## DiaSorin S.p.A.

## "Q1 2020 Results Conference Call" Wednesday, May 13, 2020, 4:00 PM 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 Q1 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, Chief Executive Officer of DiaSorin. Please go ahead, sir.

CARLO ROSA:

Thank you operator, and good morning or good afternoon to everybody and welcome to the Quarter 1 call. From DiaSorin what I will do is, I will spend some time giving qualitative remarks about how I see really not Quarter 1, but how we see moving forward the situation with the market and the company. And then, Mr. Pedron is going to take you through the numbers.

The reason why I do not intend to emphasize too much on Quarter 1 is that since Quarter 1 is fairly evident that the world has completely changed in terms of perspective and needs, and this is what I would like to focus on, because I believe that DiaSorin was one of the companies that was able to adapt and respond to this crisis situation and transform that into also an opportunity to provide very innovative products.

So very briefly, if we look at Quarter 1 in March, if you think about it has been the first months where you would start to see effects on the business in geographies outside China. However, I think Quarter 1 gave a good indication of what we are now seeing in the rest of the world in China, because what we could observe at the peak of the pandemic situation is that you see that the regular routine testing completely crashed, and this is simply related to the fact that the authorities and people themselves did not

go to hospitals any longer because of the risk of infection. As a result of that, what we have seen in China in February, March timeframe, we have seen decline of routine testing by 60%-65% which is what we see also now in the rest of geographies that are going through the pandemic wave.

Now, if we leave that to the side for one second, and we consider COVID and what would be...what has been the strategy for COVID and what we still plan to do about COVID. I think that we need to look at the way to frame the discussion around the epidemic and the clinical need. And it's very clear that today there are 2 tools which are fundamental to fight this epidemic, one is the ability to diagnose the acute infection, and today this has been...this is done primarily through the swab. And the second need now is to understand 2 things, prevalence of the infection and the second one is to answer to the question, whether patients exposed are developing or they are not developing an immune response that is protective.

So what did we do about it? Well, as everybody else but among the first in the world, we have developed right away a very fast assay for the virus diagnosis, and that has been done through a regular PCR assay designed by our system on our small MDX system, and the way that we position the product has been as an emergency product. And we have been very successful in doing so, because we can process 8 samples within 60 minutes and immediately the system was adopted...widely adopted in the U.S., in Italy and in a few other geographies where we had capacity to distribute as the analyzer that was used for triage [ph] in patients while they were waiting for the admission on the hospital ward.

In the last conference call, I said, I qualify this opportunity as 5 to 10 million dollars or euros of revenue per month, and what we have seen right now is that in fact the revenue opportunity is actually on the more  $\in 10$  million... $\in 10$  million to  $\in 12$  million per month. We have a certain

capacity, we manufacture roughly around half a million test every month that we distribute among the main geographies, we expect this capacity to increase a little bit, but not dramatically because we have some limitations on the supply chain, on this manufacturing, and we don't believe we can expand too much behind it. So that I consider as a product that will continue to deliver these kind of revenues on a monthly basis moving forward.

Then we...as soon as the molecular assay was actually developed, we then move to the second question...the second tool. The second tool is serological assay that can be used to assess immunity. And I think very successful we have done that through collaborations with major institutions in Italy and this is because of the pandemic situation in Italy there was in this centers a large viability unfortunately of patients. And so we were very rapidly we were able to collect all the clinical data that have been necessary to support both CE marking and the FDA registration.

I am very proud of the fact that when DiaSorin was granted for the serological assay EUA [ph] in the U.S. by FDA, we were the fourth company to get the certification from the FDA. And today this assay is...we started actually distribution of the assay in the last week of April. We see that this assay has been received extremely well by different governments, and in fact we have been able to get a good chunk of the volume that today governments like Belgium, Israel and other countries have assigned to companies for epidemiological study. So we are extremely successful with this product. By the way, last night we got also approval in Canada, and we are the first assay...serological assay to be approved in Canada by Health Canada for SARS-CoV-2 IgG diagnosis. And I am very proud certainly about this achievement.

So today we have provided to the market a very important tool, is a very special product because we not only have a claim outside the United States for IgG determination, we also have very convincing evidence that has been collected now in more than one center about the fact that by design of the product, we identify neutralizing antibodies. As far as, opportunity or use of this product look. Today, I prefer to talk about capacity, and today we are ramping up our manufacturing capacity, and we are looking very soon in the next week or so to move from the current 5 million test per month of manufacturing capacity to 10 million test per month of manufacturing capacity and we believe that this will allow us to actually fill up the large orders that we have received from the different European countries.

Interestingly enough, before you ask me in Italy, the government decided to go a different way. They have selected a U.S., supplier for the national tender for 150,000 test, and I did comment several times saying that the good thing about the fact that there are many companies offering products. So we are going to be supplying our products to other governments, but not to our own government.

