DiaSorin S.p.A

"First Quarter 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 First Quarter 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: Yes, thank you operator. Good morning, and welcome to the DiaSorin Quarter 1 2023 results. As usual, I am going to make my comments at constant exchange rate, and then I will allow our CFO, Mr. Pedron then to go through the numbers in great detail.

Let's start from the revenues, €284 million which is [technical difficulty] versus Q1 of 2022. Let's remember that there has been a change of perimeter since we have sold our Flow Cytometry business, so at constant perimeter business would be down 20%, and then there is a second factor that is clearly COVID. COVID is down 80% give or take compared to what we had last year, so excluding also the COVID business and the effect of the respiratory season, which is a way that we have indicated in our guidance. Then there are many businesses actually growing 3%, so in line with company expectation.

Now, let's go and discuss the revenues by technology. Let's start from the immunodiagnostic ex-COVID, €170 million which is a growth of 6% compared to Q1 last year with CLIA growing 9%, so a very positive trend. The reason for the good performance of CLIA is primarily related to the fact that North America continues to grow double-digit as a result of the success of our hospital strategy and combination of specialty maintenance.

Europe had a very strong performance in Q1, our immuno franchise grew 10% in most of the geographies, and this is due to the fact that testing volume in Europe really recover from the COVID times in Quarter 1, so there has been an effect certainly of continuous placement of systems, and again success of the hospital strategy with specialties in certain geographies in combination with increase in testing volume. So we finally see Europe going back in terms of volume to the pre-COVID times.

This growth of the immunodiagnostic franchise happened despite the headwinds that we saw in Q1 as expected in China. We saw a heavy decline in January and February due to the reopening in China and the effect of less testing volume. Although we saw a quite good recovery in March which is really enough to believe that what we see in China is going to improve in Quarter 2 and certainly improve in the second half of the year, as we I think discussed when we were commenting the expectation for 2023.

Now, if we move to the Molecular Diagnostic ex-COVID, it grew 6% in the quarter. We had a good contribution from the respiratory season, notwithstanding the fact that as we had discussed, respiratory was very strong in Q4 last year. We still had a good result in Quarter 1, especially in the U.S., and also we had recovery and growth of the non-respiratory panels.

Let me remind you that as far as respiratory is concerned, our guidance which is indicating a decline of 20% year-on-year is built on the fact that the 2024…the 2023-24 season which is what we will see, in…starting from Q4 this year is a normal flu season. And that means that probably the flu peak is going to span through Quarter 4 and Q1 for next year. So Q1 for respiratory was good, better than expected.

Let me also remind you that our year-end guidance for Molecular Diagnostic was built on the fact that starting from Quarter 2 we are going

to have the effect of the net loss of the cystic fibrosis contract which is a very relevant contract that the company had with one of the major private labs in the U.S.

Let's move to the…the LTG. LTG is at constant perimeter because here is where typically we were accounting for the Flow Cytometry business, so LTG at constant perimeter is down 11% compared to Q1 2022. This is expected, and is a combination of different events. First, we have a different pattern of orders, which are coming from some of the strategic partners when it comes to components that they buy from us to make their own products, so we expect orders to be shifted in Q2 and Q3, it's a tough comparison with Q1 '22, this quarter, because last year some of the order were actually concentrated more in Q1 than in Quarter 2.

Last but not least, we do have still a tale of chain…supply chain issues when it comes to component, although I have to say that we expect this issue to be addressed and resolved in Quarter 2, and therefore, we should not be seeing a backorder issue starting from the next quarter.

Overall, we continue to believe that year end growth of the LTG business is going to be around 7%, 8%, as indicated in our guidance. So the Quarter 1 result…the soft Quarter 1 result is primarily an effect of phasing. As stated before, when it comes to COVID, 80% down compared to what it was in 2022, and in line with what we have foreseen for the 2023 guidance.

Let me now comment some of the strategic programs, and then Piergiorgio is going to get into the details of the numbers. So let me start from the LIAISON Plex. As we've indicated, we have concluded the clinical studies in the U.S., and we expect that we are going to file for approval between Quarter 3 and Quarter 4 of 2022. This is for the respiratory panel, and then the GI panel will follow suit, in terms of clinical's and submission.

The LIAISON NES, we are starting the clinical studies in Australia for the…just to catch the beginning of the respiratory season, and we will conclude the studies clearly in the U.S. catching now the full respiratory season, and we expect to have filing done at beginning of 2024 for U.S. approval. Again, this would be Flu A, Flu B, and COVID panel.

