DiaSorin SpA

"First Half 2020 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 Half 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. Good afternoon to everybody. Welcome to the DiaSorin Quarter 2 call. As usual, I'm going to make some general remarks about the business, and then Mr. Pedron, our CFO, is going to take you through the numbers.

I think that, as you have heard from other competitors in the field of diagnostic, when you look at the business these days, you need to...you really need to look at the business 2 ways, the current business and the underlying trends and the COVID-19 effect.

So let's talk first about the underlying business. The underlying business ex-COVID, the result of the business is primarily driven by volume, associated to the fact that, especially in Q2, which was the peak of pandemic in many European countries and in the U.S., the volume per se, the business volume declined sharply, simply because patients were not available to go to hospitals, to avoid to get infected. And clearly, there is a trend. Overall, for DiaSorin in the quarter, the non-CLIA business declined roughly 30%, again, primarily driven by declining volume.

If you look at the different regions, what is noticeable that along the quarter, in quarter 2, we see stabilization or an improvement in Europe? In several European countries, we see that at the end of the quarter, the volume is roughly down only around 10%, indicating that

the situation is better. Whereas in other countries like China, we continue to see our volume that is certainly improving, but not to the level and the extent that we have seen in Europe and somehow in North America. Certainly in North America it's a question mark because we all realize they have not had the peak yet. And actually, they are still increasing in terms of prevalence of the disease. So we don't know whether this apparent stabilization that we see will continue or how that...or how it's going to behave.

From...now if you look at the COVID business, I think that we need to distinguish between COVID molecular and COVID immunoassay. COVID molecular revenues continue to be very strong. It is driven by a strong demand in all geographies, related to the fact that guidelines today do recommend to swab patients, in-patients, for sure, outpatients, to swab employees in certain geographies to guarantee that the manufacturing departments of the companies stay without getting employee infected.

So there is a surge in demand of molecular, driven a lot by North America. You know that there is a plan by the government to sharply increase the swab capacity in preparation of the coming fall. Today a report, I think in the U.S., the total number of swab is around 15 million to 20 million per month. And there is an objective by the government to get to 100 million. So a lot of pressure to the labs and to the industry to continue to supply more reagents.

As far as DiaSorin is concerned, we, as I think everybody else, has had an opportunity to deploy more systems. We now have over 1,000 MDX placed around in worldwide with a sharp increase compared to last quarter. I remind you that the positioning of our system is not point-of-care because it's a small system that can process 8 centers at a time. So what we see is that there is an increasing demand in small, mid-sized hospitals that cannot wait until the big labs, the turnaround time of the big labs where they send out. They cannot afford

technologies, high throughput and the point-of-care systems today available are too small and therefore, the MDX perfectly fit with this mid-sized hospital.

And this is certainly true in the U.S. And if you remember what was the company strategy pre-COVID, driven by QuantiFERON and penetrating the hospital market strategically, this, again, is supporting a lot. And because now we can go up to these hospitals and we can provide a solution with the COVID molecular, and we can also provide serology and our LIAISON XL and you saw that placements for LIAISON XL surged in quarter 2.

So as far as molecular is concerned, it's a matter of manufacturing capacity and the company, i.e., over the last call, I think I gave an indication in terms of what would be the objective of the company for capacity. And today, we are able to manufacture around 700,000 tests per month molecular, and we have a plan to bring that number to 1 million by year-end in anticipation again of a big demand with the next flu season, starting from October.

So now let's move to serology. Serology is a very interesting story because at the beginning of the pandemic, as soon as products were made available to customers, there was a surge in demand. And if you look at what different companies declared in terms of capacity, manufacturing capacity, it was among the number of product tests that the COVID...the diagnostic industry was prepared to provide to customers. After an initial consumption of the serology tests and I'm referring to the IgG test, the situation for us is a result of lack of guidelines.

There has been a tremendous amount of discussions at the scientific level vis-à-vis what's the value in detecting antibodies. The initial open dream was the fact that antibody detection will provide an indication of immunity. That clearly was not the case, simply because

our clinical threshold for immunity has not been defined and will be defined the day that the vaccine industry is going to declare it, once they launch the vaccine.

