# FUJ:FILM Value from Innovation

## **FUJIFILM Holdings Corporation**

Bio CDMO and Life Sciences Business Briefing December 14, 2023

## **Event Summary**

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	Chisato Yoshizawa	Director & Senior Vice President, General Manager of Corporate Communications Division and General Manager of ESG Division of FUIIFII M Corporation
	Toshihisa lida	Corporate Vice President, General Manager of Life Sciences Strategy Headquarters, General Manager of Bio CDMO Div.
	Yutaka Yamaguchi	Corporate Vice President, Deputy General Manager of Life Sciences Strategy Headquarters, General Manager of Life Science Business Div.
	Takeshi Yamamoto	Corporate Vice President, Deputy General Manager, Life Sciences Strategy Headquarters, General Manager of Bio Science & Engineering Laboratories

## Presentation

**Moderator:** Thank you very much for waiting. Now, we'd like to start Bio CDMO and Life Sciences Business Briefing.

First, I'd like to introduce the speakers from FUJIFILM Corporation.

Corporate Vice President, General Manager, Life Sciences Strategy Headquarters, and General Manager of Bio CDMO, Toshihisa Iida.

lida: My name is lida. Thank you.

**Moderator:** FUJIFILM Corporation Corporate Vice President and Deputy General Manager, Life Sciences Strategy Headquarters, General Manager of Life Sciences Business Division, Yutaka Yamaguchi. He is online today.

Yamaguchi: This is Yamaguchi. Thank you.

**Moderator:** FUJIFILM Corporation Corporate Vice President, Deputy General Manager of Licenses, Strategy Headquarters, and General Manager of Bioscience and Engineering Laboratories, Takeshi Yamamoto.

Yamamoto: This is Yamamoto. Thank you very much.

**Moderator:** Also, Corporate Vice President, Corporate Communication and ESG promotion, Chisato Yoshizawa is with us as well.

Yoshizawa: This is Yoshizawa. Thank you.

**Moderator:** Mid-term plan vision 2023, we have the core strategies. One of them is the growth of health care. Today, toward the growth, the important driver, Bio CDMO business and life science business, the growth strategy and R&D strategies are going to be presented by lida, Yamaguchi, and Yamamoto. We have a presentation on the screen. This is in English. But for Japanese version, you can refer to the Japanese version on our website. We have the URL in the chat box. And after the explanation, we'd like to start the Q&A session. To participate in the Q&A, as what's in the image in the session, we'd like to take the same procedure. We are not going to use the chat function of Zoom for Q&A.

lida is going to explain first.

**lida:** Thank you. I am going to explain the life science business. This is the overview of the Company's life science domain.



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First, just very briefly, I'd like to introduce myself. In 1991, I joined Fuji Photo Film. In 2005, I came back from the UK, and I worked in the digital camera and also optical device businesses for 15 years. In those days, we had compact digital cameras, shifting towards mirrorless cameras that are very prominent right now, and I was in charge of those businesses. As for optical devices, we had business selection concentration for the turnaround of the business.

In 2020, that was just during COVID-19, I went to Europe. We had a COVID-19 situation, but also, we had Ukraine war still ongoing, supply chain disruption problems, and energy cost increase. We have acquired Integrated Hitachi Medical and I was in charge of all of them. From April of this year, I am in charge of the CDMO business and also FUJIFILM Diosynth Biotechnologies. I am a Chairman for this company, and right now, Diosynth Biotechnologies' headquarters is in North Carolina, and I am in North Carolina right now. Thank you very much.

The life science business area consists of five businesses, including CRO business that was established this year, and then we have R&D Center as well. Today, I would like to talk about the overall business, and also for Bio CDMO, I would like to continue the explanation. Yamaguchi is going to talk about life science. And then, Yamamoto is going to talk about the strategy. Thank you.



Sustainable Value Plan 2030, SVP 2030, and these are the sales targets. We are focusing on prevention, diagnosis, and treatment. All of them should be covered as a total health care company, and we would like to be such a company. The sales target for 2030 is JPY3.5 trillion overall, and half of that, JPY1.75 trillion, comes from the health care business. That is our target.

Medical system, Bio CDMO, and LS solution—We have three pillars. And today, we would like to focus on Bio CDMO and LS Solution. And together, JPY750 billion is the target for SVP 2030.



First, 2030, JPY750 billion for this SVP goal. I'd like to talk about the realization of that goal ahead of the schedule. Right now, the Company expects to reach JPY750 billion ahead of schedule because of the increase in revenue from Bio CDMO business, so we are achieving in 2028 JPY700 billion. So, I'd like to announce today that we're going to move up the goal, EBITDA margin is the latter half of 20%.

Although changes in the we will continue to invest	market environment through COVID-19 h based on long-term market growth forec	ave a short-term impact in FY2022-2023, asts to build a stable business structure		
		Bio CDMO Life Science		
Market Environment	Impact on company	Our measures / responses		
Steady demand for conventional antibody drugs Progress in the development of next- generation antibody drugs (ADC etc.)	<ul> <li>Strong performance of antibody drugs manufacturing mainly at the Denmark site</li> </ul>	<ul> <li>Smooth launch of a new large-scale facilities</li> <li>Boosting capabilities to next-gen antibody drugs (ADC, et</li> <li>Conversion of gene therapeutic tanks for antibody drugs manufacturing (Under consideration)</li> </ul>		
Sharp downturn in funding of biotech Stagnant pipeline development and decline in the number of new clinical trials	<ul> <li>Stagnant development orders for gene therapeutics</li> <li>Sluggish demand for cells / reagents for drug discovery support</li> </ul>	<ul> <li>Temporarily slowing down investment in gene therapeuti</li> <li>Continuing to invest in cell therapies in anticipation for long-term market growth</li> </ul>		
Piling up components and consumables, which were mass purchased amidst SCM confusion during the COVID-19	<ul> <li>Write-down for inventories which nearing the end of shelf life</li> <li>Decline in culture medium as a result of clients' inventory adjustment</li> </ul>	➡ ■  ■ Reinforcement of supply chain management		
Reassessing of suppliers and changes in SCM based on COVID experiences Growing significance of BCP	<ul> <li>Increased contracts orders as 2nd / 3rd site</li> <li>Acquiring new customers due to an increase in purchase from multiple suppliers.</li> </ul>	<ul> <li>Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage o having a global footprint</li> </ul>		

The next one, because of COVID-19 situation, we have both upside and downside. The market has been impacted. Also, I'd like to talk about the impact and also actions that we're taking. This slide shows the summary of the overall structure, a very high level.

Just very briefly, I'd like to provide some information, the upside picture. After COVID-19 subsided, the demand for antibody drugs is extremely strong and also next-generation types such as ADC, bispecific. The pipeline is very fulfilled, and we have developed and also launched a lot of products, so the antibody drug industry is very good. In response, we have the Danish facility and the strong contract manufacturing activities going on, and also more than anything, we'll have to steadily launch large-scale facilities. Also, next-generation antibody drugs, such as ADCs should be strengthened. Later, I would like to strengthen, the gene therapy market, which is sort of sluggish right now. We do have the capacity. We can convert it into the antibody production. The demand for antibody production is very strong. On the downside, the funds for biotech startups are cooling, so pipeline development is sluggish as well. This is a negative impact from that.

Accordingly, cell therapy and gene therapy areas, our performance has not achieved our expectation. We do have measures against that. In the short run, we'd like to slow down the investment into the gene therapy contracts, and also, we can convert some of the capacity for antibody production and mid-term and long-term cell therapy areas and also, it's in anticipation for mid-term and long-term. 2025 and 2026 are the target to expand the capacity, so we have to be very proactive.

