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The Transcript of Plasma Innovation Business Seminar on June 23, 2022

Ken Hata: Good afternoon. Welcome to Terumo IR day. I'm Ken Hata, head of Investor Relations. I really appreciate your coming today, either in person or virtually. So, this is another hybrid IR event broadcasted from Terumo Tokyo headquarters, inviting about a dozen guests physically in this room and a larger audience online.

So today we are talking a lot about our Blood and Cells Technologies businesses. Then when we do that, we will make sure we cover our new area Plasma Innovations as well. So this is another hybrid IR event. So, you might remember we did similar things back in December last year. Yes, GS 26.

So, is this the same old hybrid event? No, there is something new. Like I'm just doing right now, today we will broadcast communication all in English. So, sorry. It started with my bad English, but I will soon turn it over to our teams from the United States. So native speakers will take over, so no worries.

Then, this event will last about 2 hours. So first 90 minutes is a presentation including a video, then we have one break between. Then, followed by 30 minutes of Q&A.

So, with that, I'm going to invite Antoinette. I'm going to ask her to introduce herself and the team, then we will start. So, Antoinette–

Antoinette Gawin: Thank you. I appreciate the opportunity to speak to each of you personally today. I am Antoinette Gawin and began my career with General Electric in the financial side of the house, working with the corporate audit staff and mergers and acquisitions for a number of years before going to GE Information Services, where I led customer support, technical operations, and then transitioned into commercial leadership roles.

I spent time leading different businesses and joint ventures for GE in the utility sector, power systems, and in the automotive sector in different parts of the world before coming into the healthcare business, where I have spent the last 20 years.

Both with GE Healthcare leading marketing and strategic planning, as well as transitioning to Baxter Healthcare, where I led market access, commercial operations, and some global

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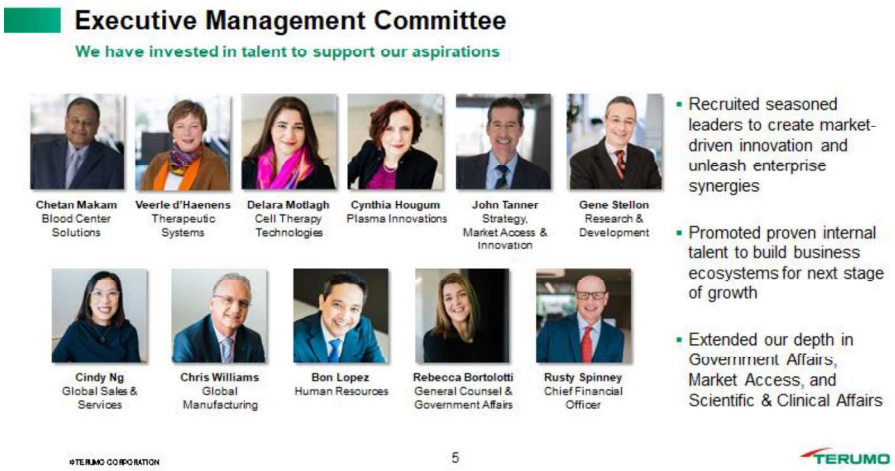
transformation programs for the CEO at the time.

So, I joined Terumo approaching my 6th anniversary. So, we will share today some of the changes that we've implemented during that time and how we have evolved through COVID in our position to grow beyond.

So, I'll first introduce my executive team before I go into that strategy. So, across the chart on the top, you see first the business area leaders.



So Chetan Makam is the general manager of our Blood Center Solutions. He has a Master's in engineering and a business degree, and spent significant time with our competitor Haemonetics before joining us to build our global services business approximately four years ago.

Veerle d'Haenens is the general manager of our Therapeutic Systems business. Veerle is based in Brussels and has a bachelor's in Chemical Engineering and spent significant time with Pfizer in the pharmaceutical space before joining Terumo, leading therapeutic systems across Europe and then serving as the regional leader for Middle East Africa in Europe, and she accepted this position approximately one year ago.

Dr. Delara Motlagh is our general manager for Cell Therapy Technologies, and Delara has a Ph.D. in Physiology and Biophysics, building off of many years of scientific research before leading Baxter's cell therapy development programs. She joined Terumo five years ago and has been instrumental in building the foundation of the cell therapy business.

Dr. Cynthia Hougum has her professional training in Chemistry and spent the bulk of her career at General Electric in the plastics division, in healthcare, launching products, leading scientific

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programs, and introducing digital ecosystems across that business. She joined Terumo just over three years ago to build our quality program and infrastructure and help us launch the plasma innovations business.

The next two individuals are not able to join us today. John Tanner has a diverse background in healthcare consulting and working with startups, and he leads our strategy and innovation team.

And Gene Stallone is our new research and development leader. He brings deep experience with the military and has spent many years with Medtronic in their surgical division.

Across the bottom, you see our delivery and support leaders. And I'll call out Cindy Ng, who–many chemists in the group-also began as a chemist, but quickly went to sales and worked for Roche and Danaher before joining Terumo five years ago. And her efforts have been instrumental in helping us return to growth around the world.

Chris Williams is the leader of our global manufacturing and delivery systems. He has 30 plus years of experience at Baxter, leading plants around the world, and then working with private equity companies to help build and optimize their production infrastructure and our support team.

Bon Lopez leads our human resource function. He's been with us for two years, bringing intense experience across Asia and the rest of the world, working for Novartis, Ortho Clinical, and other medical device manufacturers.

Rebecca Bortolotti is our general counsel. She joined us just one year ago and brings deep experience in intellectual property and technology transfer, critical as we grow in emerging markets. And Rusty Spinney is our Chief Financial Officer.

Rusty has many years of financial experience in the consumer and health areas and has been with Terumo 13 years, helping us transition both into the Terumo family and as we are building our growth plans along the way. So, you see a very global and deep experienced leadership team.

And that is necessary so we can build the right capabilities to operate in a very complex global healthcare environment. We've also built a method to promote internal talent and deepen our expertise in areas like government affairs and market access so that we can help shape the policies that affect the adoption of our products.

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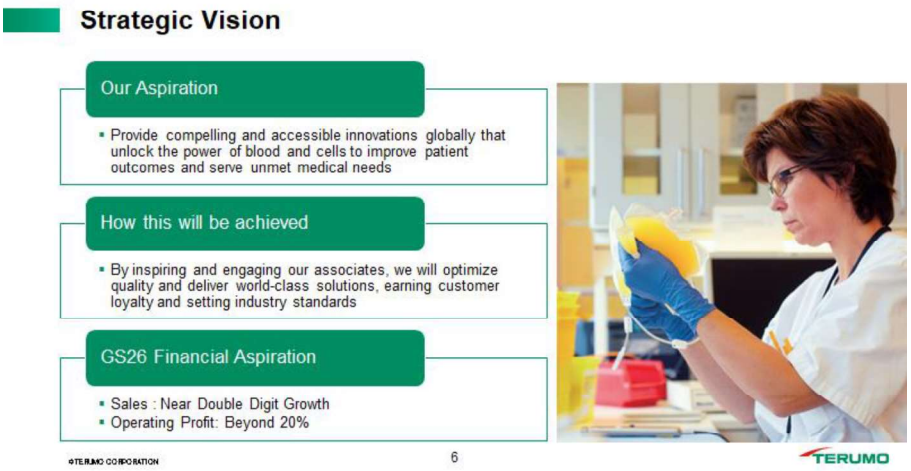

So, you heard me speak in December remotely about our Growth 26 Strategic Vision. Everything we do is anchored around serving more patients. And today, each business will highlight how we are bringing innovations to their respective areas.

And the key word here is accessible innovations. If we have great technology, but we can't get it into the hands of patients who need it, then it's a waste. So, we have built capabilities around regulatory and market access to help influence those standards of care and influence whether and how people use our products.

You'll hear about patients' unmet medical needs. As an example, there are still many people in the world who do not have access to safe blood, a simple foundation that we take for granted. And as you know, health care starts with people and purpose.

So our efforts start with our associates. And this sounds simple, but in today's environment around the world, it is more important than ever to engage your associates. If your people are not with you in spirit and heart, then it will be difficult for them to bring the best of your company to the customers and patients we ultimately serve.

This will help us earn customer loyalty and set industry standards. And those standards help us fuel growth and a continued improvement in profit.

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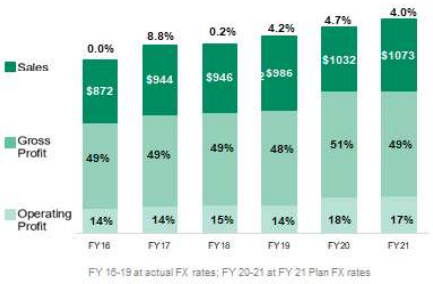
Returned to Growth – Revenue and Profit

Historical Operating Performance

US$ in Millions



FY 16-19 at actual FX rates; FY 20-21 at FY 21 Plan FX rates

Traneformational Shifts

- **Shifted investment to growth areas**
  - Diversified beyond equipment and blood
  - Built infrastructure in growth geographies
  - Sharpened strategic focus in services
- **Modernize infrastructure**
  - Optimized manufacturing footprint
  - Implemented one global quality system
  - Adopted SFDC and Service Max globally
- **Continue investing ~12% of sales in R&D**

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Over the past five years, we have focused to ensure we have predictable performance and consistently deliver on our commitments to both customers and to the different stakeholders.

We've invested in growth areas and diversified beyond our traditional equipment sales. We have built infrastructure in growth areas such as Kenya, where there is a continent that still does not have access to the basics of healthcare. And you see, these elements have helped us grow across the top line. In addition, we have modernized our delivery system and our infrastructure.

