Terumo Corporation
December 20, 2021

Q&A Session at the Announcement of 5-Year Growth Strategy with a 10-Year Vision (FY2022-FY2026)

Outlined below are the Q&As from the Announcement of "5-Year Growth Strategy with a 10-Year Vision" on December 16, 2021.

Questioner 1: The first question concerns page 7 of Mr. Osada's presentation, where he talks about how much growth there will be in the area of access expansion, mainly with the increase of the radial approach. The quoted figure for expected increase for these was JPY40 billion and JPY25 billion, respectively.

On page 9, the forecast increase in proportion of the radial approach is mentioned, and I think that's reasonable. However, I think that lower extremity arteries and cancer treatment are probably not such a simple matter. I think there are 2 factors behind this. 1 is the shift from hospitals to ASCs, or day surgery centers, where endovascular catheterization is performed. The other is the question of using a wrist approach in ASCs. Therefore, I think the thing that will show the trend best is the use of the lower limb artery approach.

The reason I say that is that the figure for ASCs in the US is already 25%, so if the wrist approach doesn't spread here, other places may be difficult. In the financial results for some other companies, there is talk of using peripheral treatment in ASC, that is, using a wrist approach. However, we are not able to see any specific movement when we look at hospitals. Has your company seen evidence of a shift from hospitals to use of a peripheral approach at ASCs?

Also, the growth of your company's access products in the past has been due to your dedicated products for the radial heart procedure, or TRI. This time, you already have Destination, Glide Sheath Slender, Progreat, and so on in the lower extremity arteries, so we know that they will grow, but this time, you have therapeutic devices. Last time, there were no stents or balloons specifically for the wrist. Since this is now available, please tell us how much of a positive impact it will have on the expansion of access products, especially focusing on peripherals. Has growth in this area already started, and if so, how much growth has there been?

Terumo (Osada): Thank you very much. As you mentioned, the transition to ASCs has started in the US. Even before that, we recognized the development of this tailwind. All countries, including those outside of the US, are facing tight medical finances, and this is creating an opportunity for the radial technique, which not only shortens the hospital stay, but also reduces complications such as bleeding.

In addition, we are facing a shortage of medical staff due to the coronavirus pandemic. I believe this is an area that the radial approach can contribute to.

Overall, the number of lower extremity interventions and surgeries has been increasing. In addition to this, the ratio of radial procedures will increase, and we believe that this is an overall structural situation that will grow. We call this radial approach to the lower limbs "Radial to Peripheral." Our strength in the area of R2P is that we will be expanding our product line to include vascular access, deeper lesion access, and the treatment products that you just mentioned. In addition, we own the patent for this R2P technique. And it protects a technique that uses a combination of parent and child catheters.

From a technical point of view, the success rate of the operation can be improved by using thinner catheters or M-coating all over the catheter, which makes it easier to reach the periphery, and less likely to kink. The fine manufacturing processes required to produce these products would be extremely difficult for other companies to imitate. I believe that no other company can match them.

We are also conducting clinical studies in Japan and the US. What we are trying to do is to collect data on the extent to which complications have been reduced and the success rate of the procedure has increased.

In addition, from a performance standpoint, the products used in R2P actually have a high unit price in the US. The unit price is higher than that of the products for femoral approach. This will support the bottom line in terms of business performance.

As I said, the radial ratio is in the 20% range, but the coronary artery ratio is 60%, 70%, and 80%. On the other hand, the reason why the percentage is low is that long catheters are made for the lower limb blood vessels. It is possible to make a long catheter, but the longer the catheter, the more difficult it is for the doctor to operate. In particular, it is difficult to push, rotate, and cut down on lesions with strong calcification such as SFA and BTK with a long catheter. So in R2P, simpler cases will be the main focus, and we anticipate that the radial ratio will increase.

On the other hand, I believe that difficult cases, such as the ones I mentioned earlier, will still be carried out mainly through a femoral approach.

Even for the coronary arteries, at the beginning of the year 2000, we did not expect the radial approach to be so widespread. It is now between 60% and 80%. We are working on these peripheral approaches with the expectation that use of the radial approach will continue to increase.

