that the 20 million related to prostaglandin sales or the batches is in December. How should we think about sort of an annualization of that effect if the restart takes a little bit longer than anticipated? So just

thoughts on if this stays down for six months, how should we think about that? Or were your comments more related to sort of the recovery of the 20 million that could be pushed into '23? Just some colour there would be great.

And then you've identified this as a – second question will be, you've identified this as a internal inspection point, which is great. But do you now need third-party validation on the processes before you can restart or during restart before you can release batches from here? Just some thoughts on the external validation now. Thanks very much.

Karl Rotthier: All right, perhaps let me start with the second question, and then, Antoine, you take, again, the '23.

Look, we are indeed in the assessment that we are currently doing, going into a detailed way on the root cause of the matter, and the remediation plan on the matter. So that's why I think depending on the outcome of this, again, I want to repeat it, which we do proactively. There is no one forcing us to do so.

Depending on the outcome of this internal assessment, we will define the remediation plan, discuss it in detail with the authorities, of course, because that's the constant dialogue that is ongoing, and then we will take it from there. 2023?

Antoine Delcour: Yeah. So regarding the sales and the sales which have been paused this year, the sales during the year are not linear. So you cannot take the assumption that if we were to have production stop for six months next year that it would be 20 million by months. And so also the assessment that's just mentioned by Karl is still ongoing. And so we'll provide an update on 2023 when we publish our guidance on 8th March as part of our 2022 full year results.

Karl Rotthier: I think, Richard, what I would also like to mention and tell you because we talk a lot about internal assessment, etc. I think it would be also interesting for you to know that we now immediately and proactively inform the market as well, because following the detection of these dysfunctions, we made that proactive decision on 30th November to pause the batch release and a second step to temporarily suspend the prostaglandin.

So it's all very recent news. We decided to immediately respond to it. And I hope that you also see that the internal assessment, which is absolutely essential, will give us the necessary details to come up with a good outcome of this deficiency that we discussed.

Richard Vosser: Excellent. Thank you.

Karl Rotthier: Thank you, Richard.

Operator: Thank you. As a reminder, if you would like to ask a question, please signal by pressing star one on your telephone keypad. Currently, we have no questions coming through. Thank you.

Guillaume Rosso: Yeah. I think we will stop there. Thank you very much to have joined this call on a very short notice. Of course, we will keep you updated when we will have more information. Thank you, everybody.

[END OF TRANSCRIPT]