# DiaSorin S.p.A.

## "First Half 2021 Results Conference Call"

## Friday, July 30, 2021, 15:00 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 First Half 2021 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. Ladies and gentlemen, good morning, good afternoon, welcome to the DiaSorin call. We are going to be discussing the H1 results. And as usual, I will make comments on at constant exchange rate, so that we can take care of the exchange factor.

First of all, this is the first conference call where we have expanded the DiaSorin family with DiaSorin Luminex family today. I was in Austin [ph] last week; I believe we acquired a great company, full of opportunities and technologies. We've got a lot of talented people and during this call, I am going to make some specific comments about the Luminex business.

So let's start from DiaSorin. When it comes to the H1 result as you have seen, we recorded in line with guidance. What is very interesting to notice is that, compared to our expectation, we have the base business which is doing slightly better than what we expected, and I have explained why. And we have the COVID business that is doing slightly worse than we expected, mainly related to the antigen testing volume that is lower than what we expected, but again I am going to give a little bit of details later on.

Now, let's focus first on the base business, and you know for us now the base business is fundamentally the CLIA business, now that the Siemens ELISA, contract was actually terminated, and so our revenues with ELISA are becoming very small. If we now look at the CLIA business, and we look at CLIA without COVID, and without Vitamin D, and if we compare to 2020 clearly there is a phenomenal growth…40% growth versus last year, but if you want to measure really how things are going, we should use 2019 as a reference, because we did not have clearly the COVID effect and the great with [ph] our CLIA business, and again ex-COVID, ex-Vitamin D is now growing 16%.

And this is the result of the fact that I said, many of the programs that we had, like the QuantiFERON, like the GI, so the speciality program is really performing well in all geographies. And I will just give you one example of successful geography which is the U.S., that as you know today, is becoming the #1 geography for the Group.

If I look at CLIA ex-COVID and ex-Vitamin D and I compare it to 2019, our business is growing 22%, and this is phenomenal. If I include Vitamin D, the 22% goes to 12% because as you know, we have lost the Vitamin D business at Quest that we had in 2019, and we don't have it today, and it was a very significant business. So notwithstanding that, our overall CLIA franchise in the U.S., is growing double-digit, and we have a lot of installations that happen over the last few months, mainly driven again by the QuantiFERON and the gastroenteric strategy.

Let me also remind you that in the U.S., we made an investment in 2019, roughly $5 million of OPEX in hiring reps**,** hiring marketing people and hiring service people to support our hospital strategy. Our target was to close the following 3 years no more than 150 hospitals, and I think we are now [indiscernible] COVID at 100 hospitals already closed, so we are

going to clearly by the end of next year, we are going to blow that number. So it is going very well, the hospital strategy, and this is very interesting because we are going to comment later Luminex…the Luminex Diagnostic business was primarily directed toward hospital market, so we find ourselves now in a very interesting position where we have a hospital program with CLIA that will benefit also from the hospital customer list that Luminex brought to us.

If you look at the XL placements in H1, 300 systems, which is noteworthy considering that typically a good contributor to XL placement was China. China is a difficult geography these days to access, and also there is a slowdown of placement in China because of the COVID situation, so we actually made better than previous year in XL placement worldwide, notwithstanding the slowdown in China, which means again as said our business in U.S., and Europe is really doing very well.

Now, let's talk about COVID, and if you know COVID for us, I put in this big family of products molecular, which makes the majority of revenues and the serology products that are split between antigen testing and antibody testing. Now in H1, COVID was roughly €180 million, in Q1 we a little over €100 million and clearly Q2 there has been a slowdown due to…and the fact that we will talk about volumes. And in Q2 we have close to €80 million.

So if we look at the molecular component, Q1 to Q2, we saw an overall decline of the COVID franchise of roughly 30%. Now, if we look at the reason for this, for molecular is…as everybody else is reporting in the U.S. there has been significant decrease in volume, which is roughly overall 60%. We are doing better than that, because of the positioning of the system, it was never intended to be high throughput system, and as you know, volumes are moving away and getting more decentralized from the

core lab and so, yes we lose volume, but not to the extent that other competitors have reported.

