Grifols

2022 Investor and Analyst Day
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Speakers

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability

Raimon Grifols, co-CEO

Peter Allen, EVP Plasma US

Daniel Fleta, Chief Industrial Officer

Bill Zabel, EVP Commercial Operations

Joana Sàbat, SVP Global Marketing & Market Access

Antonio Martínez, President Diagnostic

Albert Grifols Coma-Cros, Chief Innovation Officer

César Cerezo, SVP Drug Development

Carter Keller, SVP GigaGen

Jörg Schüttrumpf, Biotest Chief Scientific Officer

Alfredo Arroyo, CFO

Victor Grifols Deu, co-CEO

Questions From

James Gordon, JP Morgan

Julian Dolmar (?), BNP

Rosie Turner, Jefferies

Tom Jones, Berenberg

Jaime E…. (?), Santander

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Introduction

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Hello. Good morning. Before we get started, I want to share with all of you the statement I have received from the President and the Secretary of the Board of Directors. And I'm sure you will all understand why this is being addressed to you, and it says:

"On behalf of the Board of Directors, we want to welcome all of you to the 2022 Investor & Analyst Day. Regarding the unexpected news published yesterday in the Spanish media, and replicated by financial press, we want to inform that, for the time being, the Board is not analysing any increase in share capital. Please stay focused on the information that we have prepared for you, because there are many good data. Thank you."

So, that was the message, and, as stated by the Board, we want to welcome all of you to the new auditorium, for those of you in Barcelona. For those of you connecting online, we have to say that next year you need to be here, because you are missing a very nice site, a very nice new place for our meetings.

Just a few comments before we get started. As you know, this is the first hybrid investor meeting we are holding. I hope that next year we'll be able to recover the kind of meetings that we were doing before, so that you will be able to visit our sites, to visit our facilities, and to expand the meeting a bit more, so that you can get to know us better.

Today, during the day, there will be coffee and refreshments outside, if you want to have something else to drink.

Disclaimer: We have a lot of information to go through, so let's get started. And with that, I will leave the floor to Raimon Grifols, CEO of Grifols, who will start with the first presentation for the day. Thank you.

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Introductory Remarks

Raimon Grifols, co-CEO
Okay, welcome, everybody, present or even remote. Welcome, everybody, to this Investor & Analyst Day.

First of all, I will thank you, Nuria, for reading the statement of our President. Yesterday we were a little bit concerned that the news that appeared in the press would have made it that we were losing focus on today's presentations. Okay, but now I think everything is clear. Nuria read a very clear

statement. So let's focus on our presentations and the good staff that you are going to be able to see today, okay?

I would also like to thank Nuria and Dani, Monica and Eva, the Investor Relations team, for setting up all this show, and also represented for their hard work. Okay.

Regarding these presenters, today - Some of you have been following us for some years, but today we are going to see some new faces. And I would like to introduce, a little bit, each of them.

For example, we have Bill Zabel. He's our new Global Head of Biopharma, Sales and Operations. Bill is not new in the business, actually. He started the Miles Corporation, later on was Bayer Biologicals, later on, Talecris and nowadays it is Grifols.

He has a very long experience, and I can assure you that he's the guy that has more knowledge in commercial, for example in a..... He's the real-world expert in this.

Second new presenter, a new presenter is César Cerezo. He's Head of our Drug Development. He has been performing these duties in the US for another pharma company, and he joined us just almost one year ago.

Next new presenter is Carter Keller. He's the Head of GigaGen, and since March 2021 when we finally closed the acquisition of the remaining 45% of GigaGen. He's now a part of Grifols.

You will be hearing very nice things about the GigaGen technology. It's a promising technology.

We also have another new presenter, it is Jörg, and sorry for how do I spell, or pronounce, your surname? Schüttrumpf, I think. Later on you can correct the pronunciation, Jörg. Okay, he's the Head of Biotest R&D, and he's joining us today to explain the new two proteins that Biotest is bringing to Grifols. Okay, a very interesting presentation.

There's another face. It's not new, because some of you may know him. It's Antonio Martínez, but what is new is the position. He is now heading our Diagnostic Business Unit.

And last of the new presenters, also a known face for some of you, is Peter Allen. He had previous roles in the company, but since the last three, four years, he's heading up our US Plasma Procurement Unit. So it will be very interesting to meet all of them.

Well, so let us start. Thank you, for the team, for giving me only ten minutes to talk. I only have six minutes 50 left.

These past two years, what has Grifols been doing? Of course we have to thank our donors and our people for the commitment they have taken during these difficult years, because we have accomplished our goal, which is, at the end, to serve our products to our patients.

During these three years, two years, sorry, we have been especially focusing in these three areas you see here. Reinforcing our plasma supply, focusing on innovation, and we also recently made a big reorganisation within the company, that I will certainly explain to you later.

Okay, regarding our plasma capacity, and the capacity of fractionation capacity, you see here the picture in 2020, pre-pandemic. You see the figures, 264 centres in the US, 48 in Europe, 41 through our alliance with Shanghai RAAS in China. A fractionation capacity of 15 million litres.

What has happened during these two years? Here are the new figures. We have increased 90 centres in two years, but most importantly here, I would like to focus on some very specific and nice things.

First of all, you see the Canada flag with one plasma centre. We are starting our plasma business, plasma procurement business, there in Canada. Second one, you will hear later on more details, it's Egypt. We have up and running our first plasma centre. And remember that we signed the agreement with the Egyptian government only one year ago, so it has been a really fast development, and later on, Daniel Fleta will explain more details on this.

We also see, in Europe, we have expanded our footprint, not only to Germany and Austria. Now we have Hungary and the Czech Republic with new centres there. And, regarding the fractionation capacity as of today, you can see that we have increased 7 million litres, so now we are able to fractionate 22 million litres.

Regarding innovation, we have really very clearly defined, I think this was explained a little bit last year, a nice ecosystem to bring knowledge inside the company. These are the different areas where we are acquiring knowledge in order to boost our innovation. And also, we have a clear focus of seven therapeutic areas, because this is the way to really use our scientific knowledge and commercial knowledge. So we are only focusing on these area, to take the most of our people.

And at the right-hand side of the slide, you can see what is Biotest bringing up to Grifols. Later on, you will hear the presentation of Jörg and Joana. They will give you more details. But we have here the fibrinogen, the trimodulin, for the ones that do a unique polyvalent IVs, the first one and the only one in the world. And this Cytotect, which is the first treatment in the world to prevent transmission from mother to baby for CMV, cytomegalovirus. This is a very interesting product also.

Regarding the organisation, and sorry for me going too fast, but I see the clock here and I have to be fast. As you know, the people that have been following the company for years, we were structured in two areas: commercial and industrial. This was done in this way in order to get the company really international. But now, the company's international, and we thought it was time to change it and to make a big transformation.

So, why now have we divided the company in fully-fledged business units, Biopharma, Plasma Procurement, Diagnostic, Bio Supplies, and also created two layers of operations and services? What is the purpose of this change? To be [short gap in audio]. To have a stronger governance. To be more

accountable. To have less operation complexities. Especially, to improve in agility. And, obviously, to reduce time to market. This is a conclusion that will come.

Now here, regarding sustainability. The Sustainability Committee of the Board of Directors, together with our internal team, we are really, really doing a great job. And you see here three policies. We are the only company in the world that has these three policies in place, and we are very proud of them.

And on the other hand, on the right hand, you see the 30 Goals for 2030. This team, and the Sustainability Board, they are pushing us to really improve. So, good job in doing this because we really think these things have to be done.

Social Value. This is a calculation, and social return on investment, you see here the figures, what Grifols means in life for patients, €28 billion. For donors, €1.8 billion. And for local communities, €700 million. These are very, very nice figures, and make us very proud.

We also, through our foundations, still keep helping society in the way we can, and very nice, also, the figures here in the economic impact of Grifols, €7.7 billion. And especially the jobs created, indirect jobs that Grifols is creating today in the world, is 140+ thousand jobs.

Here, some data about gender and equality, adjusted the pay gap. We are reducing this. We are very proud of this. Talent development, 2.8 million training hours. This is an average of 120 hours per employee. It is a great number. Increasing number of people with disabilities working for us, cooperating with Grifols. Increasing number of nationalities, 25,000 employees.

Okay, and here about environmental. We had a target for 2030, but now people are pushing us, our internal people, the Sustainability Committee, so we have decided to go even further, increasing the thresholds, electricity going from 70% to 100% use of renewable energy for 2030. So we are also very proud of people pushing us, and we are able to deliver on this.

In my last 20 seconds, I watch my clock here - in recognition of part of what I have been explaining before, very fast, sorry, is the recognition and inclusion of Grifols in this very reputable ESG indexes, you know the Dow Jones, FTSE4Good, Bloomberg, Euronext, and for example, today, the building where we are sitting now, received last Friday the LEED Gold certification for environmental. So we are very happy about this.

And now I think I missed a little bit my time, but sorry. I would like to introduce Peter Allen, who is heading our Plasma Business Unit in the US. Thank you.

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Plasma

Peter Allen, EVP Plasma US
Thank you, Raimon. Good morning, everyone.

We're confident in our plasma collection network, globally, in its strength to ensure long-term sustainable growth. We'll look at that today through three lenses. First lens is looking at it from the footprint itself on a global basis. The second: recognising that we've grown rapidly through acquisition. We have a number of integration accomplishments that we wish to share with you as well. And then, finally and importantly, I'd like to spend a little bit of time talking about the relationship that we have with our employee engagement in concert with our donor experience. This is growing in its importance.

Let me take you back 18 months, to the very end of 2020. As Raimon just said a moment ago, on our footprint, we had a large number of donor centres in North America in the United States, and in Europe predominantly in Germany. And we had a strategic alliance with Shanghai RAAS in China.

But, if you go to the end of this calendar year, the end of it, the end of 2022, this is where we will be. So, as Raimon says, we are now in Canada as well. We have a wide dispersion of centres throughout the United States, and a lot of diversity now in Europe.

With the Biotest acquisition, we've expanded our footprint in Germany, we're in Hungary, Czech Republic, and in Austria. So, it's nice diversity that we have there.

In addition, as we said, we're now on the continent of Africa, with our joint venture that we have in Egypt. And then, of course, our position in China with Shanghai RAAS.

So, we're spread. This diversity, to me, anyway, personally I think this is going to be very interesting in the future, as we look at our medicines, taking advantage of this diverse pool of plasma.

Let's look back over the last two years in terms of the business. What has gone on? Obviously, the pandemic was a big element here, right? For all of us. But, in addition to that, we've acquired a number of businesses. And acquiring businesses and digesting these acquisitions, it's disruptive to the business, no matter - There's no other way to say it, quite frankly. It's disruptive, and we have been working through the process. I'm going to talk more about this in just a minute.

In addition to that, we've also had the US government make a decision that came out of the blue, unexpectedly, that we're no longer going to allow B1/B2 visa holders of Mexican nationals crossing the border to donate at our centres. They'd been doing it for decades, and they changed the policy without notification.

We're pushing back on that policy, of course. We believe that there'll be a change to it. In fact, we thought in 2022 that we would already have had that change, and our plans had that accordingly. We're achieving our plans without the border centres, and there's upside, obviously.

So, if you look at the calibration here of some of the growth between 2021 and 2022, you're seeing a trajectory, but if you're looking at '22, you're seeing that trajectory increase. It's getting steeper. We are gaining momentum, and we are confident in our ability to collect plasma.

There's some tailwinds and headwinds to all of this. The tailwinds, of course, with mostly the conclusion of COVID in terms of its impact on business, as well as the subsidies that the US government was impacting the entire industry with. That is now, for the most part, behind us.

We've managed our compensation with our donors. We've got a stable workforce in that aspect as well. And, with the integration of these centres and the technology sweep through all of that, I'll talk about it in a second, all of that now is working behind us and now in favour of our abilities to grow forward as well as to drive efficiencies into our business.

So, that part is working well. There is something here that is both a headwind and a tailwind, and that's inflation.

If you look at inflation for us, there's a lot of people who need to figure out how they're going to pay for fuel, how they're going to pay for food, and so, subsidising their income through donating plasma is a real opportunity. And we're seeing that in our business.

At the same time, it's a headwind because, unfortunately, of course, with inflation comes wage increases, and wage increases were part of that as well to remain competitive in the marketplace.

The B1/B2 visa, that's one of the things that, of course, we believe will be resolved. It's on a judge's desk right now. We're hoping that she's writing her opinion before her summer vacation. We'll see what happens there.

And then the last piece I want to comment on is donor compensation. During these last two years, it's risen intentionally. The entire industry's been doing this in order to get donors to come into the door. We believe that, over in a not-too-distant future, that's going to begin to subside.

Some comparisons in market share. Looking at the number of centres globally, in 2022, we have 43% more centres than we did just four years ago. That's a big chunk of increase there, and yet we still maintain our 29% market share. We feel good about that.

In terms of collections itself, in spite of all the efforts in terms of the integration work that we've been doing, in 2021, one out of every four collections worldwide is a Grifols plasma collection.

So let me talk a little bit about the acquisitions. We've acquired whole companies. We've acquired subsets of other businesses in collection centres. We've got great diversity now, across the United States and now in Canada, in terms of our centres. We're covering most places now. In Europe, same thing. Great diversity throughout Europe, as I mentioned earlier.

When you acquire these businesses, there's a lot to do, right? You have to look at all the technologies, the systems that are in place. The applications, the policies, the procedures. And quite frankly, you're marrying into another company. There's the human resource. There's the culture. All of these things are coming at you, and this is over 136 centres.

The good news is, we're getting very good at this. But it has a lot of effort that goes into that, and once you begin to sort through all that, you're looking for the gold in those hills, right? What are they doing differently that we should be doing in all of our centres? How are they thinking about that from a regulatory perspective? Why did you think it that way? Can we use that over here? Is this country that different than that country?

All of these are opportunities to keep refining your business and get leverage out of it. It takes time to do that, and once you begin to do that, now you've got six different technologies that do this, five different technologies that do that, and you begin to think about what's optimal. Which are the best technologies, and how do we roll that out? What does that look like?

And once you begin to get to that point, now you're looking for commonality, right? Common SOPs. Should we take five technologies down to two, down to one, or down – you know what's the right mix that we need to have? What are the contracts that we're doing with vendors in order to solidify that and put us in a strong position? That's the work that's being done.

Now, doing that work, you should also know that, in parallel, in 2018, we started an objective to transfer all of our centres into new donor management technology, BECS systems.

This is the software that runs your centre. We set a three-and-a-half-year goal to get all of that converted. So, while we're digesting all of these companies, we're also changing all of the technology relative to the centres, while we're at it. And we have an expression in the United States. It's 'go big or go home'. If you're gambling, you're basically putting everything on the table sort of notion, right?

We decided, at the same time, we're also going to upgrade our technology, our apheresis technology. This is the technology that's connected to our donor, and interfaces into those donor management systems. We took that on as well.

So there are a number of things that are happening in this regard, that, for us, was placing us in stronger positions, and then on top of it all, just to make things more interesting, nature decided to add a pandemic to our plate. And we continued on with our objectives. We didn't miss a beat. We had to change some of our training and do things virtually. We had to figure out how we're going to travel and do all that.

All this was done, and I'm very proud to say that, when it came to the BECS technology, which we started, it was a three-and-a-half-year plan to make all these changes. We were on time. On time, we were actually one quarter early completing that, and on budget.

So you've got the old technology coming out, you can see it finishing up this year, and the new technology rolling in. We're replacing procedures that were cumbersome. We're taking paper out of our processes, making it more efficient. You need less labour for that, greater accuracy, greater documentation.

All of those things make this business, importantly and highly regulated, more succinct, more reliable. That was the plan, and that's what we've executed on.

As I said, we replaced our apheresis devices as well. In replacing those devices, the good news is, we're getting greater yield with those collections. That was planned, understood. We'll finish that this year, as well.

So, all of these things begin to lead to greater efficiencies, and in doing all this, what was important is that our Grifols apheresis did all of the training here. And why do I mention that?

When you're doing this much change, if any of you have ever gone through an IT chance in your business, and the training that gets involved in it, or even gone to a new phone, and how is that going to work? All of these things, those differences, require training. And we have a short window to do that, so we don't disrupt our donors, we don't disrupt our business, any more than we have to.

And that training that we had was so good, because you have to have a hot team, or a team that's right there in order to take care of any issues, questions, that come up at any time. That team was actually not really needed, because when we did that training, it was the best I've seen. I've been doing this for four decades. That's the best training I've ever seen, and we didn't have questions, follow-up, or anything along that line. And in fact, our employees said, 'This is great'.

That reduces disruption. It gets you back, in terms of your game, a lot faster.

So this was important for us, to get this right, to do it one time. We're taking a lot of bites out of the apple, so to speak, and we needed to do it right and well, and we did.

So what does that mean for us? Where we are now is that we've acquired all these business. We have now got a lot of that digestion of them, integration of them, into our organisation. We're sort of through the technologies, we're implementing these things now, and we're getting to the place where we're starting to look at, how do you optimise and how do you drive your efficiencies?

When you're taking this kind of technology, phase one is to get you up to where you were. Phase two is to master the technology, and phase three of this is where you optimise the technology to the maximum potential.

Our centres are in various phases of this right now, and you'll see some of the outcomes of that.

The talent development is another area for us, as I mentioned. Our Grifols Academy of Plasmapheresis has got great game in doing things online. Online training for 13,000 people is important. How do you that well and do it right?

And, as the organisation, as Raimon just went through, it changed. In terms of globally how we changed the organisation, we have a group of people that are doing this training on a global basis. A group of people that are looking at regulations on a global basis. Safety, quality, medical. All on a global basis, and we're looking for the best practices and opportunities that go on there.

That's what's happening in this business today. Are we getting results from that? Yes. Yes, we are. If you look in terms of donor retention rate, I'm going to talk about that a little bit later in the third part, but this is a really important area for us to get that momentum. It takes a lot of work now. It's a very competitive environment.

In donor centres, how do you get a donor to come in, and want to come back to your centre? We're seeing that.

In terms of the employee, donation per employee hour, this is an expectation, right? So now it takes less employees, because of the technologies, in order complete the entire process of donor collection.

And, as we grow, you gain that leverage, right? With the manual steps that are out, it's much more efficient, and we can spend more time with our donors on that experience.

And the final piece, of course, is yield, right? We expect increase in yield with the technology, and that's exactly what we're getting.

And then you look at collections in terms of the average amount of collections per centre, and you're seeing a steady increase as our centres get through those phases of mastering the technology, becoming more efficient. We're getting better returns on our growth.

So, not only are we getting the volume, we're getting the acceleration of that. And just for this meeting, apparently, this quarter, we really buffeted. So, great stuff. I love that last bar. Perfect timing. So we are seeing the momentum, and I think that's really an important message here.

So, this last area, I want to spend a little bit of time on, because you have got the hard parts of the business, if you will, solidified parts, but then there's the soft parts of the business that also matter. And this can get lost in analysis.

But this is a very human, a unique, human business. Imagine you've never donated plasma. You're walking into a centre. And in a very short amount of time, they're going to feel the vibe of that centre, and right away, you have to establish trust, competence, commitment, compassion, and that you believe in your mission. And this is all done, generally speaking, without words.

How you message to a donor when they come in the door, that energy that you feel, the camaraderie of your people, matter. We call this the difference. We do this right, we do this well, that difference becomes more important, because what's the premiums going to take for a donor to donate at that centre versus your centre?

What's the premium to keep that employee versus going to work somewhere else?

We keep doing this right, we keep doing this well, and that premium becomes higher and higher and higher. Let me paint that picture for you.

We believe that our employees and our donors go on a journey. It's the same journey, interestingly enough. If we go to the far left on the screen, that question mark up there is some employment, and I now am in a position that I either want to change my employment or I need to supplement my income, whatever that might be.

And those light bulbs are, how do I do that? Where do I go for that? I'm in search right now. And we're just going to skip to the chase and then come to Grifols.

The dollar sign right there is because, people coming in, they need to supplement their income, or I want a different job and I need a paycheque as part of that. We do have altruistic donors. We do have donors that are compassionate, I mean, that are passionate about their donation. They have a relative, they have a friend, they have a family member that is in this position, needing those medicines, and they are deeply committed. We have plenty of those. They're regular donors. They're dynamite people.

But we also have those that are coming in because there's an economic component to it. We recognise that. But it doesn't take long on that journey to get to that check mark, and that check mark is, 'You know, I'm doing something good. I'm doing something meaningful'. I'm glad somebody made this clicker, because I need this clicker today, but I don't want to work for a company that makes clickers, quite frankly. I need a little bit more to the heartstrings, right?

That kind of piece of it, and when you have that with your employees, and when you have it with donors, they begin to realise that, 'Yeah, I have a compensation need that's part of this, but I really like what I'm doing'. And the next part of the journey you take them is to really understand plasma. That drop is plasma. Plasma is unique. It is different.

I've been in different parts of healthcare. Plasma's special. There's a group of people right over here who are sick, and they have challenges, and they live in pain and discomfort. And some of them are even at risk of their health to a very significant degree. And they need our medicines. It's their only outlet, our medicines.

And the great part is that, when they get those medicines, you couldn't pick them out of a crowd. And when you explain that to your employees, and you explain that to the donors, all of a sudden that donation is more meaningful. It's more important. And, as an employee, you do make a difference.

We do save lives. We partner with our donors to save lives. And when that message resonates, it really connects.

So now, the stars become, 'Why are we different?' What makes Grifols different? Why do you want to work here? Why do you want to donate here?

You know, plasmapheresis was invented by this company. Our innovation, our commitment to quality, our commitment and passion for safety, our look and commitment to environmental stability. All of these things that we do, and I could go on for a very long time about our company and why it is different and better. In my past life, I served all of those in this industry. They were my customers, including Grifols. Grifols is different.

And that is meaningful, and explaining that to our donors and our employees, and making that connection, you ultimately arrive at the heart, and that is the fact that I feel like I'm family. I do feel like I'm family here. I want our employees, all of them, to feel like they're family, and I want our donors to feel the same thing.

That journey is meaningful, because, as you get an employee, and you get past the point where we've assessed, and you're the right person for us, you begin to come in, the first thing is, you matter.

You matter. And once you are at that point where they understand they matter, they're partnering, they're saving lives, they're committed to this thing, and then they begin to see the development and the opportunity for growth in this company.

We have people in Egypt today. They never dreamed in their life they would be in Egypt, training people for a week, a month, a quarter, or for a whole year. That's where they are.

We have people doing the same thing in Hungary. People doing the same thing from Hungary who are coming over here, saying, you're doing something different. We like that. Tell us more about that.

