DiaSorin S.p.A.

"Full Year 2020 Results Conference Call"

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PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the DiaSorin Full Year 2020 Results Conference Call. As a reminder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions. Should anyone need assistance during the conference call, they may signal an operator by pressing "*" and "0" on their telephone.

At this time, I would like to turn the conference over to Mr. Carlo Rosa, CEO of DiaSorin. Please go ahead, sir.

CARLO ROSA: Thank you, operator, and good afternoon to everybody, and welcome to the year-end result conference call for DiaSorin. I would like to make an initial statement. This has to do with some rumors that have been reported about the company. And so, it is very clear, as you know, that in line with our strategy, we routinely explore transaction opportunities with strategic partners, and this is, you know, is done to create long term value for our shareholders. So I will not comment on any rumors about potential M&A transaction until such disclosure is appropriate or required.

Now, let's move to the discussion about results, and how we see the business progressing 2021. I would like to focus on Quarter 4. Quarter 4 is important, because it projects company results into 2021. And I'm going to comment results, as you know, as usual at constant exchange rate to avoid any misunderstanding due to the exchange rate that, you know, has been impacting company results significantly in 2020, because of the…mainly the dollar fluctuation.

So in Q4, the first news that we need to discuss is that the ex-COVID business is flat, in spite of the second pandemic wave that hit North America and Europe and this is a good news, this means that, the routine business that suffered significantly during the first wave now did not

really suffer in the second wave. So hospitals and patients especially, have learned how to manage their routine testing in spite of the COVID situation.

Now, if we look at the COVID business, for us, Q4 was a record quarter. We had over €100 million of revenues which is very significant. The majority of these revenues were related to our molecular COVID product, the rest was serology. And not only revenues were…record revenues in Q4, but also placements of systems. So if we look at the XL [ph], we have placed throughout the year more than 600 systems, and in Quarter 4, placement was 180. So again, good job, almost a third of the systems were installed in Q4. When it comes to the LIAISON MDX, so the LIAISON confirm similar picture 650 MDX placed in the year and 200 placed in Quarter 4. So the rate of placement is not stopping, and it continues to progress.

When you look at the different geographies, clearly, we see a strong growth in U.S. and Europe. This is the effect of base business stabilizing and additional COVID business. China still weak, but a significant improvement compared to previous quarters. So China, as you know, for us, as for many other companies did not represent a COVID opportunity because of the Chinese regulations and the fact that none of the foreign products for COVID have been approved by the China FDA.

So, let's look at…now that we understand the 2020 Q4, let's make some statements about 2021, and let's discuss COVID and how we see it. So…and let's start from molecular diagnostic. We continue to believe that the molecular testing remains gold standard. You know that today, 2 technologies are offered to the patients. One is molecular, the other one is antigen testing.

And you see molecular, because of performance remaining as the gold standard technology inside the labs, and inside hospital labs, whereas the antigen opportunity picked up significant business outside the hospital, so in the centralized setting with point-of-care. I think it has been brought to everybody's attention recently, the fact that the point-of-care antigen testing volume has been softening significantly. I think one company recently reported 30%-40% decline in antigen testing.

If you remember how we did comment, technologies for COVID in the last few quarters, we always said that we believe that antigen would have been the first to decline, whereas we believe that there is more resilience on the molecular testing, and this is simply because of the fact that it remains within the hospital big preference technology.

So in Quarter 1, we see that our ability to shift roughly a million tests a month of molecular COVID tests remain as it was, we don't see a decline in volume, as far as, our molecular testing is concerned. Clearly, you saw from the guidance an indication; we don't know what to expect in the second half, there are lots of variables that may affect this. But for the time being, we keep seeing a strong revenue flow coming from molecular.

Now, let's talk about our…the second component of our COVID strategy, which is the antigen test. As you know, we have developed an antigen test that was launched in Q4, and that is for routine labs, so no point-of-care routine labs on the LIAISON XL platform. The product has been CE marked and has been submitted to the FDA for EUA approval. EUA approval has not come yet this is because the FDA is taking longer than before to approve these products. Today, they are really focused on point-of-care and OTC. We believe that we are close to receiving approval in the next few weeks, but we are still waiting, although we are

commercializing in the U.S., the product and EUA according to the FDA policies.

What is the strategy for the product? It is very clear to us, that the success of this product is related to the ability of some of the large commercial labs to gain contracts from state, from 4 antigen testing for reopening. So we see that there is going to be an opportunity for consolidating antigen testing for not critical care into commercial labs.

You have seen that LabCorp a week ago or so they issued a press release where they said that they have a partnership with DiaSorin for the LIAISON antigen test which has been implemented in other labs. And we, together with LabCorp, we expect that LabCorp will get contracts from the reopening, and then we may benefit from volume coming in the U.S. with the antigen test.