Antibody drug business has been very stable and growing. During this period, we will have to be ready for the next move. Another downside is the inventory level of the materials is increasing because of the supplier issue. We have the responsibility to provide our products to customers. However, because of that, we have this excess inventory situation. However, as we have reported already, we have the expiration of the shelf life.

Because of that, we had the write-down, that had to be recorded in Q1. Right now, the inventory level has rebounded to normal. We'd like to explain this later.

And the last one is the upside. The customers, based on the COVID-19 situation, customers are increasingly moving to multiple sites, so we received inquiries for contracts as a second or a third site. Globally, focusing on Western countries, we have the network. Wherever we receive inquiries, we can be ready to address the customers' needs. This is an upside.

Based on each item, I'd like to explain today. The first one is Bio CDMO. Iida-san is going to explain. Overall strategy first. After that, antibody drug with which the demand is very strong and the business strategy for that, and cell therapy, gene therapy, and supply chain management, and the last one is summary.



First, Bio CDMO business. This is the overall picture and the demand, 8% increase. The market has been growing, CAGR, 8%. In 2030, we're expecting it to exceed USD800 billion. That means JPY100 trillion by 2030. Our focus has not been changed. On the right side, you have the graph. The market size, vertical axis, this is the 2030 market size. On the left side toward 2030, we have the CAGR. As you can see, conventional antibodies in terms of scale for 2030, USD319 billion, it's still very big. These new modalities, such as ADC and also bispecific, they are growing as well. On the right side, cell therapy, gene therapy, 30% to 40% growth rate. Overall, a very stable monoclonal conventional antibody market, and we can expect a very high growth of the new generation modalities.



Bio CDMO market, the growth is expected more than we have imagined. The average gross expectancy is 15% per year, and per modality, you can see on the right-side graph, antibody, 10%. This is conventional antibodies, 10%. Growth rates in the new modalities, CDMO ratio is increasing. Cell and gene therapies for biotechs without any facilities are increasing. For new antibody products, because of the high specification cell, they require new and very high-end facilities, so we have been requested by those companies. Such increased demand is very strong.



Also, in Denmark, productivity has been increasing right now. We have new production technology that was added. Also, Inflation is included in batch prices increase, and all of them are included in our CDMO target. We used to have JPY500 billion as a target, but for 2030, but we can attain this two years ahead of schedule. That means FY2028, so JPY750 billion. As I mentioned before, two years before the actual original goal, we can attain it.



Overall strategy of the Bio CDMO business can be summed up in one word, to be a trusted partner to pharmaceutical companies. Our mission is a trusted partner, so we redefined the CDMO business. That's what we are doing, and we call it PDMO.

Pharmaceutical companies are concentrating more resources on R&D of their robust pipeline. As soon as possible, after clinical trials and they are approved, and also, they have to be responsible for enough supply for the patients. We are responsible for the end-to-end process. You can see the elements required of CDMOs on the left channels of our strength to be trusted partners and why we can be trusted partners. The reasons are here. For CDMO, ample supply capacity is required. We do have active investments to expand capacity. We can be ready for the ups and down of demand, so the customers can be ready to ask us for any demand. Also, the next one is highly efficient, stable production. We do have very high batch success rate.

As I have mentioned, Denmark has a very high success rate. Batch success rate right now is over 98%. Customers can be relieved to have us as a trusted partner. Another requirement for CDMO business is in one word, track record to address regulatory affairs, FDA, and the others, and that's very important as well. As for this, we have such track record we can be proud of, and end-to-end service for diverse pipelines. We can address many different modalities, also, formally, to commercialization, now we are ready for various pipelines. Technology transfer, the speed of which is very important. From the customer's perspective, even if the speed of technology transfer is good, as soon as possible, we'll have to deliver the product to the patients. That is the most important thing.



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Today, I would like to talk about KojoX. You might not have heard of it, but I'd like to explain this later. KojoX, this might be an unfamiliar term, but this is a strategy on which the strength of our companies are based and will be presented. Agility is very important as well. Even if large pharma companies, from the clinical development stage to launch/commercialization stages, there are a lot of fluctuations in the demand. Also, we are very close to the western market, so we can address the fluctuation of the volume of production. We are very agile.



The next one, I talked about KojoX. "Kojo" means plants in English. "Kojo" is a Japanese word, this also means Kaizen improvement, so we created this word, KojoX. This is one of the large facilities. In Denmark, we have five bioreactor units. And next year, we are going to have six additional ones right now in construction. Totally, we are going to have 12, so we are going to split into four units each before bioreactors are going to be connected to one [downstream] processes for optimal production system. We have four units, and there are going to be, it's like copy and pasted. It's going to be 2022.

In North Carolina, we are going to have exactly the same design and exactly the same production flow to ramp up the effort. We do have the track record in Denmark that can be transferred to North Carolina. After that brushing up, we can transfer back into the Denmark site. There are so many benefits from this approach. For example, the lead time of the construction is shorter because the design period is a lot shorter. And also, in the design stage, the mandates can be reduced so we can reduce cost. We can reduce the cost by half.



And also, we have exactly the same system, same operations. For example, we have a program in Denmark that can be shifted towards the United States. Tech transfer is very, very fast. And also, it's easy for us to address regulatory requirements in every country. This is our strength.

We are going to start investing into state-of-the-art design and state-of-the-art facilities. This is our strength. This KojoX concept will be implemented not only in large-scale facilities, but also for small and medium scale as well. This was already announced, to increase capacity of the larger ones. The rest is about single use, 2,000 liters, and the smaller ones, those are CapEx spending plans, small and middle size. This is a KojoX concept based on which we would like to increase the CapEx spending. This is the overall strategy, and later, we would like to talk about antibody drug strategy.

Strong performance in manufacturing of antibody drug, mainly at the Denmark site. To prepare for further market expansion, we will smoothly launch new large-scale facilities and make early contribution to earnings							
					Bio CDMO		
Market Environment			Impact on company		Our measures / responses		
	Steady demand for conventional antibody drugs Progress in the development of next- generation antibody drugs (ADC etc.)	•	<ul> <li>Strong performance of antibody drugs manufacturing mainly at the Denmark site</li> </ul>	•	<ul> <li>Smooth launch of a new large-scale facilities</li> <li>Boosting capabilities to next-gen antibody drugs (ADC,</li> <li>Conversion of gene therapeutic tanks for antibody drug manufacturing (Under consideration)</li> </ul>		
	Sharp downturn in funding of biotech Stagnant pipeline development and decline in the number of new clinical trials	+	<ul> <li>Stagnant development orders for gene therapeutics</li> <li>Sluggish demand for cells / reagents for drug discovery support</li> </ul>	+	<ul> <li>Temporarily slowing down investment in gene therape</li> <li>Continuing to invest in cell therapies in anticipation f long-term market growth</li> </ul>		
	Pilling up components and consumables, which were mass purchased amidst SCM confusion during the COVID-19	+	<ul> <li>Write-down for inventories which nearing the end of shelf life</li> <li>Decline in culture medium as a result of clients' inventory adjustment</li> </ul>	+	<ul> <li>Reinforcement of supply chain management</li> </ul>		
	Reassessing of suppliers and changes in SCM based on COVID experiences Growing significance of BCP	*	<ul> <li>Increased contracts orders as 2nd / 3rd site</li> <li>Acquiring new customers due to an increase in purchase from multiple suppliers.</li> </ul>	+	<ul> <li>Strengthen partnerships through manufacturing ne- customers by leveraging our geopolitical advantage having a global footprint</li> </ul>		

This is the same as before, so I'd like to skip it.



Also, antibody drugs, it's 8% increase. Monoclonal antibody was 6%. In ADC multispec and bispecific, that's more than 20% CAGR.



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Within this, as we look at growth, we were to become the trusted partner. What needs to be done has been captured here on this slide, and let me glance to the left. I talked about our strength, the KojoX being one, and this will serve as the foundation by which we exert our strength and how we can offer value to our customer.

