Terumo Corporation
August 6, 2021

Q&A Session at the Financial Results Briefing for the First Quarter of Fiscal Year Ending March 31, 2022

Outlined below are the Q&As from the financial results briefing on August 4, 2021.

Questioner 1: My first question is about the comment you made about production adjustments. I believe you have commented on their downside risks to the earnings forecast for the current fiscal year, and their associated impact on lower revenue or profit. You mentioned that you saw some production adjustments during Q1. Do you think these adjustments will last into Q2, Q3, or beyond? Alternatively, do you think they have run their course in Q1 and that there will not be the impact going forward?
My second question is about the upward revision to guidance. Perhaps this is due to my lack of understanding, but it almost seemed like you just added the surplus from Q1 onto the full-year forecast. In other words, I interpreted it to mean that there are still risks for Q2, Q3, and Q4, so if results were to exceed the forecast again, then those surpluses would be added on to guidance again as they arise. Is this interpretation correct? Please tell us more about your thought process behind the upward revision to guidance.

Terumo: First, regarding your question about production adjustments, these adjustments have been included in Q1. We also see further room for adjustments to the level of inventories, so we expect these adjustments to continue in the future.
As for the upward revision to guidance, our initial expectation was for a modest impact from COVID-19 during the first half, so we set the target at a slightly lower level than normal. For the second half, we assumed that the level would return to normal.
Accordingly, the faster-than-expected recovery during Q1, led by Europe and the Americas, along with the rising speed of recovery in China, including the surplus from a temporary rise in demand in Q1, have been included in the upward revision. For the period from Q2 onward, we still expect roughly the same level as we initially planned. The latest trends in July have also shown performance in line with expectations, so that that is why we have made the upward revision in the way disclosed today.

Questioner 1: Thank you. Let me ask just a simple follow-up to that question. So, you expected a lingering impact from COVID-19 in Q1 and Q2, but Q1 performance was robust. That sounds like there is still room for overshooting in Q2. Is that correct?

Terumo: So far, the results are trending in line with the upper bound forecast that we issued. That's how things have been trending in July.

Questioner 2: In the period from April to June, the result that I thought was the most striking was at TIS in the US. Results were also good in Europe and China, but I thought they were exceptionally good in the US. Please share us the background to these results. Is it simply because of the backlog of interventional procedures being worked down? But, it's hard to imagine that doctors can increase the number of procedures by that much.
Alternatively, what is really of keen interest to us right now is whether the spread of COVID-19 has increased the urgency to discharge patients of catheter surgery early on. Have you seen any signs of an increase in catheter surgeries at ambulatory surgery centers, or ASC, which are outpatient surgical centers, where treatment is now covered by insurance?
If that is that case, then trans radial intervention (TRI) and radial techniques in which the catheter is inserted through the wrist would allow patients to be discharged from the hospital sooner. I conjecture that the expansion of such products would lead to a proliferation of Terumo's premium-priced products.
What was the driving force behind the TIS business in the US in the Q1? Why did revenue increase, and is there any factor behind the increase that would lead to longer-term trends?

Terumo: Our TIS business performed very well, and we are looking at the performance by region and on a QoQ basis. We are looking at the period from April to June compared to the period from January to March, which was also strong. As you point out, the Cardiac and Vascular business as a whole grew by 10% QoQ, which was led by the global growth of TIS, which was up 14%.
The growth is generally proportional to the COVID-19 vaccination rates and the level of recovery. Leading the recovery is North America, up 13%, and Europe, up around 13%, while laggards have been Japan, South and Central America, and Asia.
In fact, if we look at the amount of increase, the largest part of the QoQ growth came from China. This was due to a special factor, whereby distributors have stocked up on products in anticipation of volume-based procurement (VBP). Therefore, this increase may reverse in the future. But, in fact, the second-largest contribution came from North America, up 13%.
We expected demand to grow for peripheral systems, such as at ASC, like you mentioned, but the largest portion of growth actually came from the amount of revenue for access devices. Simply put, the recovery in the number of cases has been the driver behind the improvement from April to June. What you mentioned about ASC or R2P is something we hope will drive earnings in subsequent quarters.

Questioner 2: What about the ratio of TRI treatment? Do you feel like there has been an increase in the ratio amidst the spread of COVID-19?

