Sumitomo Pharma Co., Ltd.

Q2 Financial Results Briefing for FY2024

October 30, 2024

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
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[Event Language]	JPN
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[Event Name]	Q2 Financial Results Briefing for FY2024
[Fiscal Period]	FY2024 Q2
[Date]	October 30, 2024
[Time]	18:05 – 19:47 (Total: 102 minutes, Presentation: 30 minutes, Q&A: 72 minutes)
[Venue]	Tokyo Head Office and Webcast
[Number of Speakers]	5

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Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Corporate Governance; Human Resources; Global Finance Administration
Tsutomu Nakagawa	Member, Board of Directors, Executive Officer, President and CEO, Sumitomo Pharma America, Inc.
Yoshiharu Ikeda	Managing Executive Officer, Drug Research Division, Head of Japan Business Unit

	Naoki Noguchi	Executive Officer Corporate Governance; Corporate Communications Vice President, Head of Corporate Communications
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	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities Japan
	Hidemaru Yamaguchi	Citigroup Global Markets Japan
	Shinya Tsuzuki	Mizuho Securities
	Hiroshi Wada	SMBC Nikko Securities

Presentation

Noguchi: We will now begin the presentation of financial results for Sumitomo Pharma Co., Ltd. for Q2 of FY2024.

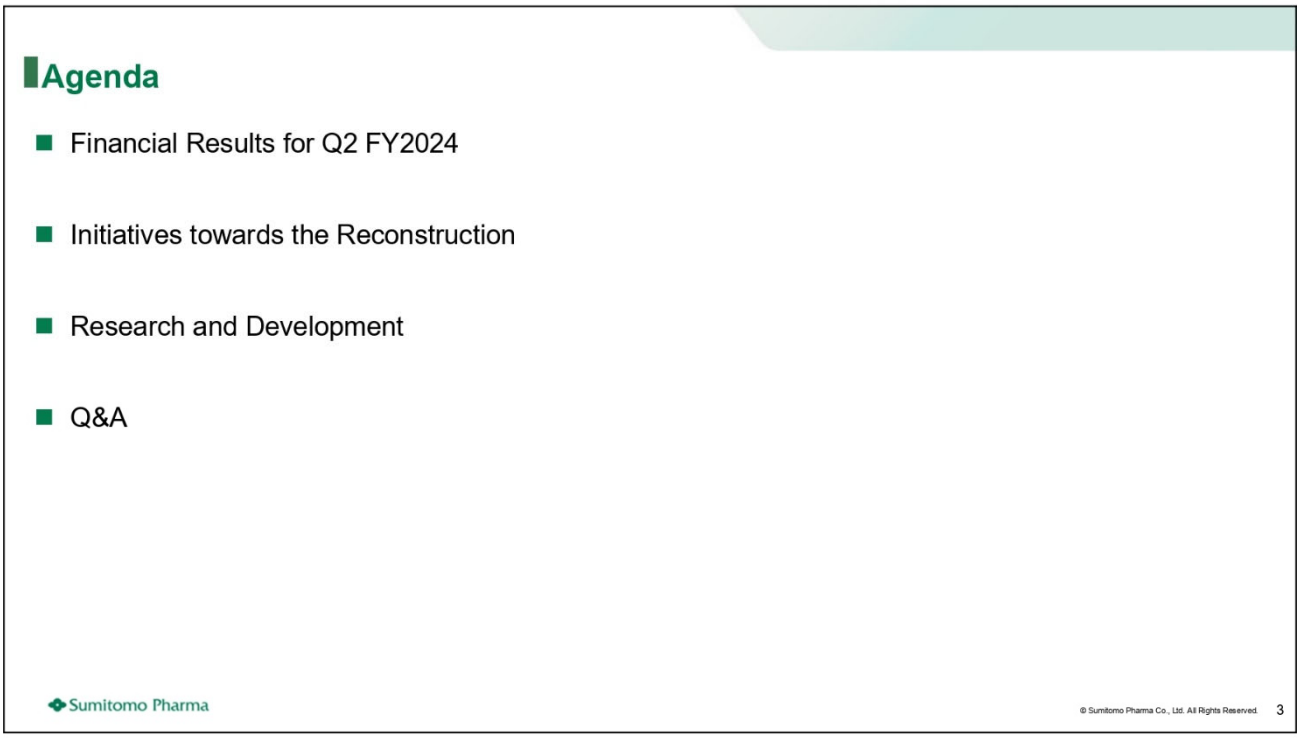
Thank you very much for joining us today. We will be conducting a live Zoom webinar at our Tokyo Head Office and from the venue.

