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DiaSorin Investor Day 2021: Immunodiagnostics

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Carlo Rosa: [00:22:26] Now let's look at the strategies in the three legs of business we have, the Immunodiagnostic, the Molecular Diagnostic and the Life Science businesses. And I would start from the Immunodiagnostic.

In immunodiagnostics, what we did for 20 years, we continue to do, which means that we do have platforms. You see it over there. We do have content, and content means assays that we continue to develop and provide to the hospitals to run more content on these platforms.

And we did very well during pandemic. We developed nine more assays in the specialty area, so fairly unique product for DiaSorin. The plan for the next three years is to develop 13 more products. And we're going to scratching 100 specialty tests, which is going to make DiaSorin as a supplier to hospital even more unique than what it is today. So this is what we've been doing for 20 years and this is certainly part of the plan for the next three years.

And now let's talk about a different content, and the content we're talking about here is getting together with specialised companies, very innovative companies and then bringing the two companies together, the content together to allow to have that very smart content deliver on our platform. So I'm going to call to the podium, doctor, please join me.

Dr Eden is the CEO of MeMed. He's from Israel. And he's going to tell you what's MeMed and why MeMed is, I think, one of the greatest asset in our industry. Please go ahead.

Eran Eden: Thank you very much. Good morning, good afternoon, depending where you are. Let's see if this works. Right. So hi, I'm Eran, again, co-founder, CEO of MeMed. I'd like to thank Carlo for the kind hospitality for what's becoming a growing partnership.

To then tell you a bit about our story. First of all, MeMed in a nutshell. We're based in Israel and growing our base also in Boston, Massachusetts, raised over $200 million in equity and also quite a lot of support from the US Department of Defence and the European Commission. A landmark FDA clearance a few weeks ago and a leader in this exciting new field called Advanced Host-Response Technologies that I'll tell you a little bit about today.

So it all starts with a simple premise, which is, the immune system, our immune system is built to tell us what's going on in our bodies. And what we do? We listen. We listen with this engine that combines machine learning, molecular and biochemical immunology and IVD in order to generate insights that can potentially transform the way that we manage patients, particularly in the realm of infectious diseases, inflammatory disorders.

The first thing we start with is the most prevalent clinical indication on the planet, a child with sniffles, or an elderly patient with cough, fever broadly. If you think about this encounter – and we've all encountered this multiple times actually in a year, we and our families, several questions come to mind. The first one, is this child in front of me, does he have a bacterial or a viral infection? If it's a bacterial infection, antibiotics. If it's viral infection, chicken soup.

I see seemingly simple problem because bacterial and viral infections are often clinically indistinguishable, which causes two problems. The first one is antibiotics overuse, roughly one in every second antibiotics is overprescribed. Less known is antibiotics underuse. One in five

patients that have a bacterial infection are not receiving antibodies some time. Both parts of the equation has both grave healthcare and health economic consequences that are plaguing the system.

Now, sure we have many technologies, and Carlo was talking about this, right? Rapid engine tests, culture and multiplex PCRs. And they're good, and they're pushing the boundaries, but there are several limitations. The first is time to results. We often want to have the solution here and now within minutes, not hours and definitely not days.

Number two, inaccessible infection sites. So you can only apply many of those technologies if you can reach the infection site but many times it's non-accessible, ear infections in children, sinusitis, bronchitis, pneumonia. That's one in four patients and those prevalent indication on the planet.

Third, even if you use a multiplex PCR, very expensive. In more than 50-60% of the cases, you're not going to detect a microorganism or the pathogen, but you still need to treat the patient. And fourth, even if you're lucky and you identify a virus, it doesn't mean that there's not a bacterial co-infection that's lurking behind and you still need to treat antibodies.

So the question is not only about fancy technologies but how do I manage this patient. Clinical value, cost-effectiveness. So when we set on this journey we imagined platform, small volume of blood a few minutes that would somehow decode fever, starting with bacterial versus viral infection to treat or not treat the antibiotics.

The paradigm, decoding the body's immune response we're measuring set of soluble proteins of the immune system together with a layer of computational algorithms and we create a barcode whether the body's waging the war on the bacteria or the virus to treat or not to treat.

Here we see this complex graph here that just shows some of the proteins that we're measuring, some which includes the world's first viral-induced[?] proteins, so it's a protein called TRAIL that your body is secreting to fight against viruses. It's a first viral-induced protein that's been cleared by FDA in 21st Century medicine. Then there is the machine learning component and again the measurement component.

First study 2009-2013, published the results over 93% performance, ROC curves. And then a series of studies prospective, double-blind, external, covering over 20,000 patients with real-world evidence published in The Lancet ID, BMJP, it's paediatrics, up-to-date far exceeding industry standard. Why? Because it's not enough that you say that it works. You have to prove it.

