Diasorin S.p.A.

"Nine Months 2023 Results Conference Call"

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MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER

PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the Diasorin Nine Months 2023 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 Mr. Carlo Rosa, CEO of Diasorin. Please go ahead sir.

CARLO ROSA: Thank you, operator. And good morning, good afternoon. And welcome to the Q3 Conference Call. As usual, I am going to give some comments at constant exchange rate about the 3 legs of the business. The Immunodiagnostics, the Molecular Diagnostics and the Life [ph] Technology. And then I will let our CFO go through the numbers.

So if we start from the overall results, the quarter was in line with the expectation. Growth excluding COVID at constant exchange rate, it was 2% in the quarter, over 3% year-to-date. So it's in line with the guidance and expectations. Although, if we look at the 3 legs of the business, we have different results.

So let's start from the Immunodiagnostics. Immunodiagnostic continues to do extremely well for the company. In Q3, growth is 6%, and has been a very strong growth in Europe and in North America and some other smaller geographies, and notwithstanding some of the weakness that we continue to experience in the Chinese market.

If we look at CLIA, which is the main component of our Immunodiagnostics. Overall in the quarter, plus 10%. So we continue to experience double-digit growth in our main technology. If we go now by the different geographies starting from Europe, in the quarter, Immunodiagnostics up 7%, with CLIA up 13%. What we continue to

experience in Europe is a combination of growing business, and sustained volume of testing in all the different geographies from Italy to Northern Europe.

We see that the trend that we've been experiencing from Q1, which is an increase in testing volumes, continues. And we expect to see it as well in Quarter 4. We believe that this is not only a post-COVID effect, but I think structurally, after COVID, there is more testing that is requested by physicians. And this goes across all the different countries, I said. And we don't see today in any particular geography any effort to curtail this increase in testing volume in terms of reimbursement decrease, which is pushed by government. So Europe is doing extremely well for the company and better than expectation.

When it comes to North America, in the quarter, the Immuno is up 13%. If we look at CLIA, standalone is plus 16%. In line with the company expectation, this is the result of the hospital strategy that is working very well for the Diasorin, because of the menu and the platforms that we have now approved in the US. And certainly, we also see a very interesting contribution coming from MeMed which I am going to comment later. So North America and Europe, the main geographies are doing very well.

If I look at the rest of the world, the quarter is negative for Immunodiagnostics of 4%, CLIA minus 3%, which is although a combination of plus and minus, if I look at Brazil, Mexico, Australia, and India, which represents give or take half of the business, we see in Quarter 3 Immunodiagnostic up 8%, with CLIA up 9%. So in this direct strategic geographies, we see the business continuing to perform according to expectation.

If we look at exports, what we see is, we see a phasing effect in the quarter due to shipments to a very relevant country for us, which is Iran, which has been delayed and are going to be actually postponed to

Quarter 4. So we see in that case a phasing issue, although it's impacting the quarter.

And then if we go to China, we continue to see headwinds, which is a combination of volume and pricing effect. The value-based pricing is not in effect yet, but we see pressure on pricing, notwithstanding that, and we clearly see the Made in China effect for some of our mainstream commodity products. We don't have still visibility in Quarter 4, and certainly we don't have visibility in 2024 when the value-based purchasing, it's got procurement, it's going to be set in place. And so once the final ruling is going to be out, then I think we'll have better visibility on China.

So overall in Immunodiagnostics, our strongest market are performing as expected. And from a strategic point of view, we are seeing…we are collecting what we've been seeding in the last few years in terms of product development.

In terms of future development, I would like to comment on MeMed and LYME. When it comes to MeMed, there has been, as you know, an acceleration in the marketing program, which has been decided at the beginning of 2023, where we have increased the number of clinical reps, which today are doing the product promotion in the market.

Digital marketing campaign and clinical studies to support the product. We see that the funnel of hospitals interested to implement the MeMed product is very rich. We are talking about over 200 hospitals so far that have been touching and evaluating the product. So we are building the funnel. And I think what is very interesting and strategic about this product is that roughly a third of these customers are actually hospitals that we did not have access before. So we are actually building a business on our install base of system along the site with new customers. So it's a very, very important door opener for Diasorin the US.