I would now like to introduce today's attendees. Dr. Kimura, Representative Director, President and CEO; Mr. Sakai, Representative Director, Executive Vice President; Dr. Nakagawa, Member, Board of Directors, Executive Officer; Dr. Ikeda, Managing Executive Officer and Noguchi, your moderator for today. Thank you.

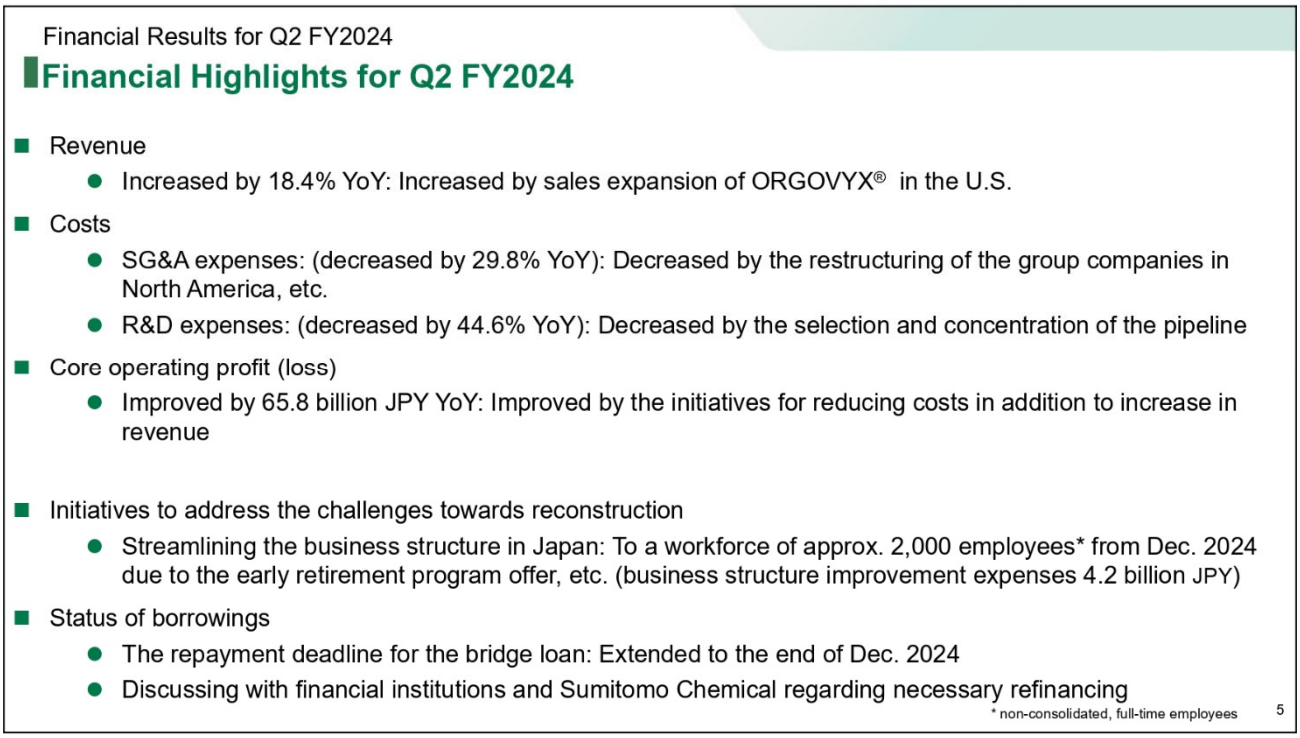
Dr. Kimura will now explain the Q2 financial results for FY2024. Dr. Kimura, please begin.

Kimura: Thank you very much for joining us today for the presentation of Sumitomo Pharma's financial results for Q2 of FY2024.

I will explain according to the materials.



The agenda for today's meeting is shown here on page 3, and it includes a summary of the financial results, the reconstruction of the Company, which is a very big issue for us, our efforts in this area, followed by research and development, and finally, a question-and-answer session.