They never dreamed in their lives they would be doing these kind of things. The dynamic of this company, if you want to have management, you want to have growth, you want to expand, it's a big organisation. There's opportunity.

So now people are at our centres, working, and it's a mission. Our donors watch every bit of this. They're sitting in that chair, they're connected to our devices, they're watching this energy. When I go to centres and talk to our donors, I ask them, 'What do you see?'

On our very best centres, our very best centres, this is being done brilliantly. Our employees believe they're on a mission. They're committed, they're compassionate. They engage with our donors, and our donors feel like, 'This is my place, this is my home'.

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One of those centres set collection records every quarter from 2019 through today. It works. This is really important, not to be underestimated. Combining this with all the technology, combining this with all these other things, is differentiating.

If we take it to the donors, every touch point with a donor, truly, you've heard this before, it's a moment of truth. Right? They look on the internet. They begin to connect with you, and begin to find you, and once you start that dialogue, digitally back and forth with them, we're learning about them very quickly. No different than all of you on your phones, and you go onto a site, believe me, they're mining you, right?

We're doing the same thing. We're trying to understand our donors. What makes them tick? Why are you different than you? We respond to that. Those are the engagements that we are doing with our donors, and once they come in that door, as I said earlier, we want them to feel the energy, feel the commitment, feel the passion and be part of this with us.

That is what we're establishing with our donors, and once you get them through the cycle and the process, then it's 'When are you coming back? We haven't seen you. We'd like to have you come, bring a friend.' All of these things are part of this engagement. It's like a 360 with them.

Underpinning all of that is technology, right? This is not complete, but we are far down this path. So it starts with here. It talks about every one of those touch points, how do we get that in? One of the things that we've done, and we are ahead of the game on, I feel confident about that, is that we've segmented our donors.

We understand that there are differences in donors. And so, how you respond to them is art. To move them from point A to point B, from looking at our site to going to our landing page to coming into the centre, all of that is art. Getting that information in and understanding it. We're building AI in a number of different areas for us, to help us with this. But ultimately, all of this information leads to, how do you orchestrate after that? Part of Austria changing, then this part of Germany. What does that mean for us? How are people's sentiments changing here? How do we respond to that? What does that look like?

It's all about the data. It's all about the data, and this is the infrastructure we've been building for a while, and we'll continue to build on. And quite frankly, I don't ever see that ending. That's... It moves.

In 2020, that was a challenge, I'm sure for all of you as well. I'm really proud of the fact that we decided, and this is another one of those 'go big or go home' moments for us, never been done before, but we decided we're going full-out campaign on awareness. Convalescent plasma was making the news. People were beginning to hear messages about convalescent plasma, like, 'What's plasma?' And it started to escalate.

We said, 'We can build on that wave.' So we went full media. Never been done before. Television, radio, web, digital, across the boards, messages, and it had an effect. I know it had an effect, because every one of our competitors have copied us. So we know it had an effect, right?

And we did, we got a boom from that, and we did it the next year, and that helped. And we learned. We've gotten a little smarter about this. I mean, you know, come on, we're just novices in 2020, we're learning in 2021, and we're getting better. Okay, it worked here, but it didn't work here. Let's stop that and continue this. Let's try this. Those kind of things are the things that we're doing and getting better at.

And this year, it's show us your good side. Each of these campaigns are really building out awareness, and quite frankly, you have to play this game. There are over 1,000 centres in the United States. You can solve the expansions going on in Europe as well. To compete in this, it's retail, right? That's where we are. And so, having this capability is now vitally important, and we're getting really good at it.

This is the 'really good at it' stuff, right? These are impressions. When you're getting a message, a signal, whether it be online or in the web or a text, an email, all of those things are impressions. And you add those impressions up, and you get movement. People begin to do things. They go to your website, then they go to your landing page, and then they come in. 30% growth. I round up. 30% growth in these last couple of months, with this particular campaign. We're getting better at it. This is really the way the game has to be played for us, and I think we're pretty good at it.

In 2021, our German colleagues, as we're on the phone with them on a weekly, daily, basis, it's like - Okay, we're doing a campaign as well. And they did it in 2021 and 2022. They tied theirs to social causes. Their knowledge of their donors, their input from their donors, is, it's not just about plasma. For us, it's these other things that are important as one, whether it be gasoline or Ukraine, or - It's tough right now, in society.

And we become their spa place. Come in, relax, connect in, and just enjoy. For some people, it's getting away from their kids. For others, it's just a place to stop a little bit. Some people want to be in and out. We have all those options available. But this is what our campaigns are doing there, and with the same results. The impressions come in. It drives human behaviour as they begin to look. We know how to connect with them, and they're coming in the door.

I chose this example in particular, because look at this right here in September. We had a dip. You know what that was from? We had a new variant, and it hit hard in Germany. I'm not sure what that number would have been, had we not done the advertising, had we not been out there doing our marketing and campaigning. I think it would have been very different, quite frankly. It works. It has an impact.

This is the business that we have. This may be considered soft stuff to some extent, but I have to say, you marry that up with the hard stuff, the technologies, the processes, the workflows, and put that together, and it is what it's about. This is a human-to-human interaction.

We are driving this business. We are confident in what we're doing. Our global footprint is meaningful, is diversified, and our volume is coming in. Our acquisitions are driving for us, now, to the phase where we want them to be. It's now time for us to begin to get a return on those investments, but now the efficiency and the optimisations are following.

We have the technologies in terms of driving our business now. Our technology, relative to the academy, and training, is now global, and we're getting the leverage of best practices. And our donor and our employee engagement, I think, is well ahead of the curve, and we're going to continue to build on that. We started that cultural change in 2017. It's not new for us, but it is making a difference.

This is where we are. We're confident in our abilities to drive our volume. We're confident in our abilities to now bring down our cost per litre over the course of time. We feel very good about our position in the market.

Thank you for listening. I'd now like to turn this - Oh. No, go ahead.

[Applause]

Okay. Thank you. That's very kind. I now have the pleasure to introduce Daniel Fleta. Daniel?

[Music]

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Egypt & Canada

Daniel Fleta, Chief Industrial Officer
All right, good morning, everyone. Thank you, Peter. I'm glad to be here with you today. I would like to update you on the progress of the Grifols global plasma self-sufficiency programme that was introduced to you last year.

I think we will all agree that, especially after Peter's presentation, that plasma is a strategic asset. Building on that, here you have a quote that, in the 63rd assembly of the World Health Organisation, they actually urge the state members to take all the necessary steps to build sustainable plasma models in their countries.

Building on top of that, also, it is true that the COVID-19 pandemic has further stressed the situation to the collection of plasma. And to finish it off, it's also true that, thanks to the new generation of diagnostic platforms and devices, anamnestic, together with the new indications for some high-prevalence diseases, we expect that this need for plasma-derivative medicines in the future will even further increase.

So, we are in dire need, the world and the nations, are in dire need to find additional sources of plasma. And we at Grifols, we think that we are the best-positioned ones. Basically why? Because of the one-stop world shop. We can offer, and we have expertise and capabilities, in all the range of services and collaboration with different institutions, or with different companies, being public or even being private collaborations.

So, we can offer services, starting with engineering, manufacturing, quality and regulatory know-how, and also implementing our products and our quality standards all over the world.

If we take a look at the wide range of different models of plasma collection that you can find out there, and that the different countries or nations are applying, you can see that there are fully public models. And here you can see, on the left-hand side, for instance, Spain, Italy, and France. Or you can have fully private models, being a little bit the paradigm of that, United States collections.

In the middle, however, there are what we call hybrid models, that, they use both. The public or the non-compensated models, together with some US-based or some compensated models. Among those, there is, for instance, the example of Canada, and Egypt, that I'm going to present to you today.

If we go closer to United States, there are other examples of these hybrid models, like, for instance, the four European plasma collection countries that account for around 55% of the total European plasma collections, like Germany, Austria, Czech Republic, and Hungary. And then we have China, which has, I would say, one of the greatest potentials to boom these plasma collections in the future.

So, now we are going to focus on these two central or hybrid models. Also, to explain to you that we also envision this collaboration and this deployment of new plasma collection infrastructures, and plasma derivatives, manufacturing sites, applying the same standards and the same procedures that we use in our current industrial footprint.

And you can see, actually, in this slide, that, coming from the 22 million litres of plasma capacity per year, that we will have in this 2022, we expect by 2026 to further expand that capacity up to 26 million litres of plasma for year. That is integrating the new sites in Canada and in Egypt. But same quality standards, same procedures, same processes, same products. At the end, the same care for the patients that will benefit from these plasma derivatives.

If we go to the first of these two projects that I'm going to update you today, which is Canada. Canada, as you know, in terms of plasma derivatives, is a fully developed market. It's a mature market, and actually you can see here that their actual per capita consumption of IgGs is among the highest ones that we have in the world.

However, there is a clear aim or mandate from the government to increase, to ramp up, this self-sufficiency for the country, so, the access to these plasma-derived medicines. We, Grifols, we've been in that country for many years, for more than 30 years, and we have been doing all the fractionation of - we have been the main operators for the fractionation of the plasma that was being collected in Canada. We are the only ones that we have a larger scale manufacturing facility based in Canada, so

we can, starting with plasma, plasma testing, release, fractionation, purification, and septic finish, we can do all those steps locally in the country.

You will see now the works that are ongoing for accommodating our processes, and we clearly think that we are the best-positioned actor in Canada to be able to deliver these products to the Canadian patients.

This is the location of our facility in Montreal. It's very close to the city. Actually, it's even closer to the airport, so, very convenient for communications. This is the land plot and the site that we bought in the last quarter of 2020. You can see that it's a relatively large land plot, and we are just occupying part of it, so we have additional expansion, significant expansion capabilities there.

We have a three-storey building allocating all the different areas from the warehouses, quality testing labs, office space, fractionation, purification, septic finish, and secondary packaging. This is a south view from the current complex, or from the current facility, and we engaged a programme to further expand the capacity and to license our products there, expanding the existing buildings by 6,600 m^2, again in a three-storey arrangement.

And you can see the different phases of this project. The first one, that it's being mechanically completed almost as we speak, is for the albumin purification and fill and finish, and this will be completed this month of August.

Then we have the fractionation that will be completed one year after, and finally we have the gamma globulin purification, and the expansion of both the raw material and the final product warehouses that will be completed, again, one year later. So we will have, starting next year, to have an albumin manufacturing site already in Canada, so, being able to process that Canadian plasma locally in the country, to be delivered to the Canadian patients.

Some pictures of the ground-breaking ceremony, and the different, let's say, mobilisation, the utilities area, and you can also that already some of the main process equipment has been already installed, and it's being finally hooked up just to start the commissioning and the validation.

If we move to the next project, that is Egypt. Egypt, I would like to emphasise here that we are delivering on our promises. This was introduced to you last year, and you can see the different milestones that we put forward in the evolution of this project. All of them have been accomplished, so we established this joint venture.

The country drafted and approved, the parliament approved the specific law that regulates blood and plasma. We have developed a structure for the plasma collection, plasma testing labs. The Plasmapheresis Academy, Grifols Academy, and also the first plasma donor centre, and we have launched already the educational programmes to bring up to speed the plasma awareness and the donors' recruitment and retention.

If we look at these different milestones in the timeline, you can see that we signed the agreement end of 2020, just one year after the plasma testing lab, Grifols Academy, and the first plasma centre were completed and were ready to start operating. That we did at the beginning of this year. Testing lab also.

And this year, 2022, we are going to start shipping plasma, Egyptian plasma, to Spain to be further processed down to plasma derivatives.

For this year, we are going to develop ten plasma donor centres. Next year, ten additional, for a total of 20. Then the fractionation plan by the end of 2024, and the purification and fill and finish for the next year.

And also to mention here that Grifols for plasma derivatives was accepted as a source plasma member of PPTA earlier this year.

Some pictures of the first plasma donor centres and the testing labs on 6 October, which is close to Cairo, and this is the first wave for the ten initial plasma donor centres' development plan, showing the three areas that we have divided, and we are implementing all in all plasma donor centres in most of, or the main, governorates or Egypt all across the country.

In regard to the facility, the works are ongoing already for the plasma collection centres, sorry, for the plasma logistics centre and for the testing labs and the headquarters, and we are also starting the fractionation and the purification plan in – near the administrative capital, so, east of Cairo.

So, key takeaways here, again: self-sufficiency plasma, and self-sufficiency's crucial to guarantee the sustainability of the plasma derivatives supply. We think that, at Grifols, we are best positioned to serve as the best-in-class partner through either private or public-private initiatives, to obtain these sustainable plasma models.

Our unique know-how and leadership, both in engineering and operations, represents, makes a difference with other competitors, and represents a competitive advantage in our case to execute these types of projects. And milestones, both in Egypt and in Canada, reflect how Grifols delivers on its promises.

The implementation of international quality standards, we think that this is extremely important to our strength, and the safety and efficacy of our plasma-derived medicines. And finally, we expect that these two projects will become a model, will become a blueprint for other countries to increase their plasma self-sufficiency levels, and we are prepared for that.

Okay, this is all from my side. Now I would like to introduce Joana and Bill. They are going to introduce to you the biopharma commercial part of this presentation. Thank you very much.

[Applause]

[Music]

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Biopharma

Bill Zabel, EVP Commercial Operations
Good morning.

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Joana Sàbat, SVP Global Marketing & Market Access
Hello, good morning.

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Bill Zabel, EVP Commercial Operations
Joana and I have the next 45 minutes with you to talk a little bit about the commercial organisation. So we're going to reflect back, we call it the vein-to-vein concept. And just to acknowledge our plasma colleagues, and something Peter said resonated with us in our planning as a commercial organisation, and we say, hey, Plasma is back.

And with plasma coming back, certainly we're looking to people like Daniel Fleta, who's talking about our ability to produce these medicines. And we're really appreciative, because Joana and I have the opportunity, and Joana's our Senior Vice President of Global Marketing. I have the commercial responsibilities and sales responsibilities for Grifols, as Raimon made mention. It's really important, with the talented group of people that we work with, that we raise awareness, and we educate healthcare professionals to make sure there's appropriate diagnosis, a timely diagnosis, and there's access to treatment with plasma proteins. And we always say we want to make sure they have access when and where they need them.

So, Joana and I are going to spend the next 40 or 45 minutes with you this morning explaining Grifols's significant role in providing these essential medicines in a growing market. And also pause and say, there's a large unmet medical need for plasma proteins around the world, and we're going to share some of that in the second part of our presentation today.

To start, though, we're going to focus on this, poised for performance. And what we want to do is show you performance before the pandemic. As Pete Allen made mention, and the organisations made mention, we took the proverbial pause last year because of supply, but we're committed to growth.

Our goal always, as Grifols, as one team, is to make sure we deliver these life-saving medicines when and where patients need them. And we, Joana and I, today, are going to spend some time with you today telling you and sharing with you why we think Grifols is in a unique positions.

This is our industry. I'll stop from the top of the funnel. And we will say, hey, Grifols is in a very favourable industry. And if we reflect back to 2020, and I'll say this is MRB-referenced data, this industry continues to grow at 7.2%. And yes, this cottage industry now has grown up to €25 billion.

With that said, there's so much more we need to do, and our mission is to improve the lives and well-being of people. From a commercial standpoint, we put the patient at the centre of everything we do, to improve the lives and well-being of patients worldwide. In fact, if you look at growth proteins from the industry, like immunoglobulin, or Alpha-1, or Alpha-1 antitrypsin, Albumin, or even rabies immunoglobulin, we would say we're just scratching the tip of the iceberg. Because if you come from the pharmaceutical industry, these products actually defy the normal life cycle. In fact, they continue to grow, and we're going to share some of that with you today.

And we believe that Grifols is uniquely positioned, because we have a focus, as you've seen with you, on therapeutic classes of interest. So, in these therapeutic areas, we said six, Raimon said seven. But very mindfully, very thoughtfully, and you'll hear this from our innovation team this afternoon, we're talking a very firm focus at immunology, neurology, pulmonology, haematology, hepatology, critical care medicine goes kind of as one, and certainly infectious disease.

As Raimon made mention now, we are really, really excited from a commercial standpoint that Grifols has taken the proverbial step back and look at their strategy. And now we have the structure and renaming ourselves from bioscience to biopharma is an inflection point of the opportunity that we have as a commercial team, both to share with you our capabilities to provide plasma medicines as well as non-plasma medicines.

And Joana will give you an example later today, with a medicine called Tavlesse, that's our non-plasma medicine.

So, if we turn, then, from here, and show growth, as I said I would share with you, we'd start by product, and we would just share with you several growth portfolio products that we have in our portfolio, I should say. And we reflect back to data, and this is Grifols data. And you look at '17 through '20, and you would say, hey, perhaps Grifols is growing faster than the market. We're growing at 8.1%. And yes, we do acknowledge, because the supply last year in markets like the US, we were impacted by supply.

However, the commercial principles we have in place to increase the awareness, educate, support timely diagnosis and treatment, will return our forecasted growth this year to high single digits, and through our long-range plan we expect to deliver high single digits to this industry. And we're going to explain why to you today.

If you look at categories like IG, three brands today. Flaba gamma dif, Gamunex, we would call that our blockbuster brand, and we're really excited. Our doctors would say we've got a Gamunex 20%. That medicine's our SubQ 20%. The brand name is called Xembify, and as Joana will share with you, we're gaining traction.

And as John Boyle would say, from our patient community Immune Deficiency Foundation, this is an important new medicine that Grifols is providing to primary immunodeficient patients. And Joana will tell you, outside the US market, we also have class labelling for [short gap in audio] deficiency as well.

IG is not the only thing growing. If we look to albumin, we can say we had a really strong start, both in China and the US. And this is comparing our comps from Q1 of this year to Q1 last year, and we're not planning on slowing down. We see strong, robust growth for albumin in the US market, and yes, thank you to Grifols engineering and our manufacturing facility, we now have this Albuteine FlexBag that Joana will talk to you about later.

How big of a deal is that? We have about six competitors now that sell vials including Grifols in the US market now. We did a customer demo. We dropped this bag on the floor. The next day, they bought a FlexBag. There's only two people that make a FlexBag, and we believe, because Grifols Engineering designed our bag, that we actually have a better bag.

In fact, we're the only ones, the only ones with a 5% 500mL solution in the world. In fact, when we were short of supply on 5% 250, we went to a major academic teaching hospital in New York City, and they experienced the 5% 500mL. And now they're only buying from Grifols, because of our engineering and our FlexBag, so, thank you, engineering, and thank you for delivering this innovation that we have.

It doesn't stop there, because we talk about Alpha-1. And Joana's going to share with you, we've been doing this for three decades, and we think we've made notable progress, and we have. In fact, as a brand, globally, even with competition - The product, the programme, and the service, wrapped around by the outcomes that we have with our unique model - We now service seven, seven out of every ten patients in the United States. And we're going to explain to you later why we're so focused with our diagnostic company. Antonio Martínez. On raising awareness, educating. Making sure we're diagnosing patients. Because we know seven out of every ten people in the world will rely on Prolastin.

And, last but not least is certainly rabies immunoglobulin. This falls within infectious disease. Rabies is the number one most infectious disease, fatal disease, in the world. Grifols is the market leader, as Joana will explain to you later, with over 80% market share. We have a new caprylate chromatography product. What does that mean? The benefit is, it's twice as concentrated with half the volume.

What does that mean if you're an ER doc and you get bitten by a rabid bat in the face, or in the hand? That medicine's got to be infused at the wound site. If you have half the volume, and you're an ER doc, and you're treating a patient, that's a meaningful clinical difference. Grifols is the only one in the consolidated market, and, as you probably saw, Santa Fe has said, we're exited the market with Inagam (?). We're exiting the market with Inagam (?), and I would say it's because Grifols has the clinical advantage with our new caprylate chromatography process.

So now, if we go from product to look at where, regions of the world we're growing in, we don't have lots of time to spend here, and we could certainly talk at the break. We could focus on the US, China, and certainly the good news coming out of Europe as well.

In the US, and here's some fun facts: we're raising awareness, we're educating doctors, we're supporting them to make sure they're looking for an appropriate and timely diagnosis that leads to a treatment. We covet the relationship we have with the doctor. We want them to write a brand choice that says Grifols on it. Gamunex, Xembify, dispense as written. And we're making a conscious effort to grow markets. We're mindful of our competition, but we wake every day and lace our shoes because we know there's a patient that's not diagnosed that's counting on our best effort.

So here's a fact. Seeing, and Raimon, thank you for that, I was at Talecris in 2011, and they came and bought us. In 2012, first full year, IG market was half the size it is today. So, 46.5 million grammes US market, now is sitting at a market when you exit, at about 105 million grammes. I would like to think that Grifols, with Flabagan (?) and Gamunex, and medicines like Xembify, are playing a key role, engaging physicians and making sure we're driving appropriate demand for our brands.

In Alpha-1, leader in our category, 70%. 60% market growth in the United States in units. We're leading the way. Market shares increased from 50 to 70%. And then one last factoid: rabies immunoglobulins in 2012, $78 million. HyperRAB, caprylate chromatography today, $176 million. At one point, the Centres for Disease Control thought the market was about half the size, because patients were going untreated.

In China, and I'll be brief, we've said favourable growth. Raimon mentioned that the Shanghai RAAS transition's behind us, double-digit growth, and we're forecasting continued growth for next year in China. And we're very excited, like I said before, with the growth that we're seeing in LBT, and we would say it's a branded pharmaceutical. It's going to be a medicine. If you treat it as a commodity, it'll be a commodity, but if we keep on doing things like this, and some of the research that we're doing in liver cirrhosis, you may get a branded pharmaceutical.

And lastly, in Europe, and we've talked a lot about this: seeing from a US market, we're now seeing pricing in Europe, much more favourable. Double-digit favourable. In fact, we're not at parity with US pricing, but when you see what's coming out of Europe, we're seeing more comparable pricing to other markets. And in fact, if we look at Europe and we consider Prolastin, and we've had double-digit growth on a medicine like Prolastin.

So, Joana, I'm going to pause here. I'm going to turn the presentation over to you, because we have a portfolio of solutions that Joana's going to talk to you about, about all of our medicines. So, Joana, I'll give you this.

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Joana Sàbat, SVP Global Marketing & Market Access
Thank you.

Bill Zabel, EVP Commercial Operations
And I'll step aside. Thank you.

Joana Sàbat, SVP Global Marketing & Market Access
Thank you, Bill. Hello, everyone. As Bill has said, I'm going to present to you now what is the portfolio for the biopharma, and what are the solutions that we have for our customers, patients, and physicians. And before going to every single one of the particulars, I also want to highlight that all these therapeutic areas that you have seen in Raimon's presentation, you see now in our presentation, is the focus also for our innovation. And you will see in the afternoon, also, the same therapeutic areas.