After five years of working hand-in-hand with FDA that has been extremely supportive, we recently received a landmark FDA clearance. It's the first technology to aid in distinguishing between bacterial and viral infections, based on the body's immune response. This is the claim that we've got. You get the same thing in the US and in Europe. So first of all, it's for both adults but also children, which is not easy but it is critical.

Second, very broad indication for use, low respiratory tract infections but also upper respiratory tract infections, systemic infections, urinal tract infections in a child who sniffles. Third, EDs, urgent cares but also upon hospital admission.

And lastly, we've been able to show to FDA that we're able to complement these multiplex PCRs or other type of pathogen detection test by identifying bacterial coinfections even if you detect a virus. Again, that was one of the challenges we talked about in the beginning.

Okay. So now we have a platform to measure it. You put sample of 100 microliters within this cartridge. You plug it inside, press the button with 15 minutes. That's basically it. And you get the results. It's a score between zero and a 100. And the higher the score, the higher the likelihood of a bacterial infection. If you have a mix infection, you get high score because you want to treat.

And so this is where we met with Chen Even and Carlo Rosa and the team, and we said, well, how can we combine forces? How can we leverage the complementary capabilities of the two companies? So MeMed brings this knowledge centre – world knowledge centre in Advanced Host-Response Technologies and clinical adoption, clinical utility, medical sale. But DiaSorin, the diagnostic specialist to the power of three, with a track record of introducing these new technologies, we thought this is a really good partner, solid install base, repetition of quality.

And if you look at these two platforms, they look very different. One is maybe 100 times larger than the other one, but they are actually based on the same technology, chemiluminescence [inaudible], which means you, can transform technologies from one to the other and you have consistency, which is critical. So you have a hub and spoke model, which is what's required to that market.

Recently, DiaSorin received a clearance in Europe for the MeMed BV on the LIAISION with what we think is a knocked out of the park roughly a year to develop something like this. The reason that this happened so fast, first of all, big kudos to the development team and the regulatory team but also the fact that these two technologies are so compatible.

The market is a blue ocean. In the US alone meeting our FDA indication for use about 200 million cases. Here, you see them segmented according from centralised to decentralised setting. If you only look at the centralised setting in urgent care, it's a multibillion-dollar opportunity potentially.

So to start to summarise, at the end of the day, it's not about the fancy technology. Sure, it's cool technology but it's – most importantly, it's about clinical value and cost-effectiveness. And the clinical value, improves the accuracy. You reduce the false negatives and the false positives. Then you have shorter time to diagnosis and you get better patient management, which we tend to forget.

I just flew from Tel Aviv over here leaving my wife and three kids, one of which has a fever, nine-year-old girl. We took her to MeMed, ran the test. It's a viral infection and no antibiotics. Today, she's back to school. And the anxiety of the parents goes down. And I get a lot of brawny pose from my wife and mother-in-law. That's a different story and very strategic.

Second part, the peer, the provider, reducing clinical uncertainty, changing patient management, hospitalisation, and of course, saving hospital costs. There's going to be a publication coming a few weeks in the journal Medical Economics proving a lot of these things again based on data.

So to close things up, the immune system has evolved to tell us what's going in of our bodies. And what we did is develop an engine using machine learning, molecular biochemical

immunology and IVD that we use to develop this first technology B versus V together here moving this forward with DiaSorin. But if we had this technology, what else would you do? There's endless amount of additional diseases and opportunities. And hopefully in the not very distant future, we're going to be able to share some of the additional products that we're working on.

So again, I'd like to really thank Carlo here for the opportunity and for a successful continued partnership.

Carlo Rosa: Thank you. Okay. So let's talk about another kind of partnership, the partnership with QIAGEN. This has been now established for now four years. And let me remind you that with QIAGEN, we had two projects ongoing. One is latent tuberculosis, which was actually launched in the US as well two years ago.

We have the Lyme disease for borreliosis, again, the product has been launched. And then we have another one that is in the cook and we are working on a new assay for cytomegalovirus infection and reactivation in transplantation. So overall, the two companies are working very well together on building this T cell franchise.

As far as the different projects, relating tuberculosis is going very well. Today, we have over 480 customers – hospitals in Europe that are using this product. We just launched it in the US one year ago. We have today 150 hospitals in the US that are using our technology, growing 25% per year.

So, so far this project has been greatly, greatly successful as a combination of the two companies. As far as Lyme detect is concerned, again, very briefly is an algorithm that allows to detect borreliosis, which is a tick borne disease. It is very, very common in Central Europe. It's very, very common in the US as well. In Italy, a little bit in the Trieste area.

One of the problem is that if this disease is not properly diagnosed, then it can really give consequences later on in life. And at that point, it's very complicated to treat the infection.