Now, let's talk about the future products, because we believe again that there are 2 products that the company now is developing on COVID. First one, let me call it a complementary product to the IgG, which is an IgM assay today. There is a lot of...there are lots of discussion about the use of IgM for the diagnosis of this disease. I've seen lots of discussions because everybody says the swab and a molecular product is the one that should be used to assess the presence [ph] of the virus during acute phase. However, as you all know, there is a chronic shortage of swabs today, and so in many countries they elected to use also an IgM assay when the swab is not available. And I'm taking as a reference, for example, France that very recently has issued a policy whereby they recommend IgG and IgM. So

we see this product more to complete our product line, really than as a strategic advantage.

However, I think that what remains today strategically important and more so if we think about the next flu season that is coming few months from now is the chronic lack of swab. So the inability of the industry to be able to provide enough reagents to allow repeated testing with molecular products and this is very understandable because molecular products are complicated. They require complicated reagents on one side and also complicated equipment.

And so, what we believe is that, we need to...by the coming season, we really need to provide to the medical community a different tool. And as has been indicated by the NIH in the U.S., and by many, many experts, the real way to do this would be to develop a sensitive test that can be done on oral swab. Now, many companies have tried some have achieved to do it. I've seen that there are initial reports on sensitivity of some of these products which are not, as good as; they should be in order to substitute or be able to complement swab testing.

We have, I think, an idea today in a partnership with a leader in this space that should allow us to develop a new generation of these products, where we hope we are going to achieve the necessary sensitivity to be able to provide a tool again for the determination of the infection during acute phase. Stay tuned, this is the current main project for DiaSorin and we are going to let, you know, more in the next couple of months.

I also would like to make another remark which has to do with, what is the effect of COVID and the success of the COVID product to DiaSorin vis-àvis the rest of the business, because we cannot forget certainly that we have 140 products on the LIAISON XL. And what is very relevant if you

remember is that, we prior to COVID we had a very precise focus on the U.S., and we said that because of the viability of the TB test, and the strong alliance with QIAGEN, our strategic objective was to develop an installed base in the hospital market. If you remember, we said today we have a little bit less than 150 customers in that segment, we are heavily skewed in the U.S., towards a big commercial labs, and we saw TB as an opportunity back then to actually enter strategically in that market.

And we have hired prior to this COVID story; we have hired 20 more reps and more people in the U.S., in the marketing department to support their strategy. Well, that came very handy...and comes very handy today because what we are experiencing in the U.S. is a very strong interest by the hospital chains on COVID serology. And what we see is that, we see an acceleration of placements of systems in the hospital market with a combination of COVID that today is the primary interest and TB.

And so one of the things that benefit of the COVID serology and the strategy is the fact that we see an acceleration of placements not only in the traditional segments where DiaSorin operate also in a segment where we wanted to enter, and now we are actually called-in because of availability of this product.

As far as molecular is concerned, you all know that the...our molecular business was primarily a U.S., business. The installed base was all in U.S., the system was designed by U.S., company. And we were actually spending time and strategic resources to develop that business more than the European one. It's certainly true that again, the availability of a high quality COVID molecular assay is allowed in Europe to completely reposition our molecular franchise. We certainly did that in Italy. We are doing it in other geographies, like Germany, where our assay has been selected for decentralized testing of COVID, in Spain where we see the

same opportunity in a country that is...has been hit hard by COVID. So as far as the molecular franchise is concerned, there is a tremendous repositioning of the company in Europe and an opportunity to develop an installed base through COVID.

Let me just make last remark, which is strategic. If you remember in June, we the company said, we strongly believe in decentralization. And as I think I did comment in the last conference call, I hate to be a Cassandra but back then we said decentralization is severely needed in case of situations where you need to face an emergency, and you need to drive patients away from hospitals. And as you know, we have pursued an acquisition of our technology from TTP, and we are developing that technology with an intent, so developing a point-of-care system that will favor...that will favor decentralization.

Well, if I ask myself, what COVID is going to leave us, once COVID will leave us, I think it will...It made diagnostic known to everybody, from taxi drivers over here to people that did understand diagnostics, and also it made people and institution realize that decentralization of certain assays especially in infectious disease is good. And so, I believe that we are going to encounter a very positive trend in certain geographies. But including Europe, not only the U.S., where decentralization is needed...and need...and a need of new generation of systems for molecular diagnostics is going to be strongly needed. So I believe that also strategically DiaSorin mid long term is positioned very well to catch that opportunity.

Now, if I may then make one more comment about the guidance. As everybody else in the industry, the world has changed and our guidance was actually issued pre-COVID. And it's very obvious that post-COVID or in COVID, things are changing, and this is why we decided as

everybody else to withdraw the guidance that did not make any sense. I see today a combination of 2 effects. I see a negative effect, which certainly has to do with routine business. And in...as we speak, the routine testing is down 40%-50% as reported even by the major labs in the U.S., but I see a positive effect by the ability of the company to reposition very rapidly with innovative COVID products.

And I believe, from what I'm seeing today, that the positives will overcome the negatives, even if I cannot quantify right now, is not serious to do it, because we see that...we really don't understand what is going to happen to COVID. And so, we withdrew the guidance, we are not going to provide a guidance today. And we are going...and we are expecting then in a couple of months to come back and discuss more thoroughly the effect on the company of these 2 trends.