First of all, we have the ability to offer, all the way from process development to commercial manufacturing, end-to-end services to customers, according to their diverse pipelines. As we engage in negotiations, we have been told that pharmaceutical companies, especially large pharmas, have been burdened with relationship with numerous CDMOs. They need to deliver on stable quality, and, of course, they're equipped. They need to, of course, pursue management of the numerous CDMOs, and therefore, they hope to be able to reduce the numbers of CDMOs that they're working with, but we were able to offer end-to-end services.

We are also equipped with capacity, not only for large scale, but also small and medium size, which means that we can respond to clinical development stations, stages, and fluctuations in demand. With KojoX, which is like a cloning system, we're able to mirror state-of-the-art facilities in Europe and also in the US, and this will allow value to the customer being swift in transfer of products and technology, smooth certification process. The 20,000-liter large bioreactors are the closest sites to our customers, and therefore, with a very short lead time, we will be able to deliver to our customers.

In terms of value to our customers, there's a sense of security about stable supply long term. To the right, vertical axis is the manufacturing volume, horizontal axis is a clinical phase. This is a major pharma example. In the beginning, they have started in-house. Once they achieved a certain level that exceeded their in-house capability, and there has been contract to FUJIFILM on a single use, where small-, medium-sized [items] have been used in numerous numbers, and they have informed us that they hope to be able to scale up to a large-

scale manufacturing tank, and this has brought us into negotiations in Denmark. In this manner, at one stage, customers go to CDMO.



Large Scale=20,000L、Small-Medium Scale\*≦5,000L

\*Small-Medium scale facilities include facilities other than those for antibody drugs (e.g. recombinant protein, gene therapy and vaccine).

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However, there's a large, of course, burden going immediately to large-scale tanks. Therefore, we start with small-, medium-sized tanks. There's a scalability that we are able to offer. Also, this is, of course, a value for the large pharmas. Therefore, now we find that some customers want us to be engaged from early stages. But whatever phase they need to call upon us, we were able to respond. Here, we are looking at capacity that resides within our company. We have the large-scale tank to the left and small medium scale single-use.

With the current situations as indicated [inaudible], in 2030, we have tracked how this will increase. As for large scale, fivefold. We have six, and this will be increased to 28 plus, of course, improvement in productivity, which will mean that we'll bring the capacity to fivefold, and also in small to medium size we will bring the capacity to twofold. How will this contribute to revenue? For this, look at the slide to the right. In large tanks, the revenue contribution is just short at 40%, 50% is small to medium size. In 2030, this will be reversed.

Overall, the capacity will increase, and our revenue target will be achieved two years earlier, and productivity will increase. EBITDA margin of 40% is targeted for FY2030.



By modality, here, we are looking at the weight for early to late phases in the pipeline, late phases, Phase III, all the way into commercial. Currently, for antibody, the sales is about 70%. They face about 70%. For large-scale tanks contributing 2030, antibody will top 80%. In this stage will increase to the higher side of 80%, and this will contribute substantially to revenue.



As we have indicated, we have a track record that we have achieved in Denmark, and let's go over this. In 2020, April to October, in Denmark, in existing six bioreactor tanks, we are looking at the number of batches of output. In the past two years, the batches have increased by 20%. Therefore, for the same reactor, the output or the batches have increased by 20%, which indicates productivity has improved. Also, on a per-batch basis, the success rate has also topped 98%, which is an indicator of high performance and productivity, which has been well received by customers. And, of course, the FDA and regulatory authorities conduct audits. In 35 times in total, we have gained positive results and FDA for 25% of preapproval inspection takes place, of which, as I mentioned, 25% of on-site inspections have been waived. This is an indicator of the trust they have earned by FDA, and six units in operation in FY2022 will be expanded to 20 units come 2026 in Denmark.



The same concept is observed in North Carolina. In each of these phases, Denmark Phase I and II, and this startup in North Carolina, the green-shaded area indicates the trial run. And, of course, this is the burden of the customer, where there's a new product launch, the customers will use a prototype, and they will use this as a sample, and they are required to store this and green-shaded areas where there are many prototypes and trial runs, which will eventually migrate into the commercial manufacturing stage.



Here, we're looking at the rise in revenue of the new large-scale facilities here on the slide. Vertical axis is revenue, and horizontal axis is the time sequence. Down below, consider this as being the size of the batch as it progresses from small to large. For example, in Denmark, 2024, there are many prototype or test batches, which means even while the time required by switchover is the same, be it small or large. However, as we progress into commercial production, the number of batches per programs leads to less frequent switchover, and then this will contribute to a higher income.



As for the negotiations that have progressed, the red area indicates the progression of commercial negotiations over the last year from December 2022. As for the update this time around in Denmark, there have been very active negotiations taking place. In 2025 and 2026, one of the tanks displayed here has been committed. This is news I would like to impart to you. Early in 2025, we will enter into full production. And earlier, with Janssen, we have entered into a partnership in North Carolina, the latest suite. As we have indicated to you, apart from Janssen, the pipeline is very strong.



The Top 20 large pharmaceutical companies, a number of pipelines are to the left and sorted out by clinical phases to the right. There are 150 programs. Altogether, these are very active pipelines that are running, and there is a possibility that we will be able to enter into a contract. Currently, negotiations are ongoing. The antibody in these pipelines will progress into commercial development, and there is high expectation. This has been an explanation of the antibody drug market.

Although there is stagnation in cell and gene therapies due to funding issue in biotech, We continue to invest based on long-term market growth trend.						
		Bio CDMO				
Market Environment	Impact on company	Our measures / responses				
Steady demand for conventional antibody drugs Progress in the development of next- generation antibody drugs (ADC etc.)	<ul> <li>Strong performance of antibody drugs manufacturing mainly at the Denmark site</li> </ul>	<ul> <li>Smooth launch of a new large-scale facilities</li> <li>Boosting capabilities to next-gen antibody drugs (ADC, etc Conversion of gene therapeutic tanks for antibody drugs manufacturing (Under consideration)</li> </ul>				
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Reassessing of suppliers and changes in SCM based on COVID experiences Growing significance of BCP	<ul> <li>Increased contracts orders as 2nd / 3rd site</li> <li>Acquiring new customers due to an increase in purchase from multiple suppliers.</li> </ul>	<ul> <li>Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage of having a global footprint</li> </ul>				

Now, I would like to explain the strategy for cell therapy drugs. This is also a slide that we have shown you a little while ago. Let's go into some details.



Bio CDMO Life

#### 2-3-1 | Market trend of Cell and Gene therapy

Source: Previous = EvaluatePharma® Oct, 2022 | Current = Company estimation based on EvaluatePharma® Nov, 2023

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Now, in the biotech fund and decline in the market compared to a year ago, from a service company, there has been a downside. Correction. As for gene, two years today for cell therapy, there's a delay between one to two years. There is a current understanding of the market situation, and therefore, we are reconstructing our business plan. As you can see, the CAGR 2028 is very high. Hence, from 2025 to 2026, we are considering what proactive action must be taken, and that will be the point in question.

2-3-2 | Cell Therapy: Investment in 2 sites in the US

Addressing the increasing demand for CDMO service for cell therapy

Fujifilm to invest USD 200 Million to Expand 2 sites in the US

Double the capacity for cell therapy at Wisconsin site and California site





Diesynth biotechnologies California Site

Bio CDMO

Offering CDMO service for iPSC-derived cell therapy by leveraging the state-of-the-art iPSC-related technologies Offering CDMO service for allogenic cell therapy such as donor-derived cell therapy by leveraging experience and track record of manufacturing commercialized pharmaceuticals and clinical drugs

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In line with the market trend, especially in the cell therapy area, in two sites in the United States, FUJIFILM has decided to invest USD200 million. There are two operating companies, Cellular Dynamics and Diosynth Biotechnologies, in the California production capacity. Now, the investment will bring it to twofold of what it is right now.