Then there was a usage of this test for epidemiological studies. It is still there, but I think the initial intent of governments to conduct large epidemiological studies eventually faded away, because there are different priorities today for governments. I'm referring to the Italian government, for example, which launched a campaign of 150,000 citizens to be tested and from what we understand from public information; they were only able to collect around 80,000. And other governments as well declared massive screening program that eventually did not materialize yet.

So today, serology is at the...the use of serology is more clinical and is related to those countries where there is an ongoing epidemic or there is a lack of swabs. Because somehow, IgG and IgM are used to complement for the fact that there is a chronic lack of swabs. So we see still opportunity for serology's in Brazil, in India, where we see adoption of IgG and IgM. But in the more mature countries, we see that the volumes have eventually declined to numbers, which are far below what were the expectation of the industries initially, as clearly, you picked up following comments from other diagnostic companies, including some large labs in the U.S.

So today, what's the future of serology? Well, we believe that the future of serology rests with vaccination and vaccination campaigns. And as it happens with certain vaccines after post-vaccination, there can be a need of determining whether the patient has properly responded to the vaccine. It's the case, for example, of some vaccines like the hepatitis B. If that happens, and even if, because it depends what the regulatory bodies eventually will mandate and/or what would the guideline will say post-vaccination, we see a potential...tremendous potential for serology that probably is going to be a combination of

classical test, venous test and a combination of probably some rapid testing that in that case, could fit the market because we don't need an excessive sensitivity, which usually is the problem with this test. But can probably be sufficient to determine whether a certain threshold of antibodies have been generated or not after vaccination. So I think that's difficult to predict what will happen with serology. We need to wait for guidelines for the vaccine.

From a geographical point of view, very clear, clearly, what I said is reflected in the performance of the company. North America has been growing dramatically for the company. In the quarter, 72%; in the first half, 42%, again, driven by tremendous adoption of swabs and initially of serology, which was actually used by some of the labs in massive volumes. Initially, again, that interest is fading away a little bit.

Then with Europe, Europe behaved well for the same reason. In Europe, we have distributed...we made available to European countries, including Italy, certainly, our home market, our molecular product and our serology product. And that has allowed Europe to grow notwithstanding the fact that we have experienced in different countries a decline of volume as said of the base business because of the COVID pandemic.

We have a black eye in China, as I think everybody else. And this is because, so far, in China, there is no foreign company through with a COVID product. And so you don't enjoy, as a company, the opportunity of COVID in China, whereas you suffer from the decline in volume. So China declined sharply for us in Q1. It continues in Q2, although we see a slow improvement in volume, but still negative.

And then let's talk about Latin America. Latin America, we all know the situation in Brazil, which for us, is the main geography. In Brazil in Q2, we did suffer by the fact that, well, first, we did not launch our

molecular assay in Brazil, and so we don't have their support of molecular. And recently, we got our serology product approved.

And therefore, we expect that starting from Q3, we will see adoption of our serological test in Brazil and that will actually revert the result of the region of South America from being sharply negative to being positive in quarter 3 and in quarter 4.

As far as the futures, I want a couple of comments. The first comment, I believe that we do have an intensive research program for COVID. And as declared, as stated before, we see that there is a need for a saliva based test, more sensitive than what is currently available to complement the chronic lack of swab. And we have a program in the direction with a partner, with a U.S. partner, in order to try to come to the market with products by the coming fall season and flu season.

And also, we believe that there is a need from a serological point of view of a qualitative test that is actually set up, for again, post-vaccination. And therefore, we are actually working in developing a new serological test for IgG determination, quantitative that standardize, that we plan to make available again by the time the vaccine is launched.

So from a product perspective, all our effort on COVID, as well the COVID program is an IgG, assay, [indiscernible] for vaccination, and saliva and another swab product to try to reach to the best sensitivity, to try to complement swab for the coming season.

At this point, just again, one remark. COVID has been an opportunity for the company, not only to establish a brand with the products we have developed, but it has been a great opportunity in North America to establish an installed base. As said before, if you remember, we had strategically, we had a plan to penetrate the hospital market with a

mind...a certain number of hospitals to be actually reached and closed by end of this year.