I hope I have answered your question.

Questioner 1: As a follow-up, you mentioned a clinical trial comparing femoral and radial approaches in terms of bleeding rate or bleeding events. Do you know specifically when the results of that trial will be available?

Terumo (Osada): I can't give you a clear answer on that yet, but the trial is in the registry. Progress is being made both in Japan and the US. We expect to be able to release the result in 2022 at the earliest.

Questioner 1: Understood. Moving on to the second question. Let me go back to page 7, which shows the overall picture of sales and operating income for innovation. In the section covering the launch of new products, I can appreciate the figure for stroke, for example. However, JPY30 billion for aortic aneurysm treatment after launch seems like quite a steep goal. Of course, there is a base in Europe and Japan with stent grafts, but that doesn't exist in the US. Considering that most of the growth will probably be in the US, how much of this JPY30 billion can be divided between thoracic, abdominal, and open stent grafts?
One of the most difficult things in creating a forecast is how to consider Thoraflex Hybrid. The reason is that this is a Japanese technique, so it was very well received in Japan. However, it is very difficult to predict whether American specialists will use it in the same way as in Japan. I'd be grateful if you could comment on this.
Also, I'm sorry, but just 1 more point. In the area of lower extremity arteries, I think this is the first time hearing about veins from your company. On page 12, there is a peripheral vascular embolization plug, which I think is a diversion of the WEB for varicose veins. Could you tell us about the forecast market size of this product? This is my last question.

Terumo (Osada): Thank you very much. The stent graft business, as you mentioned, is one of the key drivers for GS26. Our strength is that we are the only company that can supply thoracic, abdominal, hybrid, and surgical grafts as a set.
It is difficult to give a clear breakdown of the JPY30 billion, but the main part will be thoracic. The Relay Pro, a promising new product for the thoracic segment, has been approved in Japan and the US, and is now ready for full-scale marketing.
Its thin profile is one selling point. It comes in 19 to 23 French, which is thinner than those of other companies. Although a competitor does offer some 18 French products, we believe that our products are superior. Specifically, the fabric thickness and the stent wire thickness is the same level as that of the existing stent graft.
In addition, when the catheter is raised, it might cause a cerebral infarction if a blood clot jumps out. By making it a soft sheath, it is expected that there is less risk of ischemic stroke.
In some products, the tip of the stent graft is not covered with material, so there are bare metal parts sticking out. However, we have an assortment of non-bare products, where no metal is exposed. This is said to be effective in cases of dissection. It is said that the bare stent induces dissection, so the launch of this non-bare product will allow us to use it for dissection as well. We are considering expanding its indications to cover dissection in the near future.
We are not that aggressive in the number of hybrids we have in the pipeline. It is difficult to

predict how much hybrids will expand in the US and Japan. However, we are the only company that has both surgical grafts and stent grafts. We have combined them and are actually marketing them in Europe. In Europe, we have about 80% of the market share, and it will be released soon in the US. It will also be launched in Japan.
We have an expectation that the number of cases will be highest in the US, then Japan, and then Europe. Even so, we are not very bullish in our sales targets.
For veins, the product is not utilizing technology of WEB, but AZUR Plug.

Questioner 1: And how about the scale of sales?

Terumo (Osada): I can't give a specific estimate on sales, but within GS26 as a whole, we would not expect it to be very large. You can think of the expected value as an add-on.

Questioner 1: Thank you very much.

Questioner 2: In the waterfall chart on page 12 of the President's presentation, I see the analysis of the increase/decrease in operating margin. The target is to improve the operating margin by at least 2.5% over the next 5 years. If you break this down roughly, is it correct to assume that the gross margin will be around 2% and the SG&A ratio will be almost flat?

Terumo (Muto): I will answer. As you said, it is divided into cost and SG&A. In this diagram, the business mix is the cost of sales, and pharmaceutical affairs is also included in the cost of sales. Some SG&A expenses are included, so with net 2%, 1% is cost and 1% is SG&A expenses. With net 3%, 2% is cost, and 1% is SG&A due to profit improvement.