When it comes to…last but not least, I would like to discuss about MeMed. When it comes to MeMed, we have initiated a plan to accelerate adoption in the U.S., it is very clear to us that today there are 2 barriers that have to be overcome. One, that I would say is relatively limited to do with the availability of reimbursement from private payers. I remind everybody that the test is anyway covered under the DRG (ph) when you use in emergency room.

And the second barrier to be overcome has to do with the fact that this test has to be actually properly placed in guidelines, and supported by physicians. Primarily, we are talking about infectious disease specialists. And so, we decided together with the board to accelerate the investment in the U.S., starting from the second half of this year, and hiring a dedicated salesforce that will actually go, and market the product to physicians and not to the clinical laboratory. As you know, we already have a very strong salesforce in the U.S. to hit the clinical laboratory. But in this very specific case, we need to do education with physicians.

And this program is going to be a combination of 3 events. One certainly is a dedicated salesforce. The second event is a digital campaign, again tailored to support adoption of this product within specialist. And we expect that the team is going to be set in place starting from the end of Quarter 3.

We see that today, there is a lot of interest from the market when it comes to this product, because clinical evidence has been provided by MeMed, and initial clinical studies are…have been published in peer reviewed journals indicating that the intended use, which was approved by the

FDA, is in fact, obtained by hospitals when this product is set in place in the guideline. So we continue to be extremely positive about MeMed, and we're going to give you more update about the development of this market in the following quarters.

PG, please go ahead and take the lead on numbers.

PIERGIORGIO PEDRON: Thank you, Carlo, and good morning, good afternoon, everybody. In the next few minutes, I'm going to walk you through the financial performance of the DiaSorin during the first quarter of 2022. Let me please remind you that consistently with what we did over the last calls, I will refer to adjusted P&L items, therefore, stabilizing the impact of the Luminex deal related elements.

So that as usual. I'd like to start with what I think are the main highlights of the period. So again, on revenues, Q1 2023, total revenues at constant exchange rate decreased by 21%, whereas the decrease at constant perimeter of consolidation, which means without the contribution of the Flow Cytometry business, has been 20%. This result, as we just said, is a combination of the expected reduction in COVID sales down by 78% in the quarter, partially offset by a growth of the ex-COVID business by 3%. This performance is in line with the full year guidance and our expectations.

During the quarter, the ex-COVID revenues at constant perimeter of consolidation, net of the Molecular Respiratory business, which is how we gave the guidance, grew by 3% as well. As a combination of a very good performance of the immuno franchise, as we've seen, partially offset by the expected slightly negative contribution of the licensed technology business. Q1 2023 molecular respiratory business grew by 9% compared to the previous year.

Moving now to the EBITDA, Q1 2023 adjusted EBITDA at €98 million, or 34% of revenues, is in line with the full year guidance. The decrease

compared to last year, €52 million, or 35%, is mostly attributable to the reduction in COVID sales.

Lastly, during the quarter, the group generated €28 million free cash flow. Therefore recording a reduction of €88 million compared to last year. This variance is mainly driven by the reduction in COVID sales and by an increase in working capital, mostly attributable to the phasing of some non-recurring events.

To be more precise, we have had some advanced cash out of some accounts payable and delayed collection of some accounts receivable of our legacy molecular legal entity in the U.S. in order to manage its ERP system consolidation into the one of Luminex. This was part of our IT integration program.

Then we have had some one-off payment of past accrued liabilities for the Flow Cytometry business employees who moved to the buyer of this business. And then we have had an increase in input VAT, which is the result of the Italian legal entity reorganization, which you might remember took place last year. These non-recurring events are temporary in nature and will be absorbed within the end of the year.

Before moving to the P&L, let me please provide you an update on the so-called payback system for medical devices. As you might remember, this measure originally introduced in 2015 by the Italian government and never implemented since then, has been eventually reactivated in September 2022. All the operators…basically all the operators including DiaSorin, have filed legal appeals to the competent courts to challenge the decree.

To be more precise, the administrative regional court in Rome has been charged with almost 2,000 recourses to suspend and invalidate the payback regulation. The payment due date originally set for January 2023 was initially postponed by the government to the end of April, and

has recently been postponed even further till the end of June by a law decree which has been released by the Italian government at the very end of March. This decree has also introduced the faculty for each company to settle any disputes by paying 50% of the total amounts requested by the regions within June and by renouncing any pending legal action.

So according to the usual legislative process in Italy, the law decree is currently subject to the approval of the parliament which may impose changes to it. In the meanwhile, the administrative regional court in Rome, pending the final approval of this law decree and waiting for the decision that the companies might take, has postponed the hearing originally set up for June 2023.