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In cell therapy, in a single word, it has been tailor-made, time-consuming, rather autologous, but now we migrated to allogenic and iPS cell-based therapy. Up to now, it has been very time-consuming and also high cost with a long lead time, where there are many patients, but we will be able to speed up all of these activities and deliver to the patients.



This is an overview of the two operating companies. Now, California to the right, in 2025, the operation will start. Cellular Dynamic, in 2026, intends to start operations.



Here, we are looking at combining the two locations, the CDMO per modality, per site metrics. Highlighted areas indicate sites where capacity expansion is planned per modality, small to large, end to end. We will now be equipped with the capacity.



Now for the supply chain, and I would like to cover this in a single slide. Under COVID-19, the lead time has prolonged, but we need to be held accountable to deliver to our customers. Therefore, we have accumulated inventory, and this led to the write-down of inventory in Q1. The supply chain has now become more sound. We have conducted inventory management, and we have reduced inventory levels approximately 40% for the peak period. Compared to pre-COVID-19 levels, the inventory accumulation has been suppressed.





Overview Bio CDMO Life Sciences

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I'd like to talk about the wrap-up. The first is the position of the market for antibody drugs for which demand is strong and also gross driver and to increase capacity, not only in large tanks, but also in small- and medium-sized tanks, the end-to-end process to be partners for our customers. We have explained KojoX as a platform.

The second one is to reinforce service offerings for advanced therapeutics. For example, 2025, 2026 with cell therapy and also gene therapy. Also, we need to be a real trusted partner for customers to contribute customers and expand capacity to meet growing demand and also accumulating experiences in highly efficient and stable manufacturing. Also, we have to use the same technology for the other sites as well.

Thank you very much.

**Moderator:** The next one is about life science business. Yamaguchi is going to explain.



**Yamaguchi:** I'm Yamaguchi. I'd like to talk about the life science business. In 2018, as Irvine Scientific was acquired, I became the CEO in the US. Since then, I have had this career. In 2021, life science business started, I came back to Japan and started the business. From April this year, I went back to the US, and from the US, I am in charge of this business.



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Life business overview. The life science business is divided into two major segments: cell therapy and drug discovery support. In the field of cell therapy, we provide iPS cells, proprietary cells, and also, we do licensing-related patents. Also, we can obtain milestone fees and royalties, but also lead to future contract process development and manufacturing organization, CDMO business.

The second is to provide a wide range of services for each customer's development phase from basic research to manufacturing, safety, quality testing. It's such a wide range of services that we provide. It's a drug discovery support business that provides cells culture media, reagents, and related services. There is a history of our business expansion to date and the outlook.

Our business has rapidly expanded since the Irvine and Cellular Dynamics acquisition. We have acquired three major businesses. Since then, drastically, we've started to expand the business. Right now, there is an extraordinary demand because of COVID-19, and supply chain disruption was there. Overall, the market still experiences a rebound from the special situation, and we have to adjust inventory.



But recently, there is a recovery expected in the midterm and long term, our goals have not changed. For 2030, JPY200 billion is our revenue target. That has not changed. Right now, about JPY70 billion, and it's going to be JPY100 billion in 2025 and CAGR of 15% and more.

3-2	2-1	I iPSC Cell Thera	nv R&D Sun	nort : iPS Cell Lines & Licensing	
		Suppor Acquire mileston	t R&D of cell the le and license fe	rapy by actively providing iPS cell lines and IP licensing to devel es in line with the progress of development and link it to CDMO o to build a stable business foundation.	lopers. contract services
M	lain	Licensees			
		Licensee	Disease Area	Status	
N	1	novo nordisk <sup>®</sup>	Chronic diseases	Pre-clinical	
N	2	EXCITNERAPEUTICS (U.S.)	Cancer	Pre-clinical	
	3	CENTURY THERAPEUTICS	Cancer, auto-immune/ inflammatory diseases	Auto-immune/inflammatory diseases : added to the license field (Sep. 2023) , IND approved (Dec.2023) Cancer: Clinical trial Ph1 → CDMO: FCDI supplied cells for the clinical trial	Milestone fees Rovaltie
	4		GvHD, DFU, osteoarthritis, renal transplant	<ul> <li>PhI-III clinical trials for several diseases</li> <li>CDMO: FCDI has a contract for clinical /commercial manufacturing</li> </ul>	CDMO business
	5	Ryne Bio:	Parkinson's disease	<ul> <li>Pre-clinical with FCDI's therapy program(IND within FY2023)</li> <li>CDMO : FCDI provides process development /manufacturing</li> </ul>	
	6	Sana	N/A	Pre-Clinical	
_	7	U.S. Bio-Venture	Cancer	Pre-Clinical	
	8	Japanese Bio-Venture	N/A	Pre-clinical	
	9	U.S. Bio-Venture	Infection, Cancer	Pre-Clinical	

The next one is about each business. First, iPS cell therapy. The first, we provide iPS cells license and related patents to companies that are developing new therapies using iPS cells. This would lead to CDMO contract services while earning contract payments, royalties, milestones fees, [upfront] payments based on the progress. You can see major licensees. And this year, we have Novo Nordisk and IASO Biotherapeutics. We have new contracts with them. With Century Therapeutics, we have expanded the scope of our license to include immunology and inflammatory diseases. From all the cancer [immunology], [endocrinology], Century's clinical trial application was approved this month.



The next one is drug discovery and manufacturing support for pharmaceutical R&D and manufacturing support. This is the direct discovery using iPS cells. But we are a leading company in the iPS cell field, and we already have 400 locations, where we sell our products in the US, Japan, and Europe as well. We have the top sales share. We are well evaluated by researchers, and we were cited in more than 300 papers. And this year, we have launched seven products. Right now, we have 40 products in our lineup altogether.



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The unique products this year is a central nervous system disease support kit, Blood-Brain Barrier, BBB kit. This is a very unique one. Blood-Brain Barrier or BBB functions to prevent harmful substances from entering the brain by using iPS cell to conduct permeability test of new drug candidate substances in an environment more similar to that of human organism. We can address Parkinson's disease and dementia. Efficient and faster development of therapeutic drugs are possible.



Next one, culture media business, which is indispensable for antibody drug production. We are targeting serum-free culture media market. The growth of this market is around 10% YoY. We have acquired our volume, and in terms of sales, we quadrupled. Also, the share was doubled. In 2030, we aim at achieving JPY100 billion sales and total market share of 30%. That is the target.



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Culture media business. In terms of manufacturing and development, Irvine has more than 50 years of experience. They do have the track record. They have the tracks in performance, and they can customize to address various needs of the customers. They have manufacturing sites in Japan, the US, and Europe, so we can have the local delivery of the product globally from development to commercial scale. We can provide the same quality and very high-quality media. This is our strength.



#### 3-3-4 | Cell Culture Media : Global Footprint

This is our global bases of culture media. California, Irvine, this is the main site and one in the Netherlands that was opened, and Saitama Prefecture and Aichi in Japan. Also in Japan, we were subsidized by METI, the Ministry of Economy, Trade and Industry. In Minamiashigara-shi, Kanagawa Prefecture, we are going to build a new plant. 2027 is the target year for the start of operations, and we will supply the products to growing Asian markets, where the growth rate is very high. We are going to supply our products in this area. Also, we have a new plant in the US and also European plants and Japanese plants. On a timely basis, we'd like to invest into each area so that we can address the needs of each region.