Questioner 2: I understand. Thank you. If we do that, the current gross profit margin for the current fiscal year is probably 53% to 54%, although we don't have any guidance. We will add the 2%, so I think we are looking at a gross profit margin of around 56%.

Terumo (Muto): That's right. I think it would require some effort to achieve that.

Questioner 2: I think the gross margins of your overseas competitors are in the range of 60% to 65%, so the figure is still relatively low compared to your competitors. Where do you see the difference?

Terumo (Muto): I think it's in the business and product mix. In the Cardiac and Vascular Company, I think we have secured a gross profit margin that is comparable to our overseas competitors. The level of the General Hospital Company and Blood and Cell Technology

Company is a little lower than that of Cardiac and Vascular, but I think the weighted average of these factors gives us this level.

Questioner 2: Also, regarding the expenses. On a per-region basis, I think that most of the growth in sales will come from the US. Also, on a per-product basis, I think that therapeutic products will also increase. Both of these are areas where the so-called cost base will be relatively high.
For example, in terms of R&D expenses, the ratio of R&D expenses to sales used to be 5% to 6%, but it has expanded to 7% to 8% in the last 4 years to 5 years. If the number of therapeutic products increases in the future, should we assume that this 7% to 8% cost ratio will further expand toward, say, the 10% level? Or do you think expenses will stay relatively flat, even while the weighting shifts toward therapeutic products?
Also, regarding SG&A expenses, since inflation in the US has increased, there is a concern that if the percentage of sales in the US increases, the cost base will also inevitably expand. Could you comment on that?

Terumo (Muto): I think the trend is as you say, but the current assumption for GS26 is 8% in terms of development costs, for example. I think the mix is having an effect here as well.
In terms of SG&A expenses, it is true that labor costs in the US will be high, but if we look at sales and profits to match those costs, I believe that overall SG&A expenses will remain at the current level.

Questioner 2: I understand. Thank you.
The second question is about the KPI for profitability. This time, you mentioned that you are going to use ROIC, and I think you were talking about bringing the current 8% level to 10%.
If it is possible, I would like to know how you see ROIC for each company. What I am particularly concerned about is the hospital company. I think this is related to CDMO, but the cumulative investment of nearly JPY80 billion over the 5 years makes it a very asset-heavy segment. My impression is that the ROIC is probably far below what it should be.
In that case, it seems to me that the Company is not providing much shareholder value to the Company-wide average, which is probably around 8%.

Terumo (Sato): I'll let Muto give you the detailed figures, but to put it simply, in the case of ROIC, it is assumed that the figures will not be that bad because this industry is relatively healthy and has high margins.
In our case, we are not really worried about it. If you look at factors that are lowering ROIC, the main factor is goodwill. That is, goodwill from past acquisitions. Therefore, if you look at our competitors, which were mentioned earlier, they are actively engaged in acquisitions. Even high margin companies have very low ROIC.

Among the 3 companies, the Blood and Cell Technologies Company, in which we acquired Caridian BCT in the past, is the lowest. On the contrary, the General Hospital Company has not done any acquisitions at all, and moreover, its past investments are based on assets from long ago, which have been depreciated, so in other words, the numbers are surprisingly good. This means that the picture is different from what you might think.
I wouldn't call this gospel, but when we do a new M&A, if the goodwill cost is very high, it tends to distort the numbers a little bit, but that doesn't mean we don't do M&A.
So, at least on the current basis, excluding new M&A, the right way to go about things overall is to bring it above 10%. The basic policy is to gradually raise the base, which we are not so worried about at present, while improving margins and earnings.

Terumo (Muto): We do not disclose figures by company, but as was just explained, the ROIC of the Cardiac and Vascular Company is the driving force of the entire group.
As for the General Hospital Company, Alliance will be the main focus in the future, but it will take time to bear fruit because of the upfront investment. There are some investments that will bear fruit in GS26 and the next 5 years, so in that aspect, I think we are a little lower than average.
As for blood, there is also the same upfront investment, so overall, we expect to secure more than 10% in 26 years.