In summary, the whole situation is really in flux. Lending more clarity on the legal front and in the light of the recent news I've just shared with you, we have not changed the balance sheet provision booked as of the end of 2022. We will keep monitoring…we will keep on monitoring the evolution of this complex and ever-changing situation and update investors during the next quarter course.

Now, moving to the P&L, Q1 '23 total revenues at €290 million at current exchange rate decreased by 19% or €68 million compared to last year. This variance, as we said, is due by COVID and we have had in the quarter some €6 million FX tailwind, mainly driven by the USD appreciation compared to last year. First quarter adjusted gross profit at €192 million decreased by 19% compared to last year, with a ratio of revenues of 66%, in line with the same period of 2022.

The carve-out of the Flow Cytometry business alongside all the initiatives aimed at improving operations, processes and containing costs, most of them part of our broader cost synergy plan allowed us to preserve margins in spite of the reduction in revenues. And the tail of the inflationary pressure we talked about in 2022. I believe this to be a

remarkable indicator of the relentless efforts we put in place to safeguard margins.

Q1 '23 adjusted operating expenses at €115 million grew by 5% or 3% at constant exchange rate compared to 2022 with the ratio of revenues of 40% vis-à-vis 31% of last year. The worsening of the operating leverage ratio is entirely due to the reduction in COVID sales. Starting from the second quarter, we will see the benefit coming from the Flow Cytometry business carve-out.

Adjusted operating expenses at negative €2 million are substantially in line in absolute value with 2022 at constant exchange rate. Reported other OPEX include the slightly more than €3 million costs related to the Flow Cytometry business carve-out. As a result of all of these elements, Q1 '23 adjusted EBIT at €75 million of 26% of revenues has decreased compared to 2022 by 41% or €51 million.

Adjusted interest income at €1 million is better than last year by €3 million, mainly because of improved yield on our cash investments. Related adjusted tax rate at 23% is in line with 2022. Q1 adjusted net results at €59 million or 20% of revenues is lower than previous year by €38 million or 39%.

Let me now move to the net debt position at the end of March 2023. The net debt was negative for €849 million vis-à-vis negative €907 million at the end of 2022. This improvement has been mostly driven by the proceeds of the sales of the Flow Cytometry business and the operating cash generated in the quarter.

Lastly we confirm 2023 guidance as usual at previous year exchange rate. Let me remind you the guidance, total revenues minus 14%, total revenues at constant perimeter of consolidation minus 11% of which COVID at about €60 million so down by 75% Molecular Respiratory

business minus 20%. This business ex-COVID and Molecular Respiratory plus 4%, plus 6%. Adjusted EBITDA margin around 34%.

Please let me remind you that we have built as Carlo just said in our assumption an average respiratory season and that 2023 guidance does not include any possible impact from the payback mechanism in Italy. Since I said a few minutes ago, the whole situation is really influx, and the most recent news which I personally deemed positive and pointing in the right direction has made even more visible to make any reliable prediction on what is going to happen.

Now, let me please turn the line to the operator to open the Q&A session. Thank you.

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 "*" then "1" on their touchtone telephone, to remove yourself from the question queue, please press "*" then "2." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

Our first question is from Aisyah Noor with Morgan Stanley. Please go ahead.

AISYAH NOOR: Good afternoon and thank you for taking my questions. My first one is on the Immuno business. Could you confirm if the latent TB testing business was the major growth driver here or if you saw more broad-based growth across the CLIA franchise?

And then the second one is, just one for Piergiorgio on the gross margin developments which were stable year-on-year despite the sales decline. Could you quantify the contribution from cost synergies from the

Luminex integration in the quarter and if that's sustainable for the rest of the year? Thank you.

CARLO ROSA: I will take the first one on TB. TB, as you know is an important assay for DiaSorin but I don't think that itself explains the success of the programme, because the success of the program comes from the fact that we have a number of products that goes along with TB and makes then the whole portfolio acceptable for the customer. Keep in mind that especially in the U.S., we are now…once you know, we…together with QIAGEN we converted some of the large users of ELISA…of the ELISA QIAGEN product. Now we are directing our effort to go after the send-out business, and this business is certainly of the same size, but not enough…will not be enough to justify a placement. So, I would say that TB long story short is relevant, but not uniquely strategic product for DiaSorin to pursue its strategy in the U.S. hospital marketing is the strength of the portfolio that really gives value to DiaSorin the supplier in that market.