#### 3-4 | Growth Strategy



Overview Bio CDMO Life Sciences

\*serum free media for bio production

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Next slide, this is the summary. iPS cell therapy. We would like to support R&D, and also, we'd like to support those companies for the R&D efforts, licensing, and also cell lines, and also CDMO services. This is a recurring model that's promoted by us. Using our iPS cells, we do drug discovery screening, and we would like to expand our business for the preclinical testing as well. In pharmas and academia, we promote combined solutions of cells, media, and reagents.

The third one, to support them, our culture media business, our main business is going to grow, especially [inaudible], and we are closer to the customers from the development and also commercialization. Even in scale-up, we would never compromise the quality, so we can provide the same quality. In 2030, top share of 30% and over is our goal. That's how we are promoting the business.

This is it for the life science business. Next, Yamamoto is going to make a presentation.

Moderator: Now, Yamamoto is going to explain technological advantages.



**Yamamoto:** First of all, my profile. It was in 1991 that I joined this company. Biochemical engineering is my area of expertise. From 2021, I've entered into the domain of life science business, primarily antibody, cell culture media, or [inaudible] technology, and also continuous production system is an area that I have been engaged in. In 2019, as indicated here, from FUJIFILM Cellular Dynamics Incorporated, I've come to assume the position of President and CEO. I've made my way to the United States. I have overlooked R&D and spent three years in the United States in the front lines of activities related to IPS R&D. From June of this year, I have assumed my current position.

#### 4-1 | Research Organization in Life Science Field

The Bio Science & Engineering Research Laboratory(BSEL) serves as the core research institute in Life Science field, leveraging the technology cultivated photographic film business



Core technology cultivated through our original photographic film business

	•		R			
	Nano Dispersion Technology	Grain Formation Technology	Bioengineering	System Design	Imaging Technology	
¥∰++ MEMS Technology	High-precision Coating Technology	Functional Molecule Technology	Redox Control Technology	Film Formation Technology	High-recision Forming Technology	Functional Polymers

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R&D

In life sciences, I would like to talk about the research organization. Overall, in this area, we have been looking at the R&D overview on this slide. We have biosciences and engineering laboratory at the center, which is positioned as our core research institute for technology that we have captured from photographic film. What we have done is to dispatch personnel overseas and also receiving engineers from overseas, so that we have a global system in place and also an exchange of personnel.

As indicated in the center, in the BSEL, BioScience and Engineering Laboratory, the main headquarters are in Minamiashigara-shi. Just beside that, city in Kaisei at the center of the slide, this is our core and central research laboratory, where core technology that have been nurtured over the years by our companies is now being used in the BioSciences and Engineering. [inaudible] BSEL, and life sciences organic, and also process synthesis, and also analysis technology.

These technologies have been pursued here at the center to support the group activities here at home and also overseas so that we were able to continue to grow. The market is primarily outside of Japan to the west, therefore, from this center, we capture the needs overseas to engage in mid- to long-term R&D activities and also to implement in the front lines. Together in a joint study with overseas researchers across the Group, we are accumulating know-how so that we were able to contribute to the Bio CDMO business as well as life science business. Let us move ahead.



I would like to talk about the R&D over antibody production. We have the continuous production system that we have explained to you. As the first in the industry, we have been able to implement a continuous production system in the UK. This is with a capacity of 2,000 liters. It's a single-use platform by constructing GMP production facilities at this capacity.

Look at the visuals below. FY2023, that's today. For two types of antibodies, we have acquired demonstration data from 500-liter tanks, and this has been the progress achieved that we would like to disclose.

Of course, later on, we will speak on the details. But through this demo, CGMP implementation of 500 liters and moving on to 2,000 liters in production lies ahead, and we have already embarked on preparation. In addition to the 20,000-liter production, we have N-1 perfusion. As a result, we will apply this to the pre-culture stage, and this process will be introduced. By doing so, not just limited to the 2,000-liter single use, this time, it's 20,000 liters in the production line, we will be able to use the perfusion technology to produce antibody and also reduce the lead time and increase the number of annual batches. This will lead to an enhancement of productivity.



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As you're looking at this table, it captures what I've explained earlier. This is for the 500-liter continuous production platform by which demonstration and verification have been conducted. The output has been disclosed. From which, we were integrating key parameters for the 500-liter bioreactors. As indicated here, compared to the data that has been disclosed by competitors, the cell density is a maximum, and also scale is currently 500 liters. It is a maximum in terms of scale, and also, continuous culture of 40 days has been achieved, which is a top class in the market.

This has been verified in 500-liter demonstration plant and is unique to us. As indicated in the image to the right, we have the purification process. There are seven units that have been connected side by side. This will allow us to engage in a continuous purification process, and we have created such a unique platform.



Moving on. In the 20,000-liter stainless steel tank, as we apply continuous culture technology to this preculture process, this is graphically presented. Up above is the current process where the cells now have been input into a large tank. We can only increase at a fraction of tenfold. Therefore, in a 20,000-liter, this will mean that there will be, of course, numerous and frequent scale-ups involved. However, in the normal process, in the pre-culture stage, we will be able to apply the continuous system. This will allow us to achieve a density of cells, and this could be applied to the large tank, and hence, we will be able to see pre-densified cells in a continuous culture cycle. This will allow us to achieve added production.

In terms of benefits, per batch, we will be able to increase the yield by 30% according to estimates. As we move forward, in the US and also in Denmark, we will introduce 20,000-liter production facilities, and this technology will be applied. That is how we are progressing.

#### 4-3-1 | Next-generation Biopharmaceuticals

We are currently developing innovative production technology for the future growth markets of "Novel antibody areas such as ADC and bispecific antibodies", "Advanced therapies such as gene therapy and cell therapy"



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R&D

And then, I would like to now move on to speak about next-generation biopharmaceuticals. If you're looking at this table, we have indicated the next-generation biopharmaceuticals. We have the antibodies, and we also have the cell therapy, and also nucleic acid therapy, as well as gene therapy, and this has been put into a single table.

We have spoken about this in the past. We have our unique cell line, which is referred to as Apollo X, which is unique to FUJIFILM. We are working on enhancing productivity with the cell. As for the antibody, we have ADC, the new generation technology, which is expected to grow. Also, for cell therapy as well as nucleic acid, the bioscience laboratory is working on this technology, and allow me to offer some updates.



We are looking at ADC and where CDMO services will come in. When we speak of ADC, this is one facet of antibody drugs. As we see to the right, to the antibody, there is a payload as an anticancer. It is comparable to the anticancer component, and that is used for solid tumors. Of course, BDS is being used as an antibody, so this will work in a localized manner. Currently, on this modality, research is making headway, and clinical trials are very actively conducted.

Within our company, we have nurtured technology. By using these assets, we are preparing for CDMO services over ADC. What do we hope to achieve? As we have indicated to the very left, we have sorted out the issues into one and two. By using the payload conjugation, the low molecule will be used. And how will this be used, of course, is a key point in question. It's very difficult to uniformly apply this.

Hence, we are working on technology to apply this uniformly, and also antibodies will become increasingly complex. Therefore, bispecifics will be used in the ADC technology so that we will be able to apply this to contract manufacturing services. As we have indicated to the right, overseas and also on a domestic basis, we're sorting this out. Domestically, in our sites, the conjugate laboratory services have already begun. And also, synthesis linker and payload services are also conducted in the Toyama plant. GMP-scale, end-to-end services in 2026 will start and using our know-how, this will be rolled out into our overseas operations.



Moving on, and this is a reference to gene therapy. Growth in the market has been stagnant. However, it is also true that there are many unmet needs that cannot be attended in the absence of gene therapy. It is important to develop a gene introduction technology by reducing costs. The major bottleneck is AAV gene introduced into a cell. And to enhance the productivity of AAV, we need to seek concentration and introduce AAV in a continuous flow gene transfer technology that will insert the AAV genes.

Currently, AAV productivity is very low and introduction efficiency has been very low. Currently, large amounts of AAV genes are required, and we hope to be able to create a platform technology that resolves these issues.