In Europe, we have seen volumes increasing, although soft volumes and this is because in Germany, there has been a shift from the laboratory testing more into the point-of-care and OTC. And therefore, we've seen interesting volumes and interesting business develop across Europe, but less than what we originally projected, although it is getting traction in Europe.

We don't have the registration of this product still in some of the emerging countries, where we believe this is going to be substitution in those countries where molecular is too expensive, substitution of a molecular testing, and we expect that they're going to receive some of these approvals in Q1-Q2.

Now, let's talk about the third component of the strategy, which is the antibody testing. As you know, we did comment in the last calls that we

believe this business…so antibody testing for COVID is going to be the one that will stay with us and with the industry for many years. And this is because people are getting vaccinated, and there is going to be a need to test individuals and see how long the vaccine is going to last? How long the protection is going to last? And in fact, we see this happening; we see a strong demand for our antibody testing.

We see double-digit growth, and we have recently launched our new generation of serology, IgG assay, which has been developed on purpose to pick-up response after vaccination and as for immuno status monitoring of patients after vaccination. In fact, this is the only product on the market that is used in the full length trimeric spike protein of the virus, which is the same protein that is used by the different vaccines, RNA vaccine or the DNA vaccine, and this vaccine actually elicit the production by the difference [indiscernible] that it is recognized by the immune system, and that develops an immune response. So we believe that we are online...in line with our expectation with antibody, and we are expecting the approval of the new product in the U.S. in the coming few weeks.

Now, I would like to talk about the other strategic products that we have. As you know, throughout 2020, sometimes without too much success, we've been trying to draw the attention of everybody to the fact that COVID is certainly strategic but then DiaSorin is not a COVID company. And therefore, we have announced throughout 2020 certain partnerships which are strategic; I remind all of you, the one with limit [ph]. And also, we were…we announced the fact that we were completing clinical studies of key products that would have been launched in 2021.

Specifically, Lyme has been...the product has been CE marked...and Lyme QuantiFERON…has been CE marked, and the product is being launched this week when the season starts. We have a lot of expectations about this

product. Clearly, the product will require a specific reimbursement to be issued in certain countries like Germany, for example, that is a big market for Lyme. We are working with our partner, QIAGEN, to expedite some of this work in order to sustain their reimbursement [ph] and marketing efforts, in order to let the product known to the physician is in place.

So we are confident that Lyme, as discussed, long term strategic plan will become one of the key products of our T cell strategy that we developed with our partner QIAGEN, and will go in parallel with...the tuberculosis product to create franchise around T cell. I remind all of you that we believe with QIAGEN since the beginning that TB has been a success, but there is a need to expand around TB, the concept of T cell testing, and this is the commitment the 2 parties have discussed many times in the last quarters.

Now, the second one is the TB. As you know, tuberculosis was approved in the U.S. at the end of '19. 2020 has been an interesting year, we are notwithstanding pandemic. We were able to close good business in the U.S. together with QIAGEN going after the send-out business. Today, there are millions of tests that are sent-out from the periphery from hospitals to the core lab and our strategic intent was to actually provide these customers with the opportunity of bringing the test in the lab, which happened with success.

In 2021, we will see a conversion of certain key customers to the LIAISON technology. The conversion has been managed with the support of QIAGEN, and it was done, because we believe that it's very interesting for the 2 partners to continue to provide customers a big opportunity to use this technology versus all their technologies or other technologies in the market, which clearly are not so favorable in terms of throughput.

The third element that I would like to comment on is hepatitis and HIV. As you know, the full line of hepatitis HIV was approved by the FDA by December, and we are now in the U.S. in full launch of this product line. There are a handful of companies in the U.S. that are able to provide these products on a fully automated platform, and we believe this is going to be key and strategic for DiaSorin, because we will be able now to serve all the installed-base of excess…XL...sorry, of LIAISON XL that we installed in 2020, because of COVID in the U.S. now with this product line.

So we believe there is going to be an accelerated pickup of these products by customers. Not to mention and not to forget the fact that in the U.S., we work with...Beckman is our partner for HIV and hepatitis, and they also will pursue a campaign to go after the large accounts with an automation that now Beckman has, and we'll be able also to implement the use of the LIAISON XL together with Beckman instrument.

So 2021, let me just summarize, and then I'm going to leave the podium to Mr. Pedron. 2021 is going to be an interesting year where we will continue to pursue the opportunity for COVID. As I told you, we will see what is it going to be the second half for COVID. We really don't know because the second half testing opportunity is going to be a combination of…I believe, few elements.

The first one is the variant that, as we have seen now, is creating a third wave in certain European countries, still not in the U.S.

The second element is vaccination, how fast is vaccination going to performed in Europe. It looks like in the U.S. is ahead, Europe is delayed. And this does and will have an effect in terms of the adoption of diagnostic testing volumes.

And the third element is the next season of flu, where we believe that there is going to be a transition from COVID only product to a mini panel concept, where flu and COVID are going to become routine test during flu season to monitor respiratory diseases.