Well, comes Q2, we already almost doubled the target of the hospital number that we targeted for the full year. So that I see as a tremendous legacy opportunity for DiaSorin because we are penetrating with our products, we call it molecular and immunoassay segment that's strategic for the company.

And certainly, we will see then adoption on our systems of the QuantiFERON, all the specialty products that we carry on those systems. So I see a very positive effect of COVID strategically, in terms of positioning, branding and installed base.

Now I leave the podium to Mr. Pedron, who is going to talk about the numbers, and then we're going to start a Q&A session.

PIERGIORGIO PEDRON: Thank you, Carlo, and good afternoon, everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin during the first half of 2020. And I will make some remarks on the contribution of the second quarter as well.

As usual, I would like to start with what I believe are the main highlights of the period. We closed half 1 with an increase in revenues at constant exchange rate of 8.7% or €31 million. As a result of the soft first quarter, mainly due to COVID-driven reduction testing volume in China, as we discussed and a very good second quarter, up by 15.4% or €28 million. Q2 gross margin confirmed the good results achieved in Q1 '20, with a ratio of revenues of 69.1%. H1 '20 gross margin ratio at 69.1% as well, is slightly lower than H1 '19, with growth at 69.5%. I will discuss later about the main drivers behind this variance.

H1 '20 EBITDA at €154 million, records an increase at constant exchange rate compared to the previous year of 10.1%. H1 EBITDA margin, again, at comparable FX rate, is 40.2% vis-à-vis 39.8% of 2019. Q2 '20 EBITDA at €89 million or 42.9% margin, registers a very good performance, with an increase of 24% or €17 million compared to Q2 '19. Lastly, we confirm our ability to generate a very healthy free cash flow, €74 million in the first 6 months of the year, which brought the net financial position to positive €190 million. Let me please remind you that in June, we paid €52 million dividends to our shareholders.

Let me now go through the main items of the P&L. H1 revenues at €382 million, grew by 9.1% or €32 million compared to last year. The growth at constant exchange rate is 8.7%. The strengthening of the U.S. dollar against the euro is the main reason behind this FX tailwind, which has been partially offset by the devaluation of the Brazilian reals.

Considering where the U.S. dollar is trending now compared to 2019, I believe it is fair to say that we might experience in the second half of the year some FX headwind that will likely offset or even more than offset the upside of the first part of the year. H1 gross margin at €264 million, grew by 8.5% compared to last year, closing the first 6 months of 2020 with a ratio of the revenues of 69.1%, a touch below H1 '19, which closed at 69.5%.

The slight decrease in the year-to-date gross margin is the result of the following. A negative product mix coming from lower CLIA sales and higher molecular sales, which enjoy slightly lesser margins, partially offset by better fixed cost absorption as a consequence of higher manufacturing volumes. Higher distribution and freight costs, mainly driven by the fact that many commercial flights, which under normal conditions would have been used to move our goods, have been grounded because of COVID. And so we had to use cargoes, which

are usually more expensive. H1 total operating expenses at €131 million or 34.3% of revenues have increased by 2.4% or €3 million compared to last year. OPEX ratio by revenues is at 34.3% vis-à-vis 36.6% of 2019.

Here, we had 2 effects of opposite side. On one side, we have had a slowdown of activities and the consequent reduction in costs caused by the widespread lockdown measures that interested all the geographies in which we operate. On the other, we have had an increase in costs, mainly driven by the investment we made in the U.S. commercial team, aimed at sustaining our hospital strategy, as we talked over in the past few quarters, and Carlo just mentioned. H1 '20 other operating expenses at €9 million increased compared to 2019 by €4 million. As discussed during Q1 '20 call, most of this variance is driven by a non-forecasted loss we suffered in our South African subsidiary during the shutdown process, for which we have activated our insurance policy...our group insurance policy.

As a result of what I just described, H1 '19 EBIT at €124 million or 32.3% of revenues has increased compared to 2019 by 12.2% or €13 million. Q2 closed at €74 million or 35.7% of revenues, with an increase of 30% or €17 million compared to last year. The tax rate at 22.5% is substantially consistent with H1 2019. The net result at €95 million or 24.8% of revenues is higher than previous year by €11 million or almost 13%. Lastly, H1 EBITDA at €154 million is better than 2019 by €14 million or 10.3%. The variance at constant exchange rate is positive by 10.1%.