Now, I'm done with my remark, and I'm going to leave Mr. Pedron with the speech about the numbers.

PIERGIORGIO PEDRON: Thank you Carol. Good afternoon everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin during the first quarter of 2020. As usual, I would like to start with what I believe as the main highlights of the period. We closed the quarter with an increase in revenues of 2.3% or €4 million, the increase at constant exchange rate is 1.7%. Carlo has already covered the main items regarding the first quarter and the impact of COVID.

Q1 gross margin at 69.1% of revenues confirm steadily good results achieved last year. The difference with Q1, '19 which closed at 69.5% is mainly driven by a different product mix and higher distribution costs driven by COVID-19 induced global logistics issues.

Q1 EBITDA at €65 million record a decrease at constant exchange rate compared to the previous year of 3.7% with the margin, again at comparable FX rates of 37.5% vis-à-vis 39.6% of 2019. I believe though that it is relevant to underline that Q1 EBITDA net of some un-forecasted one-off loss I will discuss about in a few minutes record an increase compared to last year of 1.6% at constant exchange rate with a margin of 39.5% of revenues. Again, at comparable FX rates, and so in line with what we achieved in Q1, 2019.

Lastly, we keep confirming our ability to generate a very healthy free cash flow  $\in$ 40 million on the quarter with an increase compared to 2019 of  $\in$ 4 million or almost 12%. We closed the quarter with zero debt and  $\in$ 242 million positive cash position.

Let me now go through the main items of the P&L. In Q1, 2020 revenues at €175 million grew by 2.3% or €4 million compared to last year. The growth at constant exchange rate is 1.7%. 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 real.

Q1 gross profit at €121 million grew by 1.7% compared to last year, closing the first quarter with a ratio of revenues of 69.1% compared to 69.5% of 2019. The slight margin decrease compared to previous year, is the result of a different product mix and marginally higher distribution costs, as a result of the fact that many commercial flights, which under normal conditions would have been used to move our goods has been grounded because of COVID-19. And so, we had to use cargos, which are usually more expensive.

Total operating expense is at €66 million or 37.6% of revenues have increased by 3.5% compared to last year. The difference is mainly driven

by the investment we made in the U.S. commercial team. And this aimed at sustaining our hospital strategy has just covered by Carlo and discussed during Q4, 2019 call.

Q1, 2020 other operating expenses at €6 million increased by €3 million compared to last year. This variance is almost entirely driven by an unforecasted loss; we suffered in our South African subsidiary, during the shutdown process. For which we have activated the group insurance policy. We expect the insurance claim process to be completed within the next 18 months, 24 months.

As a result of what just discussed Q1 2020 EBIT at €49 million or 28.3% of revenues, has decreased compared to 2019 by 6.7% or €4 million. The tax rate at 23% is in line with 2019. 2020 net results at €38 million or 21.6% of revenues is lower than previous year by €3 million, or 6.6%. This difference is almost entirely due to the loss that affected our subsidy in South Africa.

Last, Q1 EBITDA at €65 million is lower than last year by €3 million or 4.5%, with a ratio on revenues of 36.9%. The variance at constant exchange rate and net of...the one-off South African loss is positive by 1.6% with a ratio on revenues of 39.5%, therefore, in line with the marginality achieved in the last few quarters.

So let me now move to the net financial position and the free cash flow. We closed the period, as I said with a positive net financial position of €216 million and €242 million of cash. And we generated €40 million of free cash flow compared to €36 million of last year.

Lastly, as Carlo just discussed, due to the significant uncertainty, regarding the duration and the impact of the coronavirus pandemic

DiaSorin is withdrawing the previously announced 2020 financial guidance.

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 your question, please press "\*" and "2." Please pick up the receiver when asking questions.

The first question comes from Catherine Tennyson of Bank of America. Please go ahead, madam.

CATHERINE TENNYSON:

Hi. Thank you very much for taking my questions. And I have 2 if may. So my first one is on the China growth number, which was a little worse than I expected. Is that a fair proxy for the exit rate that you saw in April in Europe or should we expect more significant impact from a revenue perspective, given that Europe has a greater mix of specialty higher ASP test? So that's my first question. And then secondly, can you give us, how to quantify the benefit from stocking impact in Q1, I understand early to Q2 you've been seeing [indiscernible]. Thank you.

CARLO ROSA:

Okay, I'll talk about China versus Europe. You need to understand that our business in China is very much skewed on more I would call routine testing, because the Chinese market today is...does not really accommodate yet the specialties, as we have discussed few times. And so, what you have seen in China is that lots of routine testing has pretty much

evaporated and the only business left has been the...related to pregnancy

testing. And some sort of the non-elective surgery.

In Europe, as you know, the situation is completely different, because we

do have a specialty strategy. And therefore, what we have seen is that we

have a milder effect on the European market. Notwithstanding that, if I

may...if in China we had, again 65%-70% decline in Europe, you are

talking more around 40%, which I think is in line with what has been

recorded by other diagnostic companies.