So now, I'm going to leave the podium to Mr. Pedron, who is going to take you through the numbers. Thank you.

PIERGIORGIO PEDRON: Thank you, Carlo, and good afternoon, good morning, everybody. In the next few minutes, as usual, I'm going to walk you through the financial performance of DiaSorin 2020, and I will also make some comments on the contribution of the fourth quarter. As usual, I'd like to start with what I believe are the main highlights of the period.

So we closed the year with an increase in revenues at constant exchange rate of 27%, some 2 percentage points above the full year guidance, which was calling for an increase of 25% CER. Q4 '20 confirms that the end of the previous quarters, a steady recovery in the ex-COVID business, minus 3% year-on-year at constant exchange rate and the strong contribution of the COVID franchise, mainly driven by PCR testing. Carlo already went through all of these elements.

As expected and anticipated during the last quarter calls, Q4 gross margin ratio at 67.6% of revenues is below what we saw in the previous quarters mainly because of higher COVID molecular sales, which enjoy slightly lower margins. 2020 full year gross margin at 68.4% is for the very same reason, slightly lower than 2019, which closed at 69.2%.

2020 full year EBITDA at €385 million or 43.7% of sales is slightly better than the guidance. The increase towards 2019 at constant exchange rate is

42%. Q4 '20 EBITDA closed at €128 million or 47% of revenues. Let me please remind you that during Q4 '19, we booked some one-off restructuring costs, which makes the year-on-year comparison at plus 94% CER, even more favorable.

We keep maintaining our ability to generate a very, very healthy free cash flow €232 million in the year, vis-à-vis €118 million in 2020. The net financial position is positive for €305 million with no debt and €340 million positive cash position. The difference is always between the 2 is driven by the right-of-use introduced by IFRS 16. Finally, the Board of Directors approved to propose the distribution of an ordinary dividend of €55 million, equal to €1 per outstanding share.

Now, if we move through the main items of the P&L, 2020 revenue at €881 million, grew by 25% to €175 million compared to 2017. COVID revenues contributed for €266 million, 75% of which were PCR driven. Quarter 4 revenues at €271 million grew by 50% compared to Q4 '19, 55% CER. €100 million of revenues were COVID related, whereas the ex-COVID business at €170 million confirm the recovery we have discussed about.

As expected, the appreciation of the euro against almost all the currencies in which we do business has caused some material FX headwind in the second part of 2020, therefore, closing the year with a negative effect of more or less €15 million.

The gross margin at €603 million grew by 23% compared to last year, closing 2020 with a ratio of revenues of 68.4%, 80 basis points below 2019. The decrease in the ratio of revenues is mainly driven by different product mix, lower CLIA sales and higher molecular sales, which we said enjoyed slightly lesser margins. The increase of the molecular franchise,

29% of total 2020 sales, as discussed, has been mainly driven by COVID tests.

2020 operating expenses at €267 million or 30% of revenues have increased by 2.6% or €7 million compared to last year. The OPEX ratio of revenues is 30% vis-à-vis 37% of 2019. This variance is the result of 2 effects of opposite sign. On one side, especially in Q2 and Q3, we have had a slowdown of activities and the consequent reduction in costs caused by the widespread lockdown measures that interested all the geographies in which we do business. On the other side, we have sustained an increasing costs mainly driven by the investment we made in the U.S., at the beginning of the year and the commercial team aimed at supporting our hospital strategy.

2020 other operating expenses is at €12 million higher than 2019 by €1 million or 11%. As discussed during Q1 call, the biggest driver of this variance is an un-forecasted loss we suffered in South Africa. 2020 EBIT, because of what just described [ph], closed the year at €324 million with an increase compared to 2019 of €106 million or 49%. The EBIT ratio over revenues is at 37% vis-à-vis 31% of 2019. Q4 at €111 million, increased by 112% or €59 million compared to 2019.

2020 tax rate at 22.7% is higher than 2019, which closed at 19%, because of the booking in the last quarter of the previous year of the deferred tax assets related to the intangibles, which we moved to Italy in connection with the shutdown of the Irish manufacturing site. Net of this positive one-off, 2019 tax rate would have been substantially in line with 2020. 2020 net result is €248 million or 28% of revenues compared to €176 million of the previous year, therefore, recording an increase of €73 million or 41%.

Lastly, 2020 EBITDA at €385 million is better than last year by almost €110 million. The EBITDA ratio on revenues is 44% vis-à-vis 39% of 2019, Q4 closed at €128 million or 47% of revenues. The substantial margin improvement toward last year, both in the full year, but even more so in the quarter, is driven by the operating leverage resulting from the increase in revenues, amplified by a muted increase in operating expenses, which in Q4 accounted only for 26% of sales.

