DiaSorin S.p.A.

"Third Quarter and Nine Months 2020 Results Conference Call"

Wednesday, November 11, 2020, 14:30 CET

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 Third Quarter and Nine Months 2020 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 and good morning, good afternoon to everybody. Welcome to the Quarter 3 conference call of DiaSorin. I will…I think this time we're going to make some short comments, and then I'm going to leave Mr. Pedron to go through the numbers, and then we're going to leave ample time to…for Q&A, because I've seen there are lots of questions, I believe necessary are related to the results but to the environment ecosystem after the Pfizer announcement a couple of days ago.

So I would start and comment on revenues. As you have seen, the quarter has been a very strong quarter, I think in line with what we have seen also from other players in diagnostic. And we need to look at the revenue from perspective of COVID opportunity and from what the rest of the business is doing. Rest of the business is recovering better than expected. We were coming in Q2 from a minus 35% and now in...and that was pretty much generalized in all the different geographies in Quarter 3, now we're at minus 7% with a different mix. We have U.S. and Europe with strong recovery. We're almost close to, where we were last year, whereas China is still lagging behind. And I'm going to make some comments about China, specifically.

U.S. and Europe, we have seen now constantly that testing volumes in the major geographies, in major countries in Europe are going back to last year levels, pretty much, and this for us is a combination of regular prescriptions, so that we see again going back to normality, and then combination of new business that we closed last year and growth of our product lines, the gastro…the gastroenteric line is not withstanding the COVID situation is growing over 20% year-on-year, which is phenomenal.

And then the TV program that certainly is fully incremental for us, and it's firing up, it did fire up well in Europe, and it has been firing up in the U.S. as well. So in U.S. and Europe a combination of recovery of testing volume in our traditional program is firing up, we see the traditional business doing okay.

When it comes to China, we still have a red flag in China. And I think, I heard also that no other diagnostic companies making similar comments. And the reason, we believe is, the fact that, as you know, in China, there is no…so medicine is practice, right at the hospital sites. And so hospital sites additionally are extremely crowded. And I believe still the general population does not want to go to see the doctors except for emergency cases because they didn't want to be exposed to the risk of the infection.

And the only way I think all of us can explain why notwithstanding what is happening in the rest of the world. China is still lagging behind vis-à-vis volumes. And so, we will watch carefully what happens in Quarter 4. And we hope that eventually volume is going to go back. But so, far I don't think we have lost visibility.

Now, when we…now let's talk about COVID, which is the elephant in the room, certainly business is doing extremely well. And we need to look at I think 2 components of COVID, on one side, serology and on the other side

molecular. Serology, Q2 was phenomenal and this was because there was lots of excitement about the adoption of serology for epidemiological studies and then the availability of serology to support lack of testing capacity from molecular sites. So lots of hype that eventually died pretty fast, and if you have seen comments from the major labs in the U.S., as well as, other competitors, the spike really lasted 2, 3 months, and then serology went back to where I think it deserved, which is an interesting pool [ph] to follow-up at this point, all the patients that are hospitalized, so more clinical use than general use.

In Quarter 2, I remind everybody that we had roughly €45 million revenues on serology, this is in Quarter 3 is not there. Certainly, it's not there anymore. Where I think that our projection will see serology more around, between 8 million and 10 million per quarter, which is what we believe is physiological use of serological tools, especially in those countries like Brazil, India and some of the export countries where lack of swabs and molecular testing is somehow compensated by the use of IgG and IgMs, which is an assay that we have launched a couple of months ago.

As far as the molecular is concerned, look today, I think everybody is in the same situation, there is growing, growing demand of molecular testing. And molecular is considered as we all know as the goal standard. And it is used both for clinical use and so to diagnose acute phase and also today to try to identify the asymptomatic carriers.

Sales are proportional to manufacturing capacity. In Q3, we had versus Q2 50% growth rate of our molecular testing, which is pretty much in line with increased manufacturing capacity. We're a little bit far ahead compared to what we said was our goal. If you remember, we said we would have a million test of molecular per month of capacity by the end of the year.

And I think we were able to anticipate a couple of months that capacity. So we're enjoying, you know, good, good growth, price is stable, we've positioned our assay as specialty product for triage in a mission. We have a relatively small system, our MDX that has been very successful into the hospital setting. So where we enjoy specific positioning, as well as, price premium, because we sell the ability to triage within 45 minutes, you're able to triage patients and properly redirect the COVID positive and COVID negative patients.