In the U.S., the situation is slightly different because we do have a lot of

Vitamin D business. As you know the Vitamin D...the Vitamin D

business in the U.S. as the vast majority has to do with pre-

employment...sorry pre-employment with insurance testing, the annual

checks, and all these testing has been postponed because of the fact that

people were not available to go to get tested and because of the lockdown.

So certainly the decline in the U.S. has been more severe because of the

Vitamin D dependence [ph] by the same token, that's a decline that I

expect to get back, as soon as, the routine checks will start again probably

in Q3 and Q4.

Second question is about the stocking effect in Europe? Look, it's very

difficult to assess, because it was a really different policies country-by-

country. But I would estimate the stocking was in the range of €5 million,

€6 million. But again, take it with a grain of salt, because it's very

difficult to assess.

CATHERINE TENNYSON:

Thanks so much. That's very helpful.

OPERATOR:

The next question is from my Maja Pataki of Kepler. Please go ahead.

MAJA PATAKI:

Yes, hi, good afternoon. I have a couple of questions, but I would like to start with your performance in Germany, which you know, saw very strong growth in Q1. And I was wondering whether that is related, you mentioned, I mean, stocking, but is there also something that we should read into that into conversion of the ELISA business to CLIA, is there anything that we are seeing quite an uptick from that side?

Then, thank you very much for providing us some clarity on the manufacturing capacity you have for the serology tests, ramping up to 10 million, that's obviously significantly higher than what I understood from your IR department. Is that pure allocation for the serology test for COVID-19 or is that...is that a reallocation of some other manufacturing capacity whereby you would see some...maybe some evaluation going forward to you know, what kind of tests you're going to produce?

And then lastly, Carlo, I understand you don't want to give us an exact revenue number for you know, for the monthly revenue potential of the serology tests. But you have been mentioned in Italian newspaper saying that you would at best, bill €5 per test. Is that the number we should test…take to understand the potential upside from COVID-19 serology tests? Thank you.

CARLO ROSA:

Okay. Germany, a good chunk of it. Clearly, stocking is...stocking yes...and this is because, you know, in Germany, we do have a very large private chains. And they were the ones that originally have been actually spending time in understanding the situation...logistic situation. But I have to say also that we are, as you know, at the end of the Siemens story. And so, we saw an organic growth of the LIAISON, which has to do with the fact that we converted in Q4 last year...Q3, Q4, a good chunk of customers in Germany with add-ons. And we see the benefits clearly starting from Q1. So there is a mix effect.

About the volume of testing, look certainly as...especially in the U.S., where we do manufacture Vitamin D, the fact that you see Vitamin D decline, you do have capacity. And so, what we had, it has been a reallocation of some of the existing capacity to the COVID product. However, it is very clear that we do have capacity today to allocate the current volume plus the existing volume when we hopefully go back to normality. What we have to do probably is, is to move to more than one shift in some of the sites, but that I don't see that as a problem.

Last but not least, look, I...unfortunately, I've been in the newspaper more than I wanted in the last few weeks, and I am understanding the journalists better than I did 8 weeks ago. And to be honest with you, I would not take what a journalist write about pricing ever in my life. So I think that you need to go back and you need to understand in the different geographies, what were the prices. And it is a...what I think is very relevant to understand about pricing, is that depending on the country, you really have different pricing structure. And this has to do with appreciation of certain countries on the quality of the result and the differentiation of the DiaSorin product versus the existing competitors.

Second, you have to do with...you need to deal with government tenders. And in this very specific case, the government...governments are truly investing into technologies that allow management of the pandemic. And so there is premium price that we see across the different...across the world vis-à-vis some of the good quality products.

The problem that we have today, as you know, is that Europe and the U.S., we have been at the beginning of the of this COVID story we have been flooded...flooded by low quality products that were coming from China, to a point that different governments, and different authorities, including

WHO, really started to say, hey we need to really watch after all these products, because they're not qualified. We don't understand how the heck they were validated. And so, now a lot of countries are coming back and putting restrictions on these products. And some of these products, very interesting, some of the products have been actually thrown to the market at a very low price, but some of these products especially what we call the lateral flow products have been provided to Europe at an astronomical price, okay. So long story short, don't read what the papers say, but the price is very different from country to country depending on what the government decided to do in terms of reimbursement and in terms of the government tenders and be what the competition did when the only competition available were actually products imported from China.

MAJA PATAKI:

Understood. Maybe just quickly a follow-up question Carlo, can you quantify how much do molecular tests generated revenues in March, to COVID-19 tests?

CARLO ROSA:

No, I can't, as you can obviously imagine, we just saw in March that was...but I can tell you that was very small.

MAJA PATAKI:

Okay. Thank you.

CARLO ROSA:

Okay.

OPERATOR:

The next question is from Andrea Balloni of Mediobanca, please go ahead, sir.

ANDREA BALLONI:

Yes, good afternoon, everybody, and thanks for taking my question. The first question is about the live machine. In the press, you have mentioned about a slower trend in installed base due to COVID impact in China. On the other hand, thanks to the launch of a new serology test, you have also

mentioned penetration, you're in the U.S. What should we expect as a net effect over the full-year 2020?