Let me now, please…to the net financial position and the free cash flow. We closed the period with a positive net financial position of €305 million and €340 million of cash. During the year, the group generated €232 million free cash flow vis-à-vis €180 million in 2019. The year-to-date free cash flow has been affected by an increase in working capital mainly driven by higher accounts receivable and higher inventory to sustain the COVID testing volume.

Higher CAPEX, driven by the acquisition of the PPP [ph] license, and higher installments of our platforms, and all of this partially offset by lower tax cash-out, mainly coming from a positive phasing of the…on a positive phasing of tax cash-out and the one-off €60 million exit tax we paid in 2019, when we closed our Irish manufacturing site.

Lastly, let me please move to 2021 guidance. As usual, at previous year constant exchange rate, we expect for the first half of 2021, total revenue to increase at rate of around 40% and an EBITDA margin at around 45%. Please consider that because of the impossibility of forecasting the speed of the rollout of the SARS-CoV-2 vaccination program, the unknown effect of the potential mutation of the virus and the possible development of new treatment, we are not in a position to provide the full year guidance. We will review our projection as time goes by and provide a

full 2021 guidance in case and when we will have a better visibility on the evolution of the business in the remainder of the year.

Before concluding, please let me remember you that the [indiscernible] financials are high disposed to the U.S. dollar and even more so now that the United States represents 40% of our group sales. And therefore, remember, as a rule of thumb that for every $0.01 movement of the dollar against the euro, DiaSorin revenue moves by about €3.54 million on a yearly basis.

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

Q&A

OPERATOR: Thank you. This is the Chorus Call conference operator. We will now begin the question and answer session. Anyone who wishes to ask a question may press "*" and "1" on their touchtone telephone, to remove yourself from the question queue, please press "*" and "2." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Catherine Tennyson with Bank of America. Please go ahead.

CATHERINE TENNYSON: Hi, thank you for taking my questions. I have 3, if I may. My first one, Carlo, as you've mentioned earlier, some diagnostic players in the U.S., have been talking about a substantial drop-off in antigen testing volumes. Can you just give us a little bit more color on the molecular demand that you've seen in particular in January and the February exit rate this year? And I recall, in Q3, there was an ambition to reach the…a

million molecular tests the month mark by the end of the year with the potential of expanding that to 1.2 by the end of this quarter. So given you have visibility on H1 now, given the guide. What levels of capacity are you baking into that number? And then just finally, what level of base business recovery is baked into that, too? Thank you.

CARLO ROSA: Yes. As far as, volume, I believe, I made a comment during my speech, which I'm happy to repeat. I believe that, as far as, we are concerned and the visibility that we have today, the molecular volume is stabilized. So it's stable, we don't see a decline as antigen testing companies have been discussing about the antigen test. So today, as we have discussed in the last call, we got to the 1 million, give or take per month volume of distributed products worldwide, of which, I would say is almost 60% is North America, 40% is the rest of the world. And we have a capacity of roughly 1.2 million tests. And so, we are working at 19% capacity, give or take.

And we believe that in the first half, we should be able to continue to sell roughly 1 million tests of molecular. We have no visibility whatsoever on the second half. And this is why we are not commenting year-end, if not by a concept, to me, is very clear. That comment will become part of differential diagnosis for respiratory diseases. So it's going to be relevant in the next flu season, notwithstanding the fact that vaccination is going to be, hopefully widely available. Differential diagnosis between COVID and flu is going to be implemented. Therefore, we believe that the business…the COVID-only testing is going to be switched to COVID plus flu.

Let me remind you something very interesting that we notice, as everybody knows, in 2020 as a result of all the measures that have been adopted by…in terms of behavior, masks and so forth…fundamentally

disappeared, so there was nothing [ph]. And even in our projections or manufacturing where we had volume that was dedicated to flu, eventually; we converted that volume to COVID, because flu simply was not there. We believe that, in 2021, we expect that in the respiratory flu season, availability of vaccine and the fact that certain measures will be certain restrictions are not going to be there, you're going to still…you're going to see more flu in this season.

When it comes to the antigen, what has been disclosed by certain companies, I said, already in 2020, that my expectation was that antigen will be the first one to go. And this is because, eventually, we all understand that antigen testing has pros and cons. The pros is that can be decentralized much faster than diagnostics. The con is certainly that we…the con is certainly that there is since…the TBP [ph] issue with the technology and that technology becomes viable only if you increase the frequency of testing. So I'm not surprised at all by the fact that antigen testing is softening, whereas for the time being, molecular testing is holding up.

As far as our forecast for the 2021, I believe the fundamental assumption is that the current business, so non-COVID volumes should go back in line to what they were in 2019. Clearly, you're going to still have a little bit of lingering effect in Quarter 1, and then you're going to see a pickup of that volume, where it used to be related to the deployment of the vaccine.

The question, though, that is interesting has to do with China, because there are no news, I don't know if you notice, but there are no news at all on China. What we see from our business is that there are certain regions of China where lockups…lockdown are implemented. And when there's a lockdown in China, then your base business suffers, other region where the situation is more relaxed and you see business as usual. Unfortunately,

lockdown happens in very populated areas where there is a lot of business, and this is why we see a recovery of China that is slower than the rest of the European and the U.S. countries.