To the left, we have a photographic image. At the center, we have the continuous flow gene transfer device that we have been working on. We are developing this device early part of next year. Using this device, we are ready to conduct a demonstration at customer sites. Under the conventional method, the AAV productivity rate will increase by a hundredfold. It will be a dramatic increase, and hence, by introducing this technology to the market, we hope to be able to tie this into enhancing AAV gene therapy.



Moving on, this is for cell technology, cell therapy, excuse me, manufacturing platform. iPSC, CAR-T cells, and mesenchymal stem cells. We have a competitive productive technology and also clinical manufacturing experience in multiple modalities. By leveraging this knowledge and also technology, we aim to develop a cell therapy platform for commercial production.

Here, we are looking at iPS cells, donor-derived CAR-T, and also MSC. This will indicate what process we are applying. Investigational drug production is an area in which we have a track record. In some of the operation, for example, incubators and specific devices will have to be conducted in a closed environment. Therefore, we need to create a close production process.

In terms of the track record, as we have indicated to the right, for iPS, we have already begun clinical manufacturing for immune disorders. Also, for donor-derived CAR-T, as we have indicated at the center at FDBC, we are promoting contract manufacturing for CAR-T products. As for MSC, mesenchymal stem cells, we are conducting treatment, and we are conducting a production process. We are leveraging technology in various modalities that will allow us to contribute to cell therapy.



Lastly, this is to expand on new modalities, mRNA and also LNP. I would like to offer some words. I'm sure many of you are well aware, Moderna and also Pfizer, have produced anti-COVID-19 vaccines that have been delivered around the world and have attracted worldwide attention. It is a new modality. We are working on, of course, the drug material and going on to CDM services here, domestic here in Japan.

We have our unique ionized lipids, and we are also able to process the formulation of pharmaceuticals by encapsulating mRNA and lipid nanoparticles. In fact, using LNP development as indicated in the flow down below, we start from mRNA, drug material formulation, which is combined with lipid nanoparticles, and then scale up using micro channels. The particles and mRNA will be used as drug material. By VLP, produce investigational drugs.

This platform has now been made available and rolled out here in domestic Japan. Especially for LNP, we have our ionized lipids, which are unique to FUJIFILM. In 2017, with MIP, we conducted joint research by using lipid materials, pursue drug development research. Also, for investigational drugs, for mRNA, we already have a track record, and we believe that this is a state-of-the-art technology.

For growth markets, we will create platform technology to respond to unmet needs, where we hope to be able to contribute our technology to produce competitive services to deliver sustainable business.

That is all from my side.

Thank you for your attention.

**Moderator:** Thank you very much. From lida-san, there will be explanation about ESG efforts.



lida: At FUJIFILM Group, in order to achieve a decarbonized society, we are promoting "green value manufacturing" to ensure low carbon dioxide emissions through the introduction of renewable energy. We will hold the Group decarbonization target, and let's look at the first top half of this slide. In the dark-shaded area, this is in the year 2030 against 2019 levels, we will achieve half of the carbon dioxide emissions from manufacturing and achieve net zero in FY2040.

In the green down below, this is where we are going to have carbon dioxide emissions across the entire product life cycle by 2030 against 2019 levels. This is a group decarbonization target. Alongside this target, at the life science businesses, we will work to reduce carbon dioxide emissions, and that is indicated in the bottom half of the slide.

We will tap into renewable energy. In manufacturing, we will install electric boilers, and by so doing, contribute to the reduction of carbon dioxide emissions. We have a network overseas. By bringing manufacturing close to customers, we will reduce carbon emissions required for transportation, and that is also an area in which we will be able to pursue carbon-neutral manufacturing through various active measures we'll, likewise, be taking.



Lastly, this is a summary. In life science growth strategy, I would like to put together in a single slide. Our mission is to work with our partners. Our partners being pharmaceutical companies, biotech companies, and also the academic sectors.

To our partners, we will deliver innovative drugs to as many patients as possible with speed. To this end, we will provide drug discovery support as well as risk and ample production supply capacity through end-to-end solutions. This is a mission that we need to undertake. We will need to take forward steps, the first of which is to develop high-capacity production and supply. For CDMA, we need to work on active expansion of our tanks, large and small, medium tanks as well, from API production to formulation package, and recall KojoX. This will serve as a basis for this endeavor. Also, for culture medium, we will supply on a global basis.

In the next pillar, there are many patients that are suffering where there's a lack of ample treatment. We invest in new mortalities to treat unmet diseases through cellular therapeutics. From two sites, we will increase production capacity by twofold. We will also expand iPSC lines and also licensing. And in ADC, we'll provide end-to-end services through our Toyama plant.

On our third pillar is to leverage and refine our technological capabilities. We will work on enhancing production platform technology and not just limited to a continuous production, but also in large tanks as well as gene cell therapeutics. We will develop and also enhance our productivity through new modalities.

And lastly, I've talked about carbon neutral production. [inaudible] production base is close to the market and globalizing our initiatives to reduce the distance in the market and thereby reduce carbon emissions during transportation.

Thank you very much for the kind attention.

## **Question & Answer**

**Moderator [M]:** Thank you very much. Now, we'd like to start with the Q&A session. [inaudible] question, please use the Raise Hand button. I'd like you to check your name and after I call on your name, please unmute yourself. Per person, please allow us to say two to three questions maximum, and please do it one by one. Please use the Raise Hand button to raise questions.

Citigroup, Shibano-san, please.

**Shibano [Q]:** Thank you very much for the explanation. My name is Shibano from Citigroup. There is only one question about FDB. From this year, lida-san's position, as well as FDB top position, the management was replaced. What about this background? Also, have you had any challenges because of that? Have you taken any countermeasures against that? Just a high-level explanation. Thank you.

Moderator [M]: lida is going to explain.

**Iida [A]:** June 29 was the day I assumed this position, and FDB CEO has been replaced, and Petersen is the current CEO. The background of assuming this position, one, is the business needs. It was really evolving. The business environment has been changing. As I mentioned before, small and medium size facilities were more than 60%, and the large facilities were only in Denmark, about 40% and lower. However, it's going to be reversed. Large commercial production had to be addressed. That's the place we were in. That is the background of the business.

And Lars Petersen, who is assigned to his position, we have two reasons for that. One, he was in Biogen. In Denmark large facilities, he has had experience. He was from the operation side so he's really on the operational excellence in large facilities. In Denmark, the secretary of the [inaudible] as I mentioned and the regulatory track record, as I have mentioned. He was the one who implemented these numbers.

The operational excellence in Denmark for large facilities, Lars was experienced in Denmark, and for the KojoX, it is going to be implemented as well. He is the appropriate person for that. In another one, the background of Petersen from the pharma side, where he is from a pharma industry. Before the acquisition, he was with Biogen. Before that, he was with Novo Nordisk, and he was with Roche Group as well. He was from the innovators; the pharma companies, the ones we would like to be partners with. He knows what the pharma company's value is, so he really understands this. He has the customers' perspective. We look at our business, that is very valuable. He has experience, and also, he has an awareness of challenges.

With these two reasons for the transition phase of the business, we felt he was the most appropriate person. In this new structure, July, August, September to November, it's been about half a year under Petersen. If you see, management has really transitioned and transformed during this period. Up to now in the UK, we had an acquisition in North Carolina, a small site. Depending on the site, the business models are different. They have cultures inherited from the previous companies, and also, they have different customers, and also the way of manufacturing, but we have to integrate them into one FDB.

This is a challenge for us, and we are going to address small- and medium-sized facilities, as well as large ones or end-to-end trusted partner. It is what we would like to be, as I mentioned before. KojoX for networking, for facilities, and also human resource development is very important as well. We need to have good talent fostered from within and outside as well.