And my second question is about the serology test. You have commented about an increase of capacity from current 5 million to 10 million tests per month, but when should we expect this increase, this is something that can do in the very short-term or something we should expect more in the medium-term I think about last quarter this year for instance? The next question is about the new test that you would like to launch in autumn in order to detect COVID-19. I didn't get the point. Did you see any risk of overlap in Italy or in the U.S. for instance with a molecular test you already have launched. And the real last question is about China, what's the speed of recovery there? What did you experience in March and April in terms of recovery? Thank you.

CARLO ROSA:

Okay. So the first question is net number of XL, we are actually very positive about the XL because we are building a new installed base, and a new customer base. So we see that we are going...this is going to be a year, where the number of connection [ph] placed is going to be on the high-end of what historically we've been doing.

The second question has to do with capacity. I said that we are working to rapidly...so in the next few weeks move from the current 5 million to 10 million tests per month. And by the way, you should take note of announcements made by different companies about their volumes, of their manufacturing volumes, and I think you should also verify with these companies whether eventually this is what they are saying or they are selling, because I saw numbers that I never heard in my life. But as far as we are concerned, we are talking about going to that monthly volume.

The third question is with COVID-19 in U.S. Look, they overlap. Look, as I said, if you listen to what the Americans are saying, and I think you should that as a reference, their ambition is to move to testing capacity in the range of 100 million tests per month. Because what they believe is that is...and I'm talking about ability to swab people, and that is what they believe is necessary if you want to coexist with a virus and test people routinely to guarantee that they don't spread the infection. That's an ambitious.

But I have to say that today the industry will struggle to cope with volumes of this size, if the ambition is to do routine testing, if the ambition is that before you board the plane, you want to make sure that you're not infectious and so forth. And my point is that the technology, the molecular technology has to be complemented with something that is cheaper, faster, and can be adopted, also in different settings. And, by definition, it cannot be a molecular product, in my very own opinion.

And so, the challenge is that we'll be able, we as a society will be able to cope with massive testing only and only if we will be able to achieve sensitivity of molecular with non-molecular technologies. And that's the challenge and a challenge that we have taken upon ourselves, working with a partner that is a worldwide leader in this kind of technologies and I need to leave it to that for confidentiality.

Last but not least, I think looking at China, and the speed of recovery. To be honest with you, that is the real conundrum here, because what we see in terms of volume, diagnostic testing volume in China and what people say about China going back to normality, don't see eye-to-eye. We still see in the current weeks volumes of routine testing, volumes in China down 40%. And this is not necessarily in the geographies that are hit. We've seen pretty much in many geographies in China. And that tells you

that there are still a lot of skepticism from the people, by the people to the fact that they would go to the hospitals and get tested.

So, how long is it going to take before it goes better, I have no idea. I don't know, I think the dynamic in Europe, and in the U.S. may follow the same path. Keep in mind also that the markets are completely different in China is...everything is off pocket. So patients do pay in Europe and in the U.S. [indiscernible] insurance or is covered by National Health Systems. And I don't know if that will actually favor the, what we call the go back to your normal life. And this is why I said before, I don't want to make any comment about the future and guidance, because that's a big question and nobody today has a serious answer to that question. And I don't think necessarily China today is providing you the answer you want.

ANDREA BALLONI:

Thank you.

OPERATOR:

The next question is from Scott Barda of Berenberg. Please go ahead, sir.

SCOTT BARDA:

Yes, thanks very much and congratulations on your flexibility in this environment. It's truly remarkable, how the company has changed in only a matter of weeks. With that in mind, many questions, but I focus on serology. So first question. You mentioned about the environment, which is competitive, lots of different companies now offering serology tests, and that you have some differentiation as a company. I think there are lots of companies claiming high price specificity, high sensitivity, even against spiked protein, which you target. So can you help us better understand why your product is different. And that would be useful.

And second question related to this. A lot of companies now, particularly the very high-volume players are expecting to price the tests meaningfully lower than what you highlighted or the report has picked up if you like in this €5 mark. Does that matter if they have lower prices and they are sold and does that, if you like trigger a reaction for you to reduce pricing?

And third question, please, here and again I just really want to understand this, because it potentially has quite material connotations. I don't understand why in regular interaction with the company, the discussion was more 1 million or 2 million tests per month for in the month of May, building up to 3 million or so tests per month by the end of the year. It takes time to build capacities, and all of a sudden, within a matter of weeks now 10 million, so how can...underestimate this by threefold? And actually, therefore, provide this additional capacity so rapidly, so maybe you can comment on that?

CARLO ROSA:

Okay. So as far as the...why the product is competitive, look, the way we designed the product is...and again, I don't want to give everybody a very boring biology one-on-one lesson, but today, there are, I think companies have developed product using 2 proteins, either the majority of the companies have used a nuclear protein, and nuclear protein is easy to do. Because you can make it in massive amount it's not necessarily too complicated is small, but as...that is a nuclear protein.