Last but not least, vaccination in China. We have no idea what those [ph] data shows that they are very slow in vaccinating people. So they're relying more on hard lockdown with 2 to 5 hotspot. So as far as China is concerned, we're still baking the numbers, volumes that are below the 2019 numbers.

CATHERINE TENNYSON: That's super helpful. Thanks very much.

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

SCOTT BARDO: Yes, thanks very much for taking my questions. So the first question, please, just relates to the nature of guidance that you've given this year. I appreciate that this is not a normal year for DiaSorin. But it was my understanding from previous conversation that you were looking to give a COVID and non-COVID guidance for the full year. So I wonder if...or what changed your mind in the way that you guide.

And the second related question, please, of this 40% growth that you now guide for, for the first half, clearly, very good growth. But I think that this can be broadly achieved via normalization of your base business and the current run rate of molecular, assuming no incremental year-over-year growth in serology. So I guess, the nature of the question is, can you please help us outline or outline, please, what is your explicit assumption for serology and for antigen test within the H1 guide, please?

And last question, please, Mr. Rosa. Clearly appreciate that you don't want to comment on bid speculation, of course. However, I think it is no

secret that you want to deploy capital for M&A opportunity. Can you help share with us, please what you believe the financing power of the business is, what leverage you believe is a comfortable leverage for the company and whether you would entertain issuing equity if the right target come along? Thank you.

CARLO ROSA: I would ask Mr. Pedron to actually take the first 2 questions. And then I'm going to comment on rumors, and Scott has been asking on financing. PD?

PIERGIORGIO PEDRON: Yes, I will take the first 2 questions. Thank you, Carlo. So Scott, you know, I believe that the thing is there are really a lot of moving parts. And being more specific in terms of what part of the growth in H1 2021 is going to be driven by COVID in which part by ex-COVID; and inside COVID, which part by molecular by IgG, IgM testing and which part by antigen is very difficult. There are many, many moving parts. So I believe you really need to allow us hear some flexibility, also looked at what ad appears we have…which have reported before, as have done in terms of giving COVID and non-COVID guidance. I believe the majority of them, if not the vast majority, didn't give that kind of breakdown.

So obviously, we've run several different models, simulations, what can go up, what can go down. But again, there are so many moving parts that we feel comfortable playing all of our different models with a 40% upside H1 on H1, but I believe that we really didn't feel like we wanted to go down into the detail of what is called the molecular worries, antigen…and what's the rest.

CARLO ROSA: Okay. So let me take the one on M&A. Look, it is very clear that DiaSorin has an ambition to grow and diversify its product portfolio. It is very clear that although we want to maintain our key characteristics of a

specialty company because that is what makes DiaSorin special, unique in the space. That is what our customer base is appreciating. And so if I can just give you a strategic direction, there is where we see us as potentially moving vis-à-vis expanding our product portfolio by internal efforts or by external acquisitions.

The second point I would like to make is that what COVID did to us is certainly, make the molecular franchise more relevant and more significant than it was pre COVID. And as discussed, we have developed a business that originally was a U.S-based business. We developed that business into Europe to a point that, today, 40% of our turnover…molecular turnover is coming from European opportunities, where the vast majority of new customers were actually…were taken. So COVID is…my view on COVID is clear, COVID and I really hope it's going to go away, and it's going to become part of a respiratory funnel [ph]. We are going to have roughly 800 customers that we need to serve with products. As you know, we do have in mind and, in the company; we have an internal effort to develop new generation of the MDX platform.

The MDX platform, which has been a very, very successful platform, clearly, was developed almost 10 years ago, and we are undertaking the effort of developing the MDX second-generation platform, which we expect is going to be run sometimes in 2022 that will replace the current MDX, and we are working on the fact that we believe technology for multiplexing is needed if you want to become a player in this space.

The third strategic element, we believe, that decentralization and point-of-care testing for this space is going to happen, is happening. We believe that the current platforms were designed for a certain level of decentralization, which is not what we have seen with COVID with doing testing in parking lots. So strategically, we are also looking into the

development of that kind of platform. So this is where our M&A…it's a combination of internal development, M&A activity, licensing activity and the strategic partnership is going.

In terms of…if the question is, how much can you leverage the company's products, I'm not…really I'm not able to answer that question. We have a very prudent view about that, and sometimes that has been working against the company because people say we are too prudent. But I think most of the time it's been working in favor of the company because carrying that is a liability per se. So we believe that we certainly have the ability to make an acquisition with, I mean leveraging the company.

I think we're going to be always prudent on the leverage. And our shareholders, as always said, that is available to support our M&A strategy through the proper tools. So let's wait when an opportunity will materialize. But certainly, I believe we do have the financial ability…we have the ability to finance a decent level of an acquisition.