So far…as far as the installed base is concerned, we have been able to place roughly 500 systems, additional system for a molecular, a good chunk of it is in Europe. Prior to COVID as you can imagine our installed base primarily U.S. driven. After COVID, the installed base has been growing significantly in those countries where we have elected to sell the product.

Certainly, we had to make certain decisions in terms of priorities. And as I think we have stated from the beginning U.S., Italy, we are the primary markets that we decided to serve followed certainly by Spain and France and few other placements in other European countries. So COVID is doing fine. The positioning, I believe the correct positioning and we now have another goal, which is to get to 1.2 million tests around February timeframe, which is good in the next step of increased capacity.

At the same time, we have also launched our flu assay, which now is compatible with COVID. So we can follow the trend of differential diagnosis in patients that do show up with the same symptoms. Although I think as we have seen in Australia, and now it's also fairly clear in U.S. and in Canada where we have a big installed base. The Influenza season looks like it's going to be fairly mild and I believe that this is the consequence of all the social distancing and hygiene measures that were adopted because of COVID.

The results in Australia that I've seen were unbelievable, whereas last year in June, there were 7,000 cases a month of reported flu, I think it went down to 50 a month. And so, clearly showed that this Influenza season is going to be very mild, which is a living space to actually manufacturing [ph] more COVID. And so, we're actually balancing today or manufacturing more towards COVID than flu.

There is another program that for us is very strategic is antigen testing. Antigen testing was clearly…was made available a couple of weeks ago. So it's not part of the Quarter 3 results. However, these antigen tests that we launched, I believe, is a very strategic product has been the first one, and so far, the only one to be launched with certain characteristics is, you know, as public information is Ortho, Clinical and DiaSorin the only 2 high throughput assay launch, our assay though is different than Ortho because it's quantitative and allows the actual determination of the viral load, which we believe is a very relevant characteristic of this product.

And by the same talk and the positioning is specific, because you know, there is…there are…there are a lot of point of care antigen test available out there that have been deployed in different settings to be used. These products, which is a high throughput, and is actually run on our LIAISON platform has a better clinical performance than some of these rapid antigen testing. And that…these comes without saying because the technology, the chemiluminescence technology is a much powerful technology than this laminar flow.

It guarantees traceability, which is something that some of the laminar flow point-of-care is don't do today, and this is key in my opinion. So increased sensitivity and traceability is very relevant in order to allow the identification of asymptomatic carriers, you know, that today for diagnostic

there are fundamentally 2 uses, one the swab molecular testing is used more for clinical identification, and for diagnosis and to release patients to guarantee that they're not infectious any longer, whereas the antigen testing would be...the use of it would be a widespread use in the community to identify hotspots and asymptomatic carriers.

Our assay…because of the sensitivity that it has, does allow certainly the identification was symptomatic, and this is how we're positioning it. So we expect…we launched it 10 days ago, is doing very fine. And now, we're commercializing it in the U.S. under UN and submitted for EUA approval which we expect to come in the next few weeks.

Last but not least, we're working on a new product, which is a new serological assay that we intend to submit to the agency and in the next few weeks, and this assay is intended to be a false vaccination test. And the idea shortly is to use the same protein that has been used by the vaccine companies, which is a very specific spike protein. And then use that protein to understand the vaccine and the response of the patients or the vaccinated individual to the vaccine.

It's a bet certainly, because today there are no guidelines that do recommend post-vaccination testing. But if that comes and there is going to be a utilization of serology, we believe that this assay is superior to what existing on the market, because it has been specifically designed with again, the same protein…S Protein that has been used as a candidate for most of the vaccine programs.

At this point, I'm going to leave the mike to Mr. Pedron, who is going to take you through the numbers and then we're going to take questions shortly thereafter.

PIERGIORGIO PEDRON: Thank you, Carlo, and good morning, good afternoon, everybody. In the next few minutes, like usual, I'm going to walk you through the financial performance of DiaSorin, during the first 9 months of 2020, and I would also make some remarks on the contribution of the third quarter.

So we closed September year-to-date with an increase in revenues at constant exchange rate of 17% or €91 million. As a result, if you might remember of a soft Q1, mainly driven by volume reduction in China due to COVID, and a very good in second and third quarter.

Specifically Q3, saw an increase in our revenue of comparable FX of 34% or €60 million. Carlo has already discussed at length the reasons behind these variances. As expected and anticipated during last quarter call, Q3 2020 gross margin ratio at 68.3% of revenues is below what we see in Q1 2020 and Q2 2020, which closed at 69.1% mainly because of higher sales of COVID molecular tests. Year-to-date gross margin though at 68.8% is just slightly lower than 2019 which closed at 69.1%.