Questioner 2: Thank you very much.

Questioner 3: The first question is about the current Cardiac and Vascular market environment, which was mentioned earlier with respect to R2P. First of all, putting aside the ratio of radial approach procedures, I would like to know how you see the growth of the number of catheter procedures itself. I think that rates of coronary heart disease will fall, but I also wonder what the outlook is for peripheral and neuro in particular. You mentioned in your presentation that as catheters become more and more commoditized, the prices of those used for existing, relatively easy-to-treat lesions will fall. I think this means that without good new products, the average price will go down.
In this sense, I would like to know how much of a price decline you have in mind for existing products that are relatively undifferentiated. This is my first question, relating to your perception of the market environment.

Terumo (Osada): The growth rate of catheterization procedures is a mixture of coronary artery, lower extremity, and abdominal procedures. I think the overall average growth rate will be about 6% to 7%.
As for prices, as you pointed out, prices for products with few points of differentiation will go down. It is hard to say by exactly how much, but we usually assume about 2% when we consider

this issue. On the other hand, the prices of guidewires and sheaths, which we have been selling for a long time, have not decreased. Rather, we have seen price increase with our expansion into radial approach. Considering the size mix, with the ASP assumption in our business performance, that itself will not necessarily decline. We are carrying this assumption forward in future also.

Questioner 3: Are you saying that the financial targets are made on the assumption that the price will rise?

Terumo (Osada): Overall, I think it is fair to say that the prices are flat, although we have not seen the exact impact only from prices.

Questioner 3: Thank you very much. The second question is a bit longer term. Many times today, there has been talk of the shift from selling products to selling solutions, but when we look at how sales and profits are generated, I still feel that the Company is selling products. In the last year of GS26, I would like to know to what extent the sale of solutions will be in place. You mentioned today about moving from 5 years to 10 years, so I would like to know what you envision in 10 years.
To be honest, I think it is very difficult to get money from sales of services, so my concern is that margins will go down. I would be very grateful if you could explain this as well, with supplementary information if possible.

Terumo (Sato): I'll take this question. Please don't misunderstand me when I say that we are not aiming to increase the number of separate solutions or software unrelated to devices. In the first place, the devices themselves will become solutions. If we don't do our marketing and sales activities in the context of solutions, we will no longer be able to sell the devices themselves.
We are not just trying to improve the specifications, but as I mentioned today, our solution is to position the device as part of a comprehensive solution for patients and medical professionals. As a result, we don't think about it in terms of how much the solution would cost in isolation from the device.
For example, in B2B, which has been mentioned many times today, we customize devices to meet the solutions demanded by our customers and provide them with those devices. So in a way, we are providing devices, but this is also our idea of solutions.
If you can see it in that way, I think it will be very easy for you to understand our shift to solutions without any misunderstanding.

Questioner 3: Understood. The misunderstanding has been cleared up. Thank you.

Questioner 4: The first question is about stroke. You have given us some figures, but I am not

familiar with them. I would appreciate it if you could tell us about some specific products that are already in place, and at what time and in what region they will be released.
Secondly, in the area of blood and cells, I think the new PDT business will start in the next fiscal year. That is, the CSL one. That in itself is good news, I think. With this competitive edge, please comment on whether or not you have enough technological differentiation to be considered for orders from other PDT manufacturers in the future, for example, in the medium to long term.
Thank you.

Terumo (Osada): I will answer to the first question regarding stroke. For cerebral infarction and cerebral hemorrhage, our main product for ischemic stroke is an aspiration catheter called SOFIA, which has already been released. We will continue to increase our product line. For example, we will release thicker models, and those with a wider inner diameter but with the same outer diameter.
We are also developing a stentriever in a project named ARTHUR. We are aiming to release it during the GS26 period, so we do not think that we have a complete pipeline for stroke yet. We believe that there is a lot of room for growth.
Also, a few words on brain hemorrhage. We have been selling coils, and there is the WEB from Sequent Medical, which we have purchased. In 2021, we released a very thin 17-French model, which is already on the market. This is not yet widely used enough, and I expect it to become much more widespread in both Japan and the US. It can be delivered with a delivery catheter as thin as a coil, so the market need is very high.
In addition, there is a flow diverter. Through our thin products, and the use of our unique coatings, we believe that flow diverters are another area where there is room for expansion in the fields of cerebral infarction and cerebral hemorrhage, both in Japan and the US. We believe that we can achieve total sales of JPY30 billion.