Lyme, we completed the clinical study, and I'm talking about the LymeDetect algorithm, which includes B- and T- cell response. We are completing the file and we expect to submit on time by December in the US to have possibly approval by the next Lyme season in the US. Results are promising, and we believe that the combination of T-cell and B-cell responses are really addressing the need of a better early diagnosis, which was what this product was intended for.

Last but not least, I will like to comment on QuantiFERON. QuantiFERON is continuing to grow. I think that we mirror what QIAGEN is experiencing on the market. I know QIAGEN has been reporting and commenting on the success of QuantiFERON a couple of days ago, so I will not spend too much time.

But certainly we continue to see an uptick and an interest in our technology in all the main geographies, so US, Europe and everywhere else. And we certainly see an opportunity to continue to expand this business as QIAGEN is saying both geographically because China is an untapped market as well as from a technology point of view on migrating skin to blood. Okay. So as an overall remark, I believe the Immunodiagnostics franchise is doing very well.

Now, let's talk about Molecular Diagnostics. Molecular Diagnostics is performing as per expectation. Fundamentally, we have a stable business when it comes to multiplexing. The Verigene 1 technology is holding its position slightly growing. Certainly the limitation is the technology per se which is very strong, but it's very manual as well.

When it comes to the rest of the menu, so the SINGLE-PLEX, we see a growth of a single-digit around 5% of the portfolio. What we see are 2 negative effects. One is on the revenue line on instruments, because we are comparing to 2022 where on the tail of COVID we were still selling a lot of instruments and this is not happening any longer. So

the lack of growth that you see there is mainly attributable to the sale of systems. The reagent [ph] line is again growing.

The second element that we have discussed already in the last 2 quarters is the fact that the loss of a very large contract that Luminex had with the main lab in the US which is now affecting Q3, Q4. And I think the tail of it is going to be Q1 next year and then that business will go back to where it was.

As far as, what we are doing strategically with the business, I think 3 things which are very relevant. The LIAISON Plex, the respiratory panel has been submitted as discussed, a month ago. And the interactive review has started. And you know, this is very important for us because through the first panel, we're going to get clearance also of the platform.

And clearly, we expect now to be able to play in the US market with this platform starting from the next flu season. When it comes to the LIAISON NES, we have completed the pre-clinical study in Australia. And now, we are evaluating the clinical study in Quarter 4 and in 2024. But I think we're going to give you…shed more light and give an update on this one when we're going to be discussing the long-term plan in December of this year.

Last but not least, as we had anticipated in our Strategic Plan, part of the synergy plan with Luminex was a consolidation of platforms and so we have announced the discontinuation of the ARIES platform, which was generating very, very low revenues and actually had a high cost of infrastructure that we're going to be removing the platform from the field. And this will, does have a non-monetary impact in this quarter, very limited amount of monetary impact like a little bit over a €1 million. And we'll clearly have a very positive benefit starting from next year on the margin of the company. But more than anything, we are progressing in the simplification of catalog that I think was one of

the main issues with the profitability of the Luminex business, or on as a standalone business.

Last but not least is the Licensed Technologies. Let me remind everybody that this business is a B2B business primarily, so we actually sell to life science companies, I think most of the life science companies are using our technology. And we see this business flattish. Year-to-date I think we are in line with 2022 with a mix which is actually favouring the royalty line and the service contracts, which is expected, which means that fundamentally our partners continue to sell their reagents in their markets. Although, we see today 2 very important effects, one is decrease in inventory. So destocking when it comes to instruments and when it comes to some of the raw material consumable, we expect the destocking to be pretty much completed in Quarter 4. So we will start clean 2024.

We are clearly following what our partners are saying vis-à-vis this market, but due to the fact that we have a fairly wide portfolio of partnership which include life science and diagnostic users. We see a less draconian effect vis-à-vis what some of the partners are saying when it comes to specifically biopharmaceutical and life science business per se.

So, my message is, this is a more protected business, because of the diversification of partnership geographies and applications. And so, certainly we were expecting growth, but we don't see the level decline that some of the partners actually have anticipated in their numbers.