It is noteworthy also to say that so far we didn't see any significant price pressure also because the reimbursement system in the U.S., has not been affected so far. In H2, so the guidance that you have seen includes an overall COVID business, molecular plus serology in the range of €140 million, €150 million which will put us in the middle range of the guidance, so still compared to H1, we expect 20% decrease.

As you can imagine, still very complicated to make a real assessment of what COVID effect is going to be, especially in light of the recent use with the delta variant, but it is good as it gets. This is what we have included in the guidance, and we are going to give an update clearly in Quarter 3 where things are going to have better visibility on how the season is going to look like.

Now, I will briefly comment about Luminex. I am not going to go too much in the detail, but I would like to touch base on some very important points. First point is, our guidance, and what we expect Luminex to contribute in the second half. And we expect Luminex to contribute around $210 million to our top line, of which around $30 million are COVID related products. I remind you that, because of certain number of things the COVID business, that Luminex was able to develop in last year was relatively limited, due to the fact that because of their technology was complicated for them to scale up manufacturing. This is why the COVID effect now is much less than what you could see on the DiaSorin site.

As far as, business performance, we have the LTG business, which is clearly booming, is a very profitable business for the company, and if we look at the growth compared to 2019 is, so take 2019 as our reference

normal year it is double-digit, clearly if you compare it to 2020, it is very high over 20%, but again difficult to compare things to 2020 because it was a very awkward year for I think all of us.

When it comes to the molecular business, as said, we need to split the business in 2, we have the ARIES business, which is the Single Plex [ph] business, that business is where they had an impact of COVID relatively limited in 2020. So, the loss that can happen in…and it is…sorry relatively stable, as far as, Quarter 1 and Quarter 2 is roughly around $10 million. And we expect you know, that business to decline slightly in the second half, even if again, we have no idea at all, what is going to happen in…because of the COVID effect, that business is primarily a U.S., business. So [indiscernible] let me say of the European components, it is primarily dependent on U.S., volumes.

Then you have the multiplexing business overall. The multiplexing business has been doing okay, this has to do with the fact that there is a respiratory component to it, which clearly fired up at the beginning and now as well is dependent a lot on COVID plus the flu season which nobody knows what is going to happen to flu in the second half. But more than anything, I think we should talk about the future and the future is the VERIGENE II system. Let me remind everybody what is VERIGENE II? VERIGENE II is a fully integrated sample to answer system that has been designed by Luminex to compete with the rest of the companies in this growing space.

It does have a very interesting feature which is differentiating vis-à-vis the other companies and that's the flex system that would allow customer to tailor-make and design their own panels. The launch of the VERIGENE II has been impaired by 2 events. The first one is that the company prior to DiaSorin elected to go through the agency, the FDA with a panel for

gastroenterology. And clearly that panel was…the review process was completely frozen by the agency because as you know in 2020 and still now priority is respiratory. The company then submitted an EUA for respiratory, right at a time when the FDA changed their policy and now they want a 510-K.

So we are running the clinical study for the respiratory panel. And we expect that the clinical study will be completed at the end of the season, because the respiratory…clinical study clearly is depending on the season you cannot clearly do it during the summer. And we plan to file with the FDA the respiratory and hopefully they're going to start reviewing also gastroenterology panel by Q1 next year with full launch of the platform by second quarter next year with an initial panel of respiratory and gastroenterology following the very close to it. So still, within next year, there are going to be the submission of the blood culture positive and negative.

So the full panel is going to be coming soon. We're very excited about this platform. We really believe that it does make a difference vis-à-vis the ability of customer to…customers to make affordable multiplexing compared to what they have on the market today. We are working at the scale up of manufacturing and we are going to be ready next year for the full worldwide launch of this platform.

Now, let me talk about the integration plan, I'm going to give just some flavor and then full disclosure is going to be done at the Investor Day that as, you know, has been scheduled for the month of December. As far as, integration is concerned, we have certainly some primary objectives. First one is to refocus the company on what we consider best that cannot be missed. And as an example, we are talking about the EUA VERIGENE II the INTELLIFLEX, which is a platform that has been just made available

to the partners the company works with recently for the LTG and has been the first platform that this company has been launching in the last 10 years. So there is a lot of excitement about the system that would go and possibly replace 1,000s of systems that has been installed by the company and the partners in the field over the last 10 years.