First half EBITDA ratio on our revenues is 40.2% at current exchange rate vis-à-vis 39.8% of last year. Q2 has recorded a very good result, closing at €89 million or almost 43% of revenues. Both H1 and Q2 improvements compared to last year are mainly driven by the higher sales and gross margin, coupled with a very nice operating leverage coming from the reasons that I just talked about.

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 €190 million after payments in June of €52 million dividends to our shareholders. In the first half of the year, the group generated €74 million free cash flow vis-à-vis €70 million of 2019. The semester has been negatively affected by an increase in working capital, driven by higher sales and so accounts receivable, higher inventory to sustain COVID tests volume and higher CAPEX, driven by the acquisition in Q1 of the TTP license, partially offset by lower tax cash out, mainly coming from a positive payment phasing.

Lastly, guidance. So considering the uncertainty and unpredictability of the impact of the coronavirus pandemic in the second half of the year and the risk of further widespread strict lockdown measures, DiaSorin, similarly to what's done in Q1 is not in a position to give an economic guidance for the remainder of the year.

Nevertheless, in the light of the good performance achieved in H1 and taking into account the importance of the diagnostic industry in managing the consequences of the COVID pandemic, the management is not expecting a negative impact on the results of the second half of the year.

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 Andrea Balloni of Mediobanca. Please go ahead.

ANDREA BALLONI: Thanks. Good morning or good afternoon and thank you for taking my questions. My first question is about serology test production capacity utilization. In your last conference call, you guided production capacity expected to increase from 5 million to 10 million per month. We understood that so far, the utilization is much lower compared to the top of range, if you can give us an idea about the capacity utilization in July, just to understand where to set our estimates.

My second question is about the molecular test. During the last conference call, if I'm not wrong, you guided for around 10 million to 12 million sales per month without stating the amount of test produced. Now you said that you are producing 650,000 units per month. And if I have understood correctly, you will like to achieve a level of 1 million per month by the end of the year. If you can give us an idea about the target in terms of sales by the end of the year per month?

And my third question is again about serology test, we saw in Italy, a draft law in order to allow students re-entering in the school, and one of the point included in this law is the utilization of a serology test for both students and also for teacher and so on. Do you expect this could trigger a high utilization of serology test, at least in Italy or this could represent an example also for other countries in order to increase utilization of serology tests in the school?

CARLO ROSA: Okay. Listen, I will not give volumes in July for serology. My indication is clear, serology; our manufacturing capacity is in the 10 million a month. That capacity today is clearly not used. You can go and check. If you want to have an understanding of volumes, I think

you go to LabCorp and Quest reports. And you understand what the current expectation of volume is, which is far below versus what everybody thought. I remind you that there have been statements by certain competitors where the capacity was up to 100 million per month, to 40 million per month to 30 million per month. So the industry realised that its capacity for a demand that eventually did not materialize after an initial surge. I'm saying that the big question mark is vaccination and the big opportunity is with vaccination today for serology, and we need to see what that will be.

As far as school, in the U.S...I don't know about the Italian law, to be honest, we do not have clarity these days about what Italy is doing. And I think you can share the pain with me about that. But all said and done, I look at the U.S., for example, and as far as the U.S. school is concerned, there has been actual guideline to say that testing will not be required, okay. So today, there is lots of confusion, I think in the market among experts about serology. And this lack of interest and this confusion is actually pushing for less adoption and lack of interest. And this is the difference between serology and swab because today for swabs, there is a very clear guideline. We start from the WHO and then has been transposed into the different countries. And this is why there is a clear usage and clear increased volume for swabs and a lot of uncertainty on serology.

For molecular, I gave initially an indication of revenues, but then in the last call, I also spoke about manufacturing capacity, which I think is…in this case, is a good correlation between revenue and…with the revenue simply because there is more today, demand and capacity for everybody. And so, what you can manufacture actually correspond in this case and for the foreseeable future to your revenues. And we have indicated that today, we do have an capacity overall, around 700,000 tests per month, with a plan to increase it to 1 million tests per month by year-end. And I think from that, you can...and understanding what is the price on the market, you can make a gross estimation of what

DiaSorin revenue per month can be moving forward between now and December.