September year-to-date EBITDA at €258 million records an increase at constant exchange rate compared to last year of almost 25%. Year-to-date EBITDA margin which at comparable rate is 42.3% vis-à-vis 39.8% of 2019. Q3 2020, EBITDA at €104 million or almost 46% margin registers a record performance with an increase of 54% at comparable rates.

Lastly, we confirm our ability to generate a very healthy and predictable free cash flow, €153 million in the first 9 months of the year, thus bringing the net financial position of the group to positive €256 million.

Let's now dig a little bit in to the main items of the P&L. We said the year-to-date revenues at €610 million grew by 16% or €85 million compared to last year, the growth at constant exchange rate is 17%.

The impact of COVID revenues, again at comparable rates has been €166 million year-to-date and €73 million in the quarter. As expected the appreciation of the euro against almost all the currencies in which the group operates has caused some material FX headwinds in the quarter, therefore offsetting the tailwind we saw during the first half of the year. Considering where the U.S. dollar is standing now compared to 2019, I believe it is fair to say that we will experience a similar €7 million or thereabout negative currency effect also in the last quarter of the year.

Gross margin at €420 million grew by almost 16% compared to last year, closing the first 9 month of 2020 with a ratio of 68.8%. Q3 gross margin increased compared to 2019 by almost 30% with a ratio of revenues of 68.3% vis-à-vis as I said 69.1% of H1 2020.

The slight decrease in the quarter gross margin ratio compared to the first 2 quarters of this year is mainly the result of a different product mix to be more precise, lower clear sales and higher molecular sales, which enjoy, as we have discussed several time lesser margin…slightly lesser margins. The increase of the molecular franchise 34% of the total quarter sales has been mainly driven by COVID testing.

Total year-to-date operating expenses at €195 million or 32% of revenues have increased by less than 2% or €3 million compared to last year. The OPEX ratio of our revenues is 32% vis-à-vis 36.5% of 2019. Here we have 2 effects of opposite sign. On one side, we've had a slowdown of activities and a consequent reduction in costs caused by the widespread lockdown measures that interested all the geographies in which we operate. On the other side, we have sustained and increasing costs, mainly driven by the investments we made in the U.S. commercial team, aim at supporting our hospital strategy, again as discussed a few times during these calls.

Year-to-date other operating expenses at €11 million increased compared to 2019 by €5 million. To discuss the biggest driver of this variance is a non-forecasted loss we suffered in our South African subsidiary during the shutdown process for which we have activated our group insurance policy. And we're hopeful that the whole claim process will be completed within the next 18 months.

As a result of what just described, year-to-date EBIT at €214 million or 35% of revenues has increased compared to 2019 by almost 29%. Q3 2020, closed at €90 million with an increase of 62% or €34 million compared to last year.

September year-to-date tax rate is in line with 2019. This brings us to net results of the first 9 months at €163 million or 26.6% of revenues, which is higher than previous year by €36 million or 28%. The increase in the quarter is almost 60% or €25 million.

Lastly, September year-to-date EBITDA at €258 million is better than last year by €49 million. EBITDA rationale revenues is 42.3% at constant FX and vis-à-vis 39.8% of 2019. Q3 closed at €104 million or 45.7% of revenues.

The substantial margin improvement towards last year both in the year-to-date, but even more so in the quarter is driven by the operating leverage resulting from the increase in revenues amplified by a muted increase in operating expenses.

Let me now please move to the net financial position and the free cash flow. We closed the period with a positive net financial position of €256 million

and €284 million cash. In the first 9 months of the year, the group generated €152 million of free cash flow vis-à-vis €138 million of 2019.

The year-to-date free cash flow has been affected by an increase in working capital, mainly driven by higher accounts receivable and higher inventory to sustain the COVID testing volume and sales, higher CAPEX driven by the acquisition of the TTP license and higher installment of our platforms. And all of this just partially offset by lower tax cash-out, mainly coming from a positive phasing and the one-off of €6 million exit tax that we paid in 2019 when we closed our Irish manufacturing site.

Lastly, the full-year 2020 guidance, at 2019 exchange rates, we expect revenues to increase at around 25% and then EBITDA ratio at around 43% of revenues, all at 2019 exchange rates.

Please remember that DiaSorin financials are highly exposed to the U.S. dollars, and even more so now that the United States represents more than 40% of the total sales of the group. Therefore, as a rule of thumb, consider that for every 1 cent movement of the dollar against the euro, DiaSorin revenues moved by about €3.54 million on an yearly basis.