And if you look at the mechanism by which the virus is infecting the cell, the local protein has nothing to do with it. The virus is infecting the cell through the AC2 receptor through the spike protein. So at the beginning of the product design, we decided to take a much more complicated route. And that was, let's take the spike protein, because of 2 things, a) we believe, and it was actually recommended also or evident from the initial literature that was actually getting published those days from China, that the spike proteins was extremely antigenic, okay.

The second thing was much more of a perspective. And we said, well, if you think about positioning this product vis-à-vis immunity and vis-à-vis the vaccine, there is a very good chance that the vaccine candidates are spike proteins and therefore, if you eventually need to test vaccination, that's the right way to go. And based on that, we have developed the assay, and is...has being cruel, in a sense, what we had to go through because the spike protein is heavily glycosylated so you use a timer. And so you need to take it, you need to express it in mammalian cells complicated. And we've done it through a very successful partnership with a very small company that is located in England, but phenomenal company. And because of that...and because of the ability of this company to engineer all these reagents, we were then able to scale up way before than expected the manufacturing capacity. And this is why today we feel more comfortable, because we have been stabilizing the inflow raw material and now we have quantities of these raw material that allow us to move to the...to scale up manufacturing way before than what we expect.

So what we have today? I think we have a product that has been...is very interesting has been evaluated and has been built; okay, by us to identify the antibodies. Again, spike has been validated not only in Italy but now has been validated at the Erasmus Hospital in Holland and a beautiful study has been validated that it does pick up neutralizing antibodies which are the good antibodies, and now is in the evaluation in the U.S., in the primary centers in the U.S., for the same claim. So that's a differentiating factor and this is what people understood. Lots of discussions today about immunity...not immunity what you do, which antibody to pick up and we have been leading that discussion and that to me is a differentiating factor and this is why certain governments have decided to buy our product not withstanding higher price because they understood the value.

Now, it is very clear that late comers and some of the very large companies that typically we have seen before, they don't give value to products, they give value to systems, they give value to volumes. They price it differently, and we are going to let them go their own way, and we are going to continue to fight our own battle for quality and for certain positioning, and this is why we don't need 100 million test per month as some claims they are going to make available, 100 million test per month is large screening. We are going to go for 10 million per month, but the 10 million goes for the ones that...for the clinical use and the proper use of the product. And pricing will follow as...and pricing positioning will follow. Certainly, we all know that price is only way to go which is down so we expect there is going to be some price erosion, but we are not going to follow some of the pricing crazy concepts that I have seen on the market...on the market these days. And Scott, what was the...do you have another question or did I...?

SCOTT BARDA:

No, I think you summarized all those. Thank you. Maybe just a quick follow-up here then would be just to understand this, I mean, even using a €5 number. So you know, we're talking maybe €150 million a quarter, or maybe €200 million a quarter on full demand on an annualized basis, bigger than the revenue base of the company today. I just want to make sure I understand this correctly, I guess, the question then is, if I am right there, how long does this go on for? Does this will disappear rapidly when a vaccine comes out and what do you do with the excess capital?

CARLO ROSA:

Scott, I don't know where these numbers are coming from to be honest with you. And certainly I am not making any comment on numbers of this size. Let me just make a comment. Where is this going to go? I hope it is going to go way. Now, because I am sick and tired of spending my weekends on my balcony, but all said and done, I think this is going to unfortunately take time, and I think that strategically this has to

leave...this has to leave a legacy with the company. And what is the legacy? More systems installed more hospital base in the primary market, visibility as an innovative company. These are the intangible assets we are building today that will become tangible moving forward because don't forget we do have a pipeline of products. We have a value base care. We have lots of things that we were developing before...before this pandemic.

The way we position again the product, the way we built the product is betting also on the fact that when vaccination is going to be with us, and I hope it is going to be with us soon. There is going to be a need to assess its efficacy of vaccination. So there is going to be continuous testing or that will require. And if vaccine will be built as it look like using as targets, the spike protein, well...you are very well positioned at that point because the spike protein...antibodies with the spike is what we measure today. So I see this product strategically positioned, to want them in the quarter, I have no idea Scott. I will talk to you in a couple months and we will see where the crazy world is going.

SCOTT BARDA:

Alright. Thanks very much Carlo.

OPERATOR:

The next question is a follow-up from Maja Pataki of Kepler. Please go ahead. Ms. Pataki, your line is open, madam.

MAJA PATAKI:

Yes, hi, sorry. I was on mute. Carlo, maybe just 2 more strategic questions. The first one, we have seen a couple of countries debating heavily, you know, who has to pay basically for the COVID-19 testing. Germany, we have to debate with the private insurers pushing back claiming that governments need to that. Do you anticipate that with the ramp up of testing going forward, and maybe getting out of the worse, but the volumes staying high, we will see some pushback from governments

on pricing rather than seeing the competitive spin coming through. That will be the first question. And then I will follow-up with the second one afterwards, please.