This means optimizing our manufacturing footprint, implementing a common quality system across the world, and implementing digital systems for our sales and service teams that were critical for us to operate effectively during the COVID crisis.

You see, the result of this is an improvement in gross margin, which was a direct result of those efforts. We also were able to capture price from some of our software improvements around our core products. And our objective is we continue to invest three to four times that of our near competitors in R&D, and we have to capture that value in the marketplace.

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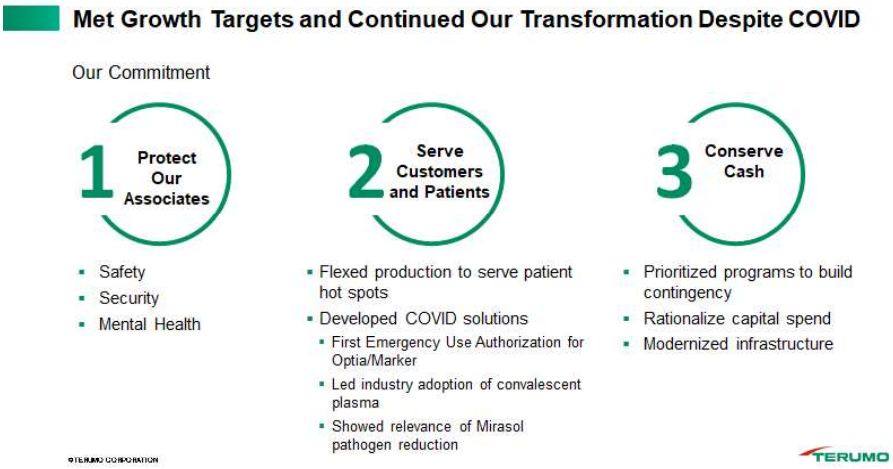

So, I will talk a bit about how we operated during COVID. COVID reinforced for us that our strategies made sense. And first, we protected our associates. So, this has allowed us to have a high retention rate. And even as there is global news about the resignation and changes in workforce, we have a high percentage of people who might leave but come back.

And that retention is critical for long-term growth. Our second priority was to serve customers and patients. So first, keeping the supply chain open. And Chris will talk about how we flexed production to really serve patient needs. But that also meant deploying our portfolio to solve COVID.

And we were the first company in the world to get an FDA emergency use authorization for the use of our Optia platform, treating patients in the ICU. We also worked closely with our customers, industry associations, and with the government to set the standard for the use of convalescent plasma in the treatment of COVID.

And this allowed us to influence the reimbursement levels so that our customers did not have to worry about losing money when they provided this therapy to patients. This showed the power of our platforms and the power of our willingness to lead in the industry.

And this has built loyalty and high retention rates amongst our customers. And the third area, of course, going into a crisis, we determined how to best conserve cash. We continued to invest in our growth programs and our modernization programs, even though they may be creating short-term pain.

So, Chris will illustrate how, despite some of these challenges, we modernized and expanded our

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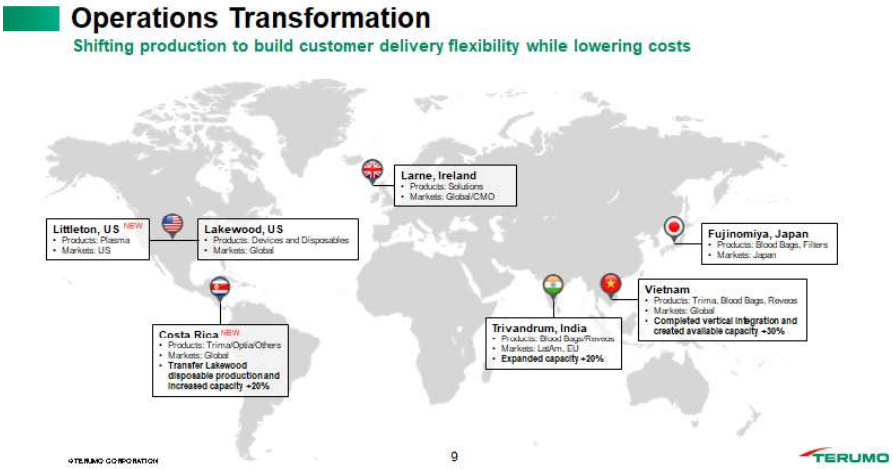
capacity to support growth.



Chris Williams: Thanks, Antoinette. Good afternoon. So, we started our global Operation Transformation program about five to seven years ago with really three principles in mind.

First of all, we wanted to add the flexibility and the capacity to serve our growth initiatives for our global company. The second principle was to have the best total delivered cost with the best quality. And third, we wanted our manufacturing network strategically located to the customers that they serve, to shorten our lead times to them.

So, this journey really began in the east with the establishment of our Vietnam factory. We have now maximized our production in that factory, as well as implemented vertical integration programs, which means that Vietnam is self-sufficient and can produce the majority of its sub-assemblies within that factory.

We also improved productivity across all of the factories that you see on this slide. We improved our productivity by over 20% over the last three years, and that allowed us to thrive during the first two years of this global pandemic.

But we're not stopping there. We wanted to look to the west now and evaluate a similar formula for the Americas to serve our customers in that region. So now we have established our Costa Rican manufacturing site that will serve both North America and South America, like Vietnam supplies Europe and the Asia Pacific countries.

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Newly Built Costa Rica Facility

Bringing the best of our global manufacturing design and processes

- Costa Rica is a proven hub for the production of medical devices
- World-class facility - increased capacity to serve global markets
- Excellent talent and supply chain infrastructure, strategically close to customers in the Americas
- Concept to full ramp in record time

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So why did we choose Costa Rica? Costa Rica has vast experience in medical device manufacturing, a very solid infrastructure, and great talent in both medical device manufacturing quality and engineering. We have built a world-class facility during the heart of the pandemic over the last 18 months, and the manufacturing plan has been in production since late 21.

And we will complete this very important initiative at the end of this calendar year. So now we have our strategic network in place, with Vietnam in the east serving those regions in Costa Rica, and in the west serving our regions in Americas.

Market Dynamics Inform Strategic Choices

Market Dynamics	Strategic Implications
Changing demographics	Donor shortages and shifts Increase in chronic disease
Disease & patient data enabling personalized medicine	Data integration expected Clinical efficacy required
Growing regulatory cost burden	Rationalize portfolio Innovate beyond equipment
Commercialization of cell therapies	Follow shift in investment: scale, logistics & patient access
Cost of care plays a greater role in healthcare policy	Reimbursement key to change standards & increase access

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Antoinette Gawin: So that work positions us for growth. And you all follow the different market dynamics. So, I highlight just a few here that are of particular relevance to the Terumo Blood and Cell Technologies business. So first, the changing demographics affect the number and type of donors that we have.

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It also affects the number of chronic diseases that people will experience. So our strategies are to follow those patients and ensure we have solutions that go through the whole continuum. So think of the fact that every diagnosis, every treatment starts with a drop of blood, and we have the beginning of that process.

You'll hear how we are following patients through their breast cancer journey. We're all familiar with the tremendous amount of disease in patient data that starts informing CAR T therapies and all the different research that's being done.

This means we have to capture our data about patients and diseases and integrate that with our equipment. You'll see in the plasma launch how we have changed the traditional model of launching a device and then figuring out how to build the software ecosystem around it. We are launching the software and the tools necessary to track that data with the device.

So it's learning from all that history. In the past, we know there's a growing regulatory cost burden and this has encouraged us to not just rationalize our portfolio. As an example, our autologous biologics business is no longer sold in Europe because of the cost of registering that product for the EU MDR.

And it's forced us to ensure we are putting services around every piece of equipment that we offer. And you'll hear examples from each of the businesses as these cell therapies become reality.

We have to follow that evolution because while we are not producing the cell therapy itself, we are providing all the tools for those developers to be successful and the tools to help them scale and follow their patients through their system.

And then the last. We all know that cost is a critical element in the healthcare systems and access around the world. So not only are we making our delivery cost-efficient, we are actively investing in government affairs, regulatory, and health economics so that we can influence the reimbursement structures around the world and increase the adoption of our products.

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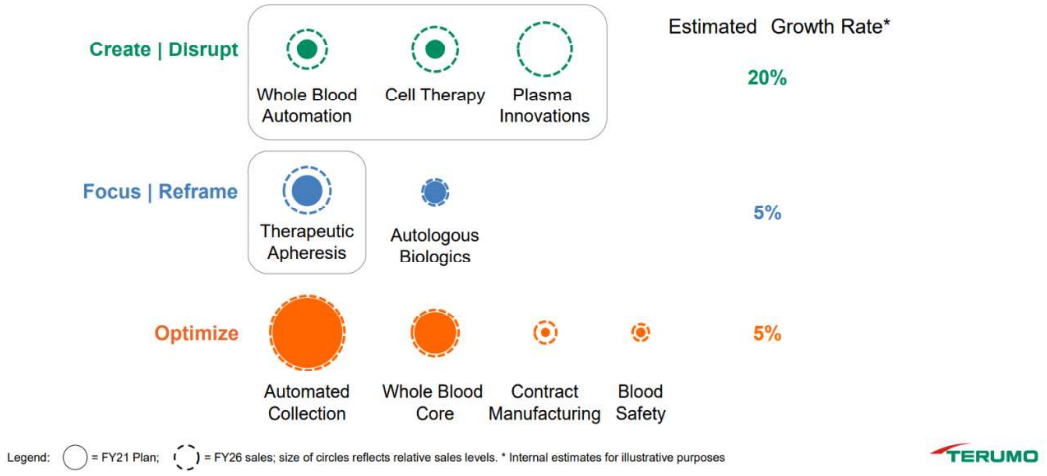
Aligning Investments with Growth Areas



So, as you look forward to expanding on how we have aligned our investments with growth areas, this is a picture of our portfolio in relative size today. And we analyzed where we see the growth. So the bottom row is our historic business area and if you could advance the slide, we looked at not just the growth rates within those areas, but how we could play. And the dotted line circle is showing that composition at the end of Growth 26. So, across the top row you see a high growth rate areas you'll hear Chetan discuss whole blood automation, Delara will discuss cell therapy and as you can see, Plasma Innovations.