Now, I'm going to leave the microphone to Mr. Pedron who's going to take you through our numbers. PG.

PIERGIORGIO PEDRON: Thank you, Carlo and good morning, good afternoon, everybody. In the next few minutes I am going to walk you through the financial

performance of the Diasorin during the first 9 months of the year. And I will make some remarks on the contribution of the third quarter.

Please let me remind you that consistently with what we did over the past earning calls, to better understand the performance of the business I will mainly refer to adjusted P&L items. Therefore sterilizing the impact of the Luminex integration elements.

With that, I'd like to start with what I believe are the main highlights of the period. As Carlo just mentioned during Q3 '23 we started the sunset program of Luminex ARIES, a SINGLE-PLEX molecular business platform, offering to ARIES customers the possibility to switch to Diasorin MDX products. In line with the synergy plan we presented after the Luminex acquisition during 2021 Capital Market Day.

I believe this to be another very important step toward the complete integration of our combined product offerings. This initiative would be accretive both at gross profit and EBITDA level starting from 2024 onwards.

The total P&L impact of the ARIES discontinuation is about €15 million, nonrecurring one-off costs. The vast majority of which has been booked in Q3. Only €1.5 million of these costs will have a monetary impact.

Year-to-date, total revenue at constant exchange rate decreased by 15%, whereas the reduction at constant perimeter of consolidation, which means without the contribution of the Flow Cytometry business, has been 13%.

This result, which is in line with the full year guidance, is a combination of the expected falling COVID sales down by €156

million in the first 9 months of the year, partially offset by a growth in the ex-COVID business in the first 9 months of the year of about 3.5%.

To be more precise, this variance…this 3.5% variance is the result of the following elements. As we saw, a very good performance of the immuno franchise, which grew by almost 7% year-to-date and 6% in the quarter, despite some negative phasing in the shipments to distributors, which moved to the very first days of Q4 '23 and as we saw a weak performance in China.

A flattish LTG business, which is expected after the spike in Q2 is recording a decreasing Q3, because of the anticipated destocking of consumables implemented by some major partners and the generous softness in the life science business, which has recently been reported by many players of the space. A negative performance of the molecular franchise and net of respiratory business, minus 7%, driven by the budgeted loss of the cystic fibrosis business with one primary commercial customer in the US.

And lastly, the molecular respiratory business recorded year-to-date a slightly better performance than 2022. September year-to-date adjusted EBITDA at €278 million or 33% of revenues is substantially in line with the full year guidance and aligned with H1 '23 margins. The decrease compared to last year, €114 million, 29%, is mostly driven to the drop in COVID sales and therefore to the corresponding worsening of the operating leverage.

Lastly, we generated €160 million of free cash flow in the first 9 months of 2023, down €92 million compared to last year. This variance is mainly driven by the fall once again in COVID sales.

Before moving to the P&L, let me please summarize for you the last episode of the so-called payback saga. As you might remember from previous earnings call, this measure here, originally introduced in 2015

by the Italian government and never implemented since then, has been eventually reactivated in September 2022, but only for the years between 2015 and 2018.

Not clear yet what might happen if anything for the years after 2018? Diasorin has almost 2,000 other operators have filed a legal appeal to the competent courts to challenge these reactivation decree. The payment due-date originally set for January 2023 after being postponed a few times was eventually shifted to the end of October…so to the end of last month.

Moving from this very complex situation, each [ph] of legal controversies, the government introduced the faculty for each company to settle any dispute by paying 50% of the total amount requested by the region and by renouncing any pending legal action.

In the meanwhile, the Administrative Regional Court in Rome has had a first hearing on October 24th, so just a few days ago, to discuss the merit of the appeals and, pending the legal conclusion of this litigation, has suspended the payment terms for the company that have made such request, including us. DiaSorin as many other companies and this is the piece of news, has decided not to settle and to continue its legal dispute which might take 3 to 4 years before reaching its conclusion.

Please note that prior to September '22 reactivation of the payback mechanism, Diasorin had already built in its balance sheet a provision based on the information available back then, and its relative risk assessment.