Last, but not least, is the ImageStream and flow cytometry new generation systems, which are coming to the market. So this company had a mission before it was a Luminex mission. And now we are making it a DiaSorin Luminex mission refocusing all the resources in this very strategic projects. By the same token, we are looking at the footprint of the company and the possibility of synergies and improvements of operations things we also have operations in the U.S. There is a full team of people that is reviewing footprint and preparing a plan that again, we are going to be able to discuss when we'll talk about the expectations for the next 3 years.

By the same token you know, to complete strategically our product portfolio, we have 2 very important projects that now are hitting the end phase of product development for DiaSorin, the LIAISON NES [ph], which is the small platform for the decentralized market, PCR sample to results in 15 minutes. And then we have the LIAISON MDX Plus, which is replacing the LIAISON MDX and will substitute actually the LIAISON MDX starting from 2022.

So my point is, now that we really bought technology in a good business, as far as molecular diagnostics is concerned, we have many arrows in our quiver, we have 4 platforms that will hit the market in the next year or so. And as far as LTG, we just launched the next generation platform. So I would say that we have many, many good things that are coming forward for the combination of DiaSorin and Luminex.

At this point, I'm going to leave the microphone to the CFO of the company, Mr. Pedron, who is going to drive you through the numbers.

PIERGIORGIO PEDRON: Thank you, Carlo, and good morning, good afternoon, everybody. In the next few minutes as usual, I'm going to walk you through the financial performance of DiaSorin during the first half of 2021. And we will also make some remarks on the contribution of the second quarter.

As usual, I'd like to start with the main highlights of the period. So we closed first half 2021 with an increase in revenues at constant exchange rate of 40%. COVID sales are up by almost 100% compared to last year, whereas the ex-COVID business is up by 21%. Please note that the revenues growth is in line as Carlo just said with the H1 '21 guidance we provided to the market when we discussed fiscal year 2020 results back in March.

I believe it is also worthwhile mentioning that the ex-COVID sales at first half are back at the same level where they were pre-COVID in 2021 and even higher as Carlo said again, if we take out, if we sterilize the lost of the Vitamin D business in Quest.

Q2, '21 gross margin confirms the very good results achieved in the previous quarter, therefore closing half one at almost 69%, just a touch below 2020 which closed at 69.1%. H1 adjusted EBITDA at €244 million record an increase of €91 million or almost 60% compared to 2020 with a margin of 47.4% on revenues compared to 40% of 2020. The growth at constant exchange rate is 64% with a margin of 47% again therefore, slightly better than H1 guidance provided when we discussed the FY 2020 which was 45% EBITDA margin at constant exchange rate.

Lastly we keep confirming our ability to generate a very healthy free cash flow €126 million in the first half, with an increase compared to last year of €52 million or 70%. The net financial position is positive for €436 million with almost €900 million cash. Please let me remind you that in Q2 in April we issued an equity linked bond for €500 million due in 2028 to finance the Luminex acquisition…to partly refinance the Luminex acquisition.

Let me now go through the main items of the P&L. So H1 revenues at €515 million grew at current exchange rate by 35% compared to last year. The first 2 quarters of 2021…in the first 2 quarters of 2021, we have experienced some €18 million FX headwind mainly caused by the strengthening of the euro against the U.S. dollar. I believe that if we consider where the U.S. dollar is trending now, compared to 2020, it is fair to say that in the second part of this year, these negative FX should be less material, even including Luminex sales that, as we know, are mostly generated in the U.S.

During the first half of the year, we booked €177 million of COVID sales, about 75% of which driven by our molecular test against €95 million of 2020, which were but then almost evenly split between immuno and molecular. I believe its worthwhile mentioning as we did last quarter that the business ex-COVID was up by 21% at constant versus 2020. But also if we look at H1 '19 it was up by 6% once we sterilize the effect of the Vitamin D business in Quest and the Siemens ELISA, as I believe we discussed in the previous quarter.

H1 gross margin at €355 million grew by 35%, compared to last year, growth in the first 6 months of 2021 with a ratio of revenues of 68.9%. The margin on revenues is not increased compared to last year in spite of the higher revenues and mainly for the following reasons. We have a

negative effect from product mix coming from higher molecular sales and lower CLIA sales. We have had an higher incidence of royalties driven by the increase in our Latent Tuberculosis sales. And all of this has been partially offset or I would say almost completely offset by the lower incidence of fixed costs driven by the higher sales volume and some efficiencies coming from the manufacturing processes of our molecular products.