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

Q&A

OPERATOR: Excuse me. This is the Chorus Call conference operator. We will now begin the question and answer session. Anyone who wishes to ask a question may press "*" and "1" on their touchtone telephone, to remove

yourself from the question queue, please press "*" and "2." 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 Catherine Tennyson of Bank of America. Please go ahead.

CATHERINE TENNYSON: Hi, thank you. I have 2 questions if I may. So, firstly can you just help us understand, what are your expectations for the phasing of the antigen testing opportunities in say 2021? And secondly, obviously after this [indiscernible], what are your expectations for how that vaccine impacts your business into 2021 results? Thank you.

CARLO ROSA: Catherine, sorry the line was not the greatest. So I hope I was very...you're very choppy, so very difficult to understand. So if I understand correctly, you want to understand the antigen opportunity in 2021, and the effect of the availability of vaccination on the business. Is this correct?

CATHERINE TENNYSON: Yes, that's correct. And then I have a quick follow-up after that?

CARLO ROSA: Okay. As far as, antigen testing is concerned, as said, antigen testing, I believe is going to be used fundamentally to trace asymptomatic in the population. And today, you know, this requires lots of volume…lots of testing volume, and today because of the lack of capacity for the molecular swap, this cannot be done using the molecular test. So I believe that, as long as, there will be a need to pick up asymptomatic individuals in the general population there is going to be a substantial demand of antigen testing.

How long is this is going to last, which I think ties to the second question? I think that anybody honest in the industry will tell you no idea. We have

no idea in my opinion simply because I was very surprised last night when without any scientific data made available, a statement was actually made by the vaccine industry say, and hey we have 90% protection. But already today, lots of people are asking really show the data and let's understand exactly what the vaccine is? How it works? How effective it is? And there are lots of questions, that I don't think, we will have an answer to…by the time the vaccine is going to be launched, and one of which is for how long is this preparation going to last.

And then the other question, I believe, is going to be, adoption…adoption rate. Today, I'm amazed to read the statistics, both in U.S. and Europe that says that half of the population does not want to get vaccinated. Okay. So, to make a long story short, I have no idea of what would be the impact of the vaccine, because we don't know what kind of vaccine we have, we have no idea in terms of how long this is going to last and we have no idea about the deployment. Okay. So I think we need to understand, and we're going to understand later in the year, I think by mid next year, when we're going to be presented with data…more secure data about efficacy and of the vaccine.

Also than I just want to make sure you understand that personally, I hope that this vaccine will have 100% efficacy, so that COVID goes away. Now, I am tired of spending my weekends in a lockdown on my balcony in Milan, as I already said few times. But all said and done, very difficult today, my appeal to make a projection.

Antigen testing is a very good tool, as long as, you need to pick-up asymptomatic people. It's also a very good tool when it comes to secondary geographies, and we've already seen in India and in Brazil, and in Mexico, some of these geographies where there is a capacity issue with molecular then IgM and Serology was used, and then antigen testing will become a

very nice and better way…improved way to actually also diagnose the acute infection. So we see an opportunity on the couple of thousand systems that we have today installed in the secondary market.

As far as molecular, as said today, we have...we don't have enough, I believe that what will happen eventually, when the pool of testing is going to shrink, the first one to go is going to be the antigen test. And the molecular will continue to be there, because there is a goal standard is the same…clearly more sensitive than any antigen testing. And it is going to be used and it is going to be extremely relevant in my opinion until the virus is going to be completely eradicated for differential diagnosis because don't forget, what you need to do, right after the vaccine is going to be made available is still to identify hotspots, and as soon as they have been identified, then you need to proceed with lockdown and lot of testing in that particular population. And it will be used again next season…next flu season for differential diagnosis will still be there. By then I don't think that the virus is going to be eradicated. So you're going to have symptomatic people that will show up with symptoms and you still want to know is it COVID or Flu. And in fact, I project that next year, there's going to be lots…much more use of flu and COVID combined at what we have seen in this season. But to be honest, we do this as much as I can tell you, because I don't have a crystal ball.

CATHERINE TENNYSON: That's helpful. And if I could just ask [ph] in a very quick one. Now you are obviously seeing the second wave pick-up again. I'm just seeing localized lockdowns, from what you're seeing in your communications with hospitals. Can you see that as an impediment to the recovery of the base business back to flat in Q4? And also just a reminder in case, I missed the start of the call. What are your full-year guidance plans for the recovery of the base business? Thank you.