OPERATOR: The next question is from Alex Gibson with Morgan Stanley.

ALEX GIBSON: Hi, good afternoon. Thanks, I think I have 3 questions left. My first one is just again on the underlying business and trying to understand when do you expect the quarterly sales to return to the kind of level that you had planned before COVID. You had, I think, earlier…saying that they could get there by the end of the year. Do you think that's possible? And then once you're at that point, do you think your business will still be growing at the 5% to 9% that you kind of expected before COVID? Or should we expect faster underlying growth coming from Lyme, TB, hepatitis? That's my first question; I have a couple of ones in there.

Second one is just on your first half guide, and if you include the approved serology and antigen testing in the U.S. already in your guidance or if that could be upside? And then lastly, if you could just comment on what your expectation for pricing is for PCR tests for your first half as well, that would be helpful.

CARLO ROSA: P.G., can you take the first question about the underlying business? And I will work on the H1 guideline and the pricing?

PIERGIORGIO PEDRON: Absolutely. So yes, Alex, I believe I need to repeat what Carlo said. Again, the fact that we didn't give guidance for the full year, it means that we don't have visibility for the full year. But I think that it's fair to say that, by the end of the year, we should go back to that kind of level that we saw pre COVID. But again, we didn't give a guidance for the full year, right? And then in terms of growth rate, I think that the 5%, 9% number you quoted is a fair ballpark number. Very difficult to understand the speed of the pickup, but as a broad number, I believe that's a good one.

CARLO ROSA: Okay. Now if I go to the H1 guideline and pricing. The…on the H1 guidance, yes, we do have baked in the fact that we have a trimeric approved in the U.S. Keep in mind that today, we already have an assay for IgG determination [indiscernible] with the S1, S2 product in the U.S. that is approved and we are selling. Primarily it will be an improvement because also we have a quantitative claim, which is needed or semi quantitative, which is needed for immune status determination. But yes, they are backed in our numbers.

As far as pricing is concerned, look, I believe that we built a model whereby we expect starting from the second half to have a 10% price effect which means that if you have a 10% price decline on second half and annualize it, we believe, it's overall a 20% price decline. Again, this

one, we pulled it from the sky, as you can imagine, because so far, we don't see a price effect and reimbursement in the U.S., are hefty. Still $50 billion of testing is being added to the Biden proposal. So there is lots of money in the U.S. for testing. But again, just for purposes and of modeling, and then we will see what is going to happen in H2 is 10% H2 annualized 20%.

ALEX GIBSON: Okay. That's great. And if I could just follow-up on the…that first half guide, and you mentioned it, like Quidel gave the guidance yesterday that they're trying to say this is a floor. This is kind of the bottom of where they really expect they're going to come out. Do you think you could…you would agree with that or with your guidance? Do you think this is a floor that we should be working at? Or is it not as conservative as that?

CARLO ROSA: Look, I…you know that I'm not…I'm refusing to give flavor because numbers and numbers, assumptions and assumption, and I don't think it's necessarily professional to say I give you a number but it's not the worst-case or the best case. So we gave you our best number, best assumption in terms of what we believe the business will do in H1. And again, I think we all need to realize that there are low to moving parts, not necessarily in my opinion about the base business where I'm more comfortable with but about the development of the COVID business. So I think you appreciate the fact that we are all in the same situation here, trying to forecast 2021 and H1.

ALEX GIBSON: Okay. Thank you.

OPERATOR: The next question is from Peter Welford with Jefferies. Please go ahead.

PETER WELFORD: Hi, yes, thanks so much for taking my questions. So there's a few. First, just if we can just go back to COVID-19 in 2020. Thanks for the visibility on this. I wonder if you can just outline for us in the fourth quarter how much of the sales, the sort of €101 million is related to molecular. And were there any antigen sales at all in the fourth quarter? I know you said the remainder was serology. But if you could help us a little bit in the fourth quarter that would be great.

Just then on the molecular platform, I wondered if you could give us any insights there into the placement of instruments you've seen. And are there still new instruments being placed in the fourth quarter? You mentioned that a lot of it was new customers in the U.S., though, have you seen a lot of existing customers increase their placements at all. It will be great if we could get some sort of clarity on what sort of trend you saw during the period and usually the early part of this year.

And then just finally on costs. I guess if we think about this year, I mean, clearly, again, there'll be somewhat of a COVID windfall. How should we think about your ability to want to, I guess, incrementally invest in things like R&D this year versus, on the other hand, should we think about basically the cost basis, the cost base, and therefore, there will be operating leverage if COVID revenues do exceed or underperform expectations? Thank you.

CARLO ROSA: Okay. So let me start from the last one. I believe that when you think…when you talk about cost, I assume you're talking about OPEX, why…so if you want to understand if we need to increase our OPEX line. And the answer is no. We believe that what we have is in line. And clearly, the development, the OPEX increase that we have historically is every year-on-year is what is needed to fuel our projects, both from an R&D perspective and a marketing perspective.