One by one, we are solving these issues. As for human resources, Lars Petersen came from innovative pharma companies. That's his background, so he does have a human network already. Using the network, he has

picked up a good challenge for leadership, so we have hired him, so the new structure of FDB is now developing. Thank you.

Moderator [M]: Thank you very much. From JPMorgan, Mr. Wakao, please.

**Wakao [Q]:** Thank you. I have three questions. First of all, I'd like to narrow down on CDMO. On slide 14, as I've heard you speak, after all, until 2028, in the coming two, three years, gene therapy, while there are some negative impacts, to offset the negative impact, you will be able to grow as we have done before or even before that and achieve the target ahead of the target date. But the implications in gene and cell therapy, do you believe that ADC will be enough to offset that? I'm not quite sure as to what would factor into achieving the target of JPY500 billion. I have come to, of course, understand that you're investing in a capacity, would that be factored in?

**Iida [A]:** First of all, for a cell therapy as to whether ADC will be able to offset the shortfall, the answer is yes. With 70% cell outside of microbials, the cell portion would account for, say, about 10% of the total. Hence, if that is stagnant, the 70% ADC, since the dividend is so strong, it is enough to offset the stagnancy in cell therapy area. Therefore, as for the CDML, CDMO rather, as to the revenue target being achieved two years ahead of schedule, more than we have come to understand and as the productivity is much higher, and therefore, the number of batches from the bioreactor has increased. That has been put into perspective and taken into account.

The unit price for batch is also being elevated due to inflationary trends for one thing. But, of course, that will be under the contractual terms and conditions and be borne or shouldered by the customer. Hence, the unit prices per batch, and also multiplying that by the output or the yield, the bioreactors and the number of batch sizes have contributed.

**Wakao [Q]:** Slide 22 on the left-hand side, you have mentioned that large-scale capacity will be fivefold. Up until this point in time, you only have the plan until 2026. Has the investment plan up to 2030 now been taken into account for the current plan?

**Iida [A]:** This is the capacity at the time of utilization. As for the already disclosed investment, the six existing, plus 22, and when 2028 comes around with full capacity, we will be achieving fivefold. For 2026, we're still midway into the full utilization, and we are looking at the numbers in which we are looking beyond 2026 into 2030.

**Wakao [Q]:** In slide 16, and let me make this my second question. Looking at this slide and hearing you speak, downstream, there is no activity downstream. When I heard you speak, the unit price per tank is going to be elevated. That's pretty clear. I think it's around JPY13 billion this time around for each tank. And then that's going to increase, right, especially in the United States? Would that be the correct understanding?

**lida [A]:** To begin with, we were looking at SVP 2030, JPY500 billion revenue target. But more than that, as we look at the number of batches currently, as we've indicated, the performance has climbed, and this has been reflected in the numbers we have disclosed today. In Denmark, performance is very high. The N-1, the perfusion, when that is applied as a technology, that will allow us to pick up on the batch revenue on a [pro-tag] basis.

**Wakao [Q]**: What that means is that on a [pro-tag] basis for 20,000 liters, that's about JPY13 billion. Is that going to increase or at least be maintained? Would that be the correct understanding?

**lida** [A]: It's more than maintained because the volume of the batch will increase. And also, as we shift over or introduce N-1 perfusion, then the [revenue] per batch would also increase.

**Wakao [Q]:** Would this mean that this top line per batch will also take increase as well? In slide 22, in 2025, EBITDA margin was to top 30%, you have mentioned. But with the composition, the contribution of the large tanks declining 50%, 2026, and the EBITDA has declined to the higher level of 20%. But earlier, what you have disclosed, and what you've disclosed this time around, what is factored in? I understand the small and medium-sized tanks are increasing and the small and medium-sized facilities will have increased more than expected in FY2026. Is that what you're saying?

**lida [A]:** I would like to respond. What we have disclosed earlier is the tank capacity and the proportion of tank's capacity in terms of the mix. In terms of liter basis, the large scale will account for a larger percentage of the total, not 50%.

**Wakao [Q]:** But the batch unit price for single use is higher, and therefore, the unit price per liter is higher. When they translated into revenue, this is what the composition would look like. EBITDA margin is the latter half of the 20% level. It seems to have declined. Why? 25%? You said on top of 30% on your earlier disclosure.

**lida [A]:** Now, we have the earlier disclosed document in my hand. In terms of capacity and sales, it is as I've mentioned earlier. This time, EBITDA top of 30%, and latter half of the 20% level. And the gap between the two, to explain this, I would have to explain the assumptions of the earlier disclosure. We have taken into account the large tanks and CDMO for 2026, we are looking at the latter half of 20% level in terms of revenue EBITDA basis.

**Wakao** [M]: Understood, so the earlier disclosure was too optimistic. In the larger tanks, the capacity was higher. I figured that the margin also increased, and I was not able to clearly get the picture. But thank you.

Moderator [M]: Next is Mr. Muraoka from Morgan Stanley.

Muraoka [M]: This is Muraoka from Morgan Stanley.

Moderator [M]: Yes, we can hear you.

**Muraoka [Q]**: Usually, I look at pharma industry, so I haven't really followed you. On pages 12 and 13, you were talking about the market trends, both pharmaceutical market trend and CDMO market trend. I thought it was a little bit of a different trend, so I would like to make confirmation about this. Pages 12 and 13, you're talking about the recombinant protein market, and that has been estimated to be really very small.

And today, you are not talking about the biopharmaceutical market, GLP-1 is really growing right now. That all goes to CDMOs well. But are you underestimating it? Or don't you have access to this market, GLP-1? GLP 1 is really increasing in the market. Is your market share increasing if GLP-1 increases? What's your approach to this market?

**lida [A]:** Yes, lida is here. On the right side, you have described, recombinant protein here. The demand for GLP-1 right now is not incorporated here, and this is about the conventional culture area. It's around 1%-plus. As that's why GLP-1, our view here is, as we say, for upstream, this is part of the culture. Micro culture, we do have facilities for upstream but not downstream, so we cannot receive orders with the existing facilities. Because of that, before GLP-1, our company is more focused on the strong demand of the antibody drugs and also at the next cell therapy, and whether if we comment on protein, we are focusing on those two. This time, we didn't include GLP-1 in our presentation.

**Muraoka [Q]:** Thank you very much. Once again, I confirm, so that means your company is not going to capture the growth opportunity of GLP-1. But without capturing it, you can expand your market with your antibody drugs, right? Is that correct?

lida [A]: Yes, yes. My answer is yes.

Muraoka [M]: Understood. Thank you.

Moderator [M]: Thank you. Mr. Okazaki from Nomura Securities, please.

**Okazaki [Q]:** Thank you very much. EBITDA margin higher part of 20%. That is the question. Compared to your competitors, 2025, 2026, it appears as if you're suffering in terms of revenue EBITDA and you have explained the scenario and also the factors by which you will be able to increase this to 40%. What specifically is going to contribute to the improvement of revenue?

Moderator [M]: Thank you very much. Iida will respond.

**lida [A]:** In 2026, we have the large-scale facilities. And, of course, we explained with the image that this will contribute to revenue. In 2026, at this point in time, the large-scale facilities, all the 28 tanks, as we see in the dark blue shaded area, will not be materialized yet. Among the competitors, investment have been suppressed to achieve revenue in existing sites. That is what the competitors are doing. However, we are working, and we are still midway into the activities by which large-scale facilities are introduced, and that is how you will understand FY2026. But as we progress to 2027/2028, all the major tanks will have started full operations. And that will contribute to the improvement of the EBITDA margin as the main driver.