CARLO ROSA: Again, we…today we don't see it as an impediment, because I think that hospitals are much better organized in terms on their ability to first triage at the entrance or they have…what they call the clean side of the hospital and the COVID side of the hospital. And therefore availability of testing right triaging is allowed immediately to separate the different patients and then admit patients in the clean air and keep it clean. And I think that today has been understood by patients, and we don't see right now a problem with testing volume, okay, anything can change. Okay, but so far, if I need to look at October and November, we still continue to see the recovery of the base business.

CATHERINE TENNYSON: Okay. Thank you so much.

OPERATOR: The next question is from Andrea Balloni of Mediobanca. Please go ahead.

ANDREA BALLONI: Yes, good afternoon and good morning. Thanks for taking my question. Congratulations for the strong set of results. My first question is a very general one I understood you don't have a crystal ball. But in any case, how do you support 2021 could evolve quarter-by-quarter assuming lot of vaccine intermodal your free COVID-19 test. I mean molecular antigen and serology, what should we expect, not in term of guidance absolutely but just in terms of general market trend?

And my second question is about antigen and molecular test. I understand why I shouldn't assume that antigen test may at least partially erode some market share to the molecular one. I mean, for example, if I believe to have flu before doing a molecular test, I may try an antigen test. And if this is negative in the end, I don't do any molecular test anymore?

And my last question is about the routine test, I didn't get your answer to the previous question. Which kind of recovery do you expect for next year? Is it reasonable to assume volume returning to 2019 level?

CARLO ROSA: Okay. I'll start from the last and go into the first. As far as next year recovery, I believe that for sure, the availability of vaccine is going to make the recovery faster. The general level of confidence, I believe, is going to return back, and this could be a problem, but there is strong expectation by people that availability of vaccine is going to address the problem. So even psychologically, I think that people will feel better about going to the doctor, going to the hospital and so forth. So I think when we look at 2021 projection, we projected that volumes are going to go back to what they were in 2019.

As far as antigen testing and why it does not cannibalize? Because the use is completely different. The…today, the PCR assay, which is the goal standard is used for clinical diagnosis. And but it's not enough, I keep saying look at the U.S., the U.S. as I said, today they do a million PCR a month, so 30 million a day. So 30 million PCR a month and they said that in order to coexist and reopen certain activities fly and you know, being able to go to watch Football, you need to do much more testing. And that cannot be done by molecular, because it's too complex and is too expensive, by the way, and it should be done by a cheaper alternative, which is the antigen testing. By the way, you said if I do an antigen test and negative, I feel comfortable.

I wouldn't, to be honest with you because one of the issues with the antigen test is sensitivity. And today there has been a work that has been published by the French Health Authorities which I…so far I found it to be the best evaluation ever that I've seen on antigen testing and what they prove is that antigen testing sensitivities compared to PCR is 75%, okay. So 75% means

that you're going to be missing 1 of the 4 which is good enough. If you want to use it for testing or asymptomatic in areas with relatively high prevalence. But then if you go to the individuals and you want to rule out with symptoms, rule out whether it is or it is not. The COVID is not good enough, you need to do PCR. This is why I'm saying; the first one to go away is going to be antigen, first all antigen testing is going to disappear in my opinion in when vaccination is going to be widely available. And again, I'm remarking widely available because you need to reduce the pool of negative patients to the virus. And then...and then PCR eventually is going to go away, meaning that the PCR will be used still for differential diagnosis with symptoms when people show up, especially during the peak season.

So what you'll see eventually is that, you're going to have a surge in volumes during the flu season, and that is going to revert more to less volume during the summer, which…and that is the signal that will tell you that COVID is going away, because it does becoming another diagnostic test for differential diagnosis and making sure that the symptomatic patient that shows up is a flu patient and not a COVID patient. And also that one is going to disappear when the virus is going to be eradicated. Okay, but think about it.

Even today, I think 20 years, 30 years after the measles vaccine has been made available in 90% of the population, whenever a 90%-95% is vaccinated against measles, you still have the measles outbreaks. Last year for us was a record year, 2019 was a record year on measles, because there were outbreaks throughout the United States. So you really need to be careful about projecting. In my humble opinion today, it is very difficult to make a projection until you really understand what the vaccine is all about.

ANDREA BALLONI: Okay. Very clear. Thank you.

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

MAJA PATAKI: Great, thanks for taking my question. Actually, Carlo, I'm sorry about, I'm going to ask just again to looking to crystal ball, which you might not have. But and it is a very clear statement from your side on what you believe might happen that antigen testing will be first to go away? Well, if you look at the PCR market, as a total you know, there is a substantial part of...substantial volume of more manual related PCR tests today that are helping to address the demand. Do you think the more manual PCR tests will go away after the antigen test?