Questioner 4: Thank you very much. Just a quick follow-up, but with the stentriever, will the current development items be sufficient? Or do you think it will be necessary to introduce more of them?

Terumo (Osada): This is a matter of timing, and since the product is still in development, we can't be 100% sure. If there is any delay, we would like to consider those similar to other companies. In Japan, the Otsuka Group is selling a stentriever called Tron, which is doing very well.

Terumo (Antoinette): We, too, are making this product and what supports it as an ecosystem available to all players. It is aimed at the entire industry of source plasma.
So, of course, my primary goal is to support my current partners, but I also want to create a

platform that will allow them to expand their market leadership position throughout the industry.

Terumo (Hata): This is a very sensitive topic because we are really just starting up with this CSL. Nevertheless, the majority of the growth in the top line of the Blood and Cell Technology Company, which is approaching double digits, comes from source plasma.
As a rough guide, we have already seen on the slide 8 of the Blood and Cell Technology Company, that the current market size is JPY800 million, and it is expected to grow by about 8%. We have heard that CSL's current share is at least 30% of this market. The target in 5 years is that the 800 will grow at 8%. I can't tell you the breakdown right now, but we are aiming for that size.

Questioner 4: Thank you.

Questioner 5: The first question is about slide 15 of the President's presentation. Specifically, I would like to ask about cash allocation. I think the last time the subject of acquisitions, shareholder returns, and so on came up, it was over JPY200 billion, and there was very little share buyback. The purchase was not very large. This time, the amount will not be disclosed, but can we expect the same level here?
In addition, above the dividend, it says that the dividend payout ratio is 30% or more. According to the securities report, the Company is aiming for 30% or more in the medium to long term. However, I don't think the figure has been more than 30% for the past 6 years, so can we expect more than 30% in the new fiscal year and during the period of the mid-term plan? Please tell us about this issue of shareholder return.

Terumo (Sato): Regarding the dividend, unlike other areas of profitability, we don't take a strict view that we must exceed 30% or 20% at all costs. The 30% figure is a rough target.
In fact, we have heard from a variety of shareholders that they would like us to exceed 30%. On the other hand, there are still some shareholders who would rather have us invest more aggressively and aim for around 30%. Taking into account such comments, maintaining a level of around 30% is what we are thinking about right now, and the truth is that we are not hyper-focused on this figure.
There are other metrics that we are more interested in focusing on, so we are really keeping our attention on those. We control the dividend on the premise that the absolute dividend will grow consistently.
Our approach to shareholder returns will basically remain the same as before. We will implement various actions in the right timing. However, there is a possibility that new regulations and laws will emerge, and we will keep those in mind and update our decisions as necessary.

Questioner 5: Thank you. Secondly, I would like to ask about the profit margin. I think there are

more and more things that the Company cannot do alone, and partnerships with other businesses are necessary for diabetes management, for example. In these types of situation, I think the profit margin necessarily goes down, but in that case, how can you increase profits and margins while also increasing the number of partners?

Terumo (Sato): This is a general statement. In the past, when we were involved in alliances such as CDMO, which was mentioned earlier, we were asked the same question. We were worried that our margins would be lowered by subcontracting. However, the partnerships we are forming now is not to provide general-purpose products that are subcontracted, but to provide differentiated technologies in very limited, very high-value-added businesses.
To that extent, we have always managed our margins clearly, and we have strategically selected businesses to ensure that margins do not deteriorate unnecessarily as this business grows.

Questioner 5: Thank you very much.