Where are we with the programme? We have the – now the product approved and launched in Europe. We are working in Germany in the reimbursement. We believe we're going to get the German reimbursement by 2023. And after that, so is part of the plan full commercial launch as far as Europe is concerned.

When it comes to the US, we are doing the clinical study. We did clinical study last year, complicated by the fact that with COVID was difficult to recruit patients. We're going to continue the clinical study this year with the intent – sorry, in 2022, with the intent of getting the product approved and launched in the market, US market by 2023. So this is going to be another strategic set in the QIAGEN-DiaSorin partnership.

Now let's move to the other platform, the LIAISON IQ. The LIAISON IQ is the CLIA[?] one, the one that actually you can find there to the left is antigen for whoever has been using antigen test for COVID is that – with a difference is that rather than visual reading, you can really have a machine read it. And then once the result is read, it can be – the result can be sent to your cell phone or to your doctor, so that the interpretation and traceability of this result is guaranteed.

Now, what did we do? I mean, that system clearly, clearly has been devised for pharmacy use. And we look at two main markets. One is the US market and one is the Italian market for

pharmacies, completely different. In the US, there are 60,000 pharmacies and a third of those pharmacies are actually operated by two main providers that have been consolidating services over the years. Pharmacies are allowed to do testing. Pharmacies that are allowed after a result has been obtained in the pharmacy, to take certain action about medications using that result. And certainly is a market that is – and is a market regulated by the FDA. So any product that goes into in that environment has to go through the FDA.

Italy is completely different. 19,000 pharmacies, growing, which is an outlier within the European community. As you know, there is a pharmacy with every church, pretty much as they say in Italy. In rural areas, pharmacies do represent a way, a point of entry to the healthcare system.

The regulatory framework pre-COVID was terrible, meaning that – for diagnostic, meeting that there was not a possibility in a pharmacy to take a test and take action. It was considered auto diagnosis. So doctors could not make a decision based on that result. COVID changed a lot. You can have COVID testing clearly in pharmacies today and you can take action with it.

And very recently, as a consequence of COVID, they changed the law. And now, you can go to a pharmacy on blood testing. You can have results that the doctor can then use to make a medical decision. So in that in a sense what we were saying before, the COVID really changed the regulatory environment under which diagnostic is performed.

What's the plan for us? The plan for us is to continue invest in this technology we're going to be using in the next three years. Italy is the primary market. We are extending menu on the LIAISON IQ and we're going to be touching areas like vitamin D. We are touching areas like celiac disease. We are going to be touching areas like ferritin measurement, everything that will allow the pharmacist at that point to take action, which is not necessarily a medication but is more supplementation.

And we believe that with that technology, we can really breakthrough in this space. Now the question is why Italy? Because we are learning. It's a very complicated segment. We're not in that segment and we want to continue to experiment until we really understand what it takes to be a player in the pharmacy market with lateral flow. Different story clearly is going to be with Molecular Diagnostics. I'll talk about it later.

Now then we have the LIAISON XS is there, very excited about this platform for a very simple reason. This platform has been designed to go to midsized hospitals, especially in the US. We got approval of tuberculosis testing very recently a month ago in the US. So we are ready to unleash this system in 1,200 hospitals in the US. And the very important factor here is that of this 1,200 hospital that today are a potential target for this system, 700 are already served with Luminex products.

And so the very interesting opportunity here, the cross-selling about the DiaSorin technology and the Luminex customer base with this product.

Last but not least is the future, what we're going to be investing in this cycle. And we expect this system to be available to the market after 2025. This system is LIAISON XL. The strategy, the reason why we're doing this is very simple. The LIAISON XL, which is today the king master of DiaSorin, that system has be launched in 2011. We now have 5,500 system displays worldwide.

We are placing over 600 every year. But that system needs a replacement. By the same token, if you look at the install base of our systems in the hospitals, 70% are stand-alone, so one hospital does well with one system but 30% of the hospitals have multiple units. And today, we are under pressure because those multiple units don't have the capacity, the consolidation is really bringing to these hospitals.

And so we are – we designed the LIAISON XXL in a modular system. So one module is absolutely substituting one LIAISON XL actually with increased throughput and two, three models are actually substituting two, three LIAISON XLs bringing it together and making it much more convenient for hospital to run high throughput.

So at that point, at the end of this project that will consume €20 million of investment with our partners that we're going to be selecting to develop this, plus probably €30 million to €40 million of direct cost in DiaSorin R&D department. So €50 million, €60 million later we are going to have the substitution of the XL and we're going to have a high throughput system to again phase consolidation on the market.

So how do we stand in Immunodiagnostic wherewithal? We go from point of care to the high throughput. We have over 100 specialty products that I mentioned at the beginning. So I feel very comfortable with the fact that this engine that does represents today 60% of our business is really well taken care of.