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# **DiaSorin Investor Day 2021: Molecular Diagnostics**

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## **DiaSorin Investor Day 2021: Molecular Diagnostics**

**Carlo Rosa:** [00:43:03] Molecular Diagnostic is why we decided to buy Luminex, as you remember. Now there is a concept that people that are not expert in this field have to understand. There are two different clinical needs for Molecular Diagnostic. One is identify pathogen confirming existing clinical suspicion.

Let me give a very simple example. These days, you sneeze, you get fever, you have flulike symptoms, you want to be damn sure that is not COVID. So what do you do? A very simple test is a molecular test that is going to discriminate between flu A, flu B and COVID. This is called single plex technology. It's a technology we have. It's a technology many companies carry today.

But then a few years ago, technology – availability of multiplexing technology, so the ability to detect from one clinical sample, imagine just one swab of your nose up to 40 different targets. These technologies really taking place into hospitals and is very important because it is identifying a pathogen in absence of clear clinical suspicion, is very expensive, is a very complicated technology. But today to be a player in the market, you must have both.

Now if you look from a technology point of view and market maturity point of view, certainly you are facing two different situation. Single plex has been there for over 20 years. So is a mature market. You have multiple suppliers. You do have an established testing. Certainly, pandemic in this segment has now pushed the utilisation of these technologies down into a decentralised setting. Okay. That's the novelty.

Until yesterday, single plex done in a hospital lab. Starting from today, there is a need of doing single plex in a decentralised setting.

Now, price pressure in a mature segment, for sure. The other thing which is very relevant about this segment is that you need to be a specialist, because as a mature segment – and this is how DiaSorin has been positioning itself with its menu, specialty menu in a mature segment with new platforms.

When it comes multiplexing, it's a complete different story. Multiplexing is the future. Multiplexing is a market that has been booming over the last five years with double-digit growth. Certainly is a market – since it is an expensive technology. It's a technology that is driven by reimbursement. And guess what? In the US, very well-reimbursed. And so the market today is primarily US market.

In Europe, there has been resistance to multiplexing because of governmental payers and payer – when government is a payer, then as an overall discussion is much more complicated about savings, at least until yesterday pre-pandemic. There is a limited number of panels available, five panels fundamentally, a couple for blood infection, one for gastroenteric infection, one for respiratory infection and one for CNS infection. It's a limited number of products that you can develop. It's not infinite, right?

And the other thing that you need – we need to take in consideration is that through pandemic when there was an issue at the beginning really to quickly differentiate from symptoms, it was COVID or not, more multiplexing with funding availability also happened in Europe.

So if you play in these two segments, you really must have a different strategy. So what's the DiaSorin strategy? Let's talk about this single plex first. Today, we are an established player in this segment. We have 2,700 customers, platforms worldwide. I would say 70% of it is in the US, 30% is spread around Europe. We have over €400 million revenues. Certainly, a good chunk of this is COVID and respiratory related – associated with this product.

We do have a very good menu of specialty products and we serve medium hospitals, small community hospital and some of the smaller commercial labs. What is the future? The future is a system that you see there is called LIAISON MDX Plus. So what's the LIAISON MDX Plus? The LIAISON MDX Plus is a system that is allowing to do single plex in a much quicker way than what the platforms that we carry today are able to perform. If a COVID testing today on a DiaSorin platform takes 1.5 hour, with a LIAISON MDX, the time is going to go below one hour. So there is certainly an improvement.

All the measure that today goes on our platforms is going to be transform this one; is going to be launched in Europe in 2022. And then clearly, you're going to have a full effect starting from the 2023. And it is for us the strategic platform that will allow us to combine what we have today into a future platform. So, as said, overall to defend and continue to grow a business of €400 million, which is what we have today in our single plex molecular diagnostic.

And I think that there is a video.

[Video]

Introducing the new LIAISON MDX Plus, the next generation molecular diagnostic solution from DiaSorin. The LIAISON MDX Plus is a highly efficient and fully integrated real-time PCR system. It offers flexibility in patient testing to meet the needs of any laboratory. With LIAISON MDX Plus, labs can perform testing in a sample-to-answer workflow with prompt reporting of actionable results within maximum 60 minutes. For medium throughput testing, the system enables real-time PCR testing starting from minimal sample input. Enhanced features such as simplified usability, touchscreen simplicity and hardware improvements enable faster turnaround time in both IVD assays and user-defined tests. The LIAISON MDX Plus system is a compact solution with ultimate flexibility and a powerful menu of tests.

**Carlo Rosa:** Okay. So now let's move to the second platform, again, always in the single plex. And it's this one. I'm particularly fond of this platform because it has been the result of strategic consideration that we made a few years ago. And the consideration was – and actually came through with the pandemic. And what we thought about is today all the molecular platform that you have out there are unfit for true decentralisation.

And in fact look at how COVID is happening. You go to a pharmacy, you don't get molecular testing. You get at best an antigen test. And just for reference, an antigen test for COVID is able to detect at best at 300,000 to 500,000 copies per ml of the virus. A molecular test today is able to detect 300 copies. So you understand that from a technology point of view, if you were able to take the molecular technology and bring it to the pharmacy, you would have an incredible, incredible benefit in terms of sensitivity.