And then a second question is, at some point in time, there's probably going to be overcapacity in the market on the PCR manufacturing side. Do you believe there's going to be a harsh pricing competition in the COVID space? And do you think it could actually extend to the other PCR testing areas? Thanks.

CARLO ROSA: Maja, I think you made a very astute comment, and thanks for bringing this up. Yes, indeed, you know, to me, what's standing today out and how is it possible that still in the U.S. they can do 30 million PCR a month and also Italy, in Italy today, they're doing 1 million, they're doing 200,000 a day, which means 6 million per month? And when you go and talk to customers, you find that is a very interesting story, it's a combination of IDD products. And so us about Roche, the usual suspects, the usual companies that have a CE Mark products as well as E-Way products, versus a plethora of entities which have been developed by hospitals that don't have a…don't get enough PCR agent from industries, buying fundamentally reagents left and right and setting up their own assays on typically Thermo Fisher open platforms or Bio-Rad open platform. At the end of the story, if you think about it, you

need the CDC protocol, you need an extraction system, and you need just a PCR instrument to do a PCR test, right.

I think and you're very right that the first one to go will be these all plethora of LDTs, it's because they carry liability, they're very time consuming by the way because there is no level of automation whatsoever. And it's very interesting. If you look at one of the most recent publication that has been issued by the FDA and what they did was, they pretty much tracked down all the assays that received EUA approval and there were 160, believe me, I don't remember that there are 160 molecular diagnostic companies in the world, right. So there are a lot of these products, lots of these assays and methodologies that have been fundamentally developed like LDTs and filed with EUA, which is no problem, because when you want to get your EUA, the burden of getting EUA is relatively small, right. And this is why; they have an EUA, because it's a short-track to registration.

Now, we're completing our 510(k), because we see that now the world is going to move from EUA to 510(k). And just to give you an understanding, the cost of filing an EUA which is combination of clinical, the clinical study is now required for a 510(k) and the filing itself is $1.5 million, okay. So now I want to see whether 160 companies that they came from nowhere, a lot of them, are they going to invest $1.5 million to get a 510(k). That itself is going to clean-up the list of suppliers. So in fact, you're right, I think antigen goes down, then I think that the LDT is going to disappear and then last the IVD companies, then when the volume then declines, and IVD volume certainly is going to go down.

From a price point of view, look it's inevitable, that eventually everything results [ph] to price, also because today, there are subsidies, which are very specific for the reimbursement I'm talking about in the U.S. very specific for COVID. And I believe that when sales are going to go to normal again,

and it’s not going to be so much pressure on volume, I think it's also the reimbursement by definition is going to, which is very generous today on purpose to push all companies to invest in research and development and bring forward onto their sales. Also the reimbursement is going to go down.

But this is…I mean this is part of life, right. There is nothing unheard of. What I don't think is going to happen is that all this scenario is a 2021 scenario. So we feel overall pretty comfortable vis-à-vis the…what is the opportunity in 2021? I think that when you talk to 2022, there is going to be lots of uncertainty. But again, it all depends what kind of vaccine are we going to have in front of us. And as of today, we don't know enough. And when the vaccine is going to be launched, we still are going to have lots of questions, because nobody will be able to tell for how long their protection will last, okay.

MAJA PATAKI: Yes, understood. Thank you very much. I have 2 follow-up. One is do you think that the pricing pressure because there is going to be such a big overcapacity from the big guys could be extended to other PCR tests as well. And then, just quickly, can you give us an update on the saliva test. You haven't really…you haven't really spoken about that. So I was just wondering if there's any updates which you can share.

CARLO ROSA: Maja, I don’t think so. Because again everything else, the regular course of business of molecular is properly priced, and the pricing will come from competition and properly reimbursed. Actually, I see something completely different. I see that thousands of systems have been now acquired by hospitals. And it's very interesting. And you see it also in our results as well, because of the fact that lots of emergency funds have been unleashed, every company is reporting that if, in 2019, we were actually 70% of our placements were going through raising rental and 30% were actually sold.

In 2020, what you're seeing is that it's completely reverse. So 70% of the equipment is purchased by hospitals and 30% is leased. And they're doing so because they have lots of money, they're called emergency funds. Now you're going to have all these thousands of equipment that all that is going to be owned by a hospital. What I think is going to be the effect is that hospitals will be encouraged at that point to decrease the send out and increase the essays that they're going to do in-house, and especially in the U.S. And so I think that there are going to be lots of incentives for these hospitals not to engage anymore with the big private labs, but do more testing themselves.