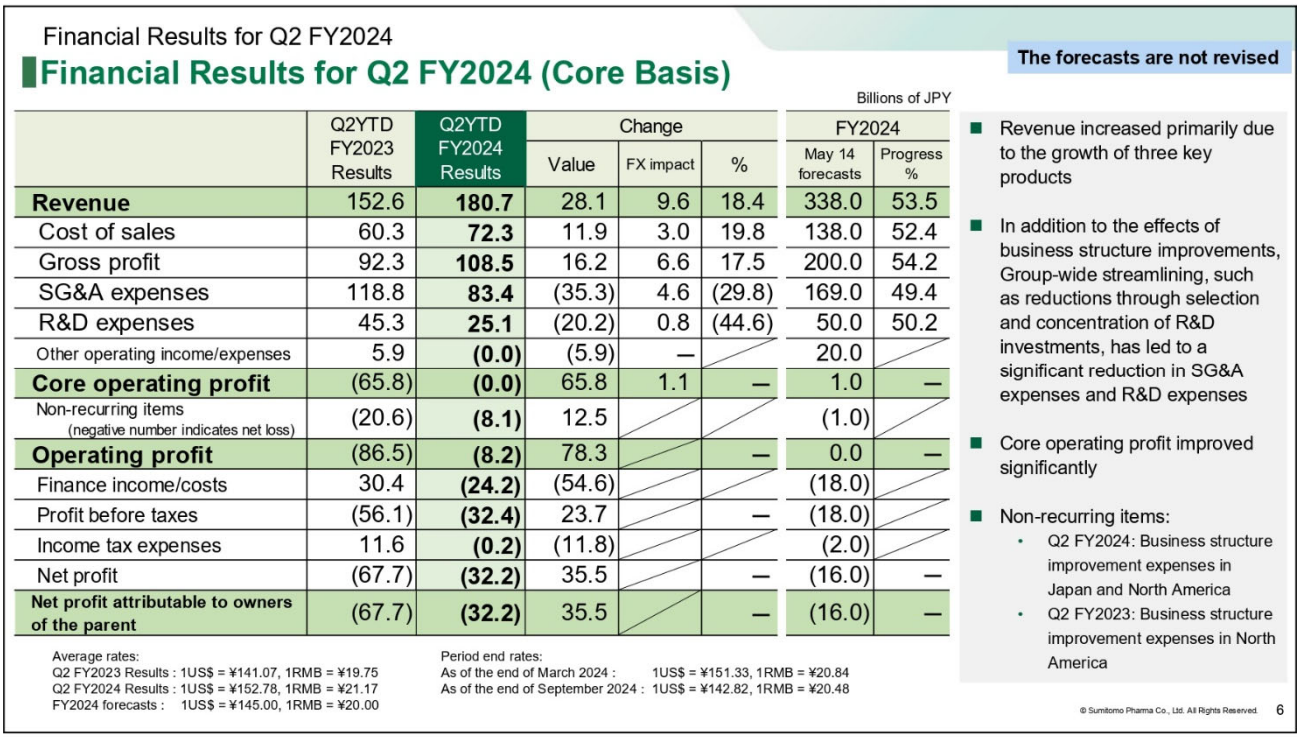


Here are the highlights of this fiscal year's financial results.

I will explain the figures in more detail later on, so I will not go into them here, but we are making progress on revenue, cost, and core operating profit in line with or even exceeding our forecasts.

In terms of challenges towards the reconstruction, the early retirement program offer is being promoted in Japan at Sumitomo Pharma at this very moment. Starting in December 2024, we will operate with a workforce of 2,000 employees, and I will explain this in more detail later.

As you all know, we have extended the repayment date of the bridge loan until September 30, 2024 and we have been discussing with the financial institutions and Sumitomo Chemical what we should do from now on. We have completed the extension of that arrangement until the end of December 2024, and we are currently in discussions regarding the necessary refinancing.