Now, pending more clarity on the legal front for the years following 2018, and considering the amount already booked for in our balance sheet in the past, we have not changed our provision for the period 2019-2022, and we have not accrued anything more from 2023. We will keep on monitoring the evolution of this complex and ever-

changing situation and update investors during the next quarter at course.

Now moving to the P&L, September year-to-date total revenues at €846 million decreased by 16% or €166 million compared to last year as we saw variance due to the expected lower COVID sales and the disposal of the Flow Cytometry business.

Year-to-date adjusted gross profit at €553 million decreased by 18% compared to last year, with a ratio of revenues of 65%, broadly in line with the same period of 2022, which closed at 66%. The curve out of the Flow Cytometry business, alongside all the initiatives aimed at improving operations processes and containing costs, some of which part of our broader cost synergy plan allowed us to preserve margins despite the reduction in COVID revenues and the tail of the inflationary pressure we talked about in 2022.

I believe this to be a remarkable indicator of the relentless effort, we put in place to safeguard margins, which has been confirmed by Q3 '23, which closed with a gross profit ratio of a revenues of 65%, despite lower quarterly sales, as it is typical for the summer months when most northern hemisphere countries enjoy their summer vacation.

The difference with the reported, so not the adjusted, but the reported gross margin in the quarter is entirely due to the provision booked for the ARIES inventory write-off, as we have just discussed. September, year-to-date, adjusted operating expenses at €342 million decreased by 1% compared to 2022, with a ratio of a revenues of 40% vis-à-vis 34% of last year. The worsening of the operating leverage ratio is entirely due to the reduction in COVID sales.

Moving to Q3, adjusted OPEX decreased compared to last year by 7%, or €8 million, with a ratio of a revenues of 41%, vis-à-vis 37% of

2022. This reduction is mainly the result of all the initiatives we implemented to control costs, the positive impact of the cost synergy plan, which followed Luminex acquisition, obviously the disposal of the Flow Cytometry business, and eventually some positive FX effects.

Adjusted other operating expenses at negative €1 million are better than 2022 by €7 million. The difference with last year is mainly driven by the combined effect of some positive one-off elements booked in the quarter, and negative ones booked last year, such as the cost of the high down project that we went through in 2022 and some material severance costs we had last year.

The difference with Q3 reported…once again reported, not adjusted. Other OPEX is mainly due to the write-off of the ARIES tangible and intangible assets, once again, as we just mentioned at the beginning of the call.

As a result of what we just described, year-to-date adjusted EBIT at €209 million or 25% of revenues has decrease compared to 2022 by 34%. Adjusted interest income at positive at €4 million is better than last year by €7 million, mainly because of improved yield on our cash investment, whereas the tax rate at 23% is in line with 2022. Year-to-date net adjusted result at €164 million or 19% of revenues is lower than previous year by €80 million.

Let me now move to the net debt position. At the end of September 2023, the net debt was negative for €832 million, vis-à-vis negative €907 million at the end of 2022. This improvement has been mostly driven by the operating cash generated in the first 9 months of the year and by the proceeds of the sales of the Flow Cytometry business, partially offset by the payment of just short of €60 million dividend to our shareholders in May 2023 and €28 million of treasury shares buyback.

Lastly, we confirm 2023 guidance as usual expressed at previous year exchange rate. Total revenues minus 14%, total revenues at constant perimeter of consolidation minus 11% and adjusted EBITDA margin around 34%.

Please let me remind you that 2023 guidance does not include any possible impact from the payback as we just discussed since the company decided not to settle and consider in your situation which is in a flux and the most recent news. We believe it is even more difficult to make any long-term reliable prediction on what is going to happen.

Let me now turn the line to the operator to open the Q&A session. Thank you.

Q&A

OPERATOR: This is the Chorus Call conference operator, we will now being 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 you to pick-up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Odysseas Manesiotis with Berenberg. Please go ahead.