Something also very important for us, that in all these therapeutic areas, we have huge medical unmet needs, and then the main goal from Grifols is to find new solutions, new products, new containers, as we'll be showing you with the FlexBag, new formulations, just at the end of the day to improve the quality of life of our patients. And also, to help the physicians' community to treat these patients. And very important to you, and you'll hear these along our presentation today, that we are also very well positioned, uniquely positioned to help the community to identify these patients, and you will see more in Ian and Antonio's presentation.

Let's go to the different therapeutic areas in detail. The first one that you have is, we put together immunology and neurology. In this area, we have a leading position with autoimmune disease, and you will see with our Gamunex, and also, we have great capabilities to keep growing, to continue growing, the immune deficiencies field.

What does that mean? Immune deficiencies, we have brands to treat the primary immune deficiency, subcutaneously and intravenously. We launched recently the Xembify, our subcutaneous 20% formulation, that we will see how great it's performing, the brand. But also, we are very well positioned and working with different programmes in secondary immune deficiencies, and you will see these in the afternoon. This is for the first one of the therapeutic areas.

Second one, pulmonology. We are absolute market leaders, as you will see, and also as Bill was mentioning. And we have also been demonstrating our capacity to continue growing. We have been leaders for 35 years with Prolastin, and today we still can say that we are the absolute leader, because seven out of ten patients that are treated with Alpha-1 in the world are treated with our brands, Prolastin or Prolastin-C, in the US.

Next therapeutic area that we're going also to talk on today is infectious disease. We have a growth portfolio to treat some life-threatening diseases, as in some patient situations, but the one that we're

going to remark today is the HyperRAB, because also we have a leader position here, and we have a product that is key on the growth, also, of the revenue of the organisation.

Haematology. Haematology, also, we continue bringing new solutions. We have a portfolio of coagulation factors, but also, we are innovating here. We have one new brand that is Tavlesse, that I'm going also to explain a little bit more. Tavlesse is a fostamatinib to treat chronic immune thrombocytopenia adult patients, and this product will launch in Europe, and you will see the traction that it's having.

Another innovation that we have in the haematology space is our fibrin sealant. We manufacture the fibrin sealant, but it is commercialised and sold by a partnership that we have with Ethicon, and it's branded in the world by VistaSeal or VERASEAL.

And, last but not least, we have an intensive care division, and we call it intensive care and hepatology. And here we are proud to tell you that, also, Grifols is the leading company in researching on this space. All the research that is done with albumin is done, nowadays, or most of them, is done by Grifols. And what we are trying to do here is to position albumin as a drug instead of a plasma expanded as it has been in the past. And our goal with albumin is to try to change some of the disease states, like the cirrhosis, and we'll talk a little bit later about this as well.

Here you have our main therapeutic areas, and now what I'm going to give to you are great examples of the good performance that we have had in the last period, and also, this is what is getting us back to growth, as we're trying to explain to you all today.

We will start with Gamunex. Gamunex is in the neurology space in the therapeutic areas. It is a leading brand. Gamunex is a 10% intervention hemoglobulin, and we continue leading this space in a very increasingly competitive market, not only the US, also in Europe. We can say that we are the absolute leader in the US with 34% of the share that we have in that country, and we're keeping this share, and you can even see on the chart that, on the last period, we are still growing.

What is Gamunex? Gamunex is considered by our customers the first response to CIDP, providing a trans neural protection to the inflammation of the patients that they need. And then also all of our commercial and clinical investments in Gamunex in CIDP are continuing to be a priority to achieve and continue to growing on this space.

Then, for us, Gamunex and the message that we want to deliver is the first responding treatment of CIDP, first product in CIDP indication, to obtain indication, first product in prescription in the US, and first product in market share also in the US market.

If we move now to the immunology space, in immunology, let me share with you the Xembify. Xembify, as we said, is our subcutaneous immunoglobulin, 20% concentrated. It's a version of Gamunex-C.

Then also to show to you that we have experience on the field, now it's a higher concentration of the Gamunex. Xembify. We launched Xembify a couple - three years ago in the US. The brand continues to roll. We're gaining market share, as you can see here, in the US, and also giving the patient and the physician another reason, another solution, to treat the primary immunodeficient patients, which is very important. And you will see, also, in the next part of the presentation, that there is still a lot of work to do, a lot of patients that are still underdiagnosed, and we're giving another solution to the physicians.

The launch of the Xembify, as I said, was two, three years ago, and it was at the time of the pandemic. Doing a launch at the doors of the pandemic was, of course, not ideal. But today we can say that more than 1,000 physicians have used Xembify in the US, with our subcutaneous formulation, and this product has been continuously gaining traction. And also, we're proud to say that 87% of these physicians that have used Xembify. They keep using Xembify on a daily basis. This is very important for us.

And this all translates to this impressive figure of the 141% growth, closing the first quarter of this year. This explains the good use that our physicians and our patients get with the Gamunex. This uptake also will permit us to continue saying that, by 2025, in between 10 to 15% of our sales in immunoglobulins will be from the subcutaneous formulation.

During the last 12 months, also another data that is important for us to highlight: during the last 12 months, Xembify has gained 3% of the market share in the PID segment, and doubling market share in only 12 months. And it's the product in the US that is gaining more share in the last 12 months. This is also something that we want to remark with the Xembify.

And it doesn't stop here, our Xembify story, because also we are very pleased to share with you that we got the approval in Europe some months ago. We are working now with all the different health technology agencies in getting the price approval, and last week we got the approval of Xembify in Australia. That is important for us, because if we look also at the data, you can see that, in between Europe and Australia, these two geographies, they have 23% of the total IG volume is in this route of administration, and subcutaneous, then, for us, is very important to launch also in this market.

You can see also on the chart that only in 2021, if we look at these two geographies, the use of subcutaneous versus intravenous product grew 12% and is expected to continue growing. For us it's very important now to start, we're planning all the launches in these countries.

Also to share with you that, based on all the market research that we have done in the countries, that we're planning to launch now. The first wave will be 2022, UK, France, and Australia, and in 2023, Spain, Italy, Nordics, and Germany. In most of them, the preferred route of administration is subcutaneous. That shows us that this is a very important timing for us to launch in the market, because this route of administration is growing year over year, because it is one of the preferred routes. And this will give us also the opportunity to achieve a 14% market share out of the US, in between subcutaneous and intravenous formulations, and will support us, and keep growing year after year, on the immunology space.

Now we change gears. I'll finish here with neuro immunology therapeutic area, and we can move now to pulmonology. In pulmonology, all of our efforts represent not only a success story in terms of leadership and good performance of the brand around the world, but also it represents our values, because we have been serving patients and physicians, overcoming any challenges that have happened during the pandemic and post-pandemic.

We have been raising awareness, helping the physicians to identify their patients with all the diagnostic tools that we have, that Antonio will explain with more details later. And the results are very clear, because year after year, you can see, no matter the complexity of the environment, during the pandemic, all these patients, or most of these patients, because of their situation, they were asked not to go to the hospital, to stay home. Then, despite all the context, Prolastin has been growing. You can see, during 2021, a 7% growth, and also keeping this growth in the first part of 2022.

Again, just to reinforce that, during the last 35 years, Prolastin is the leader on the space of the Alpha-1 deficiency treatment, and today, thanks to all these efforts, we are proud to say that seven out of ten patients that are treated for Alpha-1 are choosing Prolastin or Prolastin-C liquid.

And why is this happening? We think that it is because we have two very important strategic pillars that are supporting this. And what are these?

The first one is that, as a leader, we ensure the product supply. No matter the complexity, as I said, of the context, this has been a priority for Grifols. We have been able to maintain and increase our product supply. Also in the frame of the Alpha-1 shortage during 2020 and 2021, the world has suffered. Then we were there just to support our patients and physicians, and no matter where they were or when it happened, we were there to supply with a product.

That was one of our strategic pillars that has been also supporting us to maintain this growth.

The second one is our full commitment to support the patients through our patient support programmes. We have, in every country where we have the Prolastin available, we have what we call the patient support programmes. Our patients, they get support from these third parties. In the home infusion services, if they need any advocate in psychologies or whatever, then we offer these patient programmes to the patients.

As a result, all the patients, they'll receive more benefits beyond therapy, and it has been demonstrated that this is a loyalty for them to stay with our brand.

These two pillars are not only by themselves. These help for us to keep our 70% market share, but also, we have other pillars that are increasing awareness around the world, and also increasing diagnostics. Very, very important for us, and doing a lot of efforts on this field as well.

If now we move to another success story. This is in our infectious disease portfolio, in our infectious disease therapeutic area, and as Bill was mentioning we have the rabies immunoglobulin that is the

worldwide leader in prescription. Grifols has been continuing building in the leadership for HyperRAB. In the past years, Grifols has been working with this product, providing more solutions for the patient.

What are these solutions? Bill also mentioned, it is just concentrating more, having a higher potency of this product, and the patient, when it's infused, it's better for them. Having this higher concentration, with 300 units per mL. And also, recently, we launched a 3mL vial to provide, as I said, these solutions for them.

The sales have been continuing to grow. We have achieved a new record during 2021, and with very significant figures in terms of revenues, which makes this product also a key product for growth in the company and in this therapeutic area.

Thanks to this unique higher potency, and also the characteristics of the product, more than 1 million patients nowadays has been infused with our HyperRAB in the world, and this helps us to hold this 80% market share with this product, keeping us as a leader in the US rabies IG market. Again, a success story that we are pleased to share with you.

If we move now to the intensive care and hepatology therapeutic area, as I said here, we feel also very pleased to share that we are leaders in researching, but today I'm not going to talk about research. It's just talking about the new products that we have also been introducing in the market.

Last year, we introduced the FlexBag for Albutein in the US. Also, Bill said that this is a product fully designed, engineered, and manufactured by Grifols. We're very proud of these unique characteristics and benefits that are driving a very quick adoption in the US market. I'm saying the US only because right now we only launch in the US, but the plans are also to expand out of the US.

Also to highlight is the first product in bags that has the 5% 500mL, which is very well received by our customers, because what they want is to have the full portfolio of concentration, not only one strength. And last quarter, in 2021, we launched also the 5%, and we have seen since then, also, a lot of traction in adopting the FlexBags.

Among all the benefits that the Albutein FlexBag has, it has that improved portability and storage versus vials. We have seen the example from Bill. Also, it's not breakable, easier to use, and it's environmentally friendly. All these features and characteristics of the FlexBag and Albutein are reflected in the US for its adoption, with a 5% introduction, as I said, at the end of the period in 2021. This has been tracking, having a lot of traction, and now we're forecasting 18% of the total sales of albumin in 2022 coming from the FlexBag.

And also, to share with you that, since its launch, more than 900 hospitals in the US adopted also these FlexBags. The product is moving very, very well, and we're very proud to share this with you as well.

And just to finish now with the therapeutic areas, as I said, in haematology we have been also innovating. We launched last year, sorry, no, two years ago, Tavlesse in some markets. Tavlesse is one

of the only non-plasma products that we have in the biopharma portfolio, because we also have the TV bags in the US.

Tavlesse was approved for the treatment of the chronic ITP for adult patients. It has been doing well in markets where we have launched. That was Germany at the beginning, and then we continue with other areas in Europe, Italy, Spain, and it has been really even exceeding expectations of the volumes that we were forecasting.

But also, something for us beyond the numbers and the figures and the good performance that Tavlesse has, something that is a clear message that we want to convey to you, is that we have been showing that Grifols is prepared to commercialise products that have non-plasma. We are very, very unique in plasma, and we know what we are doing, and we are very good on that. But in non-plasma, we didn't have a lot of experience then. Our experience with Tavlesse is showing us that.

We have been launching during pandemic and post-pandemic, negotiating price and reimbursement with the health technology agencies. We will know how difficult it is, and mainly after the pandemic, but we have been working very well and also competing here with big and very well established regular pharma, let's say, not the plasma. And we feel good that we are prepared for that. This has been an example for us that, if we can do it with Tavlesse, we can do it also with many other products.

Then, again, meeting our targets for launch. After two years in Germany, things are on track, going very well, and as I said, also exceeding expectations after launching in Italy and Spain.

And also, with the awareness that we have done, and also the advocates that are the TOLs, Tavlesse has been included in national and international guidelines for its use.

And the last innovation that we have been including in the haematology therapeutic area is the fibrin sealant. And fibrin sealant, as I said, it's a product that we manufacture in Grifols, but we sell through a third party that is Ethicon. We are in the third year of the launches. You can see that 2020, we started the launches, 2021, 2022, also it's going very, very well. 2023, they are also expecting to launch in other geographies and completing the Asian Pacific and other European markets, including Spain.

And also important to highlight here that we keep working with Ethicon. There is already approved a second protein in the US market to start commercialising, and also both companies have been working with new products in the bio space. It's a partnership that started very well. We have double-digit growth, and the launches with VERASEAL and Vistaseal, the fibrin sealant, and the good partnership continues with new products on the pipeline in the portfolio.

Here I'm finishing with what are the good examples on the therapeutic areas with the new launches that we did, and how all of them are performing well and supporting the growth of the biopharma division.

And now, Bill will present more potential growth that we have in this area, because everything that we have seen, and based on the data that he will share with you, what we are treating is just the tip of the iceberg. If you see in every single therapeutic area, we can do much more work to support the community in identifying patients, in treating well, in being compliant in the treatment that they get. Then you will see it now from Bill. Thank you, Bill.

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Bill Zabel, EVP Commercial Operations
Thank you, Joana. Thank you so much.

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Joana Sàbat, SVP Global Marketing & Market Access
Thank you.

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Bill Zabel, EVP Commercial Operations
Thank you, so we're going to transition now from the first half of our presentation, where we talked to you about our portfolio of performance, and Joana, thank you for that.

You notice how we show up in the market, we're talking about solutions versus products, right? And we're organised by therapeutic area, with that discipline and focus on those specialists now. We're going to transition, and we don't have a lot of time, but we can talk on break, too.

Some of these topics, we've talked with the clinic immunology side for a weekend in Boston about just one slide here that you'll see. We have four examples. We'll probably mention three today, because we'll close on time here, but let's start with what we're doing to raise awareness, educating. Recognising, as Joana said, there's more we need to do as Grifols to help support truncating time to diagnosis.

And so we're so excited when Antonio comes up to stage next, about our diagnostics company, we're one Grifols with a lot of different assets and expertise, right? So diagnostics complements what we're doing on the biopharma side, and you're going to hear from Antonio some of the tools he has that support those efforts in our strategic pillar, truncating time to diagnosis and treatment.

Now, if we turn to primary immunodeficiency, if you're an immunologist, and I would step back here and say, for the United States of America, I'm embarrassed. According to the National Institute of Health, it still takes us 12.4 years on average to diagnose somebody in the United States with primary immune deficiency. They're stuck in our healthcare system, Fred Modell would say. They're stuck in our healthcare system.

If we look at the world's population, perhaps, 70 to 90% of people with an underlying condition called primary immune deficiency don't know they have it today. And they're probably presenting in our healthcare system with repeated infections. Let's reflect back on the US market. If I'm an investor, I want to know this. And we've had this. Clinical immunologists and fellows, and you can argue this all day long. Look at your [short gap in audio] times. We've been doing this for three decades.

Gamimune was the first intravenous immune globulin, that was launched in 1981, and as Joana made mention, we've made significant progress. And there's people that will write to Grifols saying, 'Thank you so much for saving my life.'

However, there's so much more work we need to be doing in this space. If there's 500,000 Americans yet to be diagnosed, and you're an investor and you say, I want to discount that by 80%, I don't believe the number, and you could talk to clinical immunologists, you could talk to fellows, but let's say there's 100,000 Americans.

I'm 80kg. If my dose and my insert is 300, 600mg per kg, I get a half a gramme, I'm getting a 40g dose every month. If I get infused 12 times a year, that's 480g, as an adult patient. Let's discount that to 400. If you agree there's 100,000 patients in the US market, and we've been doing this for a long time, and you agree with our strategic imperative that we've got to raise awareness and educate in a collaborative with our diagnostics groups and biopharma and our immunologists, you've just increased the size of this market 100,000 patients, an average dose of 400g per year, 40 million grammes.

It's just the tip of the iceberg. If you're in front of one of our specialists, whether it's in Alpha-1, we'll talk about, or immunodeficiency, it's just the tip of the iceberg. And yes, we've said this to you before, and we're making notable progress. Every year you see our growth.

The reality is, you've got patients like Jeffrey Modell, that in 1986 lost their life to primary immune deficiency at the age of 15. This was his picture taken at camp, and Fred and Vicki, his parents, knew by sending him to a camp he may come home with an infection. And if Vicki Modell had to say something about Jeffrey, they would say science hadn't caught up with Jeffrey.

However, today Grifols could be part of that solution. An immunologist at an academic teaching hospital did an interview with Grifols. He said to us unaided, 'There is no better time in history, there is no better time in history to truncate time to diagnosis and treatment of primary immunodeficiency.'

If you want to pooh-pooh the 100,000 patients, let's say there's 50,000. It's still an incremental 20 million grammes if you're an investor. There's more work we need to do here, and we're doing it at Grifols, because our focus is on creating appropriate demand for our brands.

We're mindful of our competition, but there's a lot more growth within what we're currently doing today, and you can say that Joana and I equally excited about the team that's going to present to you this afternoon. We've got a great pipeline that's coming. R&D investments, innovation. However,

with what we have today commercially, we're giving you a few examples, and we could talk over lunch about some of these opportunities.

Matter of fact, we could use your help. If you're in Boston or New York, you've probably seen some of the signs. "When I grow up, I want to be a fireman." We know some of these patients. They were this big when they said that. They're now firemen in Boston. We can do this if we work together.

Second example's in secondary immunodeficiency. César is going to talk to you about what we're doing in this category. Like my sister, who had cancer, with targeted therapies now, and thank God they were targeted, they obliterated her B cells, including her normal B cells. They created a hypogammaglobulinemia, a primary immunodeficiency. She couldn't fight infection. She was repeatedly sick, until she got IG.

Grifols thinks we're uniquely positioned to help in that category, from César, taking a new medicine, an important new medicine like Xembify, and looking at the role that perhaps Xembify can play in a market like the United States with an FDA licence, and chronic lymphocytic leukaemia, or CLL. This market's growing, Joana would say, probably the fastest growing segment in our market, at 10%, and we could be part of that solution.

Alpha-1. And Joana, if you could just get that folder on the table, that orange folder there. We always say, primary immune deficiency, that you may not see it. So I wouldn't believe it. You could just give me the folder, Joana. This is back from 2005, and we're going to talk about Alpha-1 antitrypsin deficiency.

We were in an academic teaching hospital, and they didn't know what Alpha-1 antitrypsin deficiency was. You know what we did? We took a step back and said, have you ever heard about chronic obstructive pulmonary disease? How many people have heard of COPD? Everybody. It's the third leading cause of death in the world. Third. We lost over 3 million people in 2019 to COPD.

Do you know, in fact, if you take a step back and actually test, that 1 to 5%, 1 to 5% may have an underlying genetic condition called Alpha-1 antitrypsin deficiency? When my great-uncle died of unexplained emphysema, perhaps it was Alpha-1. I didn't know that until I was tested in 2005.

The college of medicine, the Alpha-1 research programme, yes, I'm sitting here as one of your MZ patients, non-symptomatic, but when you look at my lung function, if I were to try to compete with Victor in a marathon, you would hear me breathing heavily. There's more work, but we're leading the Alpha-1 way.

But when you look at the United States of America, and we've been doing this for a long time, if John Walsh were here - And by the way, John Walsh, who led the Alpha-1 committee, it was Grifols that was asked to give his eulogy when he passed away, because of what we had contributed to the Alpha-1 community.

Nine out of every ten patients, 16.000 Americans, are yet to be diagnosed. And when Antonio comes to you about some of the diagnostics tools, we have a buccal swab, the screen. I either want to know I have a disease, or I want to rule it out. And that's only fair to those people that have COPD. And again, collectively as one Grifols, working collaboratively with these academic teaching hospitals, with our specialists, we can do that.

And finally, as we close in hepatology and critical care medicine, Joana mentioned this too. When you look at non-alcoholic fatty liver disease, and you think about awareness of that disease, that it leads to liver cirrhosis, and you're an investor, and you say, hey, could Grifols - I don't know if you've ever read the article by Harvard Business Review back in 2007. "Could you brand sand?"

We're suggesting albumin has been treated as a commodity too long. It's Albutein. It's a branded pharmaceutical, and we're going to demonstrate through clinical research, you can hear more about this, that there's efficacious use if it proves out of utilising products like Albutein in this diseases.

If yes, does the market grow at 15%? Do all boats rise? Perhaps. But our mission is to improve the lives and well-being of people and patients worldwide. If it's an incremental $4 million, is that interesting? It's interesting to us, but again, our focus is on the patient.

So, in conclusion, I hope what you walk away from this commercial presentation is an appreciation for who Grifols is. We're one team. We work side by side with Pete Allen's group, making sure we're raising awareness of the importance of plasma collection. You heard it a lot. It's an essential medicine. It's our raw material that goes into these life-saving medicines. We can't do it without these tremendous and talented people that we have from engineering and manufacturing.

One of our customers says Joana and I are just fortunate. At the end of seven to 12 months, we just get to carry this protein to our distribution channel, to patient infusion. So, Joana, I think we're well positioned, certainly in this market, to continue keeping growing. I'm going to turn it back to you. Thank you.

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Joana Sàbat, SVP Global Marketing & Market Access
Just to...

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Bill Zabel, EVP Commercial Operations
I guess we don't need this.

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Joana Sàbat, SVP Global Marketing & Market Access

No, it's the only slide. Yes, just to also share with you some of the takeaways of our meeting today, our presentation today, that we have also several plasma proteins identifying, as Bill was saying at the beginning, the normal life cycle process that any pharma product will have. Because this product, these proteins, they last for years, because the need is there, and it keeps growing.

And we said also at the beginning that this market is remarkable, important. We have essential medicines, and it's growing year by year. Bill put the example of, only in the last ten years, has been doubling, from 45 million grammes to 105 million grammes that are used nowadays in the US.

And we have these proteins ready for the physicians and the patients. Do you want to continue?

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Bill Zabel, EVP Commercial Operations
Thank you, Joana. If we look at our portfolio of products and our medicines, these strong key brands, Gamunex will celebrate its 20th birthday next year. And it was the FDA that came in when we were doing our clinical trials, years ago, and all we wanted to do was make more Gamimune. And the FDA came to us and said, hey Grifols, hey Bayer at the time, the process is the product. The only thing you have in common with your competitors is your [short gap in audio].