ANDREA BALLONI: Thank you.

OPERATOR: The next question is from Catherine Tennyson of Bank of America. Please go ahead.

CATHERINE TENNYSON: Thank you for taking my question. I have 2. Just following up on the previous question, in Q2, we had about €89 million of benefit from COVID. Could you roughly help us understand how much of that came from molecular versus serology, I appreciate you won't give the July run rate. But if you could give us any idea on volume to that in Q2 and how should we think about the monthly demand for serology going forward? Thank you.

CARLO ROSA: Catherine, I cannot, because I believe that even if some competitors were very analytical about the revenues and some other competitor decided that to keep the numbers to themselves. I think that this is what we decided to do. And again, the indication is follow. I don't think that what happened in Q2 is a good proxy for serology to what is going to happen in the future. And therefore, I see no value in really declining serology revenues, because it has been a peak that is not going to be repeated until there is something that will make serology as a technology needed, okay. And again, as said, the only way is going to be that post-vaccination, tighter determination.

Molecular, you can do your math. Clearly, you can do your math with information I gave you, because you understand what is the current price for our molecular test on the market. And so, do the math and understand the potential for molecular, which is certainly vast I have to say. And it is like that in the U.S., because the government has announced this grandiose plan objective to be able to get to 100 million swabs per month, okay. So it is very relevant for me that as investors

and as analysts and you guys understand that serology in Q2 has been a nice opportunity, but eventually, it cannot be repeated, whereas the solid business today stays with molecular product.

CATHERINE TENNYSON: That's it from me. Thank you.

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

MAJA PATAKI: Hi, Carlo, just to follow-up on your statements with regards to serology tests, and in general, a bit more about the outlook for COVID-19. I mean, as we…as we're passing time…as we're learning about COVID-19, you've mentioned that there could be an opportunity for serology tests in combination with vaccination. Do you believe that based on the data that we have today, COVID-19 will remain [technical difficulty] of the portfolio for a medium to long term rather than what we anticipated all in the beginning that there would be one vaccination, and you know, you might have immunity forever? So do you think that COVID-19...the opportunity from COVID-19 is obviously always changing, but do you believe that now there is a potential longer term opportunity?

CARLO ROSA: Maja, look, to be honest with you, if today, I make a public statement on this, I will be better off to explain a lot, because the probability for me to give you the right answer is fundamentally the same. But let me just give you a common sense comment. Let's talk about the vaccination. First, you understand that there are...there has been a very nice publication recently on lancet, which has, in fact, described the initial data on one vaccine. And I see that today, there is a fundamental discussion, and nobody knows yet whether…the vaccine…first efficacy, second, what is the effect of the vaccine. So you're going to be vaccinated or simply it is going to tame the infection, and avoid that the severity of the infection once you get it without vaccination.

So to make a long story short, this is what I believe. I believe that there will be a need somehow to test whether the patient has reacted to the vaccine. I see the complexity, though, because if you use a traditional or a serological assay, it means that you need to have millions of people lining up to take blood and to get blood drawn and tested. And that is a complication. I see in that sense that there is an opportunity if the technology can deliver for a lateral flow [indiscernible] something that makes the testing post-vaccination simpler, okay. So the question is, what is it going to be the opportunity for serology? And is it going to be more on the lateral flow versus the traditional immunoassay done in a lab. And I don't know that yet, because it's too recent.

As far as the opportunity, I believe, I think I share the comment that some competitors make vis-à-vis 2021. So if you heard what I believe QIAGEN said or Roche said, everybody sees that 2021, we like it or not, notwithstanding availability of vaccine, we're going to go through the hurdles of COVID, and we will need more testing for COVID. In my opinion, we will need more molecular testing because of the need to isolate people very rapidly. You see what is happening in Europe, because of the fact that this swab is becoming common practice in admitting people at the hospital, for public workers, for police people and so forth. So I see 2021 still COVID, I have no idea whatsoever what is going to be 2022. And to be honest with you, I wish to myself that COVID goes away because quality of life and economy needs a free...world free of COVID.