Terumo: I believe it reached about 50% in North America at the end of the previous fiscal year. We haven't heard anything yet about the TRI ratio rising several percentage points higher than that. This is an area where we expect further growth in the future.

Questioner 2: Okay. My second question is about the plasma collection business, which I believe you will be starting soon. I'm not sure if you would be willing to answer this question, but I think the greatest problem in this domain is the onset of severe hypotension caused by a decrease in blood volume. Competitors who have released such products are not measuring blood pressure after all.
But, based on my conjecture, Terumo's device measures blood pressure. If that is the case, then Terumo's device would have a competitive advantage from the reduced risk of complications due to hypotension. Furthermore, the amount of plasma collection hasn't changed since 1992 from 800 ml per person. The reason why the amount hasn't changed is that collecting too much blood could lead to hypotension.
If Terumo were to release a product that could measure blood pressure, then I believe it could lead to changes in the protocol itself. Would you say that my assumptions are correct? And, if so, then Terumo's product appears highly competitive against other products on the market. What are your thoughts on this?

Terumo: We can't tell you about the mechanism at this point, but the key point is how efficiently the plasma is collected, or specifically, how long the collection takes, given that the amount is predetermined. Depending on the patient, even if it is the same patient or donor, the amount of blood collected must be tailored to their state of health on that day. Even if the donor wishes for blood to be collected quickly, doing so too quickly could lead to dehydration. Therefore, we are using an algorithm to ensure that the plasma collection is neither too fast nor slow.
We can't share any further information at this point. But what we are developing would improve blood collection for all people, including operators. We are working to provide an even better product than what is available on the market. We finally completed clinical trial, and preparations are underway to apply for FDA. In this way, we have made further progress than 3 months ago. In terms of the timeline, we expect the product to be launched around the same period next year. Efforts are being made with our eyes set on revenue contributions starting from the first half of the next fiscal year. Steady progress is being made. I'm sorry for not giving a direct answer.

Questioner 2: I believe this product is being developed in collaboration with CSL. Are there any terms and conditions to the alliance, such as not being able to sell the product to other companies for several years?

Terumo: First, we are working with CSL to be successful in the North American market, which is the largest market. There are only a few players in the market, so the number of customers is also limited. Once we earn a certain degree of reputation in that market, then we would begin discussions on how to expand the product after that, and there aren't any restrictions in that regard. We can't share you the details of the contract, however we hope we can expand this business more in future.

Questioner 3: My first question is about VBP in China. At the start of this year, during the third-quarter briefing, I believed you mentioned about bidding related to PTCA guidewires in 13 provinces, excluding Inner Mongolia, expected around May of this year. Based on my own research, it seems this has been executed at the end of June. Some reports note that the prices of wires have fallen by around 60%. Please tell us how much of an impact the bidding has had on Terumo's selling prices.
Separately, in Jiangsu province, I believe there was bidding at the of June not just for wires but also for balloon catheters and guiding catheters. If possible, please also tell us the impact this has had on Terumo's selling prices.
Additionally, I'm very interested in knowing how the number of percutaneous coronary intervention (PCI) cases has been trending in China, in response to changes in prices due to the series of VBP. During the financial briefing held 3 months ago, you explained that there hadn't been much of a drop in PCI volume spurred by incentive payments from hospitals to doctors. What kind of progress have you seen in this trend over the last 3 months?

Terumo: As for VBP, bidding has already been completed for drug-eluting stent (DES) and balloon catheters, about half of which has been done at province level. The impact of the lower prices will start to have an impact from the current fiscal year. As we have stated previously, we expect the impact on the selling price of balloon catheters to be a decline of around 60%.
Bidding for the final group of products, including guidewires and guiding catheters, started around June. It has begun in Yunnan, Jiangsu, and several provinces in Inner Mongolia. Based on what we have heard, the impact is a price decline of around 20% in end-user prices. However, the impact has not been felt at manufacturers like us so far, and these price declines have been absorbed fully by distributors. All of what I just explained has been within our expectations.
The key question is volume. The purpose of VBP is not just to reduce medical expenses but also to improve access to medical care and increase the number of cases. As we stated last time, the margins that went to distributors before will basically shift to public hospitals. The additional

profits arising from there at public hospitals would then be used as the funding source for the construction of new buildings or the adoption of incentive systems for doctors in order to increase the number of cases.