So we took that, and even though we were to demonstrate bioequivalence to our predecessor product Gamimune N, in primary immunodeficiency, the largest ever, and if you're from the pharmaceutical - The largest ever clinical trial ever done. 172 patients. Only head-to-head comparison that's been done in the United States. We compared Gamamune N with IVIG now called Gamunex.

172 patients, primary endpoint, sinopulmonary infections. Statistically significant. Fewer sinopulmonary infections with Gamunex than there were with Gamimune N SD. We were to prove bioequivalence. So, in our package insert commercially, we can't talk about Gamunex being a better product. I just leave you with that data.

And our second licensed indication for Gamunex was ITP. Statistically significant. Fewer splenectomies with Gamunex than another product, and I'm sharing with you today that this industry, the process is the product. How we go about doing our business with medicines is really important when you consider who you invested in. Joana?

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Joana Sàbat, SVP Global Marketing & Market Access
Yes, and also to share with you, as a commercial team that Bill and I were, that we have the commercial infrastructure to keep supporting our innovation team in bringing new proteins to the market, and we will bring these proteins to the market. At the end of the day, again, to help the physician community and of course the patient community.

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Bill Zabel, EVP Commercial Operations
Yes, thank you, and I'll go back to Fred and Vicki Modell, because they know we're here with you today, together. And Jeffrey, their son, and Fred's in his 80s, his life, and they've dedicated their whole life to raising awareness and educating. And I would encourage you, if you get a chance and make just the mental note here, if you just watch their documentary, just the trailer, it's called *Do Something*. *Do Something*.

And primary immune deficiency could be to the left or right of you in here. Alpha-1 could be to the left or right of you. You may not know it, but it may be in the waiting room. Watch that. And Grifols has engaged with those types of patient communities, and we know that we've done a lot of things, and we've made notable products, but we need everyone's support to make sure that we're delivering on that medical need.

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Joana Sàbat, SVP Global Marketing & Market Access
Exactly.

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Bill Zabel, EVP Commercial Operations
Joana, I want to give it back to you for the rest.

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Joana Sàbat, SVP Global Marketing & Market Access
Yes, and just to finish, you will see now our next presentation. Antonio Martínez will share with you how, in Grifols, we are uniquely positioned to keep identifying these patients, bringing new diagnostic tools to the market, supporting, again, physicians and patients to be diagnosed, and at the end of the day to get the treatment that we have with all these plasma proteins.

And with that, I think we can turn to the next slide. And it's also our pleasure to, sorry, introduce you to Antonio Martínez. He's the President of the Diagnostic division, and he will do the next presentation. Thank you.

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Bill Zabel, EVP Commercial Operations
Thank you.

[Applause]

[Music]

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Diagnostics

Antonio Martínez, President Diagnostic
Good morning, everyone. Thank you, Joana and Bill, not only for introducing myself but also for facilitating my presentation and the expectations that the bioscience, biopharma business has in the Diagnostic unit.

Probably some of you already know me. I have been presenting R&D in Diagnostics. Now, after the new organisation that Raimon has explained, I am taking the position of leading the Business Unit. So now I am the President of the division, and I am, under the same umbrella, the main functions of the company.

This is our new governance. There are departments that were already in the unit, like R&D, Industrial, Quality and Regulatory, Sales and Marketing, Technical Support, and Controlling. But there are new functions that now are in the same unit.

One of them is Operations. Operations is a very important function, because we have created new, let's say, tools. One of them is a Project Management Office. The aim is to - People from this office, they will be leading the different projects across the organisation. So the aim is to increase efficiency, and to deliver on time the projects or the challenges that we will have in the organisation.

This PMO will not be only for new products or new assets. The aim is also to work in projects to increase efficiency, and also, what is more important, how to grow the business. New projects that we will bring into the organisation to grow this business.

Also, alliance with key partners. You know that Hologic and Quidel, OCD, are relevant partners for us, so these relationships will be managed from Operations.

And also, we are working on a strategy. My role in this organisation is to keep the current business, but what is more important is to grow the business, so we are working on a strategy, and we have to ensure that the strategy, once it is approved, is to be executed.

Also, new aspects are in Industrial, Quality and Regulatory. Quality and Regulatory will be together. We will have the responsibility of the Quality system and the registration of our products in the different markets. This was centralised until now. Now it is in the Business Unit.

And also, Sales and Marketing. We have new functions that are customer engagement, developing materials to engage customers like webpage or other tools, but also customer experience. And the aim is to facilitate and to improve the experience of our customers when they contact us to have

information about our products, to order our products, and also the technical service, the technical support that we'll have to provide once the platform is installed in the laboratories.

And Supply and Demand Planning will be also in the organisation.

So, we are clear what is our mission. Our mission is to develop innovative diagnostic tools to be used in the laboratories, to improve the care for donor and patients.

And how will we execute this mission? We have three pillars to follow that mission. The first of them is, obviously, to consolidate the current business. We are leaders in molecular. We are a leader in plasma, in intestinal pathogens, in donors of blood and plasma.

So we have to consolidate these businesses, but also, we have to grow. We have to get out of our comfort zone, and to identify new fields and new areas where we can expand our business. So we are working on a strategic plan to see how we can grow this business.

The second pillar is supporting biopharma. We have heard in the previous presentation that we can do a huge contribution to the biopharma business unit, developing assets and tools to identify new patients that could be treated with our plasma proteins or other drugs, that we could develop in the future.

And innovation, obviously, is in the heart of the organisation. But innovation is not only in the development of products. Innovation is also in other areas, so we are trying to innovate in regulatory, I will give you some examples, but also digital transformation.

What is clear is that we have the capabilities to execute our mission. This is a busy slide, but I wanted to show all the resources that we have to grow this business. We have platforms, we have laboratories, CLIA laboratories, clinical diagnostic laboratories, in the US and Europe, so we can offer services. We have also R&D capabilities for manufacturing In Vitro Diagnostic assets. And we have also a plant in Emeryville where we can manufacture recombinant proteins, but not only for diagnostics. We can also manufacture these proteins for therapeutic use.

So this is a big asset, also how the Diagnostic Business Unit can support biopharma business manufacturing recombinant proteins.

Regarding regulatory knowledge, Grifols has a wide experience in the IVD and pharma fields, but also now we are generating new knowledge, new regulatory knowledge, going directly to the patient. We will see the example later.

We have global presence, both for sales and technical support. So we have the world, for us. We have regulatory knowledge in all the countries, and we have presence, so we can go worldwide.

And we have technologies. I have represented here some of them. You know very well TMA, the molecular platform, but also, we have Point of Care. We have products based on Point of Care. We

have Next Generation Sequencing. We have PCR. So we have all the needed technologies to be successful in this business.

So, the Diagnostic Division has reported solid growth in 2021. I have here, in dark blue, you see the regular business. In 2020 and 2021, the volume of donations has decreased, so this had an impact in the testing of pathogens you see in our molecular platform.

But emergent pathogens have been an opportunity for this platform, and in fact, in light blue, you can see the contribution of COVID testing. So, if we consolidate both, the NAT business has growth. And also, this has demonstrated that we can go out of our comfort zone, we can explore other areas like clinical diagnostics. So, in fact, SARS-CoV-2 was a way to demonstrate that we can go to hospitals, and they can run our test.

And then BTS. Even though the pandemic hit the generations, IH has growth during 2020 and 2021, and has done a significant growth, and we will see in a nice light that I will present later.

I said that the first piece, or the first pillar, is to consolidate our business. For the molecular platform, for the NAT, we have assigned two key players. One of them is CTS. CTS is the largest customer in the world for molecular testing. It is a consolidation of labs in the US. It is around 80% of the market, 80% of the US market. We have signed a long-term agreement with them, 10+ years. This will consolidate our current business in molecular.

But also, this is an opportunity for innovation, because we have a commitment with them that we have to bring innovation to the joint business. And so we will be innovating with the leading player in this field. So we will be with the right guy to develop what is needed in the future.

And also, this will be an opportunity for growth, because we will design new assets with them, and these assets can be used globally. So they will be our partner, our testing lab, to develop these new assets and to be expanded to other territories.

And with Shanghai RAAS, as you know, they are our exclusive distributor for NAT, and in fact this agreement is already in place and the first order has already been shipped to China.

So, in immunohematology, I said this is in constant growth. In fact, CAGR has been 8.5%. This year, the growth is double-digit, even in the US, it's in the range of 30%, so we are growing really fast in immunohaematology, and the reason is because we have a worldwide penetration. We have more than 7,000 instruments worldwide.

Last year, we manufactured 50 million gel cards. So we have the ambition to be a global leader in IH. And in fact we have probably one of the best instruments in the world for immunohaematology.

Also, a new plant is being established in San Diego for manufacturing of red blood cells. This plant will be ready next year, and we also have an agreement with Haema, so we can then supply the business unit with red cells from our donor centres.

Regarding the second pillar, collaboration with biopharma, as we have seen before, 90% of the patients are not diagnosed in the US. We have reviewed the programme since starting with Grifols in 2013. We have tested close to 1 million samples, identified around 200,000 deficient patients and 16,000 are candidate patients to our treatment.

From the economical point of view, we have done an evaluation of the return of his investment and of this programme, and it is - in ten years, this return of investment is 231%. So this is a very successful programme, not only for the company but also for the patients.

This has been a journey, because we developed the asset in 2017. It was approved by the FDA. We launched this programme in Germany. At the beginning it was used in a drop of blood, but that was not comfortable for the patient, so we developed a buccal swab, a very easy way to get the sample, and this programme was launched in Spain with great success, then in LATAM.

And finally we got approval in the US, we got approval for the buccal swab in the US, and the programme was launched in the US.

But we wanted to go even further, and we knew that sometimes the patient doesn't go to the doctor. Even the patient has the symptoms, but sometimes in the US are, let's say, respiratory problems, and sometimes doesn't go to the doctor.

So we thought, how can we reach directly to those patients, to identify if they have a deficiency in Alpha-1 antitrypsin? So we started to develop a programme, going directly to the patients. This programme was presented last year. We started a clinical trial. The FDA requested a clinical trial in 500 individuals, and it should be representative of the US population, and they requested that 90% of random people should understand the result of the genetic test. So this was a real challenge.

We have run the clinical trial. It has been successful. The rate was close to 94%, so a very successful clinical trial has been completed, and in fact it has been submitted to the FDA. It was submitted last May 2022.

This is the landing webpage for the patients. They can order directly from the webpage the asset. They will receive it at home. They will test themselves, buccal swab, and they will send to the lab, and they will receive, confidentially, a report. In this report, we will recommend the patient to go to the doctor if we identify a genetic mutation responsible of the deficiency of Alpha-1.

So this is a very innovative programme, it is a breakthrough programme. Few companies in the world have been successful going directly to the patients with a genetic test. And this is - we expect approval in the next few months. In fact, we are planning to have this before November.

So we will expand this programme to other conditions, as Bill and Joana explained before. We want to expand this programme to primary and secondary immunodeficiency, also to deficiency of antithrombin III, both hereditary or acquired, and beyond.

We have a biotest, a new product, so we can expand this, we can develop assets to identify patients that could be treated with our new developments.

And this programme has been successful for Grifols, and why not offer this tool to other pharma companies? I mean, we have huge experience. More than 1 million patients have been tested. So why not partner with other pharma companies and expand this programme?

Regarding the last pillar, innovation, there is a new regulation from the European Union for In Vitro Diagnostic. This has been a huge change in regulation in Europe and has not been good for most of the diagnostic companies, because they had to change the way they register their products in Europe.

Grifols was prepared for that. In fact, the European Union has granted a grace period to be adopted to the new regulation, but we didn't need that grace period. We were on time, even without the grace period. In fact, we were one of the first companies registering a Point of Care test.

Regarding digital transformation, we have developed new tools. One of them is Bloodstream. The other one is the Blood Typing Manager. These are middleware that will facilitate customer operations. The idea is to implement this middleware in the laboratories, so they will have all the information of all the donors and patients in a single platform, and this will be a great tool.

In parallel, we have developed a portal to communicate with our customers, so all the technical information will be, or is, in this portal. It is already working. The aim is paper will disappear. Instructions for use in our kits will disappear. We will be paperless. And all the technical information will be in this portal.

I know that I am out of time, but I think that in one minute I will try to summarise the key takeaways.

The first of them: there is a new organisation in Diagnostic. The aim is to – for the new leadership, to increase efficiency and execution. The second takeaway is, we have the assets to growth, and we are working on a strategic plan to define which is our future, and to execute this strategic plan on time and on budget.

Next, we have secured our key customers. And in fact, also, we have agreements to enter into fast-growing markets like China, with Shanghai RAAS.

We have unique capabilities to support biopharma. I have shown that we can develop breakthrough platforms to go directly to the patients and to identify new undiagnosed patients that could be beneficial for them to receive our treatments.

Also, breakthrough testing, the Alpha-1 programme. And finally, digitalisation. This is a must tool to have. We need it, and we are implementing it, and within this cocktail we will be a successful division, and we hope next year we can present the first results to you.

And this is my final slide, and the end of the session this morning, and now I pass the floor to Nuria Pascual to explain some logistics about the lunch. Thank you.

[Applause]

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you, Antonio, and thank you, all the presenters this morning. I think they have been all very sharp in terms of timing, so we are okay. We will now break for lunch. We expect all of you to be back, whether physically or online, at a quarter past two.

The idea, for those of you who are connected online, is that you can stay logged in, so there is problem on that, and then you can come back with the same session. Otherwise, you have the links and everything, and you will need to go through the process again.

For those of you here in Barcelona, in our auditorium, we'll have lunch outside, and also, if you need to work, you need a desk where you want to sit for a while, by the entrance there is a room where you can - you have connections, and you can sit there if needed.

One other thing I have not mentioned before is that, at the end of today's meeting, there will be buses going. So, at 5:00 PM, there will be buses going from here, from Sant Cugat, to the airport, and also from here to Barcelona Railway Station. If you want to use, you're more than welcome. You can let us know, any of us.

I think that's all by now. Expect to see you later. Enjoy lunch and have a good time. Thank you.

[Music]

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Lunch Break

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you all for coming back, and we will now start the afternoon session, and we will initiate with the innovation part. You will have here in this presentation Albert Grifols Coma-Cros, Chief Innovation Officer, César Cerezo, Senior Vice President for Drug Development, and then Carter Keller, who is Senior Vice President at GigaGen.

[Music]

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Innovation

Albert Grifols Coma-Cros, Chief Innovation Officer
Thank you, Nuria. Good afternoon. I hope you have enjoyed the lunch and some wine. Let's go for innovation. This is the most difficult slot, probably, because of this after lunch, but we'll try to keep the momentum.

I'm going to be very fast. All of you, last year, I was introducing all of you the Scientific Innovation Office, and this year, basically, just to tell you, to give a little bit of a picture how we are evolving, the Scientific Innovation Office, to accelerate innovation.

And we are going to go, I am going to go specifically through those three objectives that we've already done, precisely, into how we do it.

So, first of all: further evolving our innovation organisation. Raimon was already speaking about this reorganisation of the full company, and those business units, so the Scientific Office, let's say, is not less. We have already signed a little bit D……, as you can see, precisely to centre its scientific area, to let them focus on what they have to do.

And at the same time, we are also introducing that controlling and Project Management Office, precisely for that, seeking that accountability, seeking that execution that we need, seeking that efficiency in general. And this is how, precisely, we are going to meet our ambition.

Those themes, those three legs, remain almost the same, Plasma and R&D, which also includes Life Cycle Management. Discovery, coming from Alkahest with their engineering plasma proteomics and data informatics. Then we have the Discovery Recombinant, which we have here Carter Keller today. Then we have this new group called Drug Development, led by César Cerezo, and we also have, last year it was there, the Scouting Group, and Scientific and Medical Affairs.

Those groups, I need to tell you, are perfectly synchronised anyway. More than ever, they know what they have to do, but they save time. We are more collaborative than ever in between groups. This is very important. Each group knows what the others are doing, just to be more efficient, and precisely to focus, that can collaborate.

So, gaining focus and speed. We call it from past to present. How can we be faster, gaining speed? Well, having the same resources that we used to have, and these times. So basically, we need to optimise and reprioritise our R&D portfolio.

So, during this year, we have been discontinuing some of the projects that we consider are not core to Grifols. We have redesigned all of our strategy, in almost nine months, I guess. Also, with commercial participation with Joana. And then, thanks to that, we've been able to initiate two new internal projects, key projects, and then the ones coming from Biotest, that Jörg is going to explain later on.

We are adopting, or reshaping, the innovative culture. You know changing culture is not always easy, but it's a culture about discipline, and scientific discipline, let's say, but also financial discipline. This means that we need to have a clear direction. We need to justify our investments in each one of our R&D projects. And we need to be sure at the end, and we can fail, this is R&D, but at least, if we don't fail, we need to see that there is a clear return on those investments.

So, again, some other things that make up, or new things that we have. For example, unique portfolio approach. Of all those groups in the past, let's say, maybe all of them, each one of them was going to their own pipeline. We have one. And we share that one pipeline, and all of us, we need to agree on that pipeline, so that it doesn't matter who it belongs to. We focus on that, and we go there, and everybody needs to collaborate.

But, from that, obviously each area, we have notified of the bonus scheme, over those milestones, to be also very objective-focused, on milestones and on that accountability that Raimon also was mentioning, that is very important.

And last but not least, and also coming back to Raimon's presentation about those ecosystems in innovation, that we think and do believe that are very important. For example, now to give just some examples.

Digital and data. Alkahest. Alkahest, apart from these proteomic bioinformatics platform. This is going to be key. For example, yesterday at the same time exactly that I'm speaking, we were opening the second bioinformatics summit. The second summit in less than six years. That means that we used to deal with data across the organisation and the scientific area, but everyone with their data.

The second bioinformatic summit, also, was the kick off for the Centre of Excellence Data and Analysis, that is going to be based in Alkahest. With a full responsibility precisely to aggregate all of the data and be able to monetise some of this data, some of the assets, or at least needs to help the business, to our investigation, to our clinic approach, to be targeting better, to use real-world data, all these things.

For example, another example. Collaborations with China. We just closed an R&D agreement with Shanghai RAAS. We are speaking with them. We are sharing our portfolio as well. We are looking to share new clinical trials together. We are also looking with this commercial Marianne and our teams, how to move into clinical trials in China.

The Endpoint Health is another example of this precision medicine, another collaboration, César is going to talk about, so I'm not going to spend more time. Ethicon. Bio-Europe.

We are looking also how to, through the scouting team, be able to invest few money in a start-up, in the early stages, not to invest so much, diversify, low risk, but the other way, be able to follow those companies.

And I'll leave it here, to César, and through our pipeline, thank you very much.

César Cerezo, SVP Drug Development
Thank you, Albert. Hi, everyone. Glad to be here and be able to present a little bit the portfolio and the pipeline that we have ahead of us. I'm not as eloquent as Bill is. I'm going to keep transmitting excitement that we have with all this pipeline, and you'll see how and why we're excited on moving forward with this.

I would just like to first start talking about, after the integration of Alkahest and GigaGen and Biotest, we've been able to consolidate this portfolio into a single one, as Albert was mentioning before. We are glad that we can expand from plasma to other non-plasma activities and programmes. We're expanding to different therapeutic modalities, like monoclonal and polyclonal antibodies, and then Carter will explain a little bit further on that, small molecule devices and other therapeutic modalities.

But always stick to the six therapeutic areas that Raimon was mentioning at the very beginning of this presentation. Just to highlight a couple of things, I'm not going to go over it, obviously, in detail to each one, of these programmes. If you look to the left-hand side, on the Discovery, Pre-Clinical column, Phase 1 and Phase 2, earlier stages of development, that's where the development, the discovery teams, they keep doing their research in plasma. But that's where all these subsidiaries that Grifols has acquired in the last few years are making a lot of work that will bring some good fruits in the short midterm.

GigaGen and Alkahest in particular, with these small molecules and the monoclonal and polyclonal antibiotic platform.

I also want to highlight the column that you see there with the Phase 3 trials. That's just a signal of how much we are investing in innovation, having all this Phase 3 compiled and combined with Biotest and Grifols. This requires a lot of investment, a lot of dedication, a lot of focus, and a lot of prioritisation of how we're selecting those trial drugs programmes that we believe are going to move the needle into the right direction.

And then, in the far end, to the right, that's something that Joana and Bill were mentioning this morning. Building up on Life Cycle Management, customer experience, patient experience, and so on and so forth.

What I'm going to do next, in the next few minutes, I'm going to focus on the big four ideas that we're progressing notably in this year, and in the next few years, they're going to keep us very occupied. I'm going to provide a little bit of a glimpse of each one of these activities.

The first one I want to talk about is Alzheimer's Disease. This is a disease that I don't think we need to explain further here. It's a very severe, debilitating disease, progressively which dementia symptoms appear and never stop until the patient gets completely disconnected from reality and is completely

disabled. With all the impact that that has for caregivers, the patient, obviously, but then the society cost.

Unfortunately and very sadly, there is still no cure for this disease. There is a lot of research ongoing in multiple pharmaceutical companies, but unfortunately there is no therapy that has produced any benefit other than symptomatic therapy. And that's why we believe that, following what I'm going to explain in the next slide, which is the history and all the different programmes that we've been pursuing in the last few years, we feel compelled that we need to move on and kick off a Phase 3 trial as a second step for AMBAR, which is our flagship here in Alzheimer's Disease.

A few figures there, I'm not going to spend a lot of time. It's a very prevalent disease. 35 million patients worldwide. It will just keep increasing as the population keeps aging. Most of those patients with dementia, they're Alzheimer's Disease. There are other causes of dementia, but they're not as important, and they're even more difficult to treat and to diagnose.

It's an elderly-focused disease, although you'll be surprised to see how, in the last few years, there are many, many patients that have been diagnosed, especially with the boom of the plasma biomarkers, at very early stages of their life. Even patients at 50, 55, we're starting to see many patients diagnosed with Alzheimer's, so that's another very severe and urgent enemy that we need to cover.

And again, it's the fifth cause of mortality, not only that is debilitating, and is massively worrisome for not only for society but for patients and caregivers.

The history I was explaining before. Grifols and the subsidiaries that we acquire, they've been building up a very nice portfolio and a strategy behind CNS neurology overall, but then Alzheimer's in particular. The left-hand side is the discovery efforts that Albert was mentioning, primarily led by the Alkahest team in San Francisco, where they have a candidate platform and technology, where they've been able to diagnose and identify more than 10,000 proteins in plasma. And that has gone to the very root of the molecular cause of CNS, different diseases in the neurology space, and in particular Alzheimer's Disease.

There are proteins that are called chronokines, that increase or decrease with age, and that facilitates that we can build up targets and pharmaceutical compounds around these targets once they are identified by these different platforms.