H1 '21 total operating expense is at €136 million or 26.4% of revenues have increased by less than 4% or €5 million compared to last year. The increase in revenues mainly driven by the COVID effect is behind the operating leverage of the period that has seen a decrease of the OPEX ratio of revenues from 34% of 2020 to 26% of 2021.

First half other operating expenses at €70 million increased by €8 million compared to last year. This variance is entirely driven by the one-off expenses related to the Luminex acquisition, which accounted for about €13 million, as a result of what just described H1 '21 EBIT at €202 million or 39% of revenues has increase compared to last year by 63%.

The tax rate at 23.5% is slightly higher than what we recorded in 2020, which closed at 22.5%, this increase is mainly driven by the fact that some one-off costs driven by the Luminex acquisition are not tax deductible in the U.S. The net result at €150 million or almost 30% of revenues is higher than previous year by €55 million.

Lastly, H1 2021 adjusted EBITDA at €244 million, 47% of revenues is higher than 2020 by 59% or €91 million. The variance at constant exchange rate is positive by 64% with additional revenues of 47%. Let me remind you that the difference between the reported EBITDA and the

adjusted EBITDA is only due to the mentioned one-ff costs related to the Luminex transaction that we discussed about.

Let me now please move to the free cash flow. In the first half of the year, the group generated €126 million free cash flow vis-à-vis €74 million in 2020. Therefore, booking an increase of almost 70% of €52 million, I believe it is worth mentioning that in this semester with a much higher tax cash-out compared to 2020, €66 million in 2021 vis-à-vis €5 million in 2020. This difference has been driven mainly by 2 elements, the different phasing accounting for about €30 million and €35 million driven by the higher profit that the group generated compared to previous years.

Lastly, let me now move to the 2020 full year guidance. As usual, at previous year constant exchange rate, which let me remind you, was for the $114, compared to the euro. In order to make the number comparable with 2020, we will also provide a breakdown of the revenue guidance between DiaSorin and Luminex business. So the total combined revenues will increase by 30…between 35% and 40%, therefore, we expect total 2021 revenues at around €1.2 billion.

We expect total combined adjusted EBITDA margin at 42%, therefore, again €510 million at constant exchange rate. Beside, please note that DiaSorin revenues at constant exchange rate and constant perimeter of consolidation should increase between 15% and 20%, out of which the overall DiaSorin business excluding COVID will represent an increase of around 15%.

Please, let me remind you once again, that the group is a very much exposed to the U.S. dollar fluctuation even more so now that we've acquired the Luminex business. So as a rule of thumb remember that for

every 1 cent movement of the dollar against the euro, DiaSorin revenues should move by about €6 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: This is the Chorus Call conference operator. And 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." We kindly ask to use handset when asking questions. Anyone who has a question may press "*" and "1" at this time that's "*" and "1." We will pause for a moment while questioners join the queue.

The first question is from Peter Welford with Jefferies. Please go ahead.

PETER WELFORD: Hi, thanks so much for taking my question. I'm curious if you could just talk a little bit about the COVID-19 first of all impact a little more. I am wondering in particular, you talked about antigen testing volumes being lower than anticipated. Just wondering, if you can give us an update on your thoughts around the potential Lab Core contracts whether or not [indiscernible] has changed with regards to your changing outlook for the COVID business?

And also I am just thinking about the recent launch of the test, so Lumos platform, **if you** like in Italy [indiscernible] could you then give us an update at all on how that's going and initial feedback from your partners that are distributing that. And you know what your thoughts are on potentially expanding that pilot program, and I guess what the triggers are

to potentially make that decision as to whether or not you are going to expand the program.

And then just a question on Luminex, if I can do, just on VERIGENE II, is there a risk, I guess, with the respiratory panels, that you're…this clinical trial, you're running? Is that flu dependent at all or RSV dependent or anything like that, I guess, [indiscernible] a highly unpredictable season. So if we assume that just COVID, I guess, is going to be around, is it still viable to run that clinical trial? If you can just talk a little bit about some of the risks perhaps to VERIGENE II launch and whether or not you're happy with the manufacturing from that point of view for a potential, I guess, FDA inspection of the manufacturing [indiscernible] VERIGENE II approval. Thank you.