And by the way, this is what we see ourselves because one of the net result of the adoption of serology in the U.S. and not necessarily by testing volume, but by the fact that every hospital is still doing serology, we're talking about on average 1,000, 2,000 tests a month. This has pushed the installation of lots of LIAISON XL as well in the proper segment, which is the hospital segment; remember we had a hospital strategy. And what we're seeing is that now these hospitals that have the XL are saying, okay, let's you know a faster adoption of TD, TD is a designated victim rather than sending it out to Quest, LabCorp, Sonic we're going to do it ourselves because now we have the XL. GI, same-story, it was in a relatively small, small mid-volume, not worth taking it itself. But now that we have the box and we have TD, now let's do also the Calprotectin, the H-pylori and all the rest.

And I think this is true for all the diagnostic companies. So what you will see is going to be that there are going to be a lot of in-sourcing of testing and less of send out and this I think should be a concern of some of the big laboratory chains in the U.S. And if I'm not mistaken, some of the CEOs already did comment on the fact that the next challenge in the U.S. market for them is going to be the fact that hospital will tend to in-source.

MAJA PATAKI: Fantastic and the saliva tests?

CARLO ROSA: Saliva tests, you need to stay tuned, because we launched it with…we launched the antigen with NPS and MS and we're now doing the clinical studies for…to validate saliva. As you know, we were able to validate saliva on our molecular test. We have a C-Mark; the only company with a C-Mark saliva claim on molecular, very proud of it. And now we're doing the clinical for the antigen. The real problem, to be honest with you is that when you…since the FDA is asking for symptomatic and asymptomatic patients, one of the problem with symptomatic patients is that they have no saliva, unfortunately, and this is because of the respiratory condition, but also the fact that everybody is under oxygen. And one of the effects of this oxygen is that it dries up completely your mucosa. So the clinical study is longer than expected more on the symptomatic, but we're working on it, and we're going to keep you updated within the next 4 to 6 weeks.

MAJA PATAKI: Fantastic. Thank you so much.

OPERATOR: The next question is from Scott Bardo of Berenberg. Please go ahead.

SCOTT BARDO: Yes, thanks very much for taking the questions and congratulations again on good, great results today. I guess with the news flow on what appears to be quite an effective vaccine, investors are increasingly focusing on the new normal for DiaSorin and where you land post this crisis. So I wonder if you could please share some thoughts as to how is the recent experience that you've seen with COVID-19 installed base, tremendous growth in margins and so forth changed in any way your longer-term perspectives of the business pre-COVID, which was for mid to high-single-digit growth and slightly over 38% or so margin. So I wonder if you could talk a little bit to

that on when potentially we could see a more normalized type growth profile for the company. So that's the first question please.

Second question, pleasing to see you have a laboratory antigen test, which I think looks to be a good one. Siemens Healthineers recently pouring a lot of cold water on the notion of laboratory based antigen tests suggesting there's not really an opportunity there because of these logistical considerations. Can you highlight why you would disagree and also again, your comments on antigen going away relatively quickly after full vaccination? Is it unfair to suggest that you move into the more numerous and bigger lateral flow opportunity at a time when the market is already starting to teeter away? Thank you.

CARLO ROSA: Okay, let me just make a joke. You always say that the test is no matter when you don't have it. So I think that I didn't hear Siemens making this statement, to be honest with you. I heard Roche saying that they're coming in December, that I heard loud and clear and I've seen that Roche made, pretty much the same comment we made, it's very important, too different, the utilization of the assay is completely different. The point-of-care does carry lots of benefit, if you want to go deep down in the community, if you want to provide to the family doctor with a tool to rapidly identify whether an asymptomatic patient that shows up is COVID or non-COVID. And then actually send the patient to avoid that all these patients rush to the emergency room and they get completely congested, fundamentally, the emergency room which is something we're experiencing these days.

However, there is a trade-off. And the trade-off that we see is performance. You saw Quidel yesterday had actually an FDA warning letter, a public warning letter on the performance of the product, because the lateral flow technology is a good technology but that carries a limitation in terms of

sensitivity and specificity, we all know, but it's a good trade-off because it's portable. So you can actually decentralize testing lateral flow.

I believe that when you take that assay and you put it into a LIAISON format, Chemiluminescence, call it LIAISON, call it Roche, call it Siemens, if they're able to do it, it would be fundamental, you go back to the typical performance of…analytical performance of a Chemiluminescence assay that from our experience, you gain minimum analog in sensitivity. And this actually allows you; I believe to get closer to the sensitivity of PCR.