We have a very solid knowledge in neurology in that side of the world, and with a very historical background, that they've been focusing on CNS activities for a long, long time.

That has led to a couple of different programmes. The first one, the first bucket I'm not going to explain further but those are the two proprietary plasma fractions that Grifols and Alkahest collaborated with in the last few years, that they have presented some positive results in small phase 2 trials. Alzheimer Disease, mild to moderate Alzheimer Disease, and Parkinson's Disease with cognitive impairment. With positive trends in the recovery of some of the functional tests.

The other leg that I want to mention, that composes this strategy, is the active immunotherapy that has been led by Araclon, another subsidiary of Grifols, that they've been focusing on the vaccine against alpha beta 40, which is one of the components of the amyloid plaque that is involved in Alzheimer Disease. And probably you read in the press release we sent out a few months ago, showing that that trial made a primary imprint of safety and reliability, and efficacy, producing a strong immune response. The team is currently working on finalising analysis of these studies.

And then you know about AMBAR. For those of you that have come here in previous years, you've heard about this AMBAR. It's a completely different way of approaching Alzheimer's Disease, different mechanism of fraction. It's a combination of plasma exchange plus albumin replacement. We believe, strongly believe, that by removing toxins from the circulation and replacing with albumin, that Joana was mentioning before, that is not a vehicle, but we believe that is a drug that has anti-inflammatory properties, we can get to a good point. And actually, we showed good results in our phase 2 trial, unfortunately not met statistical significance.

Also, the post-doc analysis in the moderate Alzheimer's patients, it was positive, statistically significant and positive.

So, with all this background, a huge unmet need, we decided to move on and launch a phase 3 trial in Alzheimer's Disease. It's going to be called AMBAR-Next. It's a double-blind placebo control global study that will have around 600 patients, with mild to moderate Alzheimer's Disease, followed up by 18 months, randomise to receive plasma exchange plus albumin replacement versus sham-control.

Again, it's a global study, with at least all the countries that you see listed there. We're finalising, as we speak, the list of countries. More importantly, the protocol has been concluded, finalised, has been submitted actually this week to the FDA, and we have a Type B pre-IND meeting on our calendars at some point in July, so start hearing feedback from the FDA. But we are very excited about this. We are expecting to have the first patient, first visit, either towards very end of this year or early next year, and we'll keep you posted on how things evolve on this aspect.

The next one is, and Bill was mentioning previously of that, is chronic lymphocytic leukaemia. We believe that this is the fastest-growing patient segment for immunoglobulins. I'm not going to detail too much, we don't have too much time, but it's a very prevalent disease in the overall leukaemia patients. It's a disease that affects primarily patients, old patients, over 70 years old. At time of diagnosis, it has, the most predominant inherent feature of this disease is that they have hypogammaglobulinemia, so that's why we believe that the use of Xembify is going to be extremely positive for these patients.

And unfortunately, it has a high morbidity and mortality, and the main reason for this is, these patients get infected very, very quickly. So the potential is there. It's a very big community and we're seeking for any indication.

And actually, again, it's a new thing that we wanted to tell you today, is that we're kicking off another phase 3 trial, robust phase 3 trial, with approximately 400 patients. It's a US-only multicentre, because

we are seeking for approval and indication in the US only. It's going to be patients with CLL and concomitant hypogammaglobulinemia, that they have recurrent or severe infections, and they're going to be randomised to receive Xembify weekly subcutaneously, plus a standard of care versus placebo. The primary endpoint would be something along the lines of reduction in major infections in this population.

Again, interactions are happening in the last few weeks, couple of months, with the FDA. The FDA gave us the green light to continue with the protocol development. We are getting feedback from them in the last few weeks, in the sense of reader responses. We're incorporating all the feedback, and we are about to send the final protocol in the next few weeks, so, expecting, again, that before the end of this year we will have our first patient enrolled in this study.

And then very briefly, and then I want to give a little bit of time to Carter to give us an update on the platform from GigaGen, we want to touch base on something that Albert was mentioning before, which is this personalised medicine that I think we will have mind. And for me, for example, that I practised many years in Spain before moving into pharma and into the US, I wish I could have had something like this when I was really practising. You'll see why.

Sepsis is one of the biggest threats for society, for patients. It accounts for almost 20% of mortality globally, and only the United States, if you see these graphs with the three big circles, it accounts for approximately 2.1 million cases per year, only in the United States.

Sepsis is a generalised infection that, when it progresses in a bad way, it can start inducing multi-systemic organ failure, and that's what you see there, the shock cases. Obviously, the numbers were reduced, and then if it keeps progressing, then it's what you have in the right-hand side, the disseminated intravascular coagulopathy (DIC). That accounts for about 6.6% of the cases in the US, based on these stats. It's very severe. It has a 40% mortality rate, and it's something that is a huge unmet need, and so far, any pharmaceutical company, any programme with any type of drug, hasn't shown any positive results.

There's no approved targeted therapy. It's just support function, support build constants, and antibiotics and things that can stabilise the patients, but not therapy that has been approved to cure these patients. And the main reason for that is, nobody has been able to really stratify those patients. I'm going to give you an example of a clinical trial that was published around 2000, if I'm not mistaken. It was KyberSept.

That was a trial that was in severe sepsis patients, with ATIII. It did not meet the primary endpoint of reduction of mortality at 28 days, but a few years after, when the same investigator did a post-doc analysis, only in patients with DIC, they found that ATIII was very positive, and actually met the statistically significant in the same endpoint that had failed in the overall trial.

What I'm trying to say is that Endpoint Health, which is our partner here, what they've been doing for the last few years, analysing thousands of samples of patients with sepsis, they've been able to develop a test that can help identify and stratify patients that have this DIC, that are at a higher risk of

having complications due to mortality from sepsis. And they've done this through an algorithm, a very novel algorithm, using 14 microRNA expression data, that they overexpress in patients with sepsis. And then, with three very validated biologically subtypes of patients of sepsis, that you see in these three little men there in the middle of the slide.

The one that we are interested in is the one that is in red, is the one that they develop coagulopathy, DIC and lucky enough, this test, again, developed by Endpoint Health, distributed by them, FDA clear and validated in the clinic in many, many patients, is able to detect this group of patients. And we are hypothesising that, by using and enrolling clinical trials of this smaller group of patients, and treating them with ATIII, we're going to be able to provide a cure for these patients, as never has been before.

The status of this so far is that we have a very solid partnership with Endpoint Health. We are supplying ATIII to conduct the clinical trials, or we will supply ATIII to conduct clinical trials. They will leverage our manufacturing capacity that Daniel was mentioning this morning. We are helping them advancing on the clinical advancement and the regulatory path, although all these activities are definitely led by Endpoint Health.

Currently we are in a state that we are waiting for their results of an observational study of around four, five hundred patients, where they are finally validating this test in the real world, in patients that have sepsis following them, prospectively and getting more and more samples. And those results, that we're expecting to come in the next few months, they will inform the pre-IND package submission that will be sent to the FDA, and also the study design of for the phase 3 study that we're about to embark on.

If everything goes well, and this is what we're hoping, again, the hypothesis, the biology, the science behind all this is very promising. The idea will be to embark on a phase 3 trial at some point, with higher endpoints of reduction in mortality in patients with severe sepsis with DIC.

And that was all I wanted to communicate with you today. I'm going to leave the floor to Carter.

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Carter Keller, SVP GigaGen
As César mentioned, I'm Carter Keller. I'm the SVP of GigaGen, and as you've seen, Grifols has a concerted effort to look beyond plasma towards new innovative therapies, to meet patient unmet medical needs. And GigaGen is a big part of that as such. Grifols fully acquired GigaGen in March of last year, and we're really excited to be a part of Grifols and to develop our programmes with their incredible resources.

At the heart of GigaGen is a really unique platform that can take an immune system, the best immune systems, whether they're human immune systems or vaccinated, immunised, humanised, animal immune systems, capture the incredible diversity of those immune systems as genetic components, which we can then recapitulate as protein therapeutics.

And we use this platform to both find exceptional monoclonal antibodies as well as to produce a brand-new class of therapies enabled by this platform and therefore unique to Grifols and GigaGen, called recombinant polyclonal antibodies.

The difference between monoclonals and recombinant polyclonals should be clear, but recombinant polyclonals look to mimic the diversity of a natural human immune response. And so, rather than one antibody directed against a disease, you have thousands of antibodies in a therapeutic mixture directed towards the disease.

Again, something you can't do without this proprietary platform. Every single step of this platform has required a tonne of innovation and is protected by multiple patents, from where we harvest the B cells of the immune system, isolate them in our microfluidic devices that we design in-house at GigaGen, and then use our molecular engineering expertise to recreate those genetic components as protein.

And I wanted to walk through one really exciting programme that we're working on right now, the recombinant polyclonal antibody therapeutics, therapeutic against hepatitis B.

Chronic hepatitis B is a huge widespread problem with significant mortality and morbidity, even with currently available vaccines and therapeutics. Around 300 million worldwide are struggling with chronic HBV, and even given current therapies, 20%of those people will go on to develop cirrhosis or hepatocellular carcinoma, HCC. And because of that, unfortunately, 800,000 people die a year of chronic HBV.

So, even though there are therapies on the market, they're older nucleoside analogues and pegylated interferon. There is a huge unmet need, and a need for more potent therapy, to address patients with chronic HBV, and that's what GigaGen is pursuing right now with our recombinant therapy.

Our recombinant polyclonal antibody therapy for HBV is derived from vaccinated human donors. These donors actually got a booster shot, and we're able to look at the immune responses that people have to that vaccine and choose only the best immune responses to the vaccine to put into our mixture. So, we take those immune cells, run them through our platform, and come out with a polyclonal antibody therapy that has thousands of different antibodies, directed towards HBV.

And because we've chosen the best immune systems, we have an incredibly potent therapy. When we look at it in pre-clinical studies, both in vivo and in vitro, what we see is that it's a thousand times more potent than current HBV therapies, and it's as potent as the most promising monoclonal currently in development today.

And the important thing to recognise is that a polyclonal response has real benefit. Because you have thousands of antibodies hitting different epitopes on the disease, you're able to cover all the genotypes of HBV, which is really important, but you're also able to address escape mutants or variants that happen when you treat HBV.

So, we're really excited about this programme. We're moving it into IMD manufacturing later this year, and then after manufacturing obviously we'll move it very quickly towards the clinic. We think it has a huge potential for patients, but we're also excited about it because it really paves the way for this new class of therapy, again, a new class of therapy that only Grifols and GigaGen can produce, these recombinant polyclonal antibody therapies.

And we can think of a lot of diseases that would be best treated with a polyclonal response. I'm sure you can too, and we've already developed therapies for different infectious diseases, immunology indications, transplant, as well as other indications we'll share with you in the future.

As an added bonus, because we capture the full immune system repertoire, we can mine that immune system for the best monoclonal antibodies. And obviously there's diseases that are defined by a specific target or a specific mechanism of action, in which it's beneficial to have a monoclonal. And so we have a couple of monoclonals in development, that we're pursuing both alone and in partnership with collaborators.

And I see the clock ticking down, so I'll invite Albert back up here to give some closing thoughts on the innovation portion of our discussion today. Thanks for your time.

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Albert Grifols Coma-Cros, Chief Innovation Officer
Thanks. 26 seconds, okay. Key takeaways, very short.

As we're saying, gaining focus and speed in our pipeline by rationalising our portfolio and adopting a more result-oriented governance. Building new innovation models in digital and data, China and precision medicine. Seeking US indication that César was telling. Leading the mild-to-moderate Alzheimer's space with AMBAR-Next, which is a confirmatory trial for our previous AMBAR programme. Partnering with Endpoint Health to treat sepsis with ATIII, this very interesting and passionate model from GigaGen's technology to create recombinant polyclonal antibody drug for a wide range of infectious disease.

And I think this is it from ourselves, and I see. And now it's clicking to another, adding seconds. Thank you very much and thank you.

[Applause]

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Biotest

Joana Sàbat, SVP Global Marketing & Market Access
Hello again. Good afternoon. For the next section of the presentation, Jörg Schüttrumpf and myself, we're going to present what is the opportunity behind the transaction in between Grifols and Biotest. I will start with that, and then I will turn it over to Jörg.

Why are we saying that this is transaction is transformational for Grifols and Biotest? Mainly it's because it will permit to maximise both companies in terms of really improving the opportunity behind the new three assets that you will see, that Biotest will bring to our pipeline, and later on to the portfolio of biopharma.

Throughout the presentation, you will see several examples reflecting how this synergy is become a booster for both those companies' pipelines, and there are several key areas that I want to reinforce at the beginning.

One of them is that it's a good fit geographically. Why do we say that? Because, if you look at the charts, Grifols has a predominant position in the US, Biotest in Europe, then this fit will really compensate both geographies, and it's good for us, for both.

Also, thanks to Grifols's size, this will permit to fast escalate Biotest projects, and you will see again some examples along the presentation, between Jörg and I.

What we provide also with this transaction: a broader reach commercially for these products. Grifols is present in 110 countries. This will help also to escalate and promote and position the products in the different geographies, especially in the US, where Grifols has a deep understanding of the market, deep knowledge, big presence. Bringing some of these products to the US, this will bring these products to their full potential, opportunity that we will have.

Another one is the Grifols strong plasma collection and fractionation capacity, that will put no limits to any demand that these products could have on the markets.

And to finish with this, what maximises the opportunities for both companies is also that Grifols R&D strong investment that will permit to accelerate some of these Biotest developments.

Then, before we get into the products, let me share again, and you have seen this in the innovation presentation today, this is the Grifols pipeline. And you have seen also in the morning, during Bill's and my presentation, that we have introduced new products to the market, the subcutaneous Xembify, Albutein FlexBag, Tavlesse. We have the partnership with Ethicon for the VERASEAL and Vistaseal, the fibrin sealant products.

We have also, and you have seen some examples presented by César, on phase 3 we have key projects for key areas, such as, we have seen, Alzheimer's, with more than 35 million people in the world suffering from Alzheimer's. Huge medical unmet need. We didn't talk, but also another key programme in phase 3 is our cirrhosis programme. The Preciosa study. There are 14 million patients in the world suffering from cirrhosis. Grifols is also trying to make an impact in supporting these patients. Another huge medical unmet need.

We have seen also the CLL program for Xembify, secondary immunodeficiencies. It is the fastest growing segment for the immunoglobulins used.

What I'm trying to reinforce here is that we have different areas where we're really growing, we're supporting with new projects. Again, we have been saying today, supporting patients, supporting physicians, huge medical unmet needs.

Another thing that we have, and we have seen also this platform, this nice platform from GigaGen. In early stages we have two companies, Alkahest and GigaGen, that will bring new platforms, new projects, these polyclonal antibodies, will support a lot, and this keeps also giving a bright future in the pipeline of Grifols.

But then if we look at what Biotest is bringing to the Grifols pipeline and the portfolio, again, this will be also three new proteins that you can see here, and you will hear a lot about the details. fibrinogen and trimodulin, these are considered precision therapies, because you are giving to these patients exactly what they need.

And another one that we're really excited about also, there is a hyperimmune for cytomegalovirus already approved on the Biotest portfolio, and they are starting phase 3 trial, you will hear from Jörg that it's going on, for a new indication for this product.

These three assets will feed perfectly with the Grifols pipeline, and it gives this more strong pipeline, robust pipeline, and a bright future for the portfolio of the biopharma in Grifols.

For the next 35, 40 minutes, Jörg and I will present what is the product, what is its background, clinical trials going on, and the market opportunity. And with that, I'm turning to Jörg, who will start with the Fibrinogen.

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Jörg Schüttrumpf, Biotest Chief Scientific Officer
Yes. First of all, a warm welcome from my side and from the Biotest side. For me it's a great pleasure today that we can here introduce to you the three new Biotest pipeline products, that Joana and me will present today. And I have to say that I, and we at Biotest also, are very excited about the great opportunity, how, together, Grifols and Biotest can capture the full value of these products.

And, yes, this is what we, in short, want to present to you. And I start, really, introducing the first product. This is fibrinogen, and this is a plasma protein and offers an opportunity to extract more value out of the litre plasma, and also expand the margins for plasma products.

What is fibrinogen? Fibrinogen is an abundant plasma protein. It accounts, alone, for 95% of all coagulation factors in the blood. It's also large and complex, and therefore it's ideally suited to be extracted from plasma. Fibrinogen promote platelet aggregation, and when it's activated, converted into fibrin, this is actually the connecting glue in the blood clots. And you can see this visualised here, on the right-hand side.

Fibrinogen concentrate is a highly pure concentration of this human fibrinogen, that can be used to safely replace, when fibrinogen is absent or deficient. And this supplementation is much faster, safer, has a greater efficiency, and also greater precision then alternatives that exist so far, which is just plasma, fresh frozen plasma therapy, or cryoprecipitates.

Fibrinogen deficiency occurs in two major forms. The one on the left, congenital deficiency, is a rare disease. This means this is an inherited disorder, and normally fibrinogen is used to treat bleeds or to prevent bleeds. As you can see on the bottom, it's really these patients have no or only very low fibrinogen levels.

The other and larger indication is the acquired deficiency. Here it's that this can affect all of us with normal fibrinogen levels. When we have a major bleeding, a massive blood loss, for example, after surgery, after trauma, or this kind of post-partum haemorrhage, fibrinogen levels can drop. And then, from all coagulation factors, the first one needed is fibrinogen. So, very often you have to substitute fibrinogen to restore the normal haemostasis, so the normal blood clotting.

One aspect in this, and to do this, and to convince, also, physicians to use fibrinogen in this setting, is a good clotting assessment. Because you have to monitor these fibrinogen levels, and what so far happened is that fibrinogen is established in places where there is also Point of Care diagnostic, and you see the most widely used instruments on the bottom here of the slide, because with this you can predict better the transfusion requirements. You also can direct very goal-directed individualised therapies, precision therapy, and improve patient outcome for these patients.

And of course you distinguish there which kind of coagulation factor is missing, and, as I mentioned before, it's the first one we think is fibrinogen.

This also has market implications but, really, this leads to more goal-oriented treatment protocols, and this field can develop rapidly.

And here we feel that, together, with the fibrinogen concentrate on one hand, and then Grifols's unique positioning in the diagnostic space, really can leverage the other expertise to bring this therapy forward and to convince people, also, to use this therapy, and expand its use.

Now, this concept of precision medicine has been already implemented in the clinical trial programme. We have two phase 3 trials. The first one is the congenital fibrinogen deficiency. Here, in this trial, it's a phase 1/phase 3 study. It's the largest clinical trial so far in congenital fibrinogen deficiency worldwide. They are treated adults and children, and the results confirm, really, the high expectations regarding both efficacy and safety.

In the first part of the trial, we could demonstrate the expectation pharmaco-kinetics. This means mirroring of fibrinogen. And pharmaco-dynamics, this means clotting. And in the second phase, the phase 3 phase, we could show also the efficacy and safety.

Altogether, 175 bleeds were treated in 36 patients, and we could demonstrate treatment success, basically, in all cases. And the study is completed so far.

The other study, in the acquired deficiency, is still running. In this trial we have two indications. One is severe spinal surgery, and the other one is pseudomyxoma peritonei, this tumour surgery. And what happened is, you can see on the right that, after, or in this surgery, you have a major blood loss. So these patients lose between one and four litres of blood, just to give you an idea. And so there comes the decision to treat.

In the surgery room, of course also fibrinogen levels are measured, and then you have the treatment with fibrinogen or standard of care, which could be fresh frozen plasma or cryoprecipitate. This is a non-inferiority study, and the good is that we already have some interim results after 120 subjects. It just came in this month. And they confirm the planned patient number, so I think that we are here on a good trek.

The recruitment is ongoing. We have now 150 of the 200 patients included. We have another interim analysis late this year, and then we expect to finish recruitment early next year.

Yes, and with this clinical outlook I want to hand over again to Joana, who will give you a little bit more insight into the opportunity behind this.

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Joana Sàbat, SVP Global Marketing & Market Access
Thank you, Jörg. I explained to you a little bit about the opportunity, but before I start, Jörg has been talking about what is a congenital indication, very rare, very few people have this congenital deficiency. But when we think about the acquired, just think, it's impossible to give a number because any of us can get massive bleeding with an elective surgery, unexpected bleeding when we have a trauma, an accident. And every single one, I hope no, but could be one of the receptors of this therapy.

Just to share that the opportunity is huge, because unfortunately, with any massive bleeding after surgery or a trauma, or an accident, the first protein that will be missing for the clotting is fibrinogen and needs to be replaced.

With that said, also, we can, if you look at this slide, you can see that it shows the consumption per capita in different countries. And you can see a very different consumption per capita. What makes the difference here in these countries? Mainly the one on the left hand, in blue, are countries where they have the indication of acquired deficiency approved, and the other ones on the right side, in grey, they don't have them. If they have the indication, countries, as you have seen, they have the adoption, they also use the clotting, viscoelastic methods, to know what will be the bleeding, what are the factors missing, and what needs to be replaced.

Here also you can see on the left side, Austria and Germany are the ones with the longer tradition in using, in having a product with an indication already approved, and also longer tradition in measuring the clot, in giving back and doing this precision therapy, and giving back what the body is needing. That is the fibrinogen. Not just giving all the blood components, just to replace also the fibrinogen.

Then, it is a good example, and also, we want to highlight here another good example. That is Canada. Canada got the indication approved in the country three years ago. Since they got the approval, they have jumped in the consumption. You can see that the consumption triplicated, just because they have the product approved.

Then, with that, this is a key indicator also that a country like, for example, US, Brazil, Australia, UK - There are many others, but I just put here some big geographies. That they don't have this product approved, then whoever comes with the indication approved, with a product approved, it can bring faith in the market.

What are these other markets using? You see in the picture, they replace the fibrinogen. They give, they don't let these patients go just because they have the massive bleeding. What they are using is fresh frozen plasma or cryoprecipitate, that has fibrinogen, yes, but also, they need to infuse much more volume to give the same amount of fibrinogen. It takes longer, of course, to infuse these products. The safety of the final product. And there are many other companies that it can bring that, of course, having precision therapy like fibrinogen concentrate, it's much more advantageous.

Then, if we look forward, and also looking at some other data that are published data, the fibrinogen itself in the market, the market could be very attractive. And it is expected to keep growing, and this is said, also, there is some published report from MRB at the end of last year, when they show, and they publish that the markets are expected to keep growing. You can see that the US keeps going around 13.5, 14%. Europe, around 6%. And this is without expecting any new product with acquired indication approved in any market.

Again, Canada is a good example. Canada, since they got the indication, they have grown 200% on the consumption of this product.

I want to share also, here with fibrinogen, that there are also other dynamics supporting the growth of the market. One of them is the expected broad indication of the Point-of-Care diagnostic tools, because these tools are the ones supporting in the emergency room. What is the amount of fibrinogen that this patient needs then?