CARLO ROSA: Peter, it was very difficult to hear the last question. But let me start from the last question and then move forward. Is the last question about the VERIGENE had to do with the FDA 483, there is no association whatsoever between the VERIGENE II and the 483, and so the problem is not the ability the site Chicago by the way, never received any injunction not to manufacture. The site has received an inspection with the regard to 483 that have been addressed and the company has been working with the FDA to close the 483 and we are waiting for the FDA to conduct an inspection, but you know and I know that for the time being the FDA unless it's a very, very urgent matter, they don't visit company's. Okay, so again disconnect from your mind 483 from VERIGENE II.

Second thing, as far as my comment head to the…about the application and withdrawal of the original 510(k) for respiratory is much simpler than what you stated, and nothing to do with quality issue. The problem was that until that day FDA was accepting EUA for respiratory panels and what Luminex did diligently, they prepared EUA submission. A week

before they submitted, the FDA approved the first 510(k) de novo, which was BioFire Respiratory Panel with COVID, and that…doing that, it reset expectations vis-à-vis EUA, so it started to reject EUA, forcing companies now to conduct clinical study for a 510(k).

Now what's the problem? When you have a respiratory panel, and you need to have a blend of fresh prospective samples, you need to run your clinical during the respiratory season, and the respiratory season will start in September. And therefore, we say that, as far as, respiratory, it's unfortunate that has been the move of the agency from EUA to 510(k), but you know, you bite a bullet and we need to…we are going to repeat during this season some of the clinical's necessary to get the data together and then we're going to submit in quarter one next year.

As far as the antigen test, which I believe is your second question. Antigen test, there was…part of the company's strategy is that the portfolio of our products, which I remind you we developed 7 products for COVID. One of the tests needed was a high throughput antigen test to work on the LIAISON XL, which we did and we got the EUA and also the…with CE mark. As far as the use of this product, it was intended as a product to be used in parallel with molecular products to alleviate the need of some of the hospital and reference centers to run given an amount of molecular at very high price, and they could self-substitute with an antigen test that would work.

Almost as well, as far as, sensitivity clear antigen test and is not as sensitive as molecular, but certainly, certainly at the fraction of price and that was the assumption. Part of that assumption was also related to the fact that LabCorp that is our primary partner would participate in the U.S. to the K12 program, reopening schools. That is a program that has been broadcasted broadly, but eventually is not coming too much in terms of

businesses as you know as other companies did now is really…these are cut at a state level more than a federal level. And when it comes to a state level, some of these states really prefer a rapid antigen test versus centralized antigen test. And this is why I'm saying, the comment was, we have certain expectations following the favorite [ph] LabCorp was participating to this bid, and there would be a program that nationwide was talking about 25 million tests per month, and that progress has been severely reduced and therefore we had to reduce our expectation from antigen tests as well.

As far as, the Lumos, which I think was your last question. The platform was launched recently in Europe, in Italy, where the 2 assays are serology assay that is intended to use for post vaccination monitoring, and swab antigen test. As you can imagine the antigen market is pretty much flooded by a lot of products, and our idea was to bring to the market a product that would have lab quality versus some of the low quality stuff that is out there.

Very recently, as you follow from competitors the volume for antigen testing has been significantly declined for this. I'm talking about the rapid testing has been significantly declined, is a combination of lower incidence plus the fact of larger viability of molecular diagnostic testing spread across different geographies. And more lately, what the antigen test is now used for certainly is not more much for diagnostic, but more for in Europe, the green pass, which means that if you don't have a green pass, so you didn't get vaccinated. Now, you need to provide the airline and/or the trains if you want to move in certain environment you have to provide proof of a test, and at the European level repository of approved test has been created, so that pharmacies could actually deliver a result of the antigen test. And according to an approved list of manufacturers, trying to eliminate the cheap low-quality stuff that was out there. We got

inserted in that list 2 weeks ago. So now we have our antigen test approved, a proof of travel, and we can really initiate the program. So far, we have 50 flagships, pharmacies that have our system installed. And we are deploying…so we expect that the deployment of this will continue through Q3 and Q4.