We are going from zero to what we believe will be market leaders. In the second row, our focus here is to reframe these offerings around the therapies and the patients that can be provided with our platforms. So, a logical evolution requires us to collaborate with many people in that disease ecosystem.

And then across the bottom, while we discuss optimization, it's important to know we still see growth across the world. Just recently, the World Health Organization identified the blood as an essential medicine. So, you actually see areas that are just beginning to invest and applicability for the things we've been selling for a long time.

But this is our growth opportunity to get those who still don't have access to safe blood. So, our business leaders will focus on the areas in the gray box, and these are the things that are embedded in our growth plan.

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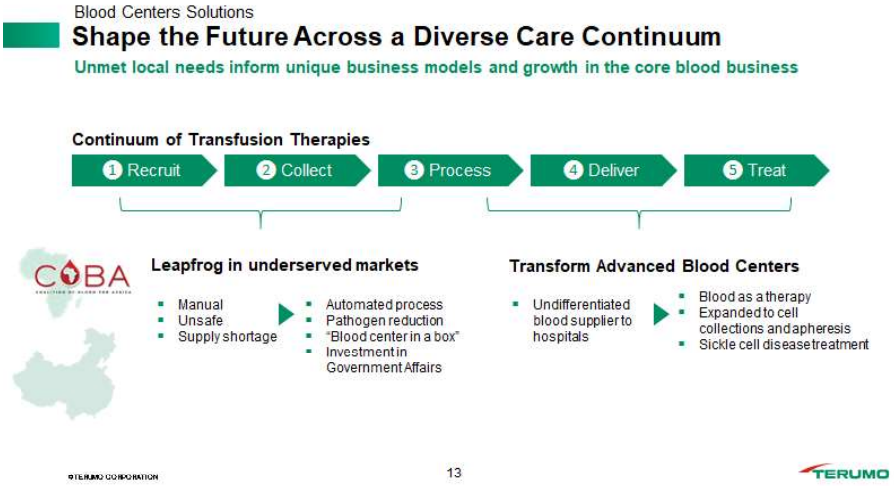

Chetan Makam: Thank you, Antoinette. Let me start by speaking about the impact of blood. Every second of every day, somebody needs a blood transfusion. Last week was World Blood Donor Day on June 14th. And for us at Terumo Blood and Cell Technologies, every day is blood donor day.

So, if you can donate, my humble request is please donate. The blood business is our foundation and heritage at Terumo Blood and Cell Technologies, the need for blood is constant, whether it's for oncology patients or for women suffering from postpartum hemorrhage during childbirth, where it affects over 8 million women and many thousands die because of the lack of access to safe blood. Blood is also needed for chronic diseases like thalassemia and sickle cell patients.

Within the blood business, we will continue to grow through geographic expansion by bringing our portfolio to all parts of the world as well as by creating ecosystems with our beyond-equipment strategy that allows us to bring services and solutions for our customers.

As we look at the continuum of the development of blood systems on the left you will see there are plenty of underserved markets like Africa and China where access to blood is a major challenge. In many cases, rural areas of developed countries also face similar challenges.

As we talk about the access to safe blood, here is an interesting statistic. 15% of the world's developed population has access to 50% of all the blood collected, whereas 85% of the world's population, the remaining 85% has access to the remaining 50%.

So as we work with organizations like COBA, the Coalition for Blood for Africa in African Nations, we are exploring the concept of what we call a blood BOMA or a blood bank in a box

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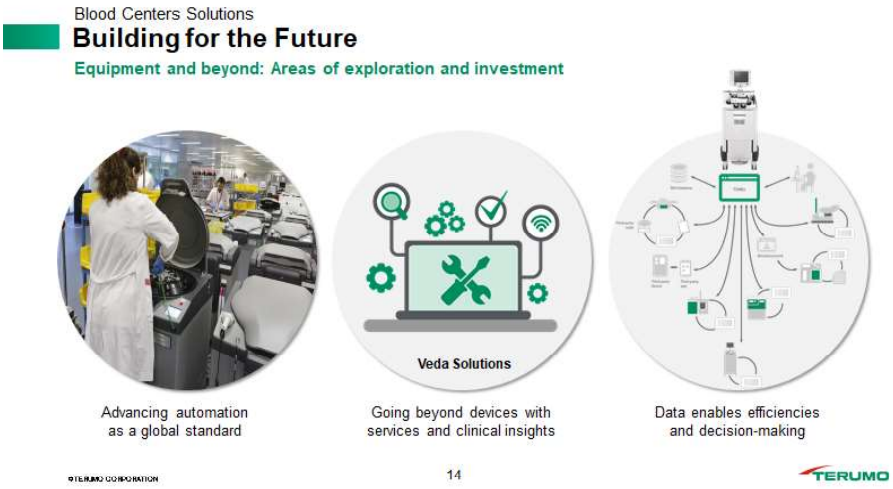
where we can complement the existing blood systems to provide accessible blood to those areas where safe blood is inaccessible today through the help of our technologies.

On the other end of the spectrum, on the right-hand side, you see that we are trying to transform blood centers through our Disruptive Whole Blood Automation technology which has two platforms Reveos and TACSI. 90% of all blood collected in the world is whole blood and therefore improving these processes and automating them delivers great benefits to many of our customers.

Whole blood automation is the process by which we separate the collected blood into components in a single step versus the current process where you have to go through multiple steps and is very labor-intensive. The conversion of these components or the blood into components in a single step provides better consistent quality of the blood products, fewer errors in the process as well as is less resource-intensive, which means we can get blood faster into the hands of the people who need it.



Our Reveos and TACSI platforms are today available and are in use in over 50 countries around the world. So, as we advance automation as a global standard with our Reveos and TACSI platforms, we are also creating ecosystems of value-added solutions under our Veda Solutions brand for services, data analytics, and clinical insights which help our customers address their business needs and gain insights into efficiencies as well.

A key element of this ecosystem is connectivity, that is connecting our devices to the systems of the blood centers both internally and externally through our TOMEs platform as well as the cloud to enable services and solutions like I talked about before to enable data analytics, insights, efficiencies as well as trace and track the blood components across their systems.

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So as we continue to advance blood as a therapy and explore the possibility of collecting cells and providing treatments for patients at our blood centers. I will turn it over to Veerle to talk about some exciting developments in our therapeutics business. Thank you.

Veerle d'Haenens: Thank you Chetan. our Spectra/Optia platform is commonly used to treat patients that don't have a lot of treatment options. Optia allows to filter from the blood the components that are in the proteins that are not meant to be there. Like, for instance, bilirubin in acute liver failure, or the proteins that are responsible for the progression of Alzheimer's disease.

We are routinely approached by potential partners for new therapies because we have a large and we are known for our quality and our high reputation there. We are, leaders, in apheresis is and Spectra/Optia is the gold standard across the globe.

Sickle cell disease is a disease with high unmet needs. Imagine the 300,000 newborns every day and 40% of them don't survive the age of twelve they are at risk of silent stroke as the sickle-shaped cells obstruct the blood from flowing freely.

Optia selectively removes the sickle-shaped cells and replaces them by healthier red cells. And our therapy is used in combination in synergy with drugs to treat the complications. It helps delay organ damage and preserves their cognitive function because these children have the hope for a cell-based cure.

And Optia is collecting the cells for a possible stem cell transplant or a gene therapy in the future. We collect the data along this treatment continuum to shape the standards of care and the data generated helps provide the evidence for improved reimbursement and access to the treatment.

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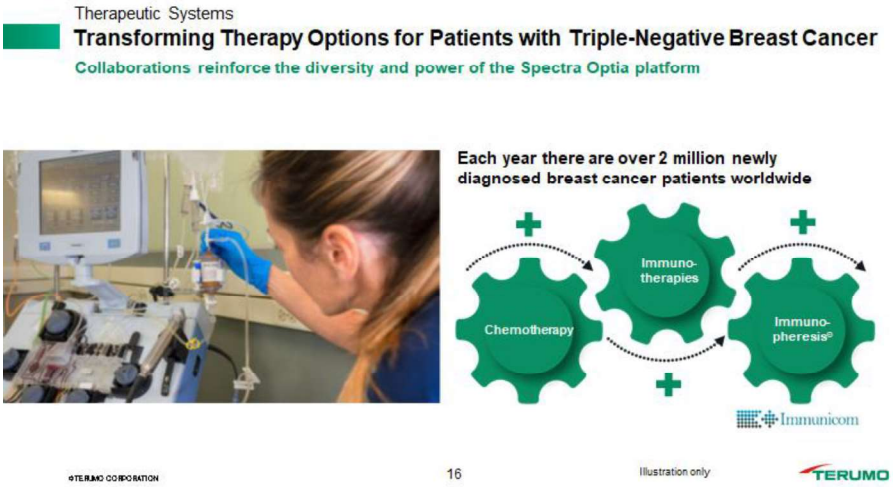
The US authorities decided upon the creation of a dedicated code for the reimbursement of our therapy and in the UK, NHS England has chosen our therapy as part of the MedTech funding mandate. This will result in improved adoption and improved access to the treatment.