The companies promoting these tools, the diagnostic tools, they are also promoting themselves. That means that they are increasing awareness of the importance of measuring the loss of fibrinogen and the importance of also treating the patients with the right amount of fibrinogen that they are losing.

Another market dynamic is also they increase awareness and education, that all the companies are doing for this precision therapy, how important it is to move from the old products to the new ones.

And the third one, that has been just also provoked by the pandemic, during the pandemic there has been a shortage on cryoprecipitate. That caused that, even in the US, there is no concentrate with the acquired indication approved, because there was a shortage. They were starting to use some concentrates that were available on the market. Then, what created this? The customer experience from the physician was very good, because they saw the advantage of treating with a concentrate, versus long volume from cryoprecipitate. Now, it creates also a preference from the physicians to use the final concentrate.

With that, just to share this, that we see a huge opportunity in these markets, and with that I'm finishing with fibrinogen, and I pass the word again to Jörg, that he will talk to us about trimodulin. That is the next protein.

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Jörg Schüttrumpf, Biotest Chief Scientific Officer
Yes. Here, I really want to present a unique polyvalent immunoglobulin. And today you already listened a lot about immunoglobulins, and this one is different.

It's really unique, because normally immunoglobulins, the polyvalent ones, just contain IgG, and you see this on the table on the right. There, in the usual indications like, for example, the immune deficiencies. Now, what our trimodulin makes different is, it has a high content also of IgM and IgA. And this basically makes it possible that, with this, you can also treat severe infections. It's developed in sCAP, severe community acquired pneumonia, and in COVID-19.

So, what is important about this mix of immunoglobulins, and different? First of all, they recognise pathogens, but especially IgM is also part of the innate immune system. This means it recognises pathogens which are formally not known by the human immune system, and it also especially recognises bacteria.

Then, IgM and IgA can be secreted and at present directly on the pulmonary surface. And we talk here about lung infections. So, this is really where the disease also happens.

And then there are strong anti-inflammatory effects, by acting through cellular receptors, for the immunoglobulins. They can scavenge virulence factors. For example, the lipopolysaccharides, which lead to inflammation in bacterial infections. And they bind and modulate also activated coagulation factors, complement factors, cytokines, and you know from severe infections, from sepsis, that there is often a disbalance and this somehow has to be under control to cure the disease.

Now, a little bit about the disease background. What is this severe community acquired pneumonia? It's a pneumonia acquired outside the hospital. Patients come to the hospital, and they are severely sick, so they are treated on the intensive care unit. And this affects more than 350,000 patients a year, and the mortality is very high. You see here a range from 23 to 58%, depending on the piece of literature that you are looking at.

And on the right, you can see that this sCAP comprises all kinds of pathogens. This means viruses, bacteria, and fungi, and COVID-19. So, SARS-CoV2 virus is just a subgroup or subtype of this sCAP.

So, how then is trimodulin used? Normally, when the patient is on the intensive care unit, or even before, they get causal therapy, all kinds of antibiotics or antivirals. And they get supportive therapy, to keep the patients alive. This means ventilation, hydration, vasopressors. And then the third column can be trimodulin, which is really an adjuvant therapy, and there is no comparable therapy available.

What trimodulin does, then, is, it downregulates and reduces overshooting immune-mediated tissue damage. By this, also the risk of lung inflammation, severe sepsis, respiratory shock, septic shock, and multi-organ failure. And at the end, it's not immunosuppressive, but in contrary, prevents also secondary infections. And all this decreases mortality in these patients.

This concept works. We could establish already in two phase 2 studies, one in sCAP, this is on the left side, and what you see is that, when we looked at the patients with inflammatory markers, here shown CAP above 70mg per litre, then especially in these patients we could drop mortality from 30.5% to just 13.8%, so, more than 50%.

And then, if we look a little bit closer and look at the patients who are even sicker, and also have low IgM levels, then we could drop mortality by more than, or 70%, from 36.6 to 11.8%.

We then presented this data to different authorities, to the FDA in the US, to the European Medicines Agency, to the Paul-Ehrlich-Institut, which is the German regulatory agency, and also to clinical experts. And all told us, just go ahead, do phase 3. Don't change anything on the study protocol. Just include these patients and go ahead.

And this is what, now together with Grifols, of course, we are planning to do, and to move this ahead this year.

Then, on the other side, was our COVID trial. We started this trial just at the beginning of the pandemic, and we already now have some results. Where we also see a reduction in deterioration and mortality in the stratified subset of patients with early systemic inflammation.

And also here we have good feedback from authorities, from the Paul-Ehrlich-Institut. The German government actually found this so interesting that they want to fund, or are funding, our phase 3 development, with a €29 million government fund. And we also got the guidance from the European Medicines Agency on an expedited pathway for registration.

And so, we set up two trials, phase 3 trials. This is our programme at the moment. Both start this year. The ESsCAPE trial and the TRICOVID trial. Both are randomised placebo-controlled double-blind multi-centre phase 3 trials, and both investigating the safety of trimodulin in adult hospitalised subjects.

The sCAP is our core indication, so this is also a larger trial with 480-780 subjects, depending on an interim analysis. The subjects are on invasive mechanical ventilation, and just when they got on the intensive care unit and get the ventilation, they are included in the trial. These subjects have high markers of inflammation, and these are patients which don't have COVID-19.

The COVID-19 patients are in the other trial. Here we plan to include 334 subjects. These are subjects on low-flow oxygen, high-flow oxygen, and also non-invasive ventilation, and these subjects are the ones we identified before with early systemic inflammation.

And with this, I hand over again to Joana, to show you really how we can move this forward.

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Joana Sàbat, SVP Global Marketing & Market Access
Yes, exactly. Here also, again, to present a little bit, what is the opportunity. And Jörg already mentioned about these 350,000 patients that are every year suffering sCAP in the world. But also, given the high sCAP patient population, and the important high unmet need, again, we said this morning, in every single therapeutic area, when we look at the patient populations that we're treating or looking to treat, that the high unmet medical need is huge. We have a lot of underlying opportunity, also, in this sCAP population.

Here we will say one of the synergies I was saying at the beginning of the presentation, of being Biotest and Grifols together, because Biotest, they have been presenting already this programme, previous to the deal being brought together. And they were mentioning that even only if you think 80,000 of the sCAP patients around the world, they will exceed their capacity.

Now, with Grifols, with our strong collection, fractionating, manufacturing, we are able to supply product to these 350,000, to really approach the full potential for these products. In this case, we see that we could be treating the 350,000 patients that there are worldwide.

If clinical results are positive, it will be a benefit, of course, of these patients. And also, on top of this high volume that I'm mentioning, moving from only treating 80,000 patients and the full potential being 350,000, if the results are positive, because this is a huge unmet need, we are sure that also we could have a high value for this specific immunoglobulin. Then we'll add volume and value, and this will increment absolutely the opportunity.

Additionally also, we have seen on the COVID trial that this has been really good in bolstering this project, from two perspectives. One, of course, in a strategic perspective, that has accelerated the development, and it's funded by government fundings, as Jörg was saying.

And also, because, despite there is a lot of vaccination nowadays with the COVID-19, we know that there will be still patients suffering of COVID, mainly at-risk population. Then they will also benefit at the beginning with this trimodulin product.

Another thing to take into account, if we look at the competitive landscape, I think we mentioned, I think it was mentioned also at the beginning of the meeting today by Raimon, that there is no competition for this product. It's unique. And we will look at the competitive landscape. We are saying that patients will be in the ICU with mechanical ventilation, then the only product that could come to the market, they have some antibiotics, but there is no specific product to treat this high-risk population.

Then we will add, also, value in being the unique product to treat this sCAP population, and also the COVID-19.

With that, we'll move to, we have presented two new assets, two new proteins, the fibrinogen and the trimodulin, and now we move to existing products, Cytotect, that is the hyperimmune for cytomegalovirus. But we need a new indication, and I'm going to explain at the beginning what is the disease background, and then what is the clinical trial going on.

What is the congenital cytomegalovirus? This is an infection that is a major cause of central nervous system and also sensory impairments that affect cognition. It would affect also language development, vision, hearing, from a new born.

Although the importance of this congenital cytomegalovirus infection is very evident, most of the maternal and foetal infections are not identified, and this is very much influenced because there is no treatment nowadays. There is no approved indication for this kind of congenital infection, even in developed countries. We can think about Europe, or we can think about North America.

This congenital cytomegalovirus is common, the infection, occurring in approximately 0.5 to 1% of the live births in the US and Europe, and also in the low-income populations, this rate could rise to 2.4% and even bigger.

The risk of transmission of the cytomegalovirus from the mother to the foetus is often estimated to be around 35% in the first and second trimester of the pregnancy. It's huge, and almost 10% of the new born will have problems at birth because of the cytomegalovirus infection. It is very big.

Despite the disability and the prevalence that we see with this congenital infection, it's the most prevalent one if we compare it to others that are very well known by the population, look at the foetal alcohol syndrome, Down Syndrome, spina bifida, and even HIV, these are all congenital that are very well known. But the prevalence is higher on the cytomegalovirus infection, and we can say that only 3% of the US women are aware of this cytomegalovirus infection, and also there is a lack of knowledge or awareness among the physicians. They don't really test if they are, sometimes because of the lack of awareness, they don't test if they have this infection. An approved treatment, of course, will help to increase awareness, and also improve diagnosis of this infection during pregnancy.

Now Jörg will explain about the trials and that are going on, and then I'll finish with the opportunity. Thank you, Jörg.

Jörg Schüttrumpf, Biotest Chief Scientific Officer
Thank you, Joana. Just to point it out, you see here, this is a huge medical need, and we are very happy that Cytotect, which is a CMV hyperimmunoglobulin already on the market, really, we can address this need with this new development.

What do we want to do, and how does it work to prevent the transmission from the mother to the unborn child? First of all, of course, Cytotect contains a lot of anti-CMV antibodies. They bind to the virus and neutralise it, but also, they present the virus to different immune cells. And these immune cells then stimulate, again, their own immune system.

But it's also so that anti-CMV antibodies in Cytotect are actively shuttled through the placenta of the woman to the child. This is a natural immunity process that happens during pregnancy, to prevent the child, and so the child here is prevented, or is protected, from within in a natural way.

And these CMV-specific antibodies, of course, then not only block one type of CMV genotype, but all CMV genotypes, and also all kinds of virus variants, also those resistant to virostatics, because of course this is a preparation with immunoglobulins from many, many donors in a polyclonal and polyvalent fashion.

Now, our trial design really is based on good clinical experience that we had here already. And what I want to show you is just one, a few data from a previous perspective observational study, which could show a transmission just of 6.5% when giving Cytotect, compared to non-intervention, where it's normally way above 30%. So, here, 35.2%. So this is fivefold less.

And from this kind of experience, we took and generated the study protocol. And we could adjust, first of all, inclusion and diagnosis criteria. Also, we learned that we have to accelerate. The treatments start to be very fast in these women, adjusting the dose, the right dose we use, and also the treatment intervals and how long we have to treat these women.

And with this, we set up the PreCyssion Trial: Prevention of Maternal-Foetal CMV Transmission. In this trial, we include pregnant women with a primary CMV infection, up to a gestational age 14. Because also, at the beginning, you have all these complications in these children, and the objective is to demonstrate efficacy and safety of CytoTect in this setting.

The study is a phase 3 trial. It's an open-label single-arm prospective multi-centre trial, and we use here a historical control group. Because of ethical reasons, we cannot have another control group here. We plan to include 80 subjects. 13 have been included so far, as of June 15, and the trial is about to start.

And with this, I will hand over again to Joana, for explaining to you a little bit about the opportunity, and also the opportunities of all the products together.

Joana Sàbat, SVP Global Marketing & Market Access
Yes, thank you, Jörg. Then we have seen now these now indications of cytomegalovirus in pregnancy, and we see here some figures. There is a huge number of new-borns with cytomegalovirus in the US and in Europe. It could range in between 30,000 to 60,000, if we put both geographies together, U5 and the US. And approximately, as we said, 10% of the new-born's will have problems when they are born.

Also to mention here that these new-born's, 10%, what we're talking about, of this whole population that we know, these published figures that are suffering from cytomegalovirus infection, is only the tip of the iceberg. Because the number of women that could be treated in order to prevent the transmission, and also all the complications, it could be much higher. But again, this is first numbers, just to show you that there is a huge opportunity.

The numbers could be, of course, dramatically reduced with an effective therapy, like the CytoTect for pregnancy that we have been presenting. Today also we can say that, even without an approved product, the paediatric infectious disease experts acknowledge that the hyperimmune cytomegalovirus is the only product with some antivirals that could really work for and treat these patients.

Then of course we think that an eventual approval of this product will lead to improve, also, diagnostic and treatment of these patients.

And also to remind that we were saying this morning that we have this infectious disease therapeutic area, and this will be completing the portfolio, because we already have some nice, as we said, the HyperRAB and other hyperimmunes in our portfolio.

Now, with that, we have been presenting the two new products plus this new indication, and let's see the timelines overall that we have for potential market approval of the three products.

And we can see here that, for the three of them, we see fibrinogen, trimodulin, and Cytotect, both geographies, US and Europe, 2024-2025 is expected market approval. And for Cytotect in pregnancy, we'll only mention here Europe. Same dates, more or less, because the intention we'll see in the next slide will be also eventually to go to the US, but this will be kind of an upside, when we will see the whole opportunity put together.

Here we see also some key considerations. Of course these are trials going on, and as Jörg has been mentioning, for fibrinogen, we expect everything goes well, but key considerations. Of course, in Europe, we already have the congenital indication approved that Jörg was presenting, and everything will depend on the At First trial that is going on, and the interim results we have seen, that are promising. But of course this is a key consideration to take into account.

Also, if we think about the US, we have a meeting with the FDA in the second half of this year, to also get guidance on how the clinical trial that we have going on will work there.

For trimodulin, also, some key consideration. Of course, the study duration will depend on the interim results. Jörg was mentioning two different sets of population or patients to be treated. The interim results will also mirror this. And approval timelines of the TRICOVID study, also, putting back, accelerating or not, the trial, the approval itself. And for Cytotect, it's going only in Europe, and right now that's the only trial going on, but also with the intention to go to the US, when possible, because we have seen also that it's a huge unmet need in the US.

We now look how Grifols's scale and commercial strength will be the key unfold for the full value of the presented proteins. You can see here, I mean, I can read all the figures, but first of all, it says the three of them will significantly improve the revenue per litre and the margins. And of course, the multiplied issues when we combine both companies.

You see in the red row, these are the figures that were forecasted by Biotest when they were only by themselves, but now, with both companies together, and we look at the broader sales force that we have in the geographies, also the deep knowledge that Grifols has in the US, the strong plasma collection and fractionation capacity.

When we put everything together, we see here the figures for the combination of the opportunity for fibrinogen, we're talking about in between $400 and $800 million US. For trimodulin, in between 1 to 2 billion dollars. And for Cytotect in pregnancies, we only give here what is the European opportunity, and then we have as an upside, we have the potential upside from the US, that we could estimate will be around $200 million US.

And then if we look at the potential upsides for fibrinogen, of course this will depend on if we are able to leverage in diagnostic tools that we have, as we have been saying repeatedly during the presentation, to have a unique position to do that. We are already working with a diagnostic team, with Antonio's team, to get something, and also potentially expanding to other geographies.

And for trimodulin, the potential upside is that there will be so many other indications that could be treated, sepsis and many others. But today we're presenting just the sCAP, because it's the focus of the clinical trial that is going on. Well, sCAP and also COVID as a type of severe pneumonia.

Then these are the opportunities. And just for closing, as I wrap up, some of the main takeaways of the presentation that Jörg and I have been giving today. This transaction, Grifols and Biotest, of course enhances the opportunity while accelerating also the pipeline for both companies, very important for us with these three new proteins.

Expands and also diversifies the plasma sourcing by adding 31 new plasma centres in Europe, and of course improving the footprint that we'll have in the European region. Important also to highlight that both companies, Grifols and Biotest, we have kind of the same values and also a family heritage

that makes this - we see that we can really work very well together, because we have these same values.

The unique opportunity of launching these two new precision therapies, fibrinogen and trimodulin, with expected market approval, as we said, by 2024 and 2025.

The unique opportunity, also, to boost our revenue per litre and expand margins, very important.

And of course, contributing to increase the fibrinogen opportunity by the figures that we saw, $400-800 million and also the trimodulin between $1 to 2 billion.

And, very important, and I think that you will all know that this is very important, to bring products to the markets, of course, to improve the revenues, to improve the margins, but at the end of the day, what is really important for Grifols is to continue contributing to improve the lives of our patients and bringing new products that are really supporting these huge medical unmet needs.

And you have seen this along through all the presentations, and even with these three, we see three huge medical unmet needs, and bringing these products to the market, we will be supporting patients and the physicians' community.

With that, we finish with our presentation. Thank you for your attention.

[Applause]

And I'm going to introduce, now, Alfredo Arroyo. He will present Investments in Plasma and Innovation Pipeline to Accelerate Growth and Profitability. Thanks.

[Music]

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Financials

Alfredo Arroyo, CFO
Good afternoon to everyone. Nice to see you again.

First of all, I'm going to start my financial presentation with a reminder about this industry, this plasma market, how attractive it is. You can find few industries out there with sustainable growth decade over decade. Not year over year, decade over decade. High single digits in the last two decades, and our outlook for the next decade is going to be the same.

And we are a global player in this very attractive plasma market. We are a leader in the diagnostic solutions and to screen for blood and plasma. Strengthening our global presence in China through Shanghai RAAS, in Europe now with Biotest, Middle East and Africa with Egypt, and Canada.

We are running the largest plasma centre network, more than 400 centres, in the world, and with an industrial capacity of more than 22 million litres. And, as you've seen in the previous presentation, we have clearly reinforced our pipeline especially with the latest acquisitions.

Over the last couple of years, we have heavily invested in both plasma innovation. We have spent €2.5 billion in plasma, plasma companies, plasma assets as well as in Biotest, which is the largest innovation investment so far. With this acquisition of Biotest, this will be, as we've seen in the previous presentation, a step up in our innovation pipeline.

At the same time, we are keeping up with our capex and R&D, regular R&D investments, to support our future growth. At the same time, not only we are investing, but we are also divesting in those non-strategic and non-profitable business lines, as well as we are heavily focused on opex savings.

And last but not least, we are very committed, a firm commitment, about achieving deleverage. I will come back to this point later on.

So, here the message is, yes, heavy investment, but this is going to pay off in the near future.

Just a few or a couple of slides about what happened last year, as a starting point. Especially the second half of last year, we had a decline, as you see on the screen, on revenue as well as on margins. And the main cause of this decline is the plasma volume drop, that clearly impacted higher cost per litre as well as revenues and margins, as I said, in the second half of the year, together with a higher R&D and SG&A, due to the integration of the new companies, GigaGen as well as Alkahest, and also certain inflation pressures.

This is just a snapshot about last year's growth. All divisions, we had good growth last year, other than bioscience that was constrained by plasma supply.

And then, talking about the P&L, and specifically the EBITDA, last year we had €500 million impact on our EBITDA. Basically, 80% of this 500 coming from volume. Volume that basically affected the sales, and also the fixed cost under absorption. Obviously, once these plasma volumes resume, this issue will be resolved.

More colour about the investments in plasma and innovation. Now on the screen we have, on the right-hand side, the €1 billion that we spent the last couple of years, in innovation other than Biotest, as well as in plasma, adding 136 donor centres.

On the left-hand side, the €900 million investment over a three-year period in capex. Specifically, those investments were devoted to a new 6 million plasma fractionation plan in Clayton, the world's largest purification and feeding plant in also in Clayton, the new albumin purification plant in Dublin, expansion of the fibrin sealant production facility in Barcelona, as well as upgrading the Grifols facilities recently acquired in Canada.

Biotest. We saw, once again, the previous presentation, this Biotest investment that is going to be a transformational investment. This is the most significant investment in innovation, and this investment, as you see in the numbers, is going to boost our performance through the launch of two brand-new proteins with a very high margin.

A few highlights about Biotest. Family-run business, founded back in 1946. Specialised in immunology and haematology, with a significant plasma pipeline to relaunch in the short term. Direct commercial presence in ten countries, and through distributors in more than 90 countries. Manufacturing sites are reaching 3 million litres production capacity. And they have already 31 plasma centres in Europe.

This transaction was closed last 25th April. Currently we own 70% of the capital, with 96% of the voting rights. On the right-hand side, you see the revenues of this company, a $500-million revenue company with $100 million adjusted EBITDA company.

So, those investments clearly, the goal of those investments, both in plasma and innovation, is to accelerate and support the growth and profitability.

So, where are we at right now? Since last year, we didn't release any public numbers. Through the end of, right after the Q1, we released a business update where we gave you some colour about Q1, but for the first half of the year, we're going to close the books in the coming days, this is what we're expecting.

Our best estimate is total revenues up by around 5%, at constant currency minus1%. This is mainly due to the diagnostic line. Remember that, last year, the cycle testing, the composite cycle testing, was terminated, and the COVID testing agreement was also terminated. This had a significant impact on the revenue side.

If we look at our 75 revenue business, which is biopharma, expect it to grow between 2 and 3%, constant currency, 9% at the reported currency. Clearly, this means that we have a strong FX tailwind during the first half of the year, and throughout the whole year.

Last year, just to remind you that we appointed our exclusive albumin distributor in China to Shanghai RAAS. So that happened April/May, so, when you appoint a distributor, the first order usually is a big order, because they need to fulfil their distributors and the channel. So it was an unusually high phasing, an unusually high order, in the first half of the year, that somehow made a distortion in the baseline of the first half of last year. So, excluding this, normalising this albumin phasing, biopharma is going to grow around 5% constant currency, and 11% at reporting currency.

When we take a look at the EBITDA margin, we expect it, our best estimate is that we will be in a range between 20 and 22%. Clearly a significant sequential improvement versus the H2 of last year, that I always said was 14%.

So we are back, we rebounded. We expected a significant rebound, not only first half but also in the second half of the year, basically on the back of higher plasma volumes, price increases, so they are therefore multiple available, and also positive product and country mix. Opex containment, even though we are facing, like everybody else, some labour cost inflations, donor compensation for the time being is still high. And the fixed plasma costs will decline through the volume recovery.

So, that's for the first half of the year. What about beyond? The full year and beyond. We're very confident that we're going to see a significant rebound in the top line, but I want to deliver to you a clear message. The plasma has come. You've heard about it. Revenues are coming, mainly in the second half of the year. That is going to be a double-digit, strong double-digit growth, and the margin will follow. Remember that our inventory cycle, it takes time. First step, plasma. Second step, revenues. And then margin will follow.