Let me remind you again that the LIAISON IQ for us was an arrow that we really needed moving forward in the decentralization strategy. We always said that we're going to try to use this as an opportunity to learn the space and create an installed base. By the same token, we've also created a serology antigen test dedicated post vaccination that we expect is going to pick up after the summer, once they debate about antibody levels on fragile and certain population will now be determined to be relevant test to be performed.

So, far I think I'm happy from what we have done, we are at the beginning of this process, and we are learning the pharmacy space that certainly for us today is an unknown, but as said with the LIAISON…with the LIAISON NES [ph], and that molecular is a platform, is going to become a segment that this company wants to play with.

PETER WELFORD: Thank you very much.

OPERATOR: The next question is from Naresh Chauhan with Interim [ph]. Please go ahead.

NARESH CHAUHAN: Hi there. Thanks for taking my question. 2 please. One on the potential for a new diagnostic in your COVID portfolio, and there is some initial data suggesting that the higher the antibody levels after vaccination, the less likely someone is to see fading vaccine efficacy. Is that…just as you

are planning on building [technical difficulty] if that's something you want to produce.

And then secondly on COVID testing pricing across the portfolio. How is pricing holding up? How is the competition faring, are we seeing some of…as you mentioned some of the low quality [indiscernible]? And just some of the bigger players remaining to some insights on that'd be helpful. Thank you.

CARLO ROSA: So, if I understood correctly, your question about antibody level. Today, there is no evidence, but a certain minimum threshold of antibody is necessary to…for protection. And there is none of the current and approved vaccines providing…provided data to prove that there is again as in other cases for example for Hepatitis B there is a cutoff level, which is necessary to hit with antibodies to be protected. I think it is going to require more time to come to the assessment, and I don't think that…is it going to be responsibility of the diagnostic industry to do so. However, what is very important is really to understand response to vaccination in different class of patients, because what data are proving today is that. A) 5 months after vaccination healthy individuals still carry antibodies but the titer [ph] is reduced 80% toward they had 21 days after the second shot. Okay, this is the first data point.

The second data point is that, you are now…if you now look at different groups of patients, so unhealthy and you look at immuno suppressed at different degrees if you look at certain patients that are taking certain drug regimen. Now, you discover that as expected there is a variety at the behavior in terms of the immunological behavior of these patients is very different. And some group of patients as expected did not even develop an antibody titer. So today, I think that there is a certain usage of antibody testing. As you saw, we are selling roughly €5 million of antibody testing

per month. We see that there is a slight pick up on that, but what we believe is that the future opportunity with this is going to be, a) on follow up on those patient groups where response to vaccine is not for sure.

The second thing is that once threshold cut off or immunity is going to be established then there is going to be more regular follow up, and therefore, our effort today is to get, as much as, possible market share on the current market now to capture surge of testing when and if that is going to happen. And I think we are with this new assay that we have designed, it is using the primary protein, the full length [ph] protein and we are really becoming gold standard of in the industry of about antibody testing. And we are enjoying market share that are coming from EDMA data in Europe that we are in most of the countries we are really #1 or #2 in terms of our market share.

About COVID pricing, it was very difficult to hear you. But again, I restate, I don't see for the time being an effect of pricing, which comes from the fact that competitors in our segment, don't forget, we don't play any high throughput segment. We play in a mid throughput segment, low throughput segment centrally not decentralized saving. We don't see an effect of pricing at all. So I think we need to understand what is going to happen in the future but all contracts that we have in place pretty much are holding the same price that were established one year ago when the pandemic started.

OPERATOR: Mr. Chauhan, do you have any other comment.

NARESH CHAUHAN: No that's fine. Thank you very much.

CARLO ROSA: Okay. Thank you.

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

MAJA PATAKI: Hi, good afternoon. I have just 2 quick follow up questions to make sure that I got it right. Carlo, you stated that throughout 2022 you are going to submit the data to the FDA for VERIGENE II. So if you would prudent for us to assume that we should see only revenues starting to come through in 2023. Would that be correct?

CARLO ROSA: You want to ask me. Hi Maja, do you want to ask me both questions or…

MAJA PATAKI: Okay, sure. I can shoot. I mean, did I get you right, that you mentioned that you are now selling or that you have now placed 50 LIAISON IQs throughout Italy, and that you are planning to placing a similar amount throughout Q3 and Q4. Is that correct?