As far as we are concerned, I would like to make a comment, what is COVID doing to us? Tremendous branding, because everybody...we were the one that you know, because of the characteristics of our technology for molecular we do not extract. So, it's the direct determination [ph] of the virus, that allowed us not to go through the hurdles of shortage of reagents for restructuring, which has been one of

the problems of other competitors. And since the beginning, we have not back ordered a single customer with COVID. So there is a reputation that we have acquired in the business. On top of that, we clearly had an acceleration of set…as said of the installed base, both of COVID and the non-COVID so the serology.

And today, as far as serology is concerned, if I look at what the company got out of it, we got cash for sure from serology, because it has been a significant opportunity in Q2. But strategically, we got an installed base of systems in hospitals, especially in the U.S., that will continue to do COVID serology at a much smaller volume than what was expected from a very large lapse. But they do COVID, they use the serology and taking our system there, they will do QuantiFERON, they will do all the rest. As I said before, we had a target of hospitals to be closed by in 2020. And by June, we already almost doubled the number of hospitals we have enrolled as customers. And this is, I think, as much as a common salesperson can say about COVID.

MAJA PATAKI: Okay. And just a follow-up, Carlo, on the saliva test that you briefly mentioned that would be for active infections, correct?

CARLO ROSA: Yes, it would be for active infection because today, if you…you know, there are assays that…and I think Quidel is a good example. So there are companies that launch product on NPS or on nasal [ph] right? So the unit you swab, and then you can test antigen with a relatively good sensitivity in the active phase of the infection. There are 2 problems. The first one is, the swab percent, which as you know, is relatively complicated, especially, you can get negatives, if you'd not done properly. So swabbing people, it's an art it's not something that anybody can do.

Saliva is a perfect medium for testing, because it really can be simply collected by [indiscernible] device. And we do have collaboration with a U.S. company that does have this kind of experience and device

on saliva collection. And this is why we believe that an antigen…antigen and something else that we've not stated yet, but...and an improved antigen test on saliva would be a tremendous tool, because it's much simpler to collect, it can be a widespread use, and it can be adopted very rapidly by hospitals. You saw that in the U.S., I believe…government has a sign up Quidel, I think they stated 700,000 tests. So the need for this kind of test is huge.

MAJA PATAKI: Okay. Thank you very much.

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

SCOTT BARDO: Yes. Thanks guys. Thanks for taking my questions. Yes, first question on serology again, sorry for that. I think at the time that you and the industry were developing serology tests, it was pretty apparent that there was no strong evidence that the detecting antibodies, IgG antibodies you know, strongly correlated with immunity. Yet, I think DiaSorin claimed that you had new...isolated a neutralizing antibody and you best to prove that. I think that you were expecting very strong lab demand as a result of that, along with the whole industry. So what I'm trying to understand is, in the last few months what has massively changed such that the industry has got it completely wrong with respect to capacity and demand and the ability to make this linked to immunity. So I wonder if you could discuss that a little bit more.

Second question, please, on the antigen test, I think, on the last call, you highlighted that this could indeed be an even bigger opportunity than serology and those expectations last quarter were clearly quite high. Along this development process, first of all, can you give us a bit of an update…are you incrementally more positive on your ability to launch a solution here at all or in full or is this still in a high-risk camp, if we could just discuss that a little bit more, that would be helpful? And last question, please, Carlo, and I appreciate that this is somewhat of a sensitive topic. Can you give us some sense and understanding for

some of the legal challenges that you've been facing in investigations in Italy? And where the company's stance is with respect to the forward positioning of the business? Thanks.

CARLO ROSA: Okay, Scott. Now, let's talk about serology, neutralization and immunity. Since the beginning, we clearly stated that we were not providing an information on immunity, and if you followed the thread of information back then, funny enough, we're more...I think where more politicians saying you know, we are going to have now the silver bullet with serology because it's going to provide what everybody was...in Italy was called the patentino d'immunità, so like the immunity card, which was obviously a surreal statement by politicians. We had devoted an amount…a certain amount of time in clinical studies to look at neutralizing antibodies because we thought that as it is true today, if eventually, in order to provide an information around immunity it has all to do with the ability to neutralize the virus. And this is why we conducted the clinical study in order to prove that.