As far as the first question, on Q4, look, we said…and if I can give you a ballpark number, we have 80% of the revenues pretty much is COVID and…of COVID molecular 20%, give or take, is COVID non-molecular, combination of antigen and antibody testing. I said as far as placement is concerned, I said that Q4 was a strong quarter for placements. So roughly 200 was on MDX and 200 was on XLs that were placed in the quarter.

So it was a very good quarter for us, which is telling you that the pipeline is…which is not only driven by COVID granted that the molecular pipeline certainly driven by COVID, but the XL pipeline is not driven by COVID at all. It's a combination of QuantiFERON, stool and the fact that we, by the way, concluded the 20…the Siemens project. Siemens project means that we have now stopped the distribution [indiscernible] from Siemens. We have converted all the customers. There was a last labor customer that came in so really; you should read it just on XL placements, really not really that much COVID related but more into the base business.

Now if you're asking, if I understood correctly, you want to understand moving forward what would be the current business growth, I believe that moving forward, we will return to the base business growth that we had historically fueled by all the new projects we have. And certainly, the fact that some of the drags that we had in the past are not there any longer. So we now realize that's strong as it used to be because we converted. And then we killed the labor line. I believe that will allow a solid growth of the base business. P.G., is there anything you want to add?

PIERGIORGIO PEDRON: No. I believe, Carlo, you covered it all. And also the number you referred to in terms of split amongst molecular and immuno sales for Q4 is the right ballpark number.

PETER WELFORD: That's great. Thank you.

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

MAJA PATAKI: Hi, good afternoon. Thanks for taking my questions. I have a couple of questions with regards to 2021, just to understand and put your comments into perspective, Carlo. I understand that you don't want to give us too many details, but I think it was in the Q3 call or even on the H1 call when you were talking about serology testing and you said it didn't develop as you anticipated. And one should look at €8 million to €10 million revenues per month just as it was developing. So my first question is with regards to what you've commented on the strong demand for serology, should we think that this €8 million to €10 million is now higher?

The second thing is when we talk about the base business recovering, if we look back to Q4 2019, it was just about the time when we had the latent TB test coming through, and then COVID-19 came. So the whole…going back to the base business, is that basically giving a base where we should then start to think what's the opportunity for you would be on the latent TB side and Lyme disease that would come on top of the base business? Or is it really a recovery to the sales number, including latent TB and Lyme?

And then lastly, when you talk about the antibody test…sorry about the antigen test, and it's true, you have been talking about the antigen test moving or falling off the cliff as the first test. But nevertheless, you have been quite positive about the opportunity also in more developing countries like Brazil due to the lack of molecular testing. Is that now something that you think will come through but at a later stage? Or is that something that you think, well, it actually…the situation has changed and it's not going to come through this way? Thank you.

CARLO ROSA: Maja, well, first, I think that we were referring to the €10 million, that was volume and not sales.

PIERGIORGIO PEDRON: Carlo, I'm sorry if I interject. I believe that what we quoted was €8 million to €10 million per quarter, not per month. It was...

MAJA PATAKI: Correct…sorry, per quarter. Yes, sorry.

PIERGIORGIO PEDRON: Never mind, Okay

MAJA PATAKI: No, no, no, per quarter.

CARLO ROSA: Okay. Okay. Sorry for the disconnect. But for the first time, P.G. and myself, we are not in the same place. Okay. So…okay. So as I told you, the …as I said, in the…in Q4, 20% of the revenues were known molecular. So I think you can do the math in terms of what would be the baseline for the non-molecular, which is primarily serology and some antigen because that has launched.

As far as the base business…sorry, as far as the antigen test, look, it's indeed, I believe that the antigen test from Core Lab is an opportunity for some of the emerging countries. We don't have registration yet. So the only registration that we have today is CE marking in the U.S., and we applied for…we applied for Canada. We applied for Brazil. We applied for Mexico, for some of the other geographies, but we don't have that yet. And we believe that, that will become an opportunity of growth.

Certainly, the strategic growth should come from the U.S. and this is why I was remarking before you saw the LabCorp press release. And I think LabCorp is a very strategic customer player. So more than a customer it is

a company we really can do business with strategically, and we both believe that notwithstanding the point-of-care and OTC opportunity for antigen testing, there is an opportunity also for antigen, high-quality antigen testing in the lab with due result because we bank on the fact that LabCorp and some other smaller commercial labs will be able to win tenders mainly at the state level for collecting swabs and then having those tested under quality requirement in Core Lab.

And I said, the result, we had to understand how this will develop in the next few months. But that, to, me is the antigen opportunity. Base business recovery, I think, Maja, there are a couple of things you need to note on the base business, which are fairly relevant compared to 2019. The first one that everything was completely forgotten in 2020, but everybody knew that, that was going to happen. The first one is the fact that Vitamin D was transitioned out from Quest because of the fact that Siemens won the contract. So in 2020, we had a good business and again…well, good, meaning that this business then was hit by volume and then eventually Quest transitioned out. So starting from 2021, our base business does not have that component.