And 85% of sickle cell patients are born in Afrika. It means that we are expanding into new geographies, and we built the capabilities with local health economic data. As an example, we performed a health economic assessment in Kenya, and we did the assessment for our therapy and other transfusion modalities and the data confirmed the benefit of our therapy with the alternatives being 40% more expensive.



During the COVID pandemic, we received the first device emergency use authorization by the FDA to treat acute respiratory failure in COVID-19 patients. The therapy is reducing the cytokines and the inflammatory proteins from the blood. And it is another proof of the concept that Optia potentially removes the proteins or can remove any protein from the blood, and it represents an untapped source of future growth.

And yet another example of how we enhance the treatment options for patients throughout their care journey is our partnership with Immunicom. The therapy, which is called Immuno Pheresis, combines apheresis and innovative technology.

Optia is wired into the regulatory approval and the therapy selectively filters out the proteins that are released by the tumor and inhibit the immune system to act. So instead of adding high doses of toxic drugs, the therapy enables the patient's own immune system to attack the cancer more effectively.

A first indication is triple-negative breast cancer and 15% to 20% of all breast cancers are triple-

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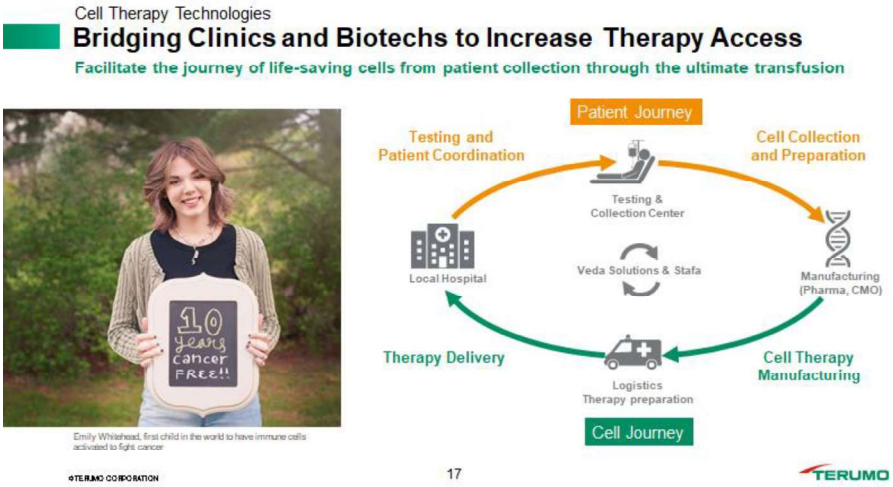
negative. It affects young women, is very aggressive, and has no viable treatment options currently. Together with Immunicom, we provide a non-toxic therapy that complements drug regimen and the data we collect along the treatment continuum will shape the future standard of care.

With this transformative technology, we are increasing and expanding our impact on the treatment of cancers. Optia is the gold standard to collect cells for stem cell transplant that is used in the treatment of multiple blood cancers. And we own the collection of the source material for cell therapies like CAR T therapy. Delara Motlagh will explain now more and elaborate on our role in these cell therapies.



Dr. Delara Motlagh: Thank you Veerle. cell and gene therapies are bringing hope to critically ill patients around the world. Emily Whitehead, pictured here, was the first pediatric CAR T patient.

When CAR T was made available to Emily, it was her last hope for life. Last month in May, she celebrated ten years cancer-free because of her CAR T therapy and she is now considered cured of cancer. Successes like Emily's are propelling this industry forward.

There are over 20 commercially approved cell and gene therapies globally today. There is an increasing number of clinical trials for cell and gene therapies, expanding the number of different indications, different therapeutic areas, and expanding geographically.

So, for example, in China is leading the world in CAR T development. This year, approximately 25,000 patients will be treated with cell and gene therapies. These will be either commercially available or in clinical trials. That number will increase to 100,000 patients by 2025.

While this is great news for patients gaining access to these critical therapies, this increased

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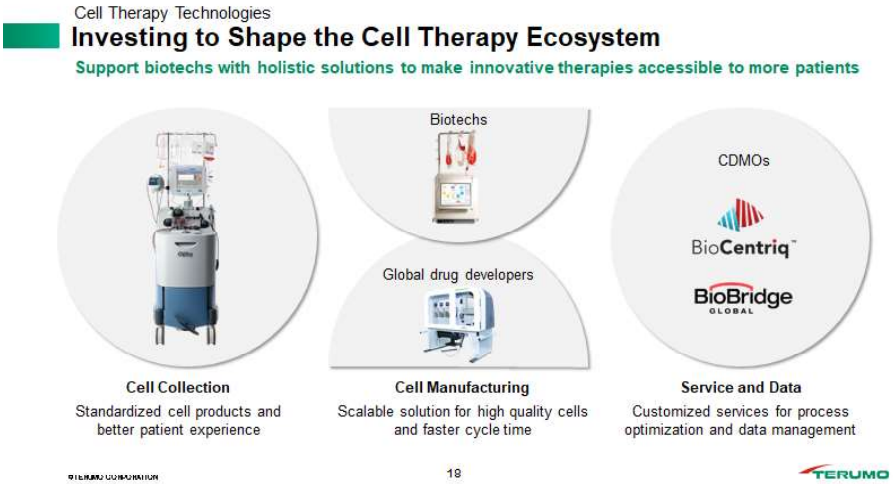
number of patients will increase pressure on an ecosystem that is already strained in capacity. Strained in capacity from a point of collection at the hospital, and also manufacturing capacity constraints.

We are facilitating the delivery of these therapies across the patient journey and the cell journey.



In the next slide, I will highlight how we are supporting this expanding ecosystem. We are building on a legacy of handling fragile cells and making key investments to support the market need and the patient need.

We support researchers through the stages of development, and by pharmaceutical manufacturers towards the commercialization. Our investments in cell collection, cell manufacturing and services are targeted to elevate the industry and advance this sector.

In cell collection, we provide standardized, consistent cell products for manufacturing while creating a better patient experience for these very sick patients. In cell manufacturing, we are providing scalable solutions that are also GMP compliant.

So suitable for good manufacturing practices. These will help provide high-quality cells and a faster manufacturing time. This is very important because it allows these therapies to get to patients faster. One of our pharmaceutical partners or customers has been able to remove five manual steps in their manufacturing process by incorporating our FINIA platform for their final formulation in their commercial CAR T production.

This allows them to more efficiently manufacture these lifesaving drugs and treat more patients. This becomes even more critical as these carte therapies become first-line therapies. We

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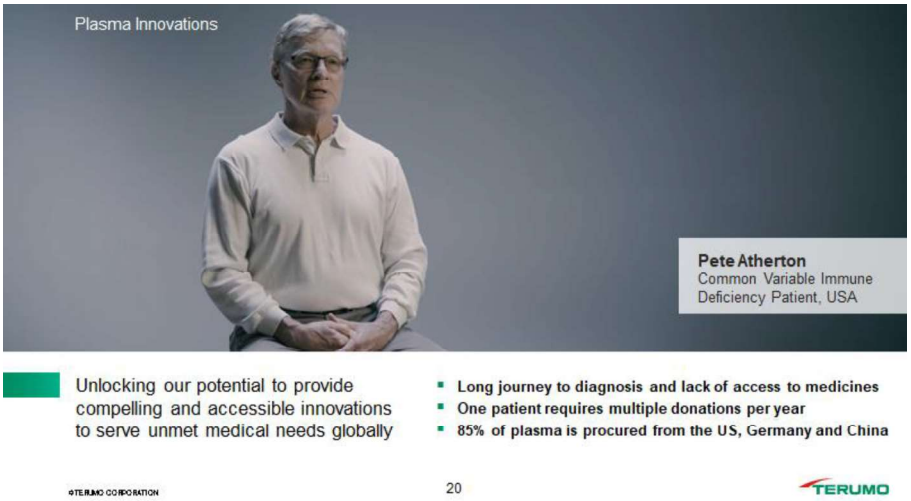
collaborate to deliver services, customized services, and data management to allow our customers to optimize their processes and standardize their manufacturing.

These holistic solutions enable our biotech customers to bring these life-saving therapies to market and make these incredible innovations more accessible to patients around the world. Thank you.



Cynthia Hougum: So, the patient is central to all that we do. So, we want to introduce that now,

Pete (Survivor patient in the video): The reason why it's important for me to tell my story, first of all, is to thank all the people involved who created these medicines. I'm just so in debt and so thankful.

The other major reason I want to tell this story is with a good diagnosis, with proper medication, you can live a wonderful life. So, I have a common variable immune deficiency. The average lifespan of a person that is not treated is age 50.

I'm currently age 70, have a very active life, and have lived a very fulfilling life along the way. Thanks to these plasma-based medicines, I really had a great start. Got recruited to Silicon Valley for a very very hot new startup. On top of that, I had married the love of my life, we had our first child, and I was on top of the world.

And then it began. I started getting what seemed like colds turned into sinus infections, and then the sinus infections got worse and worse. Picture having a mouth sore in your mouth spread throughout your sinuses and into your ears and that will bleed sometimes.

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It's so painful. Along with acting fevers. And I got pneumonia several times in a couple of years leading up to my diagnosis. I tried to do my best not to have that affect, especially on my family and my kids, which was challenging, it was quite challenging.

I did miss a few days of work, but I tried not to do that too. I went to work quite frequently with pneumonia and that was just my life and that's why I was so concerned about where's this life going. It was scary. It was very scary at the time.