And we provided a tool, ex-U.S., that has been used by several centers around Europe that appreciated that neutralizing claim. In the U.S., we did not get the claim approved, as you noticed from the packaging. So for a very simple reason because the FDA came back with the $100 billion question. Tell us, what the immunity threshold? So tell us…okay, we understand you measure neutralizing antibodies, but tell us what would be the threshold of neutralization that provide immunity, you know, that's a very smart way out of the question because we cannot...that's a question for the vaccine industry, but the signal that came from agency is look, we understand value of neutralization. By the way, you know, there are different labs that today are providing LDT solutions for neutralization. I think Quest announced it, LabCorp announced it, is a research tool, but nobody can actually claim what neutralization means until somebody will establish what the protection level. And that can only be a company vaccine...a company that has conducted a clinical study.

So this is why at the beginning...look, at the beginning, I think everybody in the industry declared that extreme capacities of this because nobody really knew what were the...how it was going to be used. And governments were making statements…public statements about their willingness to conduct very large studies with millions of people involved in this study. Well, it didn't happen in my opinion for 2 reasons. First, that eventually, if you run an epidemiological study to understand the immunity, well on the general population, you're going to have a prevalence which is very low with the exception of few places. If you go today in Bergamo, in the area where eventually it was hotspot for Italy, you would find 30%, 40% of the population, which is actually being infected. But if you go anywhere else in Italy, especially if you go south, you would find a prevalence of 0.1%? So, the concept was the exception of a clear use in certain hotspot, why should we conduct a study when the prevalence is so low.

The second information back then was the so-called [indiscernible] to reopen, if you remember you know, in all the newspapers everybody was saying, serology will allow companies to reopen. But then the algorithm was set such that you will do serology...you can do serology, but then any positive you find, then it goes to...it now enters into a program which is managed by the government, which means, a) you need to be quarantined, b) you need to get a swab until you return, and third, you're going to take…you are going to take…you and your family will be segregated until you get the results. And people here started to wonder, what's the value of this information? So I'm going to do an IgG, if God permit, I'm going to turn out positive. And if I'm turned out positive because of a past infection, I know information about immunity first. And second, I get into a nightmare, because I need to get tested, I need to be quarantined, I need to get segregated. That's fundamental, that uncertainty has created a lot of questions about…okay, why do we need to do serology? And serology today reverted to where it belongs, to clinical use, so when you have patients

which are hospitalized, then you do serology in order to understand when they develop, after the swab, when they develop the IgG and IgM as part of an algorithm, which is a diagnostic algorithm, but is not for epidemiological studies. And this is what, honestly, we see today.

There is one more usage of the serology test, which is very interesting, which has to do with the fact that one possible treatment for COVID, as you know, is a transfusion to critical patients with blood coming from donors which got infected, develop a titer [ph] and then eventually recover from that disease. There are certain protocols…experimental protocols, which have been approved in Italy, in Pavia, for example, in the U.S., but still, there is not a massive use of the product to screen donors then for donation. That is fundamentally the story around serology.

Antigen testing; Antigen testing, where are we? We are in the...we are beginning the clinical studies, and it's a complex clinical study simply because today, in Europe, you have...you understand first that you need to do a clinical study on active patients. And today, with few hotspots in Europe, you know, there are no active patients so any longer. So it's difficult to find these patients. It sounds funny, but it's terrible, the place today where to do clinical…is the U.S., because is a place where you can find lots of active patients. Therefore, we are initiating the studies with the U.S., although you know the IRB and the time it takes in the U.S., to get the clinical's approved, it takes longer than Europe. And so, today, we are in the phase where we have internal data, which are interesting and promising. But then we need to validate this data with patients that we will need to collect...we are collecting in the U.S. So I believe we are going to have more certainty around September time frame, and we plan eventually to make...to bring this product to the market, hopefully by year-end.