CARLO ROSA: Okay. Let me start from the IQ. We placed 50, and I expect a pickup in Q3 and Q4, because just we…we just establish the…let me say, the distribution network. Now, we have 3 partners that are working with us with better coverage and now we got also the approval at the European level for antigen testing for green pass or it's…I expect really that Q3 and Q4 should be better than this. Keep in mind, I am in a learning phase Maja, this is not my… this is not my home base, and so we are learning. And Maja, the way I can predict this is not as good as I am usually doing with the Excel or platform that I am more familiar with.

MAJA PATAKI: Sure.

CARLO ROSA: Second thing about VERIGENE II. No, I think that we should expect…you should expect to have revenues coming from VERIGENE II starting from second half of next year.

MAJA PATAKI: Okay. Okay, understood. And Carlo, just for my understanding, I don't want to, you know, I don't want to take up topics that you will discuss at your Investor Day, but out of curiosity, would it be fair to assume that by 2022 you will be running another 5, 6 tests on the LIAISON IQ?

CARLO ROSA: I don't know where you are taking this information Maja, and if I ever said it, my fault. I think that what we are now trying to understand is post-COVID was the positioning of the LIAISON IQ, and funny enough, and this is really funny for us, one of the most valuable products ex-COVID at pharmacy is Vitamin D…

MAJA PATAKI: Yes.

CARLO ROSA: …because clearly the logic there is to be able to assess you know, the whether there is…you are insufficient and then provide you right there over-the-counter supplementation. So I think the next product in line that you may see from us, and I would never bet this with you 2 years ago, it is going to be another Vitamin D test…

MAJA PATAKI: Okay.

CARLO ROSA: …but so far, this is the only one that we clearly understood will make sense to have.

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

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

SCOTT BARDO: Yes, thanks guys. 3 questions, please. So first, on your COVID business. I wonder if you could help quantify the serology contribution this quarter,

and more broadly, perhaps share some geographic dispersion of your molecular diagnostic business, and help us understand whether trends in U.S. and Europe are any different, whether your expectation is any different.

Second question, please related to Luminex. Assuming the warning letter disappears by the end of the year which I think your comments were pointed towards, and you look to launch VERIGENE when the researchers' panel is approved. Can you help talk a little bit about the stress hear, because in North America this market is somewhat, shall we say penetrated and the say wide...the wide space is really in Europe and then Asia where much of the market doesn't exist today. So talk a little bit about how you expect to move into those segments and create a successful business there.

Last question on Luminex, please. Carlo, you referred to the LIAISONs part of Luminex being you know, very profitable, very successful? When we look to Luminex margins as a standalone company they weren't that exciting. So am I right in saying that the molecular diagnostic business was loss-making or not very profitable and provide much of the opportunity for you as a company to optimize?

CARLO ROSA: Hi, Scott. Okay, I can see that you can do the math. If I look at…let me start from your last question, right. Without even getting too much into the detail, but I have to say that you need to look at different component of the molecular business of Luminex. Certainly, their Single Plex platform the areas was not, let me the best opportunity in terms of profitability. It was a subscale, very, very complex cartridge we are using, very complicated high cost, and therefore the profitability was not there, certainly at the volume of sales that they are having, okay. Conversely, if you look at the multiplexing and you look at the VERIGENE and the

xTAG [ph] line profitability is certainly there. But you need to understand that I have to admit as an immunoassay person. In molecular diagnostic you're never going to get the same gross margin that you get from immuno. I think that you are going to get, your EBITDA contribution from a lot of discipline under the gross margin, which is what we did when it comes to our MDX…MDX lines. We were able to get with focus more than 35% EBITDA, because we were very disciplined in the way that we integrated our molecular without immunoassay right. So, long story short, I believe that with our MDX technology and making an effort to be discipline and have automation on the VERIGENE II, you can turn also the automated…fully automated Luminex business back to where it deserves of profitability.

When you go…now if I move to the strategy on VERIGENE II, allow me to tell you that, first I am learning this business, second I really want to provide market with reliable data and commitments by the company, once I had a chance to sit down with the Luminex management and after the integration of our commercial team which is on the way and then provide you with better details. So, let me just pass on that.