And on this one, Scott, you're cynical enough to understand my comment, you know that today, there are lots of debates about the fact that PCR is too sensitive. And now there are indications again, indications and not guidelines to the fact that if you run a PCR assay and you have…you are over 33 CTs, so you're positive. But over 33 CTs, well you have detectable virus, but you're not necessarily infectious. And so everybody is indicating that the clinical relevance for infectivity is up to 33 CTs. And if you see some of the antigen tests have been actually tested, the FDA asked you to look through the spectrum. But fundamentally, the clinical claim is up to 33 CTs. We with our assay and the sensitivity that is provided by the Chemiluminescence technology, any Chemiluminescence technology, so I'm sure Roche is going to get there as well. You're getting to the level where up to 33 CTs you pretty much measure the result of the PCR, give or take with Chemiluminescence. This is why I'm saying that I see a need of an antigen test done and managed by the central lab.

And I've seen how customers that have adopted rapidly these assay are using it and then an example is one of the…in an Italian region I cannot name the hospital or the region, they use it to rule out all the asymptomatic, right and because they have a gazillion asymptomatic patients that are coming over

because they're relatives to people that have been diagnosed and then you need to understand [indiscernible] quarantine all that that jazz and story.

And the hospital today is using it to immediate very fast rollout; they're asymptomatic and free them up versus then get themselves into the quarantine. And today, lots of volume actually is going in that direction. This is why I'm saying there is a need for these antigen tests. It is going to go away because eventually when you'll be able to choose, you're going to be choosing for clinical, again diagnostic specification you're going to go for a gold standard, and gold standard undeniably is the PCR, it’s the PCR assay.

Now, let's talk about the post-COVID, post-COVID world. Okay, let me just state I don't know when the post-COVID world is going to start, okay? I think, I hope they're going to start in 2022. Post-COVID for us, if you listen, well, I know that you listen and unfortunately some of other investors did not. They were too much focused on COVID but we started to talk about the post-COVID world 3 months ago.

And to me the best mover was MeMed, and we talked about MeMed and nobody listened because everybody was enthusiastic about COVID but MeMed for us was the beginning of a new post-COVID world where certainly we have an installed base in hospitals, because of COVID. And MeMed is a fantastic opportunity because it's innovative; it's very much welcomed clinically by physicians. MeMed, the company itself spent million [ph] amounts of dollars into the clinical validation of the concept and we expect that very rapidly, they're going to have also the FDA approval, so that we can use their assay as a medical [ph] device. So MeMed to me is the post-COVID world that relate to DiaSorin 3 things in my opinion, brand recognition, because we have been faithful in loyally serving our customer base without a single day of the quarter. And this has

been recognized by everybody. And installed base that we were able to establish on molecular and immuno and last but not least, COVID will translate to everybody into lots of cash, right.

And, now the next question would be I'm going to reply before you ask the question. The question is you need to take that cash and then rightfully invest it in order to strengthen the company. And certainly M&A plays a role. And we do have a plan, as you know, we're being always careful buyers, we believe that the post-COVID time is going to be a good momentum to look into M&A opportunities, and we're certainly focused on that.

SCOTT BARDO: Thanks very much. And maybe just quick follow-up if I can. So you're right, I was going to ask you a question on M&A. But then, just to understand and maybe too difficult to answer, but the profile for the business is pre-COVID as compared to post-COVID, it is still relevant, mid-to-high-single-digit, sort of high 30s margin, and maybe to ask the M&A question slightly differently, with DiaSorin set to exceed, approach the €1 billion sales mark, do you feel confident that that is a level and watermark level that you can sustain along with M&A going forward?

CARLO ROSA: Listen, again, I pull out my crystal ball. I look into it and I say yes, because nothing changed, okay. So DiaSorin has always been a profitable company, because of the nature of the business we run, which is extremely specialized. And again sorry, if I go back to look a minute, we didn't get ourselves into another PSA [ph]. We got ourselves into far front technology, clinical technology MeMed, which is high-value products, and hopefully high profit product, certainly we will need to invest in marketing and promotion. But it's a good bet, because it’s a phenomenal clinical tool that everybody is welcoming.

So if I look at the crystal ball post-COVID, I think that we'll continue our trajectory. Hopefully, we're reinforced strategically by the proper acquisition that will give us sustainable critical mass over a billion.

SCOTT BARDO: Okay. Thanks very much, indeed.

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

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