Financial Results for Q2 FY2024

Financial Results for Q2 FY2024 (Core Basis)

The forecasts are not revised

Billions of JPY

	Q2YTD FY2023 Results	Q2YTD FY2024 Results	Change			FY2024	
			Value	FX impact	%	May 14 forecasts	Progress %
Revenue	152.6	**180.7**	28.1	9.6	18.4	338.0	53.5
Cost of sales	60.3	**72.3**	11.9	3.0	19.8	138.0	52.4
Gross profit	92.3	**108.5**	16.2	6.6	17.5	200.0	54.2
SG&A expenses	118.8	**83.4**	(35.3)	4.6	(29.8)	169.0	49.4
R&D expenses	45.3	**25.1**	(20.2)	0.8	(44.6)	50.0	50.2
Other operating income/expenses	5.9	**(0.0)**	(5.9)	—		20.0	
Core operating profit	(65.8)	**(0.0)**	65.8	1.1	—	1.0	—
Non-recurring items (negative number indicates net loss)	(20.6)	**(8.1)**	12.5			(1.0)	
Operating profit	(86.5)	**(8.2)**	78.3		—	0.0	—
Finance income/costs	30.4	**(24.2)**	(54.6)			(18.0)	
Profit before taxes	(56.1)	**(32.4)**	23.7		—	(18.0)	
Income tax expenses	11.6	**(0.2)**	(11.8)			(2.0)	
Net profit	(67.7)	**(32.2)**	35.5		—	(16.0)	—
Net profit attributable to owners of the parent	(67.7)	**(32.2)**	35.5		—	(16.0)	—

- Revenue increased primarily due to the growth of three key products
- In addition to the effects of business structure improvements, Group-wide streamlining, such as reductions through selection and concentration of R&D investments, has led to a significant reduction in SG&A expenses and R&D expenses
- Core operating profit improved significantly
- Non-recurring items:
  - Q2 FY2024: Business structure improvement expenses in Japan and North America
  - Q2 FY2023: Business structure improvement expenses in North America

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
Q2 FY2024 Results : 1US$ = ¥152.78, 1RMB = ¥21.17
FY2024 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2024 : 1US$ = ¥151.33, 1RMB = ¥20.84
As of the end of September 2024 : 1US$ = ¥142.82, 1RMB = ¥20.48

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Here are the operating results for the current fiscal year on a core basis.

As you can see, revenue was JPY180.7 billion, a significant improvement of JPY28.1 billion from the previous fiscal year.

On the other hand, SG&A expenses and R&D expenses are under control.

Here, we have shown the progress made against the forecasts from May 14 of this fiscal year, which you can consider as almost equivalent to the budget. Revenue has remained strong while SG&A expenses and R&D expenses are being controlled.

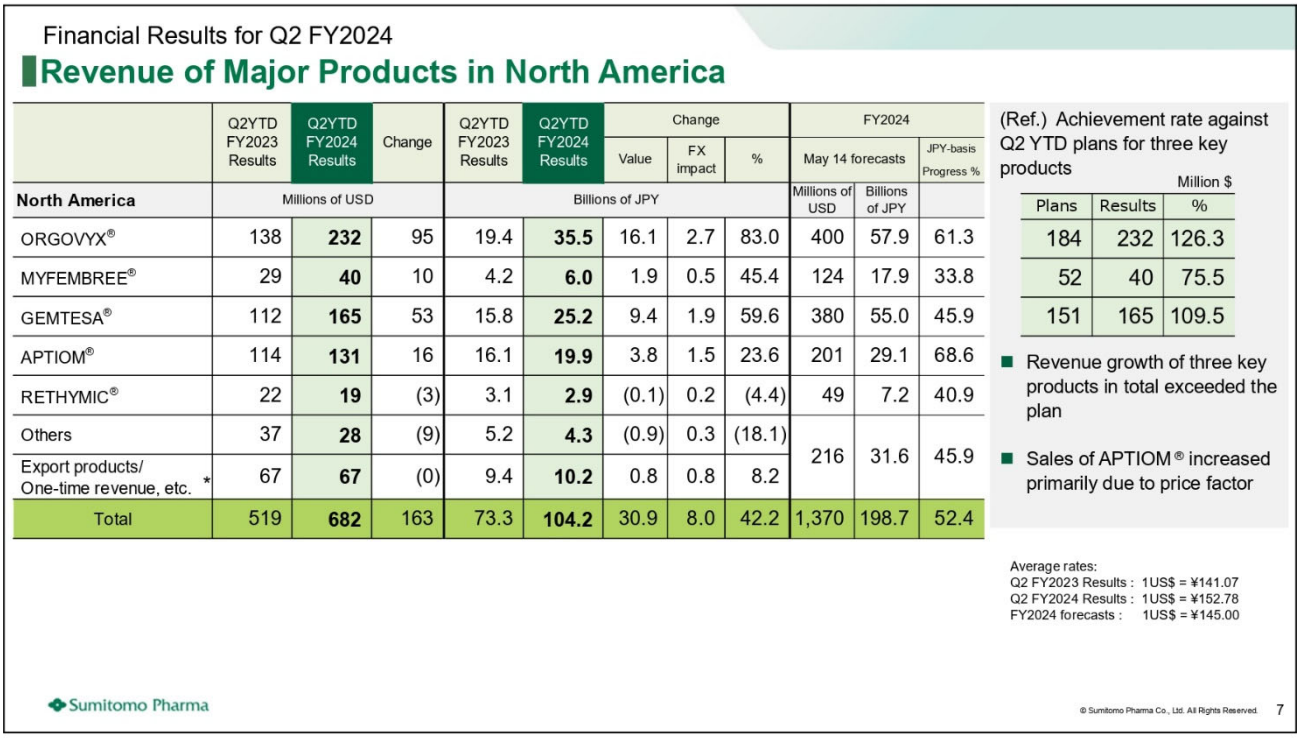
As a result, we have managed to reach this point, although core operating profit for the current fiscal year is minus JPY0 billion, actually a loss of JPY38 million.