When it comes to the COVID serology, as I told you we have around 5 to 6 million per month of COVID serology, which is relatively stable. We got 90 accounts in the U.S., that 90 accounts in the U.S. that today are using our serology product, you know, in the U.S. there is no claim allowed by the FDA on the use with vaccine, post-vaccination, whereas in Europe in the package insert we have all data to support antibody testing post vaccination and all the different variants.

When it comes to Europe, as I said before, in all the major geographies and you can verify it through the ADMA report, we are even #1 or #2. So, very well-positioned vis-à-vis the fact that the test has been recognized as

a standard, and now the question is, is volume going to pick up or not? And as I told you before, I am positive about this, because I see from on the clinical studies, the real need on certain sub-populations to monitor what the heck happens. And by the same token what we are also working on is a strategy on T-cell, with our partner QIAGEN because we believe that the right algorithm to look at post-vaccination in certain population is really go to look at the combination of T and B, and if you think about it, this would be a unique algorithm that I think QIAGEN will be the only one able to really offer it to the market. So I am really looking forward to the development and launch of this product together without our B-cell.

On the…again geographical split on molecular, we have not provided that this data ever. Let me say, if I may, that half of the business is North America and half of the business is ex-U.S., primarily Europe.

SCOTT BARDO: Right, thanks. Well, I'll look at you for color, now I'll jump back in the queue. Thank you.

OPERATOR: Gentlemen, there are no more questions registered at this time. I am sorry there is a follow-up from Scott Bardo. Please go ahead, sir.

CARLO ROSA: So you're back.

SCOTT BARDO: Maybe, just one last one [indiscernible] pushing on. Carlo, you just referred to a B-cell and of course, one of the major initiatives for the post-pandemic world for the DiaSorin is to expand upon this opportunity you got approval now for Lyme disease in Europe. Help us understand a little bit the activities the company is pursuing to develop this opportunity with reimbursement agencies and practitioners both in Europe and maybe even in the U.S., already?

CARLO ROSA: Okay. As you know, when it comes to this very innovative product, you have to go through 2 steps, one is provide clinical evidence and the second one as a consequence to this to get a reimbursement, because the assay today the T-cell component of it, is pretty much off pocket everywhere, especially in Germany where that, you know, this represents good chunk of the total market. I would say if you look at the Lyme disease market you are going to have over 60% of that market in Germany, and then the remaining is actually on the adjacent geographies. And so, the Netherlands, then you have also, Slovenia and so forth, so it's a northern European say for the time being.

Where we are today is that we have come back on that, we have agreed upon with Germany reimbursement system about what we need to achieve to get the reimbursement, we have a conducted the HTA study, so the Health Technology Assessment to prove that the algorithm actually provides not only clinical value but also reduce costs vis-à-vis the current treatment we have a series of clinical studies that are conducted as we speak, because again it is a seasonal disease, so now this is the season when you are collecting data from the patient. And so…and we clearly launched the product…but we launched the product you cannot put this product sign, now it is in the hands of regular doctor, we put it in the…together with the QIAGEN in the reference hospitals where, now they are using it, verifying it, and then hopefully we are going to be generating publication to support it. By the same token in the U.S., because if you know the difference with Lyme disease is that in the U.S., you have a specific strength. We are now conducting the clinical study on the…in the East Coast in the Appalachian region, where we are collecting the data to prove that the algorithm works also with the U.S. trend. This is not the clinical study for FDA approval, this is the clinical study on the U.S. trend to gather the data or then to the FDA and show them the

effectiveness and efficacy of this test, then to agree upon the clinical studies that it is going to be conducting in 2022.

So, to make a long story short, this is a market that you need to create. So the need is there clearly. But, you need to work on all this elements that eventually made the QuantiFERON what TB QuantiFERON what it is today as a product. So, you need to be patient with us, we are going to give you more updates, but I think we need to all focus on certain cornerstone right now, which is not revenue, but more supporting clinical studies the HTA and reimbursement, because then that is going to be triggering the vast opportunities that both us and QIAGEN has been discussing about.

SCOTT BARDO: Okay, very good. Thanks so much.

OPERATOR: Gentlemen, there are no more questions now. I'll give the floor back to you for any closing remarks.

CARLO ROSA: Okay thank you, operator. Thanks everybody, and we will see you at the Q3 results and then clearly by year end when we will have our full disclosure of the plan in Investor Day. Thank you. Thanks.