My general practitioner, one day I noticed an anomaly in the blood test and sent me to a specialist. The specialist dug down and found that my immunogenic globulin or IgG levels were quite low. And then they prescribed plasma-based medicine infusions and because of the medicines, I'm able to see my grandchildren.

I was able to help my parents as they got older. I'm just so honored and so happy with what modern medicine has done and all the donors who helped make these medicines possible. I can't even tell you how much thanks I have for these people who go in and donate. It's a lifesaving thing for many, many, many people. I'm Pete and I am alive because of plasma collections.

Cynthia Hougum: Konichiwa, it is a pleasure to see, to talk with you today. Pete is one of the lucky ones. He received a diagnosis, and he has access to the plasma-derived therapies that allow him to lead a full healthy life. But that is not the case for thousands of patients.

There is a huge unmet need for plasma-derived therapies and today I'm going to tell you why. Terumo is uniquely positioned to be able to help meet that need. Oftentimes it takes a long time to receive a diagnosis and as I travel around talking to collectors of plasma and fractionators, I hear that even after a diagnosis, they don't have access to be able to provide the plasma-derived therapies that their patients need.

Globally, many country representatives speak of wanting to be self-sufficient for plasma collection. However, currently, no countries meet the needs that they have for the existing medical indications for those therapies. And there are over 1500 investigational studies still underway.

So we have a huge unmet need that is continuing to grow. You may ask why is that? Currently, 85% of all plasma is collected from three countries: the United States, Germany, and China. And for plasma-derived therapies, it's different in a way from other blood component donations, where one donation facilitates the treatment of one patient.

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If you look at Pete, it requires 130 donations every year to provide his treatment. He has been on treatment for over 20 years, so it is a continual need throughout his lifetime. And if you or I had the misfortune to be born with hemophilia, it requires 1200 generous plasma donors to provide treatment for us for only one year. So this will continue to grow, with the current indications and future indications.

Terumo is uniquely positioned to be able to support and enable more plasma collection. We have a legacy. Our legacy is in providing high-quality blood components. And I'm going to tell you how Rika and its ecosystems is positioned to help enable more plasma donations.

When we talk to CSL, who we're collaborating with on this endeavor, they often list three reasons why they decided to collaborate with us. One, it's our legacy that I spoke about. Two, it's that we're innovative and we partner with customers to listen and provide solutions that meet their spoken and unspoken needs. And the third part they talk about is our values.

Our values at putting the patient in the center and finding solutions that will work to benefit the donor and the patient. I would like to talk to you about what we have done with Rika and the development of an ecosystem. I wanted to define the ecosystem for you.

The ecosystem is a suite of services and software that enhance the donor experience as well as operational efficiency. When I say operational efficiency, that means how a plasma donation center operates and improving efficiency there, but also improving the efficiency in terms of how the operator interfaces with Rika.

So, if we look at talking about the innovations provided here, Rika, the plasma donation system is the core. It is the heart of what we have, to improve the donor experience. The donor will experience a reduced collection time for plasma. Less than 35 minutes is needed to collect 880ml with the saline return.

So, this is 30% faster according to CSL. In addition, our proprietary separation set technology allows us to have a lower blood volume outside of the body, a lower extracorporeal volume. This is important because it provides a more comfortable donor experience, and it also enables less deferrals.

So, if you think about it, we want to attract and retain more donors in order to enable the customer to collect more plasma. A lower extra corporeal volume means less deferrals and then donors come back. In addition, we have looked to reduce manual processes through this ecosystem of software and services.

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Chris Williams will talk a little later about the infrastructure that we've put in place to support all of these features for Rika.

I would like to talk a little bit now on training. The training modules and simulation is key to a smooth deployment. There are hundreds of centers and there are thousands of systems that will need to be deployed, and they will have thousands of operators that will be interacting with them.

It was critical that we developed the training in a modular fashion, so it was easy to train and easy to test the effectiveness of the training. That is the first part, but the second part drives efficiency for the center. We interface the training modules and the training capability directly with the customer's learning management system.

The reason this is important, it eliminates paper processes, duplication of tracking methods, and this is also a key compliance area by which you're measured on in this regulated industry. What you see with Rika and those ecosystem modules are the key customer-facing portions and we will talk a little bit later about the infrastructure.

Cynthia Hougum: So now I would like to dig in a little further to talk about the design aspects of the Rika device, and Tim Costello will help me. He is the Vice President of Sales for Plasma Innovation. We designed the Rika ecosystem, the Rika device, to focus on the abilities.

Tim Costello showcasing Rika instructions

When I use the word abilities, I'm specifically talking about a number of key areas designed for usability, designed for reliability, manufacturability, serviceability, scalability, and sustainability.

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I'd like to start with usability. We spent a lot of time with the customer and the industry doing gamba and listening to what are their needs. If you look at the touch screen that we have on here, it is intuitive and it allows for an easy operator interface and there is a focus on safety. Safety is paramount for our donors.

Loading is very fast. It takes less than two minutes and with training, they rapidly improve to under a minute to load the separation set. As you heard in the video, this is a proprietary technology for us at Terumo, and it allows us to reach this shorter collection time and a lower extracorporeal volume. Very critical.

We poka-yoked the poles so the connections are different, and you cannot reverse the saline and the anticoagulant. This system can run with or without saline because I know you often don't use it here in Japan.

The other part I would like to highlight is the bottle. The collection bottle at the top has also been poka-yoked so that it only fits one way into the cradle. And the cradle has a weighing scale on it, and it's been positioned so it cannot be bumped during operation.

In addition to that, we focused on reliability. Remember, these systems are up 16 hours a day, 364 days every year. So, we want to optimize the amount of time and the service level of the systems.

We have been doing life testing on the components for years, and we have been doing subsystem and system testing continually throughout the process and we will continue through the future.

I would now like to transition to design for manufacturability and serviceability. These two I like to talk about together because they're quite synergistic. We have designed this system to be modular. That means it improves the assembly process and the testing process during manufacturing which can happen on a subsystem level but prior to final assembly.

This also makes service easy when service is needed you look at the instructions and you can go directly to Rika, pull out that module, make the change and quickly get it back into service.

In the US, service is going to be done by the customer. So that is why we focus so strongly on

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design for serviceability and service training. I'd like to talk about design for scalability. We talk a lot about our current customers, but we have listened, and we understand the industry and we have built the infrastructure and the configurability of the system to be able to scale and meet the industry needs.

So, it's built for a customer scalable to the industry. And the last ability is designed for sustainability. This is something that is very important to us as a Terumo value and also to the planet at large. This proprietary separation set is 30% less biohazard waste.

That is a very important factor when you look at the disposal cost for the customer and for packaging, it has less corrugate waste. Lastly, an area I'm very proud of is that we proactively designed for non-DEHP for the separation set.

This is not a regulation yet, but it positions us, and it positions the customer for the future. In the end, the donor is key to everything, and I'd like to reiterate a few key points around the donor experience. Safety is key, and enhanced comfort and donor experience are also key to attract and retain donors.

The collection time for plasma is less than 35 minutes for 880ml with saline. There is no more than 200ml outside of the body and so, therefore, especially for first-time donors, there's no deferral so they will come back and continue to donate. As you heard, we need repeat donors of plasma to meet the needs for plasma-derived therapies.

So overall these things position us to disrupt the market and we heard as a result of the clinical, numerous donors came to us and told us how much they enjoyed it. They enjoyed that it was fast, or it was a shorter time. And they would say I usually can watch much longer show on my phone. And then lastly, they said they would like to continue to donate on this system. So, we are positioned to move forward with this, and we appreciated the feedback from the donors.

So, in conclusion there are a few items I'd like you to take away. From a business side, we are best able to disrupt the market and meet this unmet need for plasma-derived therapies. We have the innovation and the legacy in high-quality collection of blood components.

And with Rika, we'll be able to focus on what is needed for the plasma market. In addition to that, we designed an ecosystem. An ecosystem that will streamline the operations for the customer and improve the ability of the operator.

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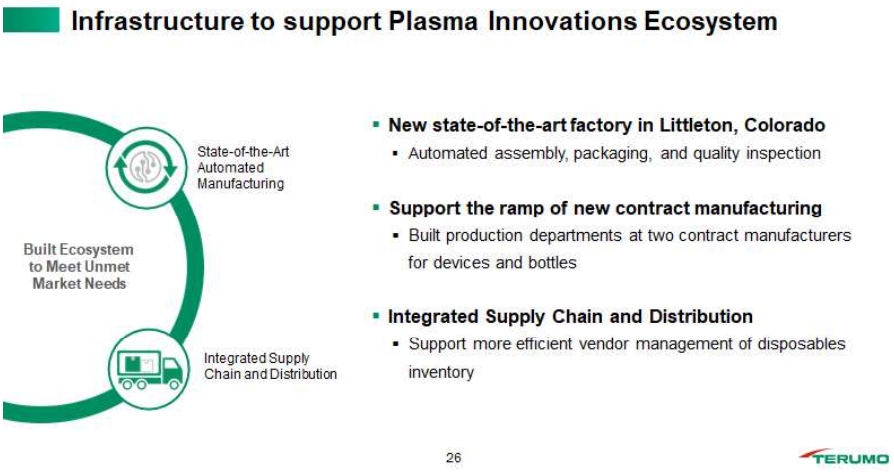
The operator, we want them to focus on the donor, not on manual processes that they need to take care of. And lastly, I would like you to understand this ecosystem may have been designed for Rika. However, it is to support, and it is applicable across the other Terumo businesses, and it is part of our digital transformation.