When looking at the conditions right now, it seems that the number of cases has in fact increased, and it is increasing more than we had expected. For example, in terms of DES, the national bidding has put quotas, or allocated volumes, to the manufacturers that won those bids. Some manufacturers who won the bids, however, are struggling to meet those quotas, resulting in a situation where a greater volume of orders than the quota is being placed to manufacturers with spare capacity.

Terumo is one of these manufacturers with spare capacity, and, in fact, we have already received orders almost exceeding the annual allocation volume in just 6 months. As a result, the sales volume has increased more than we expected despite the lower prices. As we stated earlier, revenue in the TIS business increased by 41% QoQ in China in the period from April to June compared to the period from January to March. The increase amounts to roughly JPY3 billion.

We initially expected the volume to increase for DES, which are part of VBP, but, in reality, we also saw an increase in volume for access devices and other products that distributors stocked up, to prevent shortages in light of some manufacturers that are missing deliveries. As a result, demand increased significantly for our access device sub-segment.

We expect this boost in demand to be temporary, but what we can say at the very least is that our initial concerns about the number of cases have been alleviated. We have seen a steady increase in the number of cases. However, one question that still needs to be clarified is whether the increased demand is due to the rise in the number of cases, or whether Q1 results look especially strong because of distributors that have stocked up on inventories. This is a point that needs further discernment in Q2. At the very least, we believe that the purpose of VBP has been fulfilled so far.

Questioner 3: I understand. Thank you. Just as a follow-up to that question, to what degree has the number of PCI cases recovered or increased compared to 2019 on a real demand basis?

Terumo: We've asked on-the-ground staff about this, but it's hard to decipher at this point whether the demand is from stocking up inventories or due to a real uptick in cases. China hasn't made any formal announcements, either, so it will probably take some time until we can give an accurate number.

Questioner 3: I see. My second question is about your collaboration with CSL. I'm not sure if this is something you can answer, but I'll ask my question anyway.

First, in terms of SG&A expenses, I believe you have allocated about JPY2.5 billion for the current fiscal year as expenses to be used related to the collaboration with CSL, but it seems that these expenses were not used as of 1Q. Will these expenses be used as planned? Earlier, you

mentioned that clinical trial has been completed, and my guess is that the data you gathered will be included in the 510k application to the FDA. Do you have any plans to release the data externally? Alternatively, can the data be used for negotiations with Grifols or Takeda? In other words, is it possible to use the clinical data obtained through the collaboration with CSL in negotiations with players other than CSL, given that the copyright belongs to Terumo?
Lastly, you mentioned that you couldn't share the specifications at this stage. However, I believe there are various touchpoints, such as yield or cost. What are the points from CSL's perspective that were evaluated most highly about Terumo's product?

Terumo: Thank you. I think that the results of the clinical trial will probably not be released. The timeline of the product is for revenue to start being booked in about 1 year's time, in the next fiscal year. Our next medium-term plan is also scheduled to be announced in December. So, the plan will be solidified by that time, including the status of regulatory approval.
The crucial point is the next step, where we establish a mass-production system. Progresses on both of these fronts will be fleshed out even further and will likely be clarified at that time.
What CSL expects from us, as I stated earlier, is efficiency. The focus is on how much the time of plasma collection can be shortened so that the required volume can be collected with the least burden to patients, and efforts are being made to launch the best device on the market.

Questioner 4: Regarding the decreased demand for convalescent plasma, do you think that the greater distribution of vaccines in the US has already caused demand to peak out, and do you think that demand will continue to decrease going forward? Perhaps Mr. Muto has already talked about this point, so I'd just like to confirm that point.

Terumo: Thank you. Muto hasn't explained that point yet, so I will give an explanation.
We probably mentioned this already during the full-year financial briefing 3 months ago. The spread of vaccinations has caused demand for convalescent plasma therapy, which was the next best measure until then, to shrink. We already expected this to happen, but the special demand has virtually disappeared in the April to June period. We haven't included that special demand in our outlook, so there won't be any further decline versus the outlook. The dropout of the special demand is already factored into the outlook.