Questioner 6: Listening to your talk today, I got the impression that the so-called 3-company system is functioning extremely well. There was talk of further increasing the autonomy of this system to increase the profit margin or profitability, by having individual companies shift to solutions. Is it correct to understand that this direction will be further expressed in the President's approach and in the concept of this medium-term management plan?
In other words, in terms of organizational theory, when you originally introduced the in-house company system, I think you were talking about making each company individually responsible for its own earnings, but did you start from that point?

Terumo (Sato): That's right. As you said, when we implemented the in-house company system about 10 years ago, our hope was to have each company and each business undergo strict profit management, and to have each business and each company stand on its own feet to meet the expectations of our customers. I can honestly say that it is beginning to work.
In the future, I ask each company to continue to move in the direction of rounding up expected growth, always finding growth opportunities independently.
However, as I mentioned today, there are areas in which we can use the Terumo brand to create a common management platform and market approach for the companies. We will simultaneously take integrated initiatives to further increase synergies and improve efficiency. I think that is the main message today.

Questioner 6: Thank you very much. Another issue that was not mentioned much this time was the production system, which was touched on in the cardiac and vascular company section. This is related to the so-called supply chain problem, and also the problem of inflation.

I don't think there is an answer to this question, but at least during GS26, I think your company still has about 10 factories around the world. How should we perceive the risk related to this? That is, in terms of the problem of the supply chain in the production system and the problem of maintaining production. I think that Ashitaka is still the main factory, but I wonder if we should be aware of the risk of any disruptions that may affect the entire supply chain among the factories scattered around the world.

Terumo (Sato): Thank you very much. In general, as you all know, supply chain risks are increasing not only in our industry, but worldwide. There are risks from inflation and from fragmentation, and we have learned the importance of such risk management during the coronavirus pandemic.
However, as I mentioned earlier, we cannot completely diversify our supply chain, so we have a 3-pole system: the Americas, Asia, and China. Since there are risks associated with domestic production in China, we have divided the supply system regionally into China as a separate risk and Japan to diversify risk and stabilize the supply network.
Even so, basically the main factories are still in Japan, so while strengthening the position of those main factories, we are also working to optimize and strengthen our global network by satelliting or off-shoring to places such as Costa Rica and Vietnam. Our main message this time is to optimize and strengthen our global network.

Questioner 6: I understand. Thank you.

Questioner 7: The first question is about the Alliance business of the General Hospital Company. If we assume that the number of contracted products has not changed since the plan was made a year ago, the number of contracted products will probably increase from about 12 in FY2020 by about 10 during this mid-term plan. That would give a total of about 22.
If that is the case, I think the alliance business will grow from sales of more than JPY20 billion in FY2020 to JPY60 billion or JPY70 billion, based on the data you provided today. Calculating from that, it seems that sales per contracted item will increase slightly.
I would like to ask about the reason for that. Is the pattern one of increasing production volume and sales of items that you have already undertaken, or is it the large scale of new items to be undertaken in the future? Personally, I think it's both, but which element is stronger? Which one will have a larger effect in increasing sales during GS26? I would like to ask you to explain about this.

Terumo (Samejima): Thank you for your question. As you can guess, this is double-sided. There are also factors that can increase sales of items that are currently being sold, for example, by expanding into new regions.

On the other hand, there is the aspect that some of the new products that we are going to start contract manufacturing are large. If I had to choose one, I would say that the latter contributes more to the incremental increase in sales.

Questioner 7: If so, could you tell us again about the factors behind the large size of relatively new projects?

Terumo (Samejima): I think we explained this during our webinar on September 27. Our CDMO model is very unique. Pharmaceutical manufacturers are beginning to appreciate the value of the fact that we provide a wide range of services, starting with syringe molding, development, filling, and packaging. As a result, we are getting more opportunities for new business. Therefore, compared to the past, we are now receiving relatively large orders for pharmaceuticals.

Questioner 7: Thank you very much. The second question relates to the Blood and Cell Technologies Company. On page 11 of the CEO's presentation, there is a bar chart that breaks down the factors that contributed to the increase in sales by factor. The tip of the bar chart for the JPY60 billion figure for the hematology and cellular growth area fades out at the end. Since the shape of the bar chart is different from the other elements, I guessed that there was some meaning behind the fading. Does it mean that it won't materialize that way unless some conditions are met? Is the bar chart faded out in the sense that if some other area were strong, it could go a little higher? I would like to know the meaning of this visualization.