**Okazaki [Q**]: Understood. Thank you. Second question, it has to do with continuous production. Until last year, you've said for the 2,000-liter tanks, you will establish a technology. By so doing, you will progress to 10,000-liters or large tanks. However, the investment in such 10,000-liter scale tanks will not be necessary. I believe that is how you refer to it. But now, you're talking about 20,000-liter tanks, which suggests that there is now a change in your policy.

### Moderator [M]: lida will explain.

**lida [A]**: In terms of the direction of the development, it has not changed. The technology remains unchanged, and we're looking at 40 continuous days of production in the 500 liters, so we believe that we are on the right track.

Okazaki [Q]: But when it comes to continuous process, how will this be accepted by the market?

**Iida [A]:** It's an area that requires a more thorough study with this continuous process. Let's say, if all our tanks are going to migrate to a 20,000-liter scale, I do not believe that's the case. The reason being, in terms of cost, the 20,000-liter scale tanks, the continuous process will not yet be applicable. In terms of costs, we will look at 2,000 liters or 5,000 liters, and we will be able to accommodate cost allies anywhere between 2,000, 5,000, and 20,000 liters. More likely, it's a single-use program where the budgets are too small to fit into a large scale. Perhaps that is where the continuous process will be more applicable and will come in. Hence, from that knowledge, we will look at how this could materialize into a blockbuster. We will start with single use, and then from there, consider the large tanks and the continuous bioreactor purification process. These [are why] in parallel.

Okazaki [M]: Understood. Thank you very much.

Moderator [M]: Next is Mr. Wada, SMBC.

Wada [M]: My name is Wada, SMBC.

Moderator [M]: Yes, we can hear you.

**Wada [Q]:** I have two questions. The first one, cancellation rate. Do you have the data? Apollo X, you are using cell lines to make antibodies and also for manufacturing patents. By doing so, can you prevent cancellations?

As the manufacturing volume increases, for pharma companies, are they going to make it in-house or are they going to start to use other companies? Do you have such kind of data on cancellations?

**lida [A]**: Well, today, we do not, but cancellation rate, it's different for small and medium-sized ones and also larger facilities. Small and medium-sized, because of the pipeline, sometimes they fail. Well, the cancellation rate is higher compared to larger ones. Larger ones are not zero, but the larger ones are fewer. Cancellation rate, for example, internal manufacturing from CDMO. In that sense, I have not heard about such kind of cancellations. Of course, for cancellations, our customers have to pay cancellation fees. Even if they have to pay cancellation fees, do they want in-house manufacturing or not? Well, if there are any cases like that, I think there will be very few.

**Wada [Q]:** Thank you. Assuming from what you said, to some extent, you have early phases. You have the pipeline you capture for small and medium-sized. To some extent, they are ongoing. Based on that, do you have a plan until 2030?

**lida [A]:** Yes, yes. Based on our experience, at first from process development, and the next phases, our win rate. We do have the experience, so we do have the probability. We can calculate for small and medium-sized pipeline, our [inaudible] rate.

**Wada [Q]:** Thank you. Another question is about page 28, you have the pipeline of the antibody drugs. As I see here, some total addressable market should be here. 20 companies are here. Are you already negotiating?

**lida [A]:** Yes. During the process of negotiating, possible pipelines will be captured from the customers' information. That is incorporated, and also, they are going to be focused on programs in which we can use our facilities.

**Wada [Q]:** Thank you. Order taking. From which phase do the majority of the orders come from? Do you have the data? For example, the number of pipelines on each page, are you disclosing that?

**lida** [A]: The number of pipeline in each phase is not disclosed.

Wada [M]: Understood. Thank you.

Moderator [M]: Thank you very much. JPMorgan, Mr. Wakao, you have raised your hands. Is that right?

**Wakao [Q]:** If I may. Thank you. On slide 27, this is in reference to a contract, and I welcome that progress has been made, and of course, half of US is [changing]. As for these programs, what stage are they in? On slide 28, you have indicated what is currently in negotiation, but this is on a program basis. How about in terms of volume? I figure that these are already in-market products. If there are products in the pipeline and when your efforts should fail, what are the risk?

**lida [A]:** On a volume basis, of course, if it's very limited, this will not be substantial either way. In terms of volume from our customers, from tech transfer to prototype test batches, this is an activity that is very costly. Therefore, where the demand is very stable and more certain, basically, they are already in-market products. In terms of clinical trials, I would not say it's zero, but it's very small. But once you engage yourself and when it's put to market, of course, we will be able to expect very sustainable and stable operations and also earnings for the most part.

**Wakao [Q]:** Thank you. Next, about ADC, I would like to inquire, what stage are you working on? I was not clear. Currently, you work on a lab scale in conjugates. As for manufacturing and commercial production conjugates and also payload synthesis, this is an area where you have not really engaged in. If that's the case, there is Samsung and Lonza that are very proactively investing in this area, which will mean that FUJIFILM

compared to your competitors are latecomers. How do you view this? I understand you place an emphasis on antibodies, but is there a need to really speed up on winning contracts?

**Company Representative [A]:** Thank you for your question. As for the circumstances in ADC, as you have commented, your recognition is true. In fact, to the bottom right-hand side, as we have indicated, we're looking at the synthesis linker and payload, and we're able to do this on a commercial scale. However, for conjugates, it's still restricted to lab services. Domestically, we're using the labs to accommodate orders from our clients and engaged in synthesis development.

For GMP, as you pointed out, 2026, we will implement. Hence, compared to competitors, we're at the catchup phase, and that is true. On the other hand, in terms of our technology, across the board in terms of framework design for antibody, there is clearly an absence of know-how. Therefore, IP, where the technology, we're studying how to either license-in or otherwise produce. But through these efforts, we hope to not only catch up but also grow our capability.

**lida [A]:** From lida, just to add on that point, for ADC, with major pharmaceutical company, we are hearing what they expect of us as a CDMO, and we have a project within FDB as well. Depending on the customer, some of them concentrate on conjugates only, others on linker and payload. It really depends on the customer as to what part of the operations they hope to be able to concede to CDMO. From this, we are trying to understand what position we should take.

**Wakao [Q]**: Not as if the pharmas want the CDMOs to work on ADC end to end. Now, as for linker and payload, you are equipped with cGMP facilities or otherwise, is it being outsourced?

**lida** [A]: As for linker and payload, that's the case.

Wakao [M]: You already have. Thank you very much.

Moderator [M]: Next is [Lee Sang] from Citi.

**Lee [Q]:** Thank you very much. I have one question. 28 projects under negotiation, you have 350 you said. Not all of them are going to really [deal closing]. How much can you handle it? That means 2030 onwards, that demands from the market is going to increase. But after 2030 and over, are you thinking about capacity increase? I was thinking about demand increase after 2030.

**Iida [A]:** This is lida. Totally, 350 programs altogether here. According to our experience, on the average, 23 batches are using large tanks. Simply speaking, more than 7,000 batches is the number. And then we have 28 units of the tanks that we invested into. Altogether per year, it's about 3,000 batches or so. If we are to capture all of them, our capacity is going to be really short, but while we do have competition, and we have to think about the probability of taking those orders. So these programs, some will go to commercialization stages. As for the capacity we are planning for, so far, I think we can address. We can utilize our capacity, and that should be enough. Win rate, if win rate increases as the customers like our business and the capacity might be short sometime in the future. Per program and per customer, we would like to predict the situation so that we can be proactive in making decisions.

**Lee [Q]:** Thank you. So that means so far, 2030 and onwards, you are not disclosing the plan? Or you don't have a plan?

lida [A]: Right.

Lee [M]: Thank you.

**Moderator** [M]: Are there any other questions? We have arrived at the end of the time that has been given for the session. With this, we would like to conclude this briefing session. I would like to thank you for having engaged yourself in this extended session.

Thank you very much.

[END]

### **Document Notes**

- 1. Portions of the document where the audio is obscured by technical difficulty are marked with [TD].
- 2. Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.
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