PIERGIORGIO PEDRON: Hello Aisyah. Going to the gross margin question, so I don't believe I am going to give the exact amount of synergies hitting our gross margin…contributing to our gross margin. But what I can share with you is that at the end of 2022, we had a run rate overall of north of $40 million synergies delivered since the acquisition. Let me remind you that the target was to get to 55 million by run rate by the end of 2023 and 60 million by the end of 2025. And I believe from everything I am seeing that we will deliver those targets. For this reason and for all the other different initiatives that we put in place to safeguard margins, one of them is also to increase prices to customers. I believe the 66% gross margin we see in Q1 to be sustainable for the remainder of the year.

CARLO ROSA: If I just may add consideration here. Talking about TB and the rest of the portfolio, as you can imagine TB has overall a dilutive effect on the gross margin for DiaSorin since it is a product that is licensed and commercialized with QIAGEN, and you right fully saw, you noticed that

our gross margin continues to be elevated, but this is because we continue to promote, sell products developed by DiaSorin that where we enjoy the full margin potential, okay. So Aisyah, so this is to say TB is certainly important but the gross margin effect is to do with the rest of DiaSorin portfolio. TB is dilutive for us.

AISYAH NOOR: That's perfect. Thank you very much.

OPERATOR: Our next question is from Odysseas Manesiotis with Berenberg. Please go ahead.

ODYSSEAS MANESIOTIS: Hi there, thanks for taking my questions. Firstly, could you please specify which exactly counterparts in the LIAISON [ph] license business are causing the shortages?

And secondly, could you please share of estimates of how much of a price increase you managed to take through in Q1 for most of your clinical business?

And last one on MeMed, have you had any pushback [ph] regarding the willingness of those that are willing to adopt this under DRG to pay for the assay, and are there plans to create an unbundled path to charge insurance for inpatients in an modeled fashion to the DRG payment. Thank you.

CARLO ROSA: So I will take the first and the last question. Let me start from the last one. Yes, absolutely so, there is a plan that has been shared with MeMed, and MeMed has negotiated with some of the major players, clinical study that is in execution as we speak to provide evidence to obtain specific reimbursement unbundled from DRG for this…for the MeMed assay in the emergency room environment. I think that we believe it's going to take probably between 18 months and 2 years by the time the study is concluded and the unbundling is obtained. This is full and plain responsibility of MeMed. Although the clinical study is going

to be conducted using also the DiaSorin product, okay. Today, there is no critical resistance to the adoption of the assay, because the clinical evidence is very strong. And so as we speak, there is no resistance by hospitals per se to adopt it based on any financial consideration. I believe that as we said before the clinical evidence is very strong so now is a matter of teaching and showing the evidence to the physician who are the ones that will make the…prescribe the assay, right. So is more demand generation.

On the LTG, on the parts, generally speaking the concern that we had was…had to do with supply of electronic boards that were specific for our systems. And clearly in light of the supply chain issue…overall global supply chain issue with this components, our industry which represents very small portion of the overall business was actually put in a holding pattern, because other business…other businesses good in general, and automobile clearly got the priority. It caught up, and this is I believe the first quarter when…where we get pretty much on time what we order.

And the other element which I think is relevant is that, let me call it properly owning…properly a black market, meaning that until today during shortage some of these components became unavailable on the market with the exception of some interesting suppliers that popped up all of a sudden at a cost really…very clearly with limited quantities and cost that were 30%, 40% higher than what the open market was supplying to. I believe that also this phenomenon is dying, because on the regular market now you find part at the proper price. So from what we have seen so far, there has been a tail, but this tail is closing.

When it comes to price increase. I believe that we have already communicated that as far as LTG is concerned, we followed what our partners gave to the end-user market in terms of price increase, which is in the range of 4%, 5%, and therefore we have increased our pricing to them by pretty much the same amount to cover for all the inflationary

cost that we had to experience clearly as everybody else in the manufacturing process.

ODYSSEAS MANESIOTIS: Very helpful. Thank you.

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

MAJA PATAKI: Yes, thank you for taking my questions. I have 3, please. The first one, Carlo, on the really solid growth that you've had in immunodiagnostics and also molecular ex-respiratory and ex-COVID. You mentioned in your opening remarks that we're back at pre-COVID levels. And I'm just wondering, has there been any negative impact in Q1 2022 where base testing has been still bit subdued due to COVID or is that really a clean growth number? And if so, could you maybe say why you think that volumes are now back at the path or the momentum that they were before?

The second question is around the cost for the program that you're launching to really promote MeMed more as of Q3-Q4. |Could you give us a ballpark number how much that's going to be or is it not material?

And then the last question when it comes to the pattern…the order pattern for LTGs, shall we also assume that the quarterly revenues are going to be more lumpy and more volatile or is it just something that has been a transition in Q1 and now it's going to normalize? Thank you.