So, once again, significant rebound in the second half of the year. Basically, as I said, based on positive protein-geo mix, product mix, already mentioned about the SubQ, global price improvements, and the demand is stronger as ever.

And then the margins would be globally improving through the plasma volume, plasma volume will dilute the fixed cost. Also, cost savings, although the donor fees, donor compensation will still be high as well as, at least within 2022, we've seen certain inflationary pressures on size.

Now, we're going to face some short-term challenges in the leverage ratio as a result of these 2.5 billion investments in the last couple of years. We need to somehow digest this, and then basically we need to get the return of this investment. Together with an EBITDA that, even though we are now on the right track, but we are not yet, we have not yet fully recovered from COVID. So, the combination of these two will give some help with certain short-term challenges.

However, we are fully committed, and this is our pathway to the leverage. Basically it will be a combination of two things. First, this focus on EBITDA, gradual EBITDA improvement on the back of plasma collection momentum, global price improvements, underlying demand, the product mix, and lowering the cost per litre.

The other factor is our financial discipline. Basically, based on the opex savings, $100 million, the cash dividends, as we already mentioned in previous years, no cash dividends until we reach a leverage ratio below 4x. Divestments, the ongoing divestments that we committed, haemostasis line, last year, $25 million cash in. This year, we already cashed in around $5 million, but if we meet certain milestones, we can cash in up to $75 million. We have closed the production of blood bags, so, eliminating certain losses. And then we have already agreed the sale of hospital, so, our solution.

We are also going to lower, we are lowering, the capex 2022/2023, as we are already well invested. And we are not pursuing any meaningful M&A transactions.

We are all living in a very, I would say, crazy world, very complex, from the economic perspective. Inflation, interest rates, and needless to say, the complexity of this geopolitical environment. So, there

are certain, I would say, issues that all companies are facing, and if we start taking a look, if we look to review some of them, like inflation, and when can we have a negative on labour costs? But on the other hand, we have meaningless impact on energy costs.

And then the good news is, already mentioned by Peter in Peter's presentation, that inflation, what is called the consumer inflation, there were savings. Consumer savings in the States are declining rapidly, so this will be a clear incentive to come back and donate.

Interest rates, from the latest debt financing at the end of 2019. Since then, we have a highly optimised debt structure, with a low exposure to the current and future interest rate increases, since currently we have 65% of our debt is at fixed interest rate.

On the exchange rate, we are going to enjoy through the whole year, as I said, a quite positive FX tailwind in our numbers.

Regarding the conflict, Ukraine-Russia, we have no direct commercial or industrial presence, and the amount of sales in those countries are also the minimum.

Supply chain, thanks to our cross-licensing of our facilities, we have a very efficient supply management.

So now let's focus on the interest rates, so you have more colour about where we are. This, on the screen, we see 35% floating, 65% fixed. The 35% floating debt, 13% is Europe, euro currency, and 22% is US dollar coverage.

And then, just some final remarks about where we are. Again, we are very confident about what's coming, where we are today, what's coming in the second half of the year and for the next year. So, in that sense, we are quite bullish.

After the significant 2.5 billion investments in plasma innovation, this clearly will help to, on one hand, security and future growth, as well as will help to increase the profitability.

Plasma collection momentum, that's very good news. The plasma is back. The divestments and cost optimisation, we are doing also our homework on this space, divesting what is not clearly adding any value at all.

And then the financial discipline. I just mentioned that deleverage remains a key priority. But our focus is first on EBITDA, clear focus, and together with financial discipline.

And, as I said, we are ready to respond to the current macroeconomic issues that we are all facing.

And with that, now I am going to hand over to Victor Grifols Deu, our co-CEO.

[Applause]

[Music]

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Final Remarks

Victor Grifols Deu, co-CEO
Thank you, Alfredo. Well, the session of today, it's approaching to the end. And this is the final presentation for today, and then of course we'll hold the Q&A session with all of you.

I hope that, so far, all the information, data, materials that have been presenting to you all have been interesting for you, and you have appreciated that all of them are really great for the company.

I have titled my section, this one, delivering on commitments that we outlined in the last two years, in 2020 and 2021. For those of you that attended last year's Capital Markets Day, in my section, I basically started, and went through all of that. Basically, mentioning that, in the pharmaceutical industry and precisely in the plasma industry, you need to excel in four basic pillars.

The first one is plasma procurement. The second one is engineering and manufacturing. The third one is commercial operations. And the fourth and last one, and really, really important, is innovation. And in that presentation, I stated that, in the first three pillars, of plasma, manufacturing and engineering, and commercial operations, I think Grifols is in line with our peers in the sector, some of them even being kind of leading positions, providing manufacturing and engineering.

And I admitted that at Grifols, maybe, innovation was not at par to our peers. And the message I tried to transmit to you last year was that we will change that, and we want innovation in Grifols to be at the same high, high level as the rest of the three pillars. And probably you have seen it, and I think last year already you realised that innovation was a structural piece on our whole package that we presented to you.

And, in a way, I think this has been the same for today. So I will explain to you, I will try to reinforce the message that now Grifols is delivering on our commitments, on our promises.

And the other one that I mentioned that I wanted to give a boost or to reinforce, is our core, through making sure regarding profitable businesses, focus on businesses that are really core for the company, and kind of discontinuing or divesting the ones that were either not profitable or not good for us.

And the third leg, this is a new piece, probably, to you all, is the new organisation. You have seen it. Raimon has presented that. You have seen new people on the stage that probably you didn't know from Grifols in the past.

So, regarding innovation, we have this great ecosystem across the globe, from Barcelona to north of Spain in Bilbao, now in Germany with Biotest, our hub in Dublin, North Carolina, and the west coast of the US with the two sites, one in San Francisco and the other one in San Diego for diagnostics.

And this great ecosystem, with this new approach that Alberto and the team have explained to you, is really delivering on our promises, on our commitments, on boosting for Grifols's innovation piece. You have seen examples.

On both sides, new additions, and as important as these new additions, at least to me, is that we have reprioritised some R&D projects that were in our pipeline, which make no sense, probably, in the Grifols that we are today, for various reasons. Profitability, maybe the landscape has changed. There are other therapeutic modalities out there, so it makes no sense financially, let's say, to pursue those opportunities.

And we have discontinued, that has been said previously to me, eight of these projects that were not any more of interest for us, and it is a consequence when you focus your team on the projects that really matter for you, and on top of that you get savings from discontinuing all those activities.

And this acceleration of our innovation, you have seen it. Just a summary from my side. All these new projects. Here we have seven examples, the key ones, the most important ones. The secondary indication for our gamma globulin subcutaneous. ATIII in Sepsis. AMBAR, continuing this journey in this very, very complex disease where now, there is no real treatment out there. We are giving a boost to our GigaGen platform. This is beyond plasma. It's in the plasma space, but it's beyond plasma, clearly.

And then fibrinogen, this exciting project for us. You have just seen, two presentations ago, what a great potential that is has for patients and for the company.

From those seven projects listed here, Xembify has been really accelerated last year, so, delivering on my words from last year. ATIII is really new. That's an indication that, one year ago, was not existing in Grifols. AMBAR-Next has been an acceleration. This year, GigaGen, they accelerated to prove the platform with COVID. This has helped them to understand better the platform, and this has accelerated our hepatitis B project there.

And clearly fibrinogen, trimodulin, and hyper CMV gamma, it's new projects to Grifols. So I think this clearly testifies, it's a testimony of this commitment from now on, we started last year, on accelerating on innovation.

Then, reinforcing our core. Raimon has said it, and Dani has highlighted as well in his section. I think, regarding the core, meaning manufacturing and plasma procurement, the assets, the real things that you can touch that we have, are here. It's real. 400+ plasma centres. Beyond US. I think Grifols is well positioned in that kind of geographical diversification regarding plasma procurement. You know the story of Europe for us. We started three years ago with Haema. Now these kind of novel approaches regarding getting plasma.

In Egypt it's a reality. In one year, under COVID, we have been able to set the regulation in the country together with the government, and to open, we were there last November to inaugurate. It's real. There are beds, there are people, there is already activity, just in one year. And in a pandemic, that's amazing.

And regarding manufacturing sites, Grifols, I think, is well known for capacity and engineering. And Biotest has nothing more but adding additional capacity to that, so I think, on here, our core is more than ever really reinforced.

And regarding geographical footprint, when you will join Grifols and Biotest, Biotest and Grifols, it's a perfect fit. We have a strong presence in the US, while they don't, and they have a strong presence in certain European regions where Grifols was not really active. So, again, perfect fit from a geographical standpoint, in this case on the commercial field.

Then, if we move back to diagnostic, Antonio has stated, now we are in this stage of redefining ourselves in diagnostic. We are defining nowadays, as we were speaking about, the future strategy of the company, but we have solid, solid, solid fundamentals on the current businesses that we have.

He has mentioned the CTS agreement, the largest customer worldwide. We have secured a long-term agreement with them, that will not only bring commercial upsides for us, but as he mentioned and pointed out, potential nice development together.

With our important customer, and then the agreement with Shanghai RAAS to enter our DMA technology clearly in the plasma space in China.

Bio Supplies. That's a new division. I think it's four years old, maximum five, I think. The progress is fantastic. This year, we just incorporated into this adventure Access Biologicals. We already had 50% stake, now we have the remaining 50, now it's a reality. It's a Grifols company, and it's nothing but adding energy and know-how and portfolio to Grifols. Here you see the progression, from 18 to 21, 2.6x this business has increased, the business that started really from scratch.

And, very important, it's a business that delivers this very nice profitability of between 35 and 40% EBIT. So, nice growing, unmet need, and with high profitability.

Then, on optimising the business, the focus, the portfolio. I stated last year that we will do some divestments and some structural cost optimisations, and this has been done. It's a reality. We were meeting last in June '21, so, in October '21 we announced the divestment of one product line or business line, under the diagnostic division, haemostasis. This is done.

VCN, this was an R&D company that was not good for us. Interesting product, but not good to Grifols. We decided to divest that, with a good return on that project as well. Blood bags was losing money, business for us. It was in the Diagnostic Division as well. We decided to discontinue that. We stopped our manufacturing in that in south of Spain in our Murcia plant.

And Hospital Division, probably you have seen. You will see later in my presentation. This division had really disappeared from the spectrum. There's still activity there, one that's interesting. It's under 'others', you will see later on. But whatever was not interesting for us, either losing money or non-core for us, we have decided to divest. And the piece that we want to divest, it's already, it's almost done, almost done. So, again, delivering on our promise.

And cost optimisation, again, we have done it. We have an internal programme called Fit for Growth. Basically this means taking a look at departments that need to be fitted. We have done so, and the R&D prioritisation that I have just mentioned. All in all, over those two activities, we expect on an annual basis to deliver for us $100 million per year, to be sustained.

Then the organisation. This is a new piece. And by new piece, I mean this is only one month old. We announced the organisation, just Raimon and I knew about that, we announced to them about this, the organisation. It's in place. It's already working. You have seen new faces here on the stage. This is a result of this new reorganisation. Raimon has said it. We basically reorganised commercial and manufacturing. This was good in the past, but nowadays it was not working optimally.

Now everything is under one single, let's say, management or umbrella. We have created biopharma. We have separated plasma procurement. In the past, it was under bioscience. We have separated that. They are very, really, two different animals, two different stories. It's a retail business, as Peter has said, to a manufacturing partner business. Nothing to do. So this is to gain focus. We have a team now only obsessed to collect plasma at the right cost for us.

Biopharma, I think Bill stated that it's a small tweak, maybe, it's just two little words, but it's from bioscience to biopharma, indicating that we have now in Grifols appetite to go beyond plasma. By beyond, I mean plasma will be the core, no doubt, but whatever comes out from non-plasma, it's more than welcome. And GigaGen, it is a perfect example here, or Tavlesse, that is a reality.

As I have stated in previous slides, Hospital has disappeared. You will see no more Hospital division being reported, even though, as you can see under the others, between brackets, these healthcare solutions, whatever's interesting from that division has remained. Basically will remain in Iberia and mostly in Spain. Just retaining whatever was profitable.

You have seen through these different charts that Antonio and Albert presented to you, this concept of strategy, transformation, PMO. Clear. This is new to Grifols in the sense that we have created a specific department just to help the management team of each piece, in this case ourselves, Raimon and myself, to make sure that whatever is key for Grifols to be executed, from a tactical or strategic point of view, is executed. And this strategy and transformation office is the perfect body to make it happen.

This is my last slide. I will put it all, even though it's animated. I kind of segment the last five years, which are the five years that Raimon and I have been in the office. As you can imagine, it has not

been easy us both as a CEO, with all what has been going on around the world. And apparently, it's not stopping, now with the conflict in Eastern Europe. But the message here, in this conclusional slide.

Business. From 2017, pre-pandemic, we were going very well. Sales were growing at this kind of regular 8% that the industry was growing. Grifols was there with our commercial structure. Our costs per litre were for the total years of this period, really stable, meeting inflation, meeting anything. So, really delivering on that, and the consequence of that was those nice EBITDA margins around this 28%.

But unfortunately, the pandemic came, February 2020, and you know the story. I will not tell you. But we have been very resilient on that during those two years. We have done a lot to try to overcome the situation. We have executed on Egypt, we have executed on Canada, acquiring the Montreal plan. We have executed on Biotest, and so on.

Regarding launches, many, maybe examples that have been executed during the pandemic. Xembify, Tavlesse, fibrinogen with our friends from Johnson & Johnson, Ethicon. Probably I will miss some of them, but we have really made it. We have done a reorganisation in the middle of the pandemic. We have accelerated innovation. I have put to you examples.

And to come, honestly, what we have today as a company, I think, is, I want to say much, much better, but it's something different to what we started the pandemic in, February 2020. Honestly, I feel it. I think Raimon feels the same as we do, and the rest of the team feels the same.

The Grifols that we have today, it's really poised for this new era that we want to embrace. The market is there. The plasma market is there. Robust demand, it's there. Pricing environment, it's kind of positive, and the pandemic has done nothing but improve this pricing environment outside the US, because if countries need – or want these products to be in their hospital, they need to pay more for that. So the gap between Europe and US in pricing has kind of narrowed.

So, strong fundamentals. I think Bill or Joana mentioned, we are just grasping the tip of the iceberg regarding the core indications that we have. There is more underneath, underwater, and we have the right structure, the commercial one plus this perfect fit with our diagnostic team. Not many companies have the ability to have an in-house diagnostic to support the diagnosis of the diseases that they are targeting commercially.

And if we add to this solid core, our underlying business, the new projects, the new innovation that is coming, you have seen it's a reality. Of course R&D can fail, no doubt. But you have seen that we have many, many great opportunities, that if we add to this, I think the future for the company, it's to stay here for a long, long time.

And that's all from my side. Thank you so much. Thank you for you guys coming. After the last three years, without seeing real face-to-face with all of you. A thank you to the Investor Relations Team, for putting together this event with great materials. Thank you to the presenters, and we have some

board members here as well, so thank you for attending this session, and thank you to you all again for coming.

[Applause]

[Music]

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Questions and Answers

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
[No audio] … see you, and we can take your questions, and presenters can see who is asking. When you connect to Zoom, you need to introduce your name and institution, so that we can call you when it is your turn to ask the question. Okay, that's online questions.

Then, for those of you here in the room, very simple. Raise your hand. Say your name. And that's it.

So I'll try to remember the order in which you're asking. You have micros. Those are in front of you, in the lower side of the seats in front of you. You just need to press the button. There will be a red light, and that's it, you can ask your question. So I think that's more or less it. I think I had no other warnings. Let me check.

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Video Played

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. Perfect timing.

Okay, thank you all. All the presenters here? Who is missing? So, I think you are first. Do you want to start? Yes.

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James Gordon, JP Morgan
Hi, thanks for taking the questions. One question on financials and margins, and then I was also going to ask an innovation question as well.

The financial question was just on margins. I think before, you set targets for 2024 in terms of the top line of profitability, but I haven't seen the targets reiterated in the deck today. So, with things like COVID, perhaps, having gone on a bit longer, should we now assume the '24 and '26 targets that you previously set get moved out a little bit? And is that because you get the operating leverage comes

back more quickly, but the gross margin takes a bit longer to come through and to return to where it was before? That was the first question. Can you hear me all right on that?

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Alfredo Arroyo, CFO
Okay, it's true that a year ago we set up a target for 2024. The COVID impact is lasting longer than expected. However, our targets remain the same, but maybe with one year delay.

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James Gordon, JP Morgan
Thank you. The innovation question was, I know it's quite early days, but we've now got an FcRn inhibitor on the market, Vyvgart. I know there's some immunoglobulin used in treating the disease at MG, so are you seeing any impact already from Vyvgart on immunoglobulin cells in MG, and could that be a bit of a priority for what you might see for the use of FcRns for the diseases ITP and CIPD?

And maybe just more broadly, I think there was also a comment on the slides that you see growth in immunodeficiency outpacing any erosion for autoimmune. But can you just remind us how much of your sales in immunoglobulin are now people with immunodeficiencies versus autoimmune use?

And maybe if I squeeze a final bit in, could innovation of being a biopharma company mean that you try and get some more pharma-style products for autoimmune?

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Maybe you have those data now top of your head. If not, we can send them the details. But you have...

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Joana Sàbat, SVP Global Marketing & Market Access
Maybe we don't have all the data, but what we can say, it was difficult to follow your question, sorry, but if I understood well, you're asking what is the amount for our, in general, the immunodeficiencies? In general, you said?

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James Gordon, JP Morgan
For immunoglobulin, the breakdown between autoimmune versus immunodeficiency.

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Joana Sàbat, SVP Global Marketing & Market Access
Yes. Correct me, Bill, but I think it could be half and half. But with the immunodeficiencies, secondaries growing the fastest, versus all the other ones. Of course, CIDP in terms of autoimmune is also big, but when you are asking what we are seeing now, of these FcRns, the main impact is the small indication - indication of ITP and MG. Of course there is some use of immunoglobulins, but it's really small. But maybe we can provide more figures, but a big feature will be like this.

Immunodeficiencies, absolutely, primary and secondary is growing and not impacted at all. And, as we said in the key takeaways, that even CIDP, because nowadays there is still no group of the product - going on, we think we'd still outpace any erosion that could come from the alternates.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Also, if I may add to that, James, the breakdowns are very different, US and Europe, so maybe we can provide some colour on this afterwards.

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James Gordon, JP Morgan
Thank you.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Okay, thank you. Maybe now we can have one online. We have Julian Dolmar (?) with BNP. Hi, Julian. Can you hear us? We cannot hear you.

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Julian Dolmar (?), BNP
You cannot?

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Yes, now.

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Julian Dolmar (?), BNP
Okay, cool. Thank you. Good afternoon, everyone, and thanks a lot for all this very interesting presentation as always. I would probably limit myself to two questions.

The first one would relate to sales development. You have made it very clear that the collection recovery is now on track. Are you confident that your sales groove could actually return to the historic range of high single digits as soon as the back half of 2022?

And the second question relates to donor fees. It was indicated that you would now expect donor fees to start subsiding in the US. At what pace would that happen? Are we talking about something that could last maybe 12 to 18 months, and then roughly back to what they were pre-COVID? Or is it way too optimistic to see things that way? Thank you.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you, Julian. Maybe you start, Bill?

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Bill Zabel, EVP Commercial Operations
You want me to take the first half? Sure. So, we do expect, to answer your question, that we return, as we stated in our presentation, Joana and myself today, that we return to high single-digit growth. Once that plasma comes back into the commercial organisation, we have plans to grow at high single digits.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
And the donor fees?

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Peter Allen, EVP Plasma US
Yes, the question related to donor fees. This is market-driven, and so we will, right now, we'll follow the market. And our belief is that it's likely that the market is going to trend down. From a timing standpoint, it's a bit uncertain. But the fees have been very high for a couple of years, and in view, I don't see that as sustainable.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Okay, thank you. Thank you, Peter, thank you, Julian. So, here in the room. I don't think I can remember all that. You start.

Rosie Turner, Jefferies
Hi, just a couple from me, if I may. On Biotest, I think, with the acquisition presentation, you gave us some cost and revenue synergies, and I just wondered if there was any update to those numbers today, with the acquisition having closed.

And then on the new AMBAR trial, is there any timeline when we can expect to see results, whether that's an interim or a full phase 3 readout? Thank you.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you.

Alfredo Arroyo, CFO
Biotest numbers, I refer you to, as you know, in Germany is obligation to provide a high-level outlook, a high-level guidance. So I refer you to the Biotest website, and Biotest communication.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
And for the second part, maybe, César?

César Cerezo, SVP Drug Development
On the AMBAR-Next trial, I think it's a little bit premature to tell you. We haven't even gotten feedback on the FDA. Just maybe wait a couple of months, three months, maybe we can resume in three, four months and we can be a little bit more clear on what's the feedback from the FDA. It's a long trial, so we don't expect results in the short term, but I think it's a little bit premature yet.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. Tom, on the other side? There are a couple.

Tom Jones, Berenberg
Tom Jones from...

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
No.

Tom Jones, Berenberg
Working? I've got two questions, one on plasma and one on R&D. On the plasma side, we're all kind of looking at plasma collections normalising, but how far do you think the whole industry is below where demand of plasma proteins currently is? Because obviously, benchmarking where we are now versus where we are in 2019 is a bit meaningless, because demand has continued to grow over the last couple of years, even if supply hasn't.

So I guess what I'm working towards is, yes, collections are increasing, yes, output is increasing, but how long do you think it's going to take the industry to get the whole market, inventories, etc., and demand and supply back into balance? Is this a six-month project? A one-year project? Do you think it's going to take two or three years? Just some measure there would be helpful.

And then the second question on R&D, I think, without Laura Balin (?) or Veronica here, someone has to ask you a tricky R&D question. It's very clear that you've been open that your innovation has not been as strong as your competitors', and I think a lot of what you're doing, it's very clear and very obvious and very well thought through, but the bit that I think a lot of investors are struggling with is, if one looks at Grifols's historical R&D performance, everything was very slow.

What comfort can you give us that your pace of R&D, it's not so much what you're doing but how quickly you're getting it done, is going to improve in recent years? And if I look at the current example, AMBAR, AMBAR read out I think October 2018, we saw the data. And you're looking at starting another trial in October 2022. That's four years. That's quite a long time to mull over a trial design if I'm being honest. So maybe some comfort on not just what you're doing, but the pace of innovation improving for the company.

Peter Allen, EVP Plasma US
The first part of this is, relative to the industry and getting back to pre-2019 levels, from an industry standpoint, I don't focus on it. I focus on Grifols. And I look at when we will get back to our levels of collections. And our trends are there now in terms of the collections, and the amount of donors that we're seeing. We're not at exactly 2019 levels, but we are, our trends are all there.