The world needs more plasma, and we need to meet these patient needs. That is our vision and that is our mission. So this product and ecosystem is designed to do just that. And now I would like to pass this over to Chris to talk about our infrastructure.

Chris Williams: Thanks, Cynthia. And now was our operations team's job to create both the manufacturing network and create the supply chain to support this new plasma collection business. First of all, we chose to do the separation set as Tim and Cynthia showed internal to our manufacturing network.



We built a brand-new plant about 30km from our headquarters during the heart of the Pandemic. And this is a state-of-the-art facility that can house four automated lines to not only support our current customers but expand for growth.

This production line is not only automated assembly, it has automatic packaging. And each production line has over 20 automatic visual cameras to assure the best quality possible.

And lastly, to distribute the product around the United States, we partnered with a major distribution company to manage the inventory in detail across multiple distribution centers across the US. But now let me turn to our exciting new factory in Littleton, Colorado.

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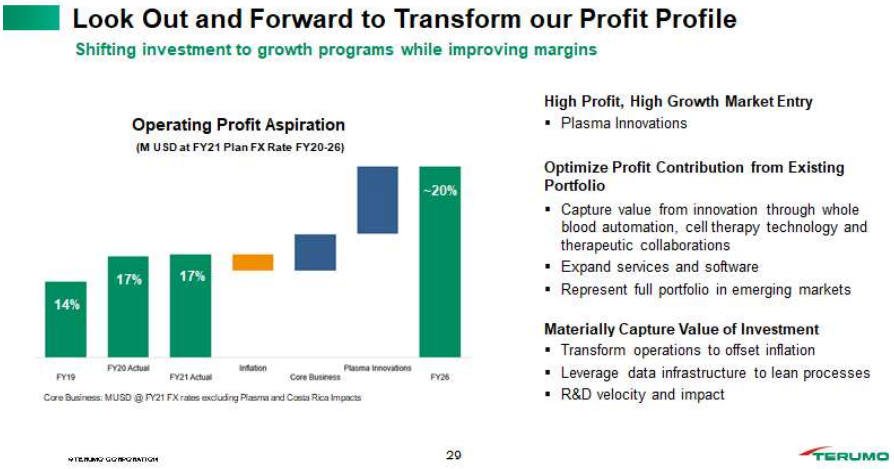
As you can see from the slides, we built this factory in 2020 during the heart of the Pandemic. It is a 16,000 square meter facility with multiple clean rooms that can house four automated production lines for both our current customers and for future growth.

Not only did we establish this manufacturing facility, but we also had to expand our Lakewood Sterilization facility as well as installed state-of-the-art emission controls to protect our environment. So now let me show you a quick video from a few weeks ago where we had our grand opening of this brand-new state-of-the-art manufacturing facility.

Video playing

Chris Williams: And now back for Antoinette.



Antoinette Gawin: So, you've seen a lot of pieces, and this illustrates how it comes together at the profit level. You see in fiscal year 20, the work that we did to improve our profit was on target and positioned us to absorb some of the complexity we're all aware of with the global operating environment; supply challenges, the Russia-Ukraine war, and inflation.

So, as we go forward, you see that not only are we positioned to absorb some of those impacts, but that we will continue growing and optimizing profit from our existing portfolio, where we will be capturing the value of those innovations and growing through the whole blood automation, through the cell therapy infrastructure, and through therapeutic collaborations.

We are deploying that portfolio in many different geographies, creating ongoing growth, and of course, launching the plasma innovations business. As Cynthia indicated, the investment in plasma innovations helps update the rest of the portfolio. As you think Kinari, Miata, these are all

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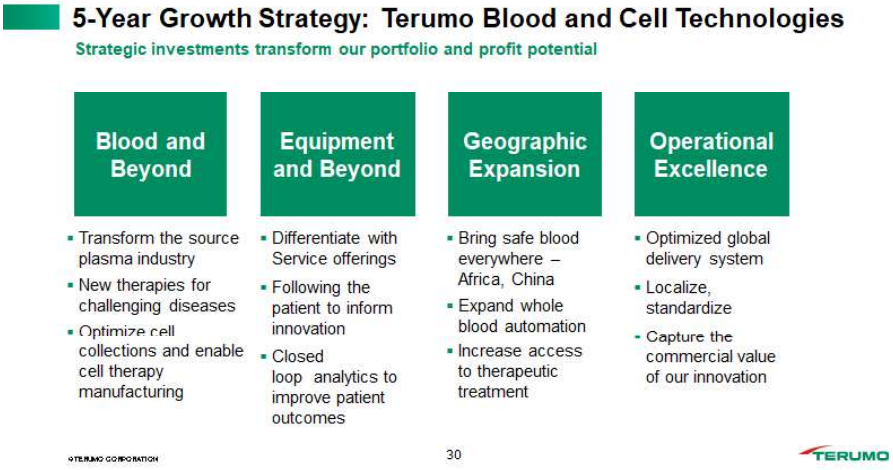
relevant to all of our existing businesses today and can help modernize those customers' infrastructure. And we will continue adjusting our pricing and our efficiency targets so that we fully capture the value of those automations and those investments.



So, to summarize our growth strategy, you've seen how we are combining deep knowledge of our customers, operating environments in that patient ecosystem so that we can identify services, data solutions, things that go beyond equipment, but help inform our next generation of innovation.

You've seen our investments grow with blood and beyond, so that we fully leverage all of the legacy we have and the power of the solutions we have already brought to bear in the market.

You saw how we will connect some of these innovations in different geographies that have patience we have yet to serve. And the label Operational Excellence barely conveys the level of transformation we've undergone.

Establishing two brand new factories from Greenfields despite COVID and shifting and enhancing our supply chain so that we can continue delivering and meet our customers' expectations; shifting product where it needs to be and shortening cycle times and delivery times.

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Unlocking our Potential to Serve More Patients

Multiple Myeloma | Sickle Cell Disease | Acute Lymphoblastic Leukemia | Common Variable Immune Deficiency

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So, we've shared our return to growth strategy despite some of the adverse global realities. I hope you feel our fierce commitment to serving patients, those who take advantage of our solutions and therapies today, and our commitment to finding ways to bring these innovations and technologies to those patients we have yet to serve.

We are focused on our associates, our customers, and our patients in building good will. And that gratitude and good will are what will help propel us to capture the next billion dollars of growth and our continued investment in people, in, process, and our portfolio helps create a virtuous growth cycle.

We will generate more profit which allows us to invest even more and sustain that level of innovation to the industry. So I appreciate your time today and we will be opening the floor for questions.

Ken Hata: So now 2:30, so perfect time management. Great. So, 30 minutes at least. We want to have 30 minutes, no time to waste. So, if you have a question then Kohtani san please. Kohtani san from Nomura will be the first to ask questions.

Mr. Kohtani (Nomura): Hi, so thank you for your extension. It was absolutely impressive. It's obviously very different from your competitors' devices. So, I just want to two questions. One, I just really want to understand the benefit of the Rika device, these will be competition. If I were Takeda or Grifols or CSL, the last thing you want is the donor to not come back, right? Of course. That's why the deferral is a very important thing. I'm trying to understand so with Rika, because the extracorporeal blood volume outside the body is limited to, I think it was 200ml or something like that. So, there is less stress on the red blood cells and so you won't have the chance of having

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that hematocrit deferral.

And I'm trying to understand how because if there is a deferral that donor obviously can't give blood on that day, so they just don't come back or do they go to some other competitor's lab? How should we think about that deferral?

Also, the feature Rika I think you mentioned is the pressure monitor that's in there and I wanted to understand how that works because I think you said something about personalizing the draw. Does that mean that one of the concerns with the plasma collection I thought was overdraw and the chance of having hypovolemia from that?

I think that's a very rare event actually. But is that the reason why the pressure monitor is there or is there something else just to monitor the equipment in general just on the advantage of Rika so that everyone understands how different it is.

Antoinette Gawin: Let me address that question regarding the deferrals and the personalization. And then Cynthia can build if necessary. So, the deferral is important. Our customer has shared that if the experience is unpleasant or there is an issue, then the donor is unlikely to come back, period.

Donor experience in the chair, so to speak, is critical. When we talk about the sensors and personalizing, all of the sensors are designed to optimize the flow through the device and back to the donor so that we don't overdraw or under draw.

And many of the sensors are there for safety to allow an operator to be consistent. There is a current statistic with our customers that operator turnover can be as high as 45% or 50% in the industry. So, if you have new operators coming in we have done everything we can to build safety mechanisms within the machine to prevent any risk. Cynthia, would you like to add anything?

Cynthia Hougum: The regulation requires that if there is more than 200ml outside the body at the time there'd be an issue, the donor is required to defer for eight weeks. Our system and what makes it so unique is that the proprietary separation set has a very small channel. So therefore, there is never more than 200.