ODYSSEAS MANESIOTIS: Hi, thanks for taking my questions. Great to hear some encouraging KPIs from MeMed in the US. So first of all, could you touch on where these discussions with the 200 hospitals interested in the assay are focused? And is there a lot of willingness to adoption prior to the DRG unbundling? And on the back of that, your previous midterm guide implied this franchise could generate low to mid double-digit million sales by 2025. Are you still confident this is achievable?

And secondly, could you please remind us of the basic specs of LIAISON PLEX? I understand there's a cost advantage with the PLEX panels, but how does time to result in ease of use compared to the newer platforms that we've seen in this market? And at what time length should we expect GI and steps to be in the market post-lunch pre-flu season next year? Thank you.

CARLO ROSA: Okay, I'll take third question. Let me start from PLEX first. Clearly, as we have described, the system I think is part of the course with other systems that today are available on the market. The differentiating factor, as we have again discussed, is the positioning of the system which makes more financially viable for some of the account to do multiplexing versus other solutions where there is…in our opinion, excessive cost in performing the Plexing.

When it comes to ease of use, it's simply a result out, single cartridge. When it comes to menu, we're not going to comment on menu now. I think that we're going to give a more detailed explanation on our view on menu development during the LTP presentation, which will happen in December…around mid-December of this year.

When it comes to MeMed, yes, I reiterate the concept that the opportunity we see is what you describe in 2025. I think that bundling was not expecting, or unbundling was not expected to happen after 2 years after launch. And I think that today our partner MeMed is actually working to achieve that result, together with reimbursement coming from the private insurance. I believe that clinically it should not be a surprise the fact that there is an interest because there are very strong clinical evidence provided by MeMed on the use of this product.

And I think as I stated several times, every time we have repeated our own clinical studies, we were able to pretty much confirm the very high negative predictive value that this test has with the bacterial

infection, which is actually the added-value for this algorithm. So I'm not actually surprised by the fact that you have…is a perfect assay for hospitals.

And I think that what we are understanding in terms of the position in which is interesting is that there is a high level of interest on the small to midsize hospitals, where it is more complicated to penetrate the high end of the hospital market, but simply is because of technology availability, current platforms that are wide available in very large hospitals, but they're still lacking when it comes to the small midsize hospitals and where clearly there is more interest because with a very easy assay, with immuno assay, you can actually discriminate quite rapidly between bacterial and viral. Again, we're going to give, I think, a more detailed view on MeMed the opportunities during the LTP discussion.

ODYSSEAS MANESIOTIS: Very clear. Thank you.

OPERATOR: The next question is from Maja Pataki with Kepler Cheuvreux. Please go ahead.

MAJA PATAKI: Hi. Thanks for taking my questions. I have a couple. Carlo, just very quickly, when you talk about the discontinuation of the ARIES platform and you know, consolidating the test menu on the LIAISON MDX, is that on the existing platform, because I think you mentioned at the Investor Day in 2021, that you're planning to have a next generation platform in the market that would combine the test menu. That's one question.

And then the second question. You mentioned a delay in Iran for some of the instruments. Could you just remind us how big Iran is? I remember a long time ago, it represented enough big parts that it had an impact on your revenues when there were the sanctions and given

the uncertainty or the instability in the region, it was just good to have it for modelling purposes.

Then the next question, when you talk about lower instrument sales on the molecular side, is that a swap from instrument sales versus instrument placements? So you know, we've seen a high degree of instrument really being. purchased during the COVID period and now we're returning to the reagent rental model or is it really a decrease in instruments that you're putting into the market?

And then my last question is purely for clarification. When you talk about the strong growth in an immuno, you referred to CLIA. Is that CLIA X Vitamin D or is that including vitamin D? Thank you.

CARLO ROSA: Maja, long list.

MAJA PATAKI: Long list, I know. I'll repeat it, it's Friday afternoon, late. I'll repeat if you have clarity…

CARLO ROSA: No, don't worry. I know you. You're trying my memory. Okay, let's start from the last, which is easy. All the CLIA numbers now I'm giving are with Vitamin D inside, right. And so, I'm referring to the full CLIA franchise. So 10% does include clearly a decreasing Vitamin D, and which will continue forever, I believe, as a combination, mainly at this point of pricing, because pricing continues to decline. And a strong increase of all the other product lines.