Terumo (Hata): There are 2 sides to this. It's true that that's the only part that's cloudy. As you say, this is for the JPY60 billion part. As I mentioned earlier, the majority of our business is in the area of plasma collection, which has not yet been approved, and we are preparing for it. In that sense, there are uncertainties. That's the downside.
However, as another questioner asked earlier, there is an upside as well. When we made the announcement today, it had to be different from other announcements, so I hope you will recognize that positive aspect.

Questioner 7: Understood. Thank you. That's all from me.

Questioner 8: I am looking at page 11 of the 5-year growth strategy. Under the drivers of growth, in case of the Cardiac and Vascular Company, therapeutic is JPY80 billion and access is JPY65 billion. If we consider the degree of contribution of new products, how would the figures look?
As you mentioned earlier, it might be difficult to make a general classification for example of the aspiration catheter because it is an upgraded version, but please tell us how much the expected contribution to the effect of so-called larger new products is.

Terumo (Hata): To put it very crudely, access will include the increasing ratio of radial procedures. The raw base will increase, and as Osada mentioned earlier, in R2P there is an effect from price increase, which will increase the margin.
More than half of the growth from therapeutic devices will be in the area of stent grafts which are now being rolled out in the US. Those products which are no yet available, such as stentrievers are included in therapeutic devices as well. Does that answer your question?

Questioner 8: Understood. Thank you. On to my second question. Although this wasn't mentioned today, in the Chinese market, you have been conducting clinical trials of renal denervation for hypertension since around 2014. What are your current efforts, expectations, and updates?

Terumo (Osada): As you mentioned, renal artery ablation is currently undergoing clinical trials in China. We are now on track to complete patient registration this year.
In addition, a small clinical enrolment and confirmation of the primary endpoint has actually been completed in Japan. We are now in the 3-year follow-up phase.
On the other hand, we would like to consider full-scale clinical trials while monitoring the market situation, so we have not yet reached the point where we can formally consult with PMDA or other such organizations.

Questioner 8: What do you imagine the time axis to be?

Terumo (Osada): In China, we are already expecting to complete the registration of patients, so we are thinking that we will be able to file a pharmaceutical application as early as next year.

Questioner 8: I understand. Thank you.

Questioner 9: I would like to ask Antoinette a question. Listening carefully to what you said earlier, I think the image was that your plasma collection device would come out and it would replace the NexSys PCS® 2 from Haemonetics, or other similar devices. There is also a question of consumables.
However, there was also discussion of centrifugation and purification of the plasma. This would all be managed as 1 process by software.
In that case, this will probably not only replace that device, but also provide a full solution, which will replace the existing CSL contract.
What I would also like to ask is how much of a benefit will it be to do this? If we can understand this, we can consider the possibility of going to other companies such as Takeda, so could you

please explain this?

Terumo (Antoinette): Thank you for your question. This ecosystem includes everything that the plasma center administrator needs for operations. So, it includes the interface with us. Our efficiency will also be affected.
So, we monitor the performance of these assets, receive complaints, questions, and so on. We also do field service, maintenance, and so on.
We have a very comprehensive data feedback loop, so we can very proactively monitor devices and prevent downtime, which is a problem with current platforms.
We have received very positive feedback from the center directors in our efforts so far. This will change the way things are done at the centers, change how the backend processes work, and ensure that operations proceed much more smoothly.

Questioner 9: So, this is more than what Haemonetics can offer with its smart software platform at the moment. Up until now, I thought it was just patient ID maintenance or plasma tagging. So, it's a more comprehensive solution than that.

Terumo (Antoinette): Yes. Competitors have an interface to a donor management system, while we have this for the whole ecosystem. We are also partnering with this new DMS provider to move forward with additional next generation products.