It's always less than 200ml. So, at that point, even if an issue would arise, you'd stop the procedure, but then they could come back in a short time to be able to give another donation. So that's, I think, the first part and as Antoinette said, the sensors make it smart in terms of the pressure because sometimes that can vary during the donation process depending on if the donor is squeezing the

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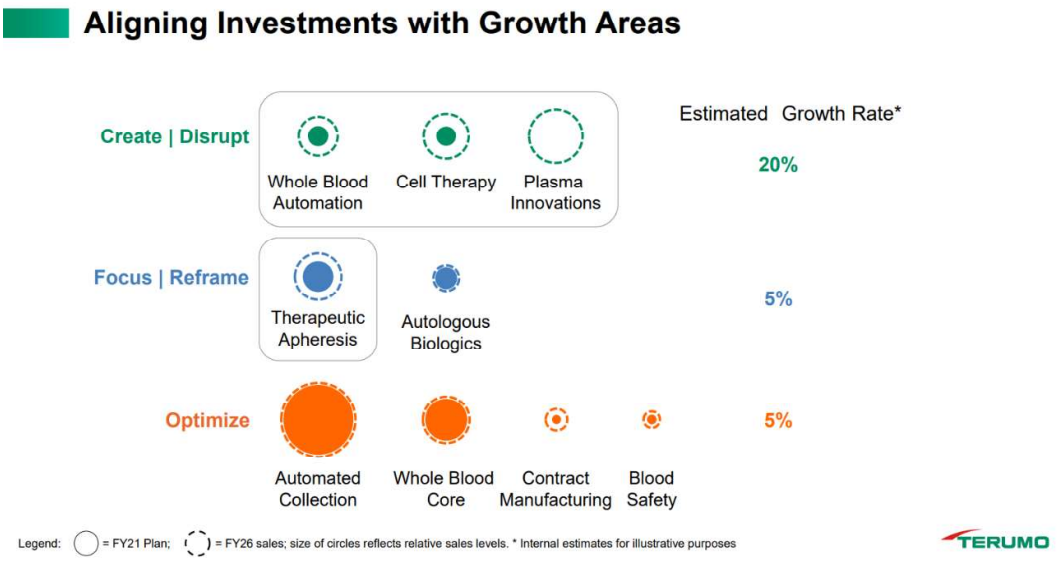
ball and it changes the venous pressure.

Mr. Kohtani (Nomura): So, thank you. The second question is about the market. I think the growth rate that you've provided on that was, I think on page ten. And by the way, this is very helpful because we don't have a lot of visibility into a lot of these areas. The question I have is therapeutic apheresis.

I understand this is just like a whole bunch of indications that are rolled into this area, but when we do just take a look at the pharma pipeline, there is a lot of innovation going on. So, you do see a lot of drugs that are being developed for myasthenia gravis, CIDP, you know, you name it.



I guess there is autoimmune encephalitis, there's just a lot of antibodies, FcRns, Il6, C5s. So, I`m just sort of worried that that growth rate might be a little bit might change because of pharma innovation. I don`t know what base indications there are in therapeutic apheresis, I guess the way we should think about it is because there are so many indications that just having a few drugs to enter the market doesn't really matter. Is that the way we should think about the growth rate of this?

Antoinette Gawin: Thank you for the question regarding the therapeutic growth rate. I will address that question and then ask Veerle to build from my comments. So, a few variables. One, we have just begun in many areas to understand how to selectively filter for some of those proteins or things that don't belong, as Veerle said.

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Many drugs create additional side effects and so in some cases this therapy is a complement to that drug treatment. So that is the first thing. The second is apheresis is a relatively unknown procedure because it isn't a pharma offering today, if you will.

And many of these rare diseases are at the earliest stages of discovery. So, we see that we can support for many years a much lower-cost alternative with – to repeat the last portion of my comment, we see that many of the diseases we treat are very rare or difficult to diagnose and are at the earliest stages of drug development.

So, we see a complimentary growth path with a relatively low-cost alternative that can help follow the patient through that whole life cycle. Veerle would you like to expand?

Veerle d'Haenens: Indeed, and there are so many rare diseases that there is no treatment yet. And as I said, we have this concept that Optia could remove any possible protein in the blood. So, I see the potential for new diseases to be treated. I see potential certainly also in the space of oncology, where there is instead of adding toxic drugs, we can remove and accomplish the same mechanism of action without toxicity.

And as Antoinette was saying, I see also much potential to be complementary for some of those newly developed drugs where we can enhance and speed up the action and the activity of those drugs when those patients are starting their treatment.

Antoinette Gawin: And I am not the chemist in the group or the scientist, but if you think of all those -- apologies for that disruption, if you think of the work we did during COVID to help filter out the impact of the cytokine storm, many of these drugs are introduced and the patient's immune system overreacts and the risk is that, that cytokine reaction will harm the patient before the medicine has a chance to cure.

So, our product we know today can help filter and mitigate those cytokines. So that alone creates a powerful complement to some of that drug development.

Mr. Sakai (Credit Suisse): Thank you very much for your presentation. It's been very impressive. And I have a couple of questions.

The first question is the kind of US macro environment, the business environment, I must say. As far as Fresenius Kabi is concerned, Kabi restriction is concerned, Japan is kind of in a unique situation. Still, there are several restrictions, and you may experience that restrictions when you

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come to Japan. By the way, welcome to Japan anyway.

So as far as I can think of what I can see from CNN or whatever, seems the US business environment is getting back to normal. Are there any concerns or short-term risks that may impact your business plus or minus? Because a couple of years ago, I remember you benefited from the COVID plasma collection for COVID patients. Are there any one-time or extraordinary risks that we should think of going forward? That's my first question.

Antoinette Gawin: Yes. So, thank you for the question a round COVID, environmental risks and potential impact. So first, some of the COVID restrictions affected discretionary procedures.

And in the case of therapeutic apheresis, as an example, there was a fear for patients to go to the hospital. So that did have some short-term impact. We believe that has normalized now, but it spurs people to look for new alternatives and it spurs us to look at how do we bring those therapies closer to the patient and to the point of care, instead of taking a sick person to the hospital.

So, we are actively involved in a US program called Hospitals without Walls, which is designed to transfer the reimbursement structure from a hospital into whatever site of care might occur. So that is one example. The other area I see as a positive because we were leading from the front during COVID, and that emergency use authorization occurred in six weeks from idea to implementation.

It built confidence both with our associates and our customer base, that we have the capabilities to truly help influence the environment. And that has created tremendous goodwill. Recently, Cindy and I met with our global distributors and their CEOs around the world, and their gratitude and their willingness to work with us through our current supply chain dynamics is tremendous. And as you know, no company is left untouched by that.

So, the last area I'll comment on, and this is on operating pressure, and I'll make a comment and then ask Chris to add on top of that. As you know, going into COVID, people, everyone, businesses, people begin buying things they think they might need. And what we have seen is a distortion in the supply chain signals.

That is taking some time to flush through the system, but it has also highlighted where we have gaps. So, our factory realignment has been so helpful during this environment because we are closer to our customers, and we've increased capacity.

At the same time, there are little things, and I'll use a simple example. We're all wearing the masks.

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The material used to make masks in that protective gear is the same material we use to cover our kits. So, there is a shortage of the simple sheets of paper to cover the kits.

And you might say, well, that's simple to replace. Right. Your competitor uses plastic, but we use the material because it's resilient and strong and it is integrated with our sterilization. So, each one of these creates its own level of complexity. Chris, I'll add you to add from that.

Chris Williams: Thanks, Antoinette. I think there are two short-term challenges that we face in other medical device companies around the world.

And the first is obviously the cost freight that's air shipment by land or sea up and lead times are taking longer. That's why we're well-positioned with our global network around the world as we manufacture our products close to the end customer.

The second is raw material availability. As Antoinette mentioned, some of the simple things that you take for granted packaging materials, resins, and electrical components are in short supply around the world. We've taken a very active approach to this.

I'll give you a couple of examples. We are qualifying additional sources of resin suppliers over the last six months. And then we are moving some of our raw material production, like injection molded components, closer and closer to our factories.

We just recently moved the injection molding of about nine of our components from a US factory to Singapore that supports our Vietnam factory. We will be evaluating more vertical integration opportunities on a case-by-case basis as we look at taking control of our own destiny by extruding more of our own tubing, injection molding, and more of our components within our own factories, versus relying on other companies.

Mr. Sakai (Credit Suisse): Thank you. Just a second question, a quick one. The initial investment to install Rika, I mean, CSL, are you subsidizing anything for this insurance investment?

Antoinette Gawin: So, the question is around subsidizing the investment for Rika and CSL?

Mr. Sakai (Credit Suisse): Yes.

Antoinette Gawin: Yes. So, we are not subsidizing. We have an exclusive contractual agreement with CSL, but we bore the full amount of those development costs.

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Mr. Sakai (Credit Suisse): Okay. This is a hypothetical question. Do you think the CSL is going to have more capacity to raise the correction fees while they are getting more plasma compared with others?

Antoinette Gawin: So, let me repeat to make sure I understand the question? So, you're asking if we believe CSL will raise their fees they pay to donors because they're collecting more plasma?

Mr. Sakai (Credit Suisse): Yes, that's right.

Antoinette Gawin: Yeah, I don't think we can comment on that. I know we have some insight into their strategies, but we're not at liberty to discuss, and I'm not sure we all agree anyway.

Mr. Sakai (Credit Suisse): All right, thank you anyway.

Ken Hata: I'm going to ask somebody online. Can you speak loud so that I can hear you?

Interpreter: Yes.

Ken Hata: Okay. So, do you see any questions from Yamaguchi san from Citigroup?

Interpreter: Not at this moment, no.

Ken Hata: Okay, people, online, please utilize chat functions so that we can pick up and read out your questions. So, unless you type in, we cannot pick up. So, while we are waiting, if somebody in this room has more questions. Okay. Yokota san from BofA.

Mr. Yokota (BofA): Hi, this is Yokota from BofA. Thank you very much for the thorough presentation today. I`m just trying to get a bigger picture of the ecosystem. I think that was one of the biggest topics for today's presentation.

So just to make sure, I'm looking at slide number 23. The diagram. Is this focused more on it says, the customer? So, I'm guessing this is CSL for now and not the donor themselves, is that correct?

Antoinette Gawin: Thank you for the question. Let me the address and then Cynthia can add if she feels appropriate. You'll see the donor reflected in the design aspects of the plasma donation system itself. Some of these other tools are really designed for the center operators and the center managers so they can do their own planning around their donor experience.