CARLO ROSA:

Okay. Maja, to be honest, I have no idea. What I have seen, this is why, you know I think everybody today is trying to understand the space, and I think that I notice few things. I have seen the U.S., very proactive, and what the U.S., did if you think about it, it is said that they put lots of pressure on suppliers to supply the U.S., and the U.S., labs go by the same token, they put on the table a very hefty reimbursement. You have seen for molecular \$50 for a low throughput, \$100 for high throughput, and so they said...what the government said is I...you know lots of companies have to put a tremendous amount of effort to provide products to the community. What people don't understand is that companies like DiaSorin, but everybody else did the same. You and R&D people doing other things, and now you had to take all your people and put all of them to do COVID. Otherwise, you will not explain how the heck usually takes 18 months to develop a product, and now we took 8 weeks, right. So there is a cost that companies are incurring into because of this...of the story. And I think the U.S., government has been the one that recognize that and have been very generous in my opinion through...to their own industry supporting the industry with what they could which is money to the system to allow the people to get tested.

How is this going to move forward? I have no idea...I really don't know to be honest with you. I certainly know that there is going to be competitive pricing, yes that I understand. I believe that is going to be more on the serology than on the molecular simply because on the molecular there is going to be a chronic...chronic shortage moving forward. And so, there is going to be more demand than supply and that will keep I believe molecular pricing high. Serology it may be different,

but I really have no idea how the reimbursement policies are going to move.

MAJA PATAKI:

Okay. And then just lastly, I think you were elaborating on that already a bit based on Scott's question how to think that this is going to develop in the long run even when we have vaccination. Do you believe this will take the same kind of characteristic like the flu test or do you believe it's going to be a different kind of dynamic since there will...there will be a high push for the vaccination for the whole society?

CARLO ROSA:

Listen, Maja, you are making me smarter than I am, because I wish I had that answer to be honest with you. What I know is just one thing. I think the next flu season is going to be very challenging, because if you think about it...take Italy, for example, Italy was actually hit by this virus toward the end of the flu season, and also this year, we had a beautiful warm weather so the spring actually came very early.

Now, we are getting into the real flu season that will start in October/November, we are going to have all the symptoms of flu...regular flu, and you are not going to have a vaccine unfortunately I believe, and you are going to have a strong need for differential diagnosis. So what I am saying is that there is a need...there is a social need by companies to bring forward certainly more capacity on molecular testing, but I believe also technologies that would allow a more widespread use of reagents for acute testing. Right, so I see the fall being very complicated, but I hope I said before then long term who knows, I hope that COVID will go away. I really hope so through vaccination.

MAJA PATAKI:

Thank you very much, Carlo.

OPERATOR:

The next question is from Giorgio Tavolini from Intermonte. Please go ahead, sir.

GIORGIO TAVOLINI:

Hi, good afternoon, and thanks for taking my question. I was curious to see if at this early stage, do you see any demand for COVID-19 test by single local firms, banks, enterprises to allow employees to return to work. And if so, do you have the technological...the right technological platform to provide very point of care test for COVID-19, I mean, for these terms or small enterprises? Thank you.

CARLO ROSA:

No, we don't, because we are not playing in that place, as said many times we work with...in a central lab, and we do not intend whatsoever to get ourselves into the figure-pricking technology. That is a complete different game today. Let me just remind you some facts. And the facts are the following; there is a WHO recommendation that says guys you need to be careful with lateral flow and these technologies because there are too many products are there that has been not validated to the point that the WHO has imitated a program to validate some of these assays and discriminate between the one of low quality and one of high quality. And I am not pointing fingers to anybody, and I am not hinting that by definition a finger prick [ph] assay is of low quality, I am just saying that today, the WHO said, you don't know...we don't know. So we need to conduct an evaluation to the point that they recommended CLIA analyzer go through the WHO document which I think is April 2020, they say today the technologies to be used are CLIA analyzer with a specificity and sensitivity which are over 90% to 95%, that's their recommendation.

Now, different story...different question you are asking about going back to work and testing? Look there is a plenty of discussions in the different countries and different legislations about that. And today, there is not a legal requirement to actually test employees for COVID-19, actually what

you realized today is that a lot of companies have decided to offer, it is a benefit to their employees that do have...they do want to get tested on a voluntary basis to know whether they've been in contact with the virus or not. But, certainly is not mandatory. And that is not a market we are going after today, this is not our positioning and how company has decided to do it, is actually not my business to be honest with you.

GIORGIO TAVOLINI:

Okay, thank you. And just a follow-up, are you cooperating with the pharmaceutical companies that you provide, I don't know clinical studies for vaccines with the testing COVID-19?

CARLO ROSA:

We have initiated contacts with some of the candidates, the problem you know, the problem...the real problem is that today you have so many companies having claiming that they do have...they don't have a vaccine which is very difficult to understanding to work with. But, yes, we do...we have initiated a screening of who is out there, who is working with vaccine with vaccinations. But, what we saw which is very interesting is that, the vast majority are actually working around using the spike protein as the protein for vaccination and that's comforting our decision in terms of which antigen to use.

GIORGIO TAVOLINI:

Thank you very much.

OPERATOR:

The next question is from Hugo Solvet of Exane BNP Paribas. Please go ahead.