Questioner 9: I think that this time, there is also the 3 Ds thing, right? This makes it look like Deviceuticals is being upgraded quite a bit, relative to others. In terms of the scale of sales, you are capturing a part which is not yet that large.
As you mentioned, the unit price is going up, and I think there is 1 more thing: new devices are quite complicated, aren't they? For example, the G-Lasta® continuous injection device, which has already been announced, would probably have to be more expensive per unit than the syringe for NESP® injections to make it worthwhile. Is it correct to say that when this grows, beyond 2026, for example, the Alliance in Deviceuticals will be quite large?

Terumo (Samejima): The high level of technology inherent in our devices and our commitment to discussing with pharmaceutical manufacturers from the very beginning have been highly rated. Within GS26, we will finally be able to talk with overseas pharmaceutical manufacturers, so I expect that the potential will be quite large.
In my slide presentation, I talked about appropriate capital investment and capacity expansion, including the establishment of a new plant. Although I cannot give you a sense of the scale of the project, I expect it to grow significantly and continue double-digit growth.

Questioner 9: Do high-end devices also contribute to some extent?

Terumo (Samejima): Yes. In this sense, we are expecting a certain amount of sales contribution from the pre-fillable PLAJEX business and the bundled business. The number of overseas customers for these kinds of core business, which don't include things like catheter tips or bases, is steadily increasing. We expect to see some contribution to sales here.

Questioner 9: I have 1 last question for the CEO. In the area of diabetes, I believe there was talk of JPY50 billion. If you look at today's slide, there is a figure of JPY8 billion written somewhere. This is certainly a strategic matter, so with CGM, I believe your company has already gotten a handle on algorithms and insulin pumps to some extent.
Is it correct that this will take some time due to the relationship with CGM? Or in some cases, will things get bigger if you move faster? This is my last question.

Terumo (Sato): Within the future expansion, there are some areas where there could be more clarity with respect to CGM. Then there is SMBG in which we anticipate the user ratio decrease, therefore, this figure is the sum of all these factors.
As Samejima explained earlier, we have a full lineup of products, so I don't know exactly about 2026, but I think it is hoped that we will be able to expand this business a little more after 2026, and Diabetes Management is and will be one of the segments we focus on.

Questioner 9: Thank you very much.

Terumo (Sato): 1 more point. You asked about CDMO earlier, and the important message is that when we look into the future, people will think that we are in the medtech industry, and that is where our core competence lies. There is a drug market that is 4 to 5 times as large as the medtech industry, and that market is also changing and growing rapidly.
Our strength is not just rooted in medtech, but as I explained earlier, we can also apply it in the form of drug delivery. When we expand our frontiers, we are not only focusing on medtech, but also on the unique capability of Terumo to leverage the power of medications to grow. The appeal of that business is that by expanding in this way, Terumo will be able to find new frontiers. If you look at it that way, I think it will change the way you look at Terumo.

Questioner 10: Thank you for your presentation, Antoinette. What I was interested in was this source plasma. So, CSL is expected to be more efficient and have a higher yield, but does this higher yield mean lower downtime? Does it mean that the patient can take less time to donate the same amount of plasma?

Terumo (Antoinette): Thank you for your question. First of all, the processing speed of this device is faster. Even in clinical trials, we are now seeing a significant improvement from existing devices. The algorithms in the product can optimize for the physique of the donor.
With the competitors' existing devices, if the donor is of a larger physique, sometimes the donation goes back to the donor. This happens when the volume outside the body exceeds a certain amount. In this case, it may not be possible to collect plasma from the donor. If that happens once, the donor won't come back. So, there is a big advantage in that area.
The third big advantage is that we have a very reliable device. Therefore, we believe that the downtime, maintenance, and servicing time will be significantly improved over the existing system. I believe that we already have good data in those areas.

Questioner 10: Regarding timing, Haemonetics said that their sales to CSL in the US will no longer be there after next June, but your product will be in place by the middle of 2022?

Terumo (Antoinette): I can't talk about the timing because we don't have FDA approval yet. 510(K) has already been filed, however, the clearance has not been passed yet. I believe it will pass, but as you know, the FDA has much backlog right now. I think this is a major factor that will affect our rollout.

[END]