CARLO ROSA: Okay, let me start from the volume question. I want to be very specific, I was referring to volume increase specifically in the European countries because what we saw is across all European countries and across very different product lines, we saw an increase in volume, and we went back and we compare testing volume at certain sites to what the testing volume used to be in 2019. And we saw that for most of these hospitals now we are going back to that level. It means, as said before, that we certainly had an increase in Q1 compared to Q1, 2022, because in Q1,

2022 we were still suffering from reduced volume because of COVID, okay.

Let's be clear. So the growth that we saw in Europe, U.S., we didn't see the same effect. I'm specifically referring to the European situation where the business in Q1 grew 10% immuno. There is a component which is volume recovery that we believe certainly will continue short term so also in the next few months would…but at a certain point it's going to be levelling-off, because also in 2022, in the second part, there was a recovery of volume.

The second question is related to the MeMed so called marketing effort, my ballpark $5 million in 2023, which is a combination of digital campaign and hiring of a salesforce…clinical salesforce.

The third question you have, I believe is to do with the LTG. The LTG business is B2B primarily, as you know, so it is bumpy by nature. So I believe that you're going to see recovery starting from Quarter 2, because we have certain orders, the cadence of…some of the orders will happen in Quarter 2. And then you may see some bumpiness in Q3 and Q4, but overall, we expect that by year-end we are going to get to the 7%, 8%, which was indicated by the guidance. There is no signal or reason to doubt that.

The other element which is very interesting, you know, we have which is also strengthening this argument is the fact that part of our revenues are coming from royalties. And royalties are an indication of the end-user business of our partners, and we see that the royalties are actually increasing mid-single-digit, which is telling you that the bumpiness we see in Q1 has to do more to the ordering pattern of the component from us, rather than the end-user business, which continues to increase as normal.

MAJA PATAKI: Okay, thank you very much. Thank you.

CARLO ROSA: Thank you, Maja.

OPERATOR: Our next question is from Shubhangi Gupta with HSBC. Please go ahead.

SHUBHANGI GUPTA: Hi, thanks for taking my questions. So first, can you please talk about the market size of this MeMed test that differentiate between viral and bacterial infections?

And second, as you mentioned regarding LTG, so you are seeing increase in royalty business. So is there any difference in gross margin of this segment compared to others?

And the third one is related to product delays? So you have been facing some product delays, including like VERIGENE and LIAISON XS? Can you sort of give a timeline on that? Thank you.

CARLO ROSA: I'm taking a deep breath. Okay, let's start from the one, I remember. So the product delays, you're saying the LIAISON XS. I don't think we had a LIAISON XS was actually launched few years ago. So I think you're referring more to the LIAISON Plex, and the LIAISON Plex and LIAISON NES, I believe that, during this call I've given an indication of the fact of where the project status is, status of the clinical study, which again, has been completed for the Plex. And so, we are compiling document for submission. And then on the NES where we start the clinical study in Australia.

When it comes to the MeMed market size. I think that there are different ways to slice this onion, if I…or peal [ph] this onion. And I'll try to make it simple for you, if you look at one segment with…that we believe is the one that can be readily capture, which is testing of kids in emergency room showing with fever, without origin, right, this is what we're talking about.

In the U.S., there are roughly 5 million admissions every year, and in Europe pretty much almost the same 4.5. So just to make my calculation simpler, I assume that you have 10 million admissions, and that is defining the market size for this product, then you multiply by a price that I don't think we never disclosed. And so, you need to figure it out from what some of the analysts have actually projected. And you come up with a market just for kids that can be measured in hundreds of millions of dollars of euros depending on the currency that you're like.

The third question has to do with the LTG. Sorry, I don't remember.

SHUBHANGI GUPTA: It was about the margins, you know if we can say something about the margins of the LTG business?

CARLO ROSA: No, I don't think I can specifically say anything about the margins of the LTG business except for a qualitative remark as you can understand there is a component to this business which is royalty. And then there is another component of this business, which is reagent, and then there is a third one which is instruments. Okay, without sounding funny, the royalty margin is clearly 100%. The component business is very similar to the margins that we experienced today with our immunoassay franchise. So if elevated and when it comes to instrument, which is a mean to an end for us is a way to provide to our users the ability, actually to run their products and generate revenue. So royalties ins U.S., components, we are talking about margin that is relatively low. But again, our margins we're not…we're not a company that makes money selling instruments even in the LTG. We make our margins, helping our partners to sell products and saw royalties and then providing them with components.

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

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