In terms of the timing of that, with inflation being a big driver now, I would say that that's going to be helpful in terms of a tailwind for us in driving there. So I'm confident that we will be back at those levels. Specific timing, a lot of dynamics there, and I don't think I have that answer for you.

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Tom Jones, Berenberg
I guess my question's not so much about 2019. If the pandemic hadn't have happened, if normal was, say, 100 in 2019, normal in 2022 would have been 120, 125 sort of area, given the growth industry. So referencing getting back to 2019 is sort of missing the point.

The question is, how long is it going to take you and the industry to get back to where you would otherwise have been, absent a pandemic? Because the demand is kind of there, from what we can see.

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Peter Allen, EVP Plasma US
Yes, so, I'm not sure how to answer that question, to be direct. It happened. The pandemic happened. In fact, there's still waves of that out there. So, in terms of our trajectories, and driving back in terms of the performance, it's a different market. There are so many more centres. It's highly competitive, and marketing is necessary to be a big driver in all of this.

So, in terms of the trending and driving back, we are demand-driven. And so that's how we focus. The only way I know how to answer that question.

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Victor Grifols Deu, co-CEO
I need to compliment. I think, Tom, you always raise great question. I think, honestly, it has been a reset in the industry. The same has happened, I don't know, in the airline industry. I received 10 emails from Lufthansa two days ago that they don't expect to, they don't have employees. So the landscape has really changed. In the plasma space, not only collections but maybe as well in the hospital setting, postponing surgeries and so on.

So really, I think it's a reset. If the pandemic would have had only six months long, maybe your question, it's really good, but now I think it's - I think we should forget about pre-pandemic, and really, it's reset, and wherever it comes, it will come. And whoever is better prepared to get to that, the best and probably the winner, no?

And to your question about giving you confidence about, okay, Grifols traditionally has not been performing in innovation delivery, I tried to convey that message this afternoon. New organisation, new focus, new energy. You have seen here many, many new people. I can tell you, Tom, and the rest, that if a trial doesn't go on because it has failed because of the trial, not because of Grifols not executing any step that needs to be done when doing a trial. I don't know if I answered. I can't prove it. It's nothing I can bring you. But I think last year you have seen great, great progress, and this will happen when, really, it's on making the trial happen.

Tom Jones, Berenberg
Yes, perfect. And just one follow-up question on R&D. You did put them on the slides. But the Alkahest project didn't really get a lot of attention in the presentation. Should we read anything into that? Or was it just you didn't have enough time today to go over them again?

Victor Grifols Deu, co-CEO
No, we have taken out, basically, the name of Alkahest, for no special reason. In Albert's fifth slide I think it was second. When you see Discovery there, that's Alkahest, okay? And they continue with their programmes in proteomics, as they did, and so on. I don't know if we can add something on this.

César Cerezo, SVP Drug Development
There are some problems with their advancing. They're in earlier stages of development, and some others that have results that we need to consider how we're going to decide how to move forward with these programmes. But some of these clinical programmes, they are still under consideration, under evaluation, and then plus the discovery and the research activities.

Tom Jones, Berenberg
Perfect, that's very helpful.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. Let me know turn to one online. Jaime E..... (?) from Santander. Jaime, can you hear us? Yes?

Jaime E.... (?), Santander
Hi, yes, good morning. Can you hear me? I think so, yes.

Thank you very much. Two questions from my side, one regarding Shanghai RAAS. If I'm not wrong, the fiscal year ends in March. Any figure or anything you can tell us on its performance, I think it would be very welcome, because I think it's a very big opportunity you have there?

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Jaime, sorry to interrupt. Just a second. Can we put the volume up? Because it's a bit difficult to hear from here.

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Jaime E.... (?), Santander
Okay, and I will try to maybe speak louder.

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Victor Grifols Deu, co-CEO
Now it's better, yes, thank you.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Now it's better, yes.

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Jaime E.... (?), Santander
Okay. Yes, basically if you can give us any figure on the performance of Shanghai RAAS last fiscal year, that would be very useful, as I think it's a great opportunity there.

Building on this, if I recall well, in January 2023 you have the option to buy a majority stake. How do you think about that? Would that be an opportunity?

And then, regarding your deliberate commitment regarding A and B shares, do you think that there is an opportunity of collapsing both A and B shares by doing a scheme where you can raise money? Like, okay, 1 billion without diluting shareholders, and at the same time increasing the free float of Grifols, which would bring a significant re-rating. I would like to know, what do you think about that? Thank you very much.

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Alfredo Arroyo, CFO
Okay, thank you, Jaime. Regarding the Shanghai RAAS performance, as you know, it's a public listed company in the Shanghai Stock Exchange. They are outperforming. They're doing a great job. Top line growing double-digit with an EBITDA margin close to 40%. So they have around $600 (?) million in cash, so I mean, it's an amazing business.

To the second question, regarding also Shanghai RAAS, currently we are the leading shareholder. And then in 2023, we'll see. When the time comes, we'll see.

Regarding the A and B unification of these shares, this has been already on the table, and is still there, and we'll figure out what to do.

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Jaime E.... (?), Santander
Okay, thank you very much.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you for that. Now we can move to the central part. I think you were here first.

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Liam ..... BPI (?)
Yes, good morning. Two questions, two follow-ups on previous questions. The first, on plasma collections. I think they've recovered quite quickly during the first part of the year, so are you in a position to revise your targets of plasma collections for this year?

And the second question, you are quite clear regarding the possibility of not doing a rights issue right now. My question would be, under what conditions, or what do you need to happen, for you to launch an equity issuance?

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Peter Allen, EVP Plasma US
In terms of our goals for this year, we're not revising them. So we have a plan. It was an aggressive plan, and we're confident in achieving it. I missed the second. The second question was for me? I didn't understand it.

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Liam ..... BPI (?)
The second question was regarding the possibility of doing a rights issue. What would need to happen for you to do a rights issue?

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Peter Allen, EVP Plasma US
To do a…? I'm sorry.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
For us to what?

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Liam …… BPI (?)
An equity issuance. To issue capital.

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Alfredo Arroyo, CFO
It's been already discussed a bit this morning, at the initial statement. Right now we are focused on EBITDA, to clarify to everybody. EBITDA is our priority, together with the financial discipline. And we don't need capital. We have more than 1.3 billion liquidity, so that, today, is off the table.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Yes.

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Alberto, (?) Equities
Hi. Can you hear me all right?

The first question would be, you have mentioned that the EBITDA targets for 2024 and 2026 may be delayed due to slower recovery, and maybe I also have seen that you are looking to launch the products from Biotest's pipeline in 2024, 2025. That's maybe a slight delay from the original timeline. Does that imply also a delay in your commitment to lower leverage below 4x and 4.5x?

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Alfredo Arroyo, CFO
Yes. Our commitment is to deliver these to these – to de-lever the company, to these 4x, but again, as the slide said, it will take a little bit longer because on one hand we are adjusting a little bit, as you saw in Jorg's presentation, the timeline of the launch of Biotest products. And then the COVID impact, especially with the still – high compensation, it's going to take longer than expected. But, as we have

done in the past, when we had high leverage, we always came back to reasonable levels, which for us is 4x, which is disclosed in our financial policy.

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Alberto, (?) Equities
Okay, then I have a couple of questions on innovation. First, on AMBAR, again, as has been mentioned before, it's been a long time since the first readout of phase 2, phase 3 clinical trial. I want to know what has been the main reason for pursuing a new phase 3 clinical trial, whether it's the data you've seen from the real world evidence of your Ambar centres, or whether it has been discussions with EFSA or FDA. What has been the main reason to launch a new clinical trial?

Then also, for phase 3 confirmatory trial, I would say that 600 patients is not that large a sample, so if you could give us some detail on the reasons for this study in terms of size. And then also whether we could see any news from EFSA when they renew their guidelines, whether you're considering them issuing an opinion on, with the data we have thus far, or should we wait to see the results from the potential new clinical trial? Thanks.

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César Cerezo, SVP Drug Development
I'll take part of this, and then others can chime in. The decision was, as I mentioned in the presentation, there's a real unmet need on these patients. There are multiple pharmaceutical companies trying to focus on prodromic and early stages of Alzheimer's Disease, but repeating everything that the team has done, the data from the real world data centre, here in Barcelona has confirmed the data that we have from AMBAR. There have not been any major issues in any patients.

So we needed to take a decision. And Tom before was asking about, let's move forward. So we made the decision, early January, February, we've run as much as possible to make this happen as quickly as possible. We're going to interact with FDA. We've already submitted this week the pre-IND package. It was basically that we thought it was the time to make that decision. That's in terms of your first question.

With regard to your second question, we are powering the study on at 80% on reality, because it's going to be a co-primary endpoint. It's going to be like an 80% power. And that sample size is way above this power for this study. So we feel confident that, with this number of patients, at least now, again, this is all very premature. We need to hear feedback from the FDA. Then we'll reassess if we need more patients, yes or no. Depends on how they make us do the statistical analysis towards the end of the study.

We are considering, if needed, to do some other mitigation plans in terms of recalculating the sample size, but so far, with the data and the biostatistical work that we've done, we feel pretty comfortable that with this, at this point, it's enough with the sample size. It's well above power.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you.

Alberto, (?) Equities
Okay, and last question, on GigaGen. If the recombinant polyclonal antibodies finally work, and you have a full repertoire of human antibodies, and you can just pick and choose the best combination for any disease that can be treated with this, where does this leave human-derived immunoglobulin? How would you see, I mean, if GigaGen has, thankfully it's within the scope of applicable, but what would be the Grifols, if that becomes a reality?

Carter Keller, SVP GigaGen
So, what are the next types of products? I think that all the hyperimmunes are on the table, if you can improve them. And then, looking past hyperimmunes to IG, there's a lot of grammes of IG that are made. Making that many grammes recombinantly would use up all of the bioprocessing power in the world, so you would have to make something much more potent, use less of a dose. So we're studying the issue, and we've got a lot of things in development to address the issue.

Alberto, (?) Equities
Okay, thanks.

Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. We had, yes. Over there, sorry. In the back, I don't see, there is not much light, and I don't see very well. Sorry.

Elizabeth Walton, Credit Suisse
Can you hear me okay? Oh, that's very loud. Thank you very much for taking my question. I have two. First one is on plasma collection. You've talked a lot today about the donor experience being key to retaining donors coming back time and time again. Your peer has recently switched their partner for the plasma collection technology, and with that are looking to gain some efficiencies. They're claiming a 30% reduction in time for collection, and I'm just curious how you think that stacks up versus your technology that you're rolling out at the moment.

And then my second question is on pricing in the US. Perhaps you can help us understand how you see the pricing environment at the moment, from immunoglobulins. Can we expect multiple price rises this year, as we saw last year? And can you quantify those price rises? Should we think of them as being low single digits or potentially as high as mid-single digits? Thank you very much.

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Peter Allen, EVP Plasma US
I'm familiar with that technology. In fact, our organisation has been looking at that same technology as well. That's the industry I came from before I came here, and any time you're using percentages like a 30% reduction, of what? What process? What's being included in that? So, if you take the entire donor time, that's not what they're saying.

In spinning red cells, you can only do it to a certain degree, and then you begin to burst red cells. So there's a limit in terms of what they can do, from the actual centrifugation process, and from a time standpoint.

At the end of the day, for me, the donor experience is really going to be driven off of the entire experience, including when they're connected to the device. A couple of minutes might be important in the scheme of things, but over the course of basically 60 minutes or so, it doesn't have as much drive.

There are some donors who will certainly look at that and say, I want the fastest procedure in order to get me in and out. And others, and the majority, are not quite driven that way. It's about the entire donor experience.

And so we have access to that same technology if we want to do that or go that route. It's certainly a possibility for us to evaluate. We will evaluate it in setting. But from a 30% standpoint, in terms of thinking about the entire procedure, in and out of a donor, from the moment they walk in to the moment they get out, that is not a 30% reduction.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. And maybe on the pricing, Bill?

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Bill Zabel, EVP Commercial Operations

Sure. I'm assuming we're responding back to a question on IG pricing for immunoglobulins, but if there's other questions with our other products, as well - But with regards to IG pricing, we would say we provide premium value for the products, like a Gamunex and a Xembify, and a flava gamma that we put in the market. We would say, for that premium value, it probably warrants a premium price, which we enjoy today in markets like the US.

So we've also said our mix has been favourable too, if you look at what's happening in European pricing right now. And again, it's not at parity to the US pricing, but it's getting closer, and it's very favourable.

With regards to pricing in markets like the US, you've seen our behaviour before, and we've taken moderate price increases on brands like Gamunex. And certainly we launched Xembify in the US market at a premium to Gamunex. So we will look at every opportunity to create value for the market, and where we create that value, we'd be looking to take the appropriate price.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. We'll go back to online. Julian, I think you have a follow-up.

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Julian Dolmar (?), BNP
Yes, thank you for having me again. Can you hear me?

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Yes.

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Julian Dolmar (?), BNP
Yes, okay, thank you. Good. Two questions left on my side, please. One is on R&D, and more specifically, and it was not a highlight of today, but I think it was in the slide that you are still developing a subcutaneous version of Alpha-1, which apparently is currently in phase 2. Could you provide any kind of expected timeline for that product to reach the market? And I'm obviously asking the question in the context of the development of a recombinant version of Alpha-1 for, if I understand well, here the purpose is to make the life of the patient easier.

So, if you were to get to the market with your subcutaneous version, would that probably mean that this argument around convenience would be reduced from the competition? So, what are your thoughts on that one?

And the second question is on the Mexican border. Just to understand what is the timeline there. I think you communicated that maybe the order is on the desk of the judge, and maybe before her vacation. Does that mean that, if she were to sign the order, would that mean that the Mexican border would reopen immediately?

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Peter Allen, EVP Plasma US
It should. I'm not a lawyer, but once she puts out that decision, then the obligation is now on the Customs and Border Patrol to change their order. That should be done immediately.

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Raimon Grifols, co-CEO
Yes, but regarding timing, this is a court decision. The judge has to write his decision. Maybe it's before summer, or maybe it's after. We cannot either control. It's in his or her hands to really write the decision, and to make it effective, so timeline we don't know. Hopefully before summer vacation, but we depend on a third person that is not, obviously, under our control. It's obvious.

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Peter Allen, EVP Plasma US
Let's hope it's a typical US summer vacation. It's about a week.

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Julian Dolmar (?), BNP
It's better than French vacation. It's better than French vacation, anyway. That would be quickly.

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César Cerezo, SVP Drug Development
And then with regards to the timeline for the subcutaneous, it's a very small phase 1/2 study that was required by the FDA before we potentially do a phase 3. It's a pKa study, so it's very small, 15, 16 patients. We kicked it off a few months ago. Hopefully we will get some traction in terms of enrolling this. We don't have, we cannot provide yet any estimated timings about a trial.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. And we had some - Again? Yes. Oh, sorry. I had not seen you. Okay, thank you.

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Benita Grual (?), Citi
Hi, thank you. Two questions, please. You talked about, first half reported margin of about 20 to 22%. How should we think about margin evolution in the second half? Could it be higher than 20 to 22%?

And the second question is, given the price difference between the SubQ IG and IV IG, why are you targeting only 10 to 15% penetration with Xembify? Thank you.

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Alfredo Arroyo, CFO
Your first question, as you know, we don't provide any guidance. I already provided, in my presentation, high-level outlook for the top line, which is going to be, as I said, very strong, double-digit. But we don't provide guidance for the second half EBITDA margin.

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Bill Zabel, EVP Commercial Operations
[No microphone] If this is on, I can probably pick up on the second question with regards to Xembify. As Joana mentioned, we have an opportunity this year to launch the product in global markets, and we spoke at lunchtime a little bit about the history and the launch of Xembify.

I applaud Grifols for taking a concerted effort when we launched that in '19 November and if you refer back to that time in the market. The IG market was tight. So, from an ethical standpoint, when you look at the conversion factor of 1 to 1.37, we said, when is the right time to launch that IV formulation – so people can reach at the time?

We went back to our patients and our doctors, and asked them, what is an appropriate time? And that's what I quoted back today, from firstly one of our patient groups at the time. And they said Xembify is in fact an important new medicine. We did that in November of '19, it was called a soft launch, because we wanted to make sure the patients at the time had access to products like Gamunex, continued to have access to Gamunex. But we got carried away with Xembify.

We're at a commercial meeting as I mentioned before in February, in Miami, where we were training the whole sales force, to launch Xembify, and then COVID hit.

And as Peter said today, we think there's an indication that plasma's coming back, one patient at a time, one doctor at a time. And as Joana shared with you, those thousand doctors that are writing for Xembify right now, 8.7, or 9 out of every 10 patients, are coming back with Xembify.

So I think we want to grow in a responsible way. We can't be everything to everybody, but I think Grifols's commitment is that person with rare disease, and we want to honour that commitment we have, and we want to ensure, if it's your mom or dad or your sister or brother that rely on that medicine, you get it when and where you need it.

There are opportunities that we see, where it's appropriate for patients, and like in the United States with the primary immunodeficiency indication, they actually accelerate the growth. We want to leave that in the hands of the dialogue we have with the immunologists, and that patient relies on that route of administration. We do believe there's room for growth. So I hope that answers your question.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you, Bill. Do we have anybody that I'm not seeing? Oh, you had another one? Yes, sure.

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Alberto, (?) Equities
Hi, thanks for taking me back. I had a couple of questions first. On the new product launches, Xembify and the FlexBag in albumin, you have seen significant uptake. I want to know whether, how to understand this in terms of cannibalisation or substitution of your own products with a margin uplift, because it's a more premium product, or whether this is allowing you to gain market share?

And the second question would be regarding the balance sheet and the divestments you have announced, that you are divesting part of the hospital business. Are there any other assets that could be sold in the coming quarters?

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Victor Grifols Deu, co-CEO
Not really. Those were the targets that we had last year, and we have executed on them. Really, there is no more pieces regarding this.

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Bill Zabel, EVP Commercial Operations
Do you want me to start? You'll mention, and Joana and I will play back on forth on each of them, you mentioned that new product, the Albutein FlexBags that we launched in the US market. I think your question was, are we cannibalising our own business or are we getting growth from new customers? And it's a combination of both.

We've converted major academic health systems in the United States that have purchased, certainly, our competitors' bag before, and see value in Grifols's bag. And we've also had customers that relied on our vials at a lower price point, by the way, and we've converted them to our FlexBags at our premium price.

So I hope that answers your question. We're scaling our platform down, right? So we have limited ability to grow outside what we have now. When GWWO comes on in Ireland, our plan is to convert

more of our customers to the FlexBag, and we really think we have a value story we could build around the FlexBag.

Again, keep in mind, when we're competing now with a vial, we have a handful of competitors. When we're talking about a bag, we limit our competition to one other person, right? So once we have a customer that believes that there's value in the bag, then we convince him of the value of the FlexBag. And again, there's a major academic teaching hospital. We put the 5% 500mL in their hands, and they use that now. The competition doesn't have that. Advantage Grifols, right? So we look to do more of that and building that value story up. I hope that answers your question.

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Victor Grifols Deu, co-CEO
Let me add, just potentially, if this is a product that has great appetite for our customers, because it's convenient and so on, we have the capability to do the same product, the same presentation, for gamma globulins. And in this case, Grifols is the only one really able to do it. T..... now, they don't have Baxter helping them. So really, if this is a presentation that is of interest for our customers, we can do it as well in gamma globulins.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Yes.

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Marisa McCummons, MST (?)
Thank you. Obviously, I've been covering the industry for a long time, and since, I think, I was first introduced to the company, to the industry, have heard how Europe is going to increase their plasma collection through donors, unpaid donors. Do you think the recent shock, and obviously there's a huge emphasis and onus put on the US to keep on supplying the rest of the world for plasma products, do you think there's any chance of change in Europe, and they will look at having paid donors?

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Peter Allen, EVP Plasma US
Most nations are looking at how you become self-sufficient, and for a majority of that, of course, it's a percentage of that. This is a dialogue that's increasing. The conversations in Europe have been going on now for the last few years, in terms of how are we going to be more self-sufficient? We're beginning to see that, with the number of centres that are growing, that there's a commitment to this, and Grifols is demonstrating that commitment to it as well.

So, yes, I can see that Europe is continuing to expand. The question is, what percent of it is coming from the US, and how much of the US collections are being consumed by the US? Because it's a growing market as well. These things will be sorting themselves out.

Egypt took the initiative to look at being self-sufficient. Others are watching that model, and Grifols is poised in a perfect position to look at any nation that's looking at becoming more self-sufficient, Europe or elsewhere, and being supportive of that kind of approach. I think there's always going to be a balance of the amount of plasma that goes across the ocean, and as long as the laws allows that to happen, this is where we are.

I hope that answers your question.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you, and there was one more at the back.

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Elizabeth Walton, Credit Suisse
Hi, thank you for taking my follow-up. It's a question on the alpha antitrypsin competitive landscape. We've seen a lot of activity, albeit in early stages, by biotech companies looking to develop either recombinant proteins or gene editing approaches which could render Prolastin obsolete. So I realise these are early, and maybe not going to enter the market until sort of middle of the decade or later, but I'm curious as to how you're thinking about that competitive landscape evolving, and what you may or may not be able to do to mitigate some of that. Thank you.

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Victor Grifols Deu, co-CEO
Maybe, Nuria, this one can be answered by Jose.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
For their answer.

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Victor Grifols Deu, co-CEO
Alpha-1. Alpha-1, no? Yes. Jose is from...

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Jose
Can you hear me?

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Yes.

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Jose
Yes, okay. The competitive landscape for antitrypsin, we have, probably you know that Vertex has discontinued its programmes. So these and another companies - see the fact that has also a molecule that has disclosed data is not so good. Regarding the other – I mean the others that are at a clinical, let's say discovery stage, are gene therapies and gene therapies still very early. It's very challenging with the case Alpha-1, because you need very high levels of the protein, it's not so easy. And these are the main competitors, so we don't see any threat from this new biotech or more innovative disruption coming in this decade.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Thank you. So, if no more questions, we are approximately on time again, so that's good.

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Raimon Grifols, co-CEO
On Grifols time.

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Nuria Pascual, VP, Corporate Treasury & IR & Sustainability
Sorry? Okay. So, thank you, all presenters. Thank you to all your teams, because there is a lot of people who have been also helping in getting these presentations together.

We do hope you have found these sessions valuable, and we hope to see you again next year, whatever the format, whatever the place. And thank you all for joining, through online or coming here to Barcelona to the new auditorium.

So, bye-bye and thank you very much.

[Applause]

[Music]

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END