Questioner 4: Okay. Thank you. My other question is about the plasma collection business with CSL, which has been touched on in earlier questions. If I recall correctly, CSL has established over 200 blood centers throughout the US, which have gradually shifted from large-scale blood centers to smaller ones. I have heard that blood centers are scattered across the US, such as next to drugstores. And the approach to plasma collection has been changing, where donors would visit those local centers and show their arms to donate blood.

That's not the point of my question, but I believe the major premise is that the product would replace all of the current devices that are being used by CSL. What's the length of time, or timeframe, that be required for this to materialize? I would appreciate it greatly if you could share with us your thoughts on the timeframe.

Terumo: Thank you. CSL has plasma collection centers in nearly 300 locations. I have heard that CSL has the greatest number of centers in the US. As you stated, the trend is for donors to visit these centers as much as twice a week to donate their blood. There are nearly 300 of these centers, and we expect to receive orders for the product at all centers from Haemonetics, which will need to replace their old devices with new ones.
CSL has emphasized the efficiency of operations, so taking too long to replace these devices would be operationally inefficient. So, we plan to replace existing devices with our devices and systems at all 300 of the centers across the US in the shortest time possible. The actual length of time is difficult to estimate at this time, but the goal is to complete the replacement as soon as possible.

Questioner 4: Okay. Capital investments are expected to increase considerably from the second quarter. The reason for this includes the ramp-up of facilities for plasma collection. Do these products account for a large portion of investments? JPY82 billion is your forecast for this fiscal year, correct?

Terumo: In the order of biggest investment project, this one is the largest one. Investments for production facilities have mostly been booked up to the previous fiscal year. The additional portion of investments that will be booked in increments of JPY10 billion or so will be the costs required for setting up the devices at the 300 centers, as you said earlier.
The business model of this is almost like loaning these devices for free. In other words, these devices will generate disposable revenue, meaning that the cost of the devices will be on our balance sheet even though they are set up at the 300 centers, so that is what will additionally be booked going forward.

Questioner 4: Okay. Sorry, the amount of capital investment for the current fiscal year was JPY85 billion. I said the wrong number earlier. Thank you for your answer.

Questioner 5: My first question is about the Blood and Cell Technologies business. I understood that you mentioned how demand for blood component collection would decline a little once the impact of COVID-19 is mitigated. But demand seemed to have trended relatively steadily in 1Q, so could you tell us a little about the current situation along with your future outlook?

Terumo: Blood component collection had grown at a faster speed than whole blood collection up to now, but we expected this trend to reverse soon. However, the demand for blood component collection didn't drop as sharply as we thought, as Q1 was still in a transitional period. Demand for whole blood collection is rising, but the return hasn't reached the pre-COVID level. We expect the mix to return to past levels, probably at an early stage during the current fiscal year.
Although the segments are still small and have stagnated for a long time amidst the COVID-19 pandemic, there are finally signs of a recovery in Therapeutic solutions and Cell therapy technologies. These are the segments in the Blood and Cell Technologies business with high margins. Overall, even if blood component collection were to fall, we expect these 2 small segments to serve as a buffer against any large declines in the margins.

Questioner 5: Thank you. My second question is about SG&A expenses. In the initial forecast range, I believe you mentioned that the level of SG&A expenses wouldn't change significantly regardless of the upper or lower bound of the range. However, have you increased your assumption for SG&A expenses in the revised forecast compared to the level in the initial forecast? Please share with us any insights you may have.

Terumo: There are three factors behind SG&A expenses: first, there were expenses that were initially expected that were delayed until the second half; second, there were expenses that were supposed to be used in Q1 that ended up being unused; and third, there will be an increase in expenses that had already been expected in the second half.
The main change reflected in the earnings forecast this time is the expenses that were supposed to be used in Q1 that ended up being unused. The expenses that were scheduled to be used in the first half but delayed until the second half include expenses to respond to European medical device regulation (MDR), and source plasma. These expenses have been pushed back to the second half.

Questioner 5: In that case, do you think that the overall expenses will not be much different from the level of SG&A expenses in the initial forecast? Sorry for my lack of understanding.

Terumo: That's right. The portion of the expenses that won't be used is added to the upwardly revised profit forecast. So, if you exclude that factor, then expenses are generally as we expected.