**HUGO SOLVET:** 

Hi, thank you. Thanks for taking my question, you mentioned Carlo, in your prepared remarks, your increased ability to access and enter labs. Thanks to your COVID-19 offer? And also strike contract for TB product. Are you able to drive the premium when converting the accounts and when are you expecting volumes to normalize and possibly pickup? And

follow-up to that would be an update on line product that you are developing considering COVID is delaying a lot of trials; do you expect any delays here? Thank you.

CARLO ROSA:

So sorry...the first question if I understand correctly as to do with TB and the crossover...

**HUGO SOLVET:** 

Yes, are you able to drive premium when converting accounts?

CARLO ROSA:

Yes, we do. We do have the ability to drive premium, because again that strategy if you remember from...primarily in the U.S., was driven by the fact that we are going after send outs and that were very expensive in the U.S. And so, on average I think we did comment before that we were getting around 25% premiums over current pricing because of that positioning. And again, what I see that is working beautifully on that program is that, it was frozen certainly around January, February timeframe because of the pandemic. But, now the fact that hospitals do want the COVID assay then we are able to actually jump start it back again, because once we install the XL, then you get pretty much 2 birds with one stone, the serology and the TB business.

As far as, Lyme is concerned, look I think that your result because we have all the collections centers step up, they are in Germany, in Austria, in Holland, we are more in Italy certainly in some of the northern regions. The good [ph] result, because we don't know certainly look I was joking last night with the Head of R&D, during the lockdown is very difficult to get line, because either you get it in your balcony or that you don't go out in the woods. But, now they are reopening especially in the northern part of Europe then we expect that Lyme is going to pick up again, and in fact we saw few patients showing up in Germany already. So I honestly don't know it is difficult to tell, whether we will be able to collect the necessary

amount of patients, during the season or not. And we need to wait a month or so and see how it goes.

**HUGO SOLVET:** 

Thank you very much.

**OPERATOR:** 

The next question is a follow-up Scott Barda of Berenberg. Please go ahead, sir.

SCOTT BARDA:

Yes, thanks very much, I know you [indiscernible]. So I just want to understand a little bit further your views on the different sorts of elements where serology testing can be used, I mean, epidemiological work is clearly one of the near-term considerations, and you've talked about being used in the commercial sector and so forth. But you know, some players are claiming that their antibodies and it's also being used as a disease escalation marker, which is used for in treating these critical patients. Is that a quality that you think your product has, and therefore could see extensive use in hospitals, both managing the crisis and reactivating them to normal elective procedures?

Last question, I missed that early, please. Just to understand, I mean, in some ways, the serology test had some characteristics to rapid rise you had in Vitamin D, which obviously has remained at a high-volume and declined for a long time. I guess, at that point, you use that capital and cash from Vitamin D to strengthen the organization. So are you starting to nurture ideas to use any potential windfall here to strategically strengthen the business?

CARLO ROSA:

The answer is obviously yes, to the second one. Because, I think that remember we have an obsession and the obsession is that we want to get bigger in the U.S., because we see this as the market where an innovative company can really make it. And we...as...we have been looking for

targets and opportunities and with the proceedings coming from this we are going certainly to invest in that market, because we want to again...strategically we want to get bigger there. So yes, the answer is, we are seriously looking at that.

First question Scott, it is difficult to...I didn't really understand what you mean about escalation marker? Can you just repeat it for me?

SCOTT BARDA:

Yes. Some conversations we've had suggest that by doing serology tests on critical patients on a regular basis and working how quickly their IGG response rises; this is a prognosis for where you have a cytokine storm and end up on a ventilator. So in the sense, it's a marker of disease escalation, which a lot of intensive care surgeons say a very useful additional unexpected application for these antibodies. I'm just wondering whether this is a quality or an attribute that you are aware of for your own product, is it an interesting angle or is it something different.

CARLO ROSA:

Look what we have seen, and I can tell you, we saw ourselves during the clinical studies, but you also see now published everywhere is that critical patient that are in ICU have tremendous high titer of IGG. Okay, whereas hospitalized patients that are not in critical care has a lower level of IGGs. And then people that are been exposed, but there are symptomatic usually have low level of IGGs. Now, if you read little literature, what this suggests is that in this high antibody response, you may have ADE antibodies, those antibodies that actually allowed virus to infect to...get bound to the microphage and then elicit the inflammatory response. And this would explain why this very high antibody titer actually is associated with patients with worst prognosis.

But, I think that this is true so far with antibodies level measured with different products. So I don't think is specific of the product, it has to be

with the antibodies per se. What is a very intriguing project? To be honest with you, will be to try to understand if you can identify the best, the good antibodies, neutralizing from the bad antibodies which are the one that do bind to the protein, but actually favour the inflammatory response. And that's something that I have seen in few research...is a research group...and I have seen few research group starting to focus on that, keeping in mind that the first indications on that...on this concept we are actually discovered in 2012, with the original SARS. So is there for sure, this negative effect of antibodies. But, today is a research product more than commercial.

SCOTT BARDA: Okay, I can ask questions, but I will stop now. Thanks so much.

CARLO ROSA: Okay.

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

CARLO ROSA: Thank you operator. Take care. Bye-bye.