Third element is the legal. Look, unless you are Italian, it's very complicated to describe the legal system. But I'm trying to do it the

best I can, and clearly, I'm not going to make any statement vis-à-vis the current DOJ investigation, because it's not...I cannot do anything like this. Well, the situation is very simple, there has been a legal case, which has been brought up by a competitor…a Chinese competitor, in under...in front of the administrative court in Pavia, and that was against the agreement, which was a clinical experimentation between us and the hospital in Pavia and the claim of the company was that, that agreement which was...gave DiaSorin an unfair advantage in terms of its ability to develop a serology assay.

In the first degree, the administrative court actually ruled in favor of the company, and so the net result was that the agreement between us and the hospital which at that point was concluded because the experimentation was concluded was in fact, declared nil and invalid without repercussion on the DiaSorin product per se. Then we appealed to the high court in Rome and the high court in Rome ruled recently to say that the...actually, the first administrative court ruling is and then it indicated...the court in Rome asked the Minister of Research in Italy to give an opinion whether the clinical study, which was conducted in Pavia between DiaSorin with the San Matteo Hospital was something that was common, let me say, or it did, or if it showed anything there that would be unusual in the way it was conducted. And…but as we speak today, the court...the high court ruled that the first court ruling has been declared nil and suspended, okay. So we are now waiting for the Minister of Health to provide a report to the high court, and then we expect that by year-end, the high court is going to rule the initial indications of the high court. I'm not going to comment, but if you read what the high court said, I think, I believe you understand what inclination of the court is. And this is from an administrative point of view.

The company also has provided to the Department of Justice in Pavia, documentation to look from a penal point of view, the agreement, again between DiaSorin and San Matteo. And I think that what we

have seen in the news is, that I can comment on, is that the Department of Justice has decided to initiate an investigation, again, based on San Matteo and DiaSorin agreement, which has been declared today valid by the high court. That's the interesting part. So the final judge [ph] is initiating investigation. They came to the company, and they've taken information about all the development work that has been done in DiaSorin for the development of the serology asset.

And this is where we sit today. So today, there is no affect, as far as, the business is concerned, the company continues clearly to operate. You know, that as far as, penal [ph] responsibility is not with the company, is to do with the company legal representative. So the company continues to operate as is, continue to manufacture products and serve customers. And we're waiting to see what the DOJ will decide to do, but you know that it may take a long time. And this is what I can say factually for what has happened in the last 90 days.

SCOTT BARDO: Okay. Thank you very much, Carlo. I will get back in the queue.

OPERATOR: For any further questions, please press "*" and "1" on your telephone. The next question is a follow-up from Scott Bardo of Berenberg. Please go ahead.

SCOTT BARDO: Thanks very much for the follow up. Just a real quick one. Piergiorgio, I wonder if you can help, I think you're expecting then a recovery of your base business in the second half of the year and pretty high continued growth in molecular diagnostic, which as you've said is coming broadly from the U.S., and you can tell sizable margin. So the nature of the question is, this 43% EBITDA margin that you post here in the second quarter, I mean, is this a basis that you can progress from in the second half of the year? Any understanding about the sort of profitability development of the businesses for the rest of the year unfolds would be very helpful?

PIERGIORGIO PEDRON: Yes, Scott. So it's very difficult to make projection for the second part of the year. And that's the reason why we are not giving the guidance, but I believe that 43% margins, I'm not expecting to be able to maintain such level of margins in the second part of the year, also because these margins in Q2 have been driven by the fact that OPEX has been very low. As I believe…I said during my remarks, we have had a slowdown or a lot of activities because of the lockdown measures in all of our geographies. Now activity is picking up again. So our people do travel, see customers on a recurring basis. A few projects, which we put on hold at the beginning of the pandemic are now picking up again. So I'm expecting OPEX to pick up again.

Besides, as you know, and I believe we have discussed it a few times, margins of molecular products are lesser kind of than CLIA products. So what I'm expecting to see is some kind of pressure on the gross margin, which will be somehow offset by some operating leverage, but not to the extent we saw in Q2. What I believe it's fair to say is that, I think, we should be able to maintain an EBITDA margin around, let me say, 39%-40% by year-end. But I'm not expecting to see anything like what we saw in Q2 for the reasons I just mentioned.

SCOTT BARDO: That's very helpful. Thanks indeed.

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

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