And this is what this cute system actually is all about. It's a small system, has been designed in working together with a British company that – from where we acquired all the rights for this technology two years ago. It's been designed for physicians, for pharmacists, for very small hospital. So decentralisation of molecular testing. And I keep saying think about it, think how the pandemic would have been different if two years ago rather than and then having nothing, we would've had a system like this able in an ambulance to do a COVID testing in 15 minutes.

Unfortunately, nobody had it. But I think we learn from the pandemic and the next wave that will come, if it will come, companies will have technologies that will really allow the decentralisation of molecular testing. What's the benefit of decentralisation? We really spoke at length about it. But the most relevant thing to me of the decentralisation is the fact that you can take action where the patient and if the patient need action right there.

So decentralisation should not be a mantra for everything. Many, many clinical conditions can actually be taking care and are taking care much better in a hospital but there are certain things that you do not want to take care in a hospital. There are infectious diseases where you don't want infectious patients to walk in a ward. And this is what is all about.

And there is a video on this one as well.

[Video]

LIAISON NES, a novel point-of-care molecular clear wave solution from DiaSorin. Patient samples can be directly loaded into innovative ready-to-use cartridges, which simplify the laboratory workflow, enabling actionable results in approximately 15 minutes. The smart user interface makes near-patient testing possible with best-in-class accuracy and quality. A fully integrated system with enhanced connectivity allows a streamlined and error-proof experience. LIAISON NES is a compact and portable solution for healthcare providers or pharmacists, bringing sustainable and accessible solutions closer to the patient.

**Carlo Rosa:** Okay. So now let's move to the third element, which is multiplexing, which again is what we – the reason why we bought Luminex. Now, Luminex is a multiplexing company. And today, they already have over 1,000 systems installed in hospitals, mainly in the US, which are using these technologies.

From a revenue perspective, it does represent, for DiaSorin, a little bit over €100 million per year, so it's an established brand. We do have today all the five panels that I was mentioning before. What is the problem? We have it in a format that belongs to previous generation. It requires hands on time.

So what did Luminex develop and what did we really buy with Luminex? This technology, the LIAISON PLEX. LIAISON PLEX is actually displayed over there. This is not intended for decentralisation. This is intended for laboratory use. It goes inside the hospital.

What does it do? As said, there is a very small cartridge you're going to see. You put the sample of the patient inside. You load it. You wait two hours. And in two hours, you're going to know whether it's one of the 20 bacteria that the assay can detect, of the 20 viruses the assay can detect. So very specific precise diagnosis. Think about it, an algorithm whereby we can use the MeMed technology, just for the first screening and then if it is bacteria, let's understand what kind of bacteria disease using actually this technology. And there is a video for this one as well.

[Video]

Introducing the LIAISON PLEX system, a molecular sample-to-answer solution designed with flex testing capabilities. With the ability to scale up to six modules, the LIAISON PLEX can fit the labs' budget and throughput means. This system is fully integrated and performs extraction, amplification, hybridisation and detection, all in one cartridge. The proprietary Flex software enables users to test and pay only for selected targets with the option to unmask results as needed. This provides laboratories and clinicians with a cost-effective diagnostic tool designed to improve clinical outcomes.

**Carlo Rosa:** So let me just explain to you what is the difference. Today, there are already systems out there that can do multiplexing, but what is that we offer is called flex the plex. What is the problem today? So if you're a hospital, you want to run one of these multiplexing, you're going to pay for 40 different results, because companies are going to sell you a cartridge. Within that cartridge, you have 40 different between viruses and bacteria. You're going to pay for all. What is the problem with this system? It's very expensive. 60% of the times it's negative when you're paying for 40 different results. The way the Luminex is positioned, and this is extremely interesting. So the cartridge does contain the possibility to get 40 different results. But the customer is going to pay only for 20, a basic panel.

So they run the basic panel. And if within the basic panel of 20, they get what they want, they don't need to go behind that. But if they want to open up results, they buy credits from us. And spending the credits, they can get on the same sample additional results. So it's really providing customers with the needed flexibility to adopt this technology in a cost convenient manner – matter. And this is very, very important for two things.

In the US, because today, notwithstanding the fact that the reimbursement is generous, there is a pushback on cost. The second thing in Europe. In Europe, the problem, there has always been pushback on cost, because one of this test is costing €150 at least for each patient. Now hospitals can design their own panels, they can pay for a minimum panel and they can decide which one they want to open up, which results they want to have and what they want to pay for depending on their budget. And this is very innovative and goes behind the issue we were discussing before, the costing element of providing innovative technologies to the market.

So what do we have at the end of the story? We do have a slew of new technologies. When it comes to molecular diagnostic, which today it does represent 35% of our business, in the next three years, we're going to be launching three different platforms, very innovative, as we described. This is why I am saying starting from a business that today overall is \$500 million, \$600 million, based on that platform on that customer base, we're going to hit the market with this new platform. So very exciting as far as the opportunities that DiaSorin does have in this growing business.