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We have seen that at each CSL, Takeda, Grifols, everyone looks at that slightly differently. So, this is a set of tools that they can use to help optimize their system. The other thing I would highlight with this integration, the device is the initial enabler, if you will, and we've tried to think through end to end.

So just as an example, as we did our Genba work, there are operators. The typical operator is my height; or Cynthia's height, but the pallets were stacked very high.

So, we actually changed the size of the pallets for the bottle so when they come out of production and go to Sterilization and then into a vendor-managed inventory and onto the center, there's no additional strain on an operator in the center where they're lifting or lowering beyond their capabilities.

So, we've tried to think of usability through the whole system, and then that will help the centers attract more donors. Did I address that ok?

Mr. Yokota (BofA): Thank you very much. So that means potentially you could track donors' data from this ecosystem. But I guess the donor's data is more the plasma collection center's responsibility. But is that possible? And I feel like that would be a better patient journey for the donors.

Antoinette Gawin: Yes. So, there are specific data in Rika. So, I'll let Cynthia talk about how we are looking at patient-specific data and the center's role there.

Cynthia Hougum: Thank you for the question. I think you can hear me.

Mr. Yokota (BofA): Yes, I can hear you.

Cynthia Hougum: Thank you so much for the question. If you look at the data that is collected from a donation standpoint, it is anonymized. However, from our side, we have long had a history of looking at data. Based on that, it's a foundation to look at performance systems as well as donation data from the donor.

We look at both of those in collaboration. We discussed with the customer in terms of how we can use that to look at and how they can use it to look at operational efficiency, to look at other parameters.

Mr. Yokota (BofA): Thank you very much.

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Ken Hata: Hello, hello. This is working, so I think we got a question from Barker san, from Jefferies, then followed by Morgan Stanley MUFG Hayashi san. So, if you can see the questions, could you?

Interpreter: So, the question from Stephen Barker from Jefferies is, when do you expect to be able to sell the Rika system to customers apart from CSL. And two, theoretically how much of this market can you take over before competition authorities might become concerned?

Antoinette Gawin: Okay, thank you very much for your question.

Interpreter: And I will interpret now the question in Japanese as well.

Antoinette Gawin: Okay.

Interpreter: Now feel free to answer. Thank you.

Antoinette Gawin: Thank you very much for the question. We will start deployment with CSL next quarter so that will initiate that process. And per CSL, we anticipate a nine to twelve-month deployment cycle to ramp their facilities within the United States. In addition, then we will honor our exclusivity contract, and during that time, we will also continue in discussions to understand the needs of the other fractionators in the industry. That concludes my remarks.

Interpreter: And how much of the market do you think you can take before competition or anticompetitive views from the government will change?

Antoinette Gawin: We can't really hypothesize around that. So, I appreciate the question. What I will say is we know that this is a dramatically underserved market. Many countries have no capability for this. So, we see ample opportunity for growth collectively across the market before any type of concerns would be raised. But we can't hypothesize on those. Thank you.

Ken Hata: So, could you move it to Hayashi san's question?

Interpreter: This question is from Mr. Hayashi at Morgan Stanley MUFG. In the Rika ecosystem, we understand that the Littleton factory plays a very central role in the supply chain. However, are you considering putting up a new factory to serve markets other than the US? Or do you anticipate that the Littleton factory will continue to supply the entire world going forward?

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Chris Williams: Yeah, thank you for your question. At this point, with the investments, that we have approved with the production lines, that we will put in Littleton we will have excess capacity when fully operational, stabilized; and improved to support incremental demand.

Ken Hata: Does Hayashi san have another question?

Interpreter: Just one moment, please. Yes, I will read the question in Japanese first. So this question is what are the reasons that the Plasma Innovation business is able to achieve a higher gross profitability and operating profitability than other product lines? Is it because of the pricing being attractive, or is it because the Littleton factory is more efficient in its manufacturing processes? Or any other reasons, please answer that. Thank you.

Antoinette Gawin: Thank you for the question. I'll address that, and then the team can add on as necessary. One unique aspect of the plasma market is a high level of standardization. So, every plasma center in the CSL network, as an example, follows the same operating procedures and has the same SKUs.

If I contrast that to blood centers around the world, each blood center has its own operating procedures, and that may vary between countries and within countries. So we have hundreds of SKUs from a disposable perspective to serve the blood centers, we have one with CSL. We also have a differing level of complexity in terms of the number of parts we need to procure and manage.

So that ecosystem you saw built around Rika allows us to train operators once to deploy one maintenance procedure, so it does help create more profit in the system.

Cynthia Hougum: Please add a comment. In addition to what Antoinette has stated, we have looked at how we could optimize the use of our investment through smart automation.

And we've also built smartly so that we can scale beyond our current customers to be able to reutilize some of those investments. So, all of those things actually make us a very streamlined business.

Ken Hata: Okay, actually, Yamaguchi san from Citigroup, I got questions through email. He's not allowed to use the chat functions on them because of the Citigroup's restrictions. So, I got a question here. Impact on gross margins for emerging market expansion and Rika business expansion. So, this means if we enter into the emerging market, is that going to improve the gross margin or it's gonna be lower.

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Then separately, so, you know Rika machines that`s going to improve the gross margin? I think the answer is yes, but I think his focus is emerging market expansion. Sounds interesting, but what's the impact on the gross margin?

Antoinette Gawin: Yes, so thank you for the question. I will address that and then ask Rusty to expand as appropriate. So, the emerging marks. So, Rika, yes, long-term will improve our gross margins because of the simplicity we referenced relative to our existing business models.

The emerging markets, as you know, have different sources of funding. So our initial investments there have focused on government affairs and building coalitions and public-private enterprises so that we can operate differently. So that will influence where the funding comes.

We are also heavily reliant on distributor networks in some of those markets and are looking at the technology, the software, and the services to help us identify new business models that will help us still protect a reasonable gross margin. Rusty, if I could ask you to add any comments.

Rusty Spinney: Happy to. I would, first, with respect to Rika, in the plasma innovations business, it will help our operating profit margin because of the lower SG&A and back-office requirements due to the automation and some of the very creative ways we've built the ecosystem.

With respect to emerging markets, we are very complex. So actually, there are some products in some emerging markets that have some of our highest margins. So, I think it's product by product and country by country, depending on what's really driving or impacting our gross margin levels.

I think we'll continue to build out our manufacturing capabilities, as Chris indicated, by moving to lower cost, efficient factories in Vietnam, Costa Rica, and India, closer to the customer. That will also help our gross margins in those growing and emerging economies.

Antoinette Gawin: I will expand with one additional example that may help illustrate that variance that Rusty discussed. Veerle referenced earlier the sickle cell disease treatment that is prevalent in Africa. Two-thirds of people have the genetic marker that will indicate they may have sickle cell disease.

Today, their option is a very expensive drug, if they have access to that drug. So, our alternative is dramatically lower cost for the government and for the patients, but it does not require us to drop our margins because we still remain a viable and cost-effective, and clinically effective alternative.

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Ken Hata: Yeah, okay. Actually, Yamaguchi san has a second question. This is simple. So TNB, triple negative breast cancer, Immunicom, is it approved? That's a question. If not, then when do you expect the approval?

Antoinette Gawin: So, thank you for the question. I will ask Veerle to talk through the specifics of that.

Veerle d'Haenens: Yes, and thank you for the question. The treatment for triple-negative breast cancer using the combination of Optia and the column from Immunicom has received CE mark approval for the removal of the soluble tumor necrosis receptor factor.

So we have the approval to go on the market and we are currently working with Immunicom to bring that on the market in a limited controlled release in four countries in Europe.

Ken Hata: Thank you. So, do you see any other questions from Ueda san or Tokumoto san?

Interpreter: Yes, just one moment. Yes. Okay, we do have a question.

Ken Hata: Okay, whose question is that?

Interpreter: So, this is a question from JP Morgan Securities Naoko Saito san. And the question is in Japanese. I'll first read it in Japanese. So, this question is about the fact, which was just mentioned, that Rika requires safety and cybersecurity to be in place.

And at this time, are there any regions where those safety or cybersecurity may not be able to be guaranteed? And if you're deploying to countries other than the United States, is it basically going to be just the developed countries, such as in Europe, where you'll be able to deploy? Could you please respond to that?

Antoinette Gawin: Thank you for the question. You are asking about the Rika safety and cybersecurity features and whether and how we can guarantee those in other countries. So, I will address and then ask Cynthia to expand. The safety features are built-in around the ability of the operator and safety features to protect the donor.

Those would transfer regardless of where the device would be used. From a cyber security, I believe, as in any equipment, we would have to evaluate those requirements, just as we do today with things like data privacy or other enabling features. So, Cynthia, would you like to expand?

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Cynthia Hougum: Yes, just a bit. So, we developed it to look at cybersecurity. It is a cloud-based application, and we're leveraging the security from the cloud in order to protect the data and the data privacy, as Antoinette stated. And we will continue to look at evolving cybersecurity needs as we go forward globally.

Ken Hata: Okay, thank you very much. So, if you see one more question we can take.

Interpreter: Understood. Just one moment. So, we have a follow-up question from Stephen Barker. How many of the four production lines are being used now to supply CSL? And in Japanese, how many of the lines are being used to supply CSL at this time?

Antoinette Gawin: Thank you for the questions, as they are our first customer, all of the existing lines are being used in support of CSL.

Ken Hata: Okay. Thank you very much. So, it's past 3 by more than ten minutes, so we want to wrap up this program here. Thank you very much. So, thank you to everybody in this room and online as well. Thank you very much.

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