Now, second is Iran. Look, I don't want to give…you remember well. We did suffer in the past from Iran. In this case, I honestly don't see an effect as we had back then. I think it's more of a phasing of the shipment. But overall, it's around less than €10 million of business in Iran. It's all clear, by the way.

When it comes to instrument, I'm referring to the sale of systems because as you stated and I think everybody is saying during COVID, everybody bought systems without tomorrow. And now, clearly there is slowdown in…so there is no capital available any longer. And so, you go back to the typical model of reagent rental, you don't sell anymore and that line suffers from that.

And the last question was ARIES, right? So on the ARIES, this was a very controversial technology and actually was one of the technologies that were scoped by the FDA. And since the beginning, a combination of the size of the business, very limited. The fact that we had…with the exception of one assay, we had everything on the MDX that we can offer to the customers. And the extent of work that our engineering had to do, you know, to take care of obsolescence of parts. And the fact that we don't see a future for this technology.

All-in, since the beginning, we said, let's get rid of it, which we are doing elegantly. We gave 12 months last by to our primarily US customers. This technology was primarily in the US. And then we're going to cleaning…we're going to clear the market from this technology. A great benefit in 3 ways. A), we are addressing…we are limiting the work that we…it had to be done to redo all validations for the FDA. Second, we are limiting and free up resources of engineering for the development of new platforms. And the third element, I think we are clarifying for customers the portfolio of products that they need to run products.

MAJA PATAKI: Okay. Thank you.

CARLO ROSA: Thank you.

OPERATOR: The next question is from Aisyah Noor with Morgan Stanley. Please go ahead.

AISYAH NOOR: Good afternoon, Carlo and Piergiorgio. Thanks for taking my question. My first one is on China. Do you have any early thoughts about what proportion of your testing menu could see VBT next year, and based on what you've seen so far, what magnitude of price cuts that could be seen?

And the second question is on the US Hospital's strategy. Where are you tracking against the 50 hospitals per year target, and how much would you say is driven by the doubling of the US sales force you mentioned I think last year that would be helpful. Thank you.

CARLO ROSA: Aisyah, good morning. Yes, look, when it comes to China, today is a little bit over €5 million that would be subject to the current VBT in the 17 provinces. Okay. So it's a relatively minor. What everybody expect to see is on the price effect of anything that goes from 50% to 65%. And that's the…this is what I think today the expectation from the businesses. So today is a relatively small effect. But it can be more than €5 million if it is extended in Beijing and Shanghai and the other provinces where a lot of our businesses concentrated.

When it comes to the US Hospital, actually 50 was the old target. So the first 3 years it was 50 per year done. And then starting from 2023, our target is actually 75, 90, 90 for a total close to 250 new hospitals. And we're actually tracking above that number when it comes to 2023. So it's working really well.

AISYAH NOOR: Great. And then just to follow-up with Piergiorgio on the ARIES integration, you mentioned there could be a slight impact on growth in EBITDA next year. How big is the ARIES business today? And if it is low revenues, then would it be a small impact on margin or would that be countered by the fact that it has a higher cost structure? Just some thoughts on moving parts for 2024?

PIERGIORGIO PEDRON: Yes, so I would say, hello Aisyah by the way, I would say that the ballpark number, in order to assess the impact on our EBITDA for next year, positive obviously impact on our EBITDA is a number between €5 million and €10 million. That's what we are expecting. And that is coming from 2 factors. One, the fact that the ARIES…without COVID, the ARIES business was actually you know, having almost a negative impact at the EBITDA level, whereas all the business that we will be transferring to the our…to the existing Diasorin, MDX offering will enjoy much higher margin. So as a combination of those 2 effects, let me say, lower costs coming from the ARIES platform and much higher margins. On the molecular platform, we are expecting to have a positive impact in the range of €5 million to €10 million next year.

AISYAH NOOR: Okay. Thank you very much.

PIERGIORGIO PEDRON: Thank you.

OPERATOR: Mr. Rosa, gentlemen, there are no more questions registered at this time.

CARLO ROSA: Thank you, operator. Bye-bye.