The other thing is that we have been phasing out ELISA in 2020, which is not going to be there in 2021. So notwithstanding all this, so you're asking me how do you… how do you see 2021 finish and the opportunity in 2022. If you look at last quarter, notwithstanding this, the lack of Vitamin D and notwithstanding, certainly, ELISA, our overall business is fairly flat compared to the last year. So this should give you a baseline. In terms of once 2021 is all over how to expect growth of a cleaner business, cleaner meaning that without the drags of the Vitamin D at Quest plus ELISA starting from 2022 forward.

MAJA PATAKI: Understood. Thank you.

OPERATOR: So the next question is from Andrea Balloni with Mediobanca. Please go ahead.

ANDREA BALLONI: Yes. Thanks a lot for taking my question. Good afternoon, everybody. My first question is about QuantiFERON. If you could give us more color about what to expect in 2021 as we have seen some very positive comments from QIAGEN. How should we model this level of sales that was almost 0 in 2019 and I guess the same in 2020?

And my second question, I'm sorry for that. I lost the answer about the pricing environment for a molecular test in the U.S. and Europe, if you can repeat it again. And my very last question, sorry for asking again, in the follow-up about H1 '21 guidance, I understand pretty well there are many moving parts. But what I can see is that the largest part of this moving part is something quite positive. And if you compare with €380 million reported last year, a 40% increase is around €150 million. If I sum up the recovery of the test you have lost last year, which were around €60 million, if you sum up molecular test that should have production capacity 3 time compared to the level of last year. And then there is also serology and new antigen test. Is it correct that the only negative part is the one related to Vitamin D and ELISA that you have just commented? So the only reason why your guidance looks to be quite cautious is related to these 2 items?

PIERGIORGIO PEDRON: Carlo, do you want me to take the question on the guidance.

CARLO ROSA: Please. But also, please remind that when they say that in Q2, we had €47 million of serology peak last year, so serology COVID last year was outstandingly strong in one quarter. So don't forget that. But P.G., please take note through the guidance.

PIERGIORGIO PEDRON: Yes. I mean, I don't want to…I mean I don't want to do the modeling for him, but I will try to give some color. So yes, I mean, in H1 last year, we had almost €100 million of COVID sales. It is true that the negative elements that we discussed about are…and one…and those are the ones that Carlo just commented, right? It's the Vitamin D in Quest, and it's the former ELISA, Siemens ELISA business. And for all the rest, Andrea, I'm sorry; I can't do the modeling for you. I believe that we stand behind the 40% increase in H1. We said, considering the visibility we have in the first part of the year, the x COVID business, we said, is going to be back to normality, we believe, by the end of the year. That's much more predictable business in a way, as long as you are not going to have a second measure of lockdowns because of new mutation of the virus which are going to make the vaccination program less effective. And that's basically it.

ANDREA BALLONI Okay. The other question was about QuantiFERON and pricing for molecular.

PIERGIORGIO PEDRON: Carlo, do you want me to take it? Or do you want to take it, the one for QuantiFERON?

CARLO ROSA: P.G., I'll do QuantiFERON. And if you can just do molecular because it is a repeat of what we said already 2 times during this call. On QuantiFERON, I think you can take the comments that QIAGEN made because…and see what we expect that notwithstanding the fall of volumes that happened in 2020, we believe that…and QIAGEN stated that in 2021, volume should go back to what they were in 2019. So to that part, you need to have growth coming from conversion at higher price, plus the fact that send out which we are planning to capture in the U.S. but because when you said that in 2020, QuantiFERON was 0, that's not really an

appropriate statement because in 2020…in 2019, we had launched the CE Mark product in Europe. So we had granted at lower volumes because of COVID, we had all the European business that was actually developed and with over 250 accounts using our products in Europe, so not 0 at all. P.G., you do molecular?

PIERGIORGIO PEDRON: Yes. So I believe what we said regarding molecular pricing is that, so far, we're not seeing any pressure, any material pressure at all. We didn't give any guidance for H2, but what we believe it might happen, but as Carlo very clearly said, it's just a broad-based assumption is that we are expecting some…sooner or later some price pressure there. And what we said is you can say, if you need a ballpark number, 10% in the second part of the year, which could be annualized full year at 20%. But again, so far, no price pressure. It's a broad assumption that we made thinking about half 2, but nothing has been seen so far.

ANDREA BALLONI: Okay. Thanks a lot for repeating about the price.

OPERATOR: This concludes our Q&A session for today. Mr. Rosa, the floor is back to you for any closing remarks.

CARLO ROSA: Thank you, operator, and thanks, everybody, for staying so along with us. Thank you.