We are targeting JPY1 billion in core operating profit for the current fiscal year, and as I have indicated, this means JPY1 billion in core operating profit, including the sale of JPY20 billion worth of businesses. This means the target excluding the sale of businesses is JPY19 billion in core operating loss. I hope you will understand that this time, not including the sale of the businesses, core operating profit became minus JPY0 billion.

As for non-recurring items, operating profit was minus JPY8.2 billion due to business structure improvement expenses of about JPY7 billion in Japan and the United States.

The big part is the financial income/costs here, and this shows that our subsidiary has liabilities denominated in yen. We have loans to our subsidiaries denominated in yen, and the exchange rate at the end of the period resulted in a foreign exchange loss, but this has almost disappeared today, and the exchange rate moves daily.

In Q1, this was a significant figure, but I explained that it has nearly disappeared as of that date. That's the situation we are in.



Financial Results for Q2 FY2024

Revenue of Major Products in North America

North America	Q2YTD FY2023 Results (Millions of USD)	Q2YTD FY2024 Results (Millions of USD)	Change (Millions of USD)	Q2YTD FY2023 Results (Billions of JPY)	Q2YTD FY2024 Results (Billions of JPY)	Change Value (Billions of JPY)	Change FX impact (Billions of JPY)	Change %	FY2024 May 14 forecasts Millions of USD	FY2024 May 14 forecasts Billions of JPY	JPY-basis Progress %
ORGOVYX®	138	**232**	95	19.4	**35.5**	16.1	2.7	83.0	400	57.9	61.3
MYFEMBREE®	29	**40**	10	4.2	**6.0**	1.9	0.5	45.4	124	17.9	33.8
GEMTESA®	112	**165**	53	15.8	**25.2**	9.4	1.9	59.6	380	55.0	45.9
APTIOM®	114	**131**	16	16.1	**19.9**	3.8	1.5	23.6	201	29.1	68.6
RETHYMIC®	22	**19**	(3)	3.1	**2.9**	(0.1)	0.2	(4.4)	49	7.2	40.9
Others	37	**28**	(9)	5.2	**4.3**	(0.9)	0.3	(18.1)	216	31.6	45.9
Export products/ One-time revenue, etc. *	67	**67**	(0)	9.4	**10.2**	0.8	0.8	8.2			
Total	519	**682**	163	73.3	**104.2**	30.9	8.0	42.2	1,370	198.7	52.4

(Ref.) Achievement rate against Q2 YTD plans for three key products

Million $

Plans	Results	%
184	232	126.3
52	40	75.5
151	165	109.5

- Revenue growth of three key products in total exceeded the plan
- Sales of APTIOM® increased primarily due to price factor

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07
Q2 FY2024 Results : 1US$ = ¥152.78
FY2024 forecasts : 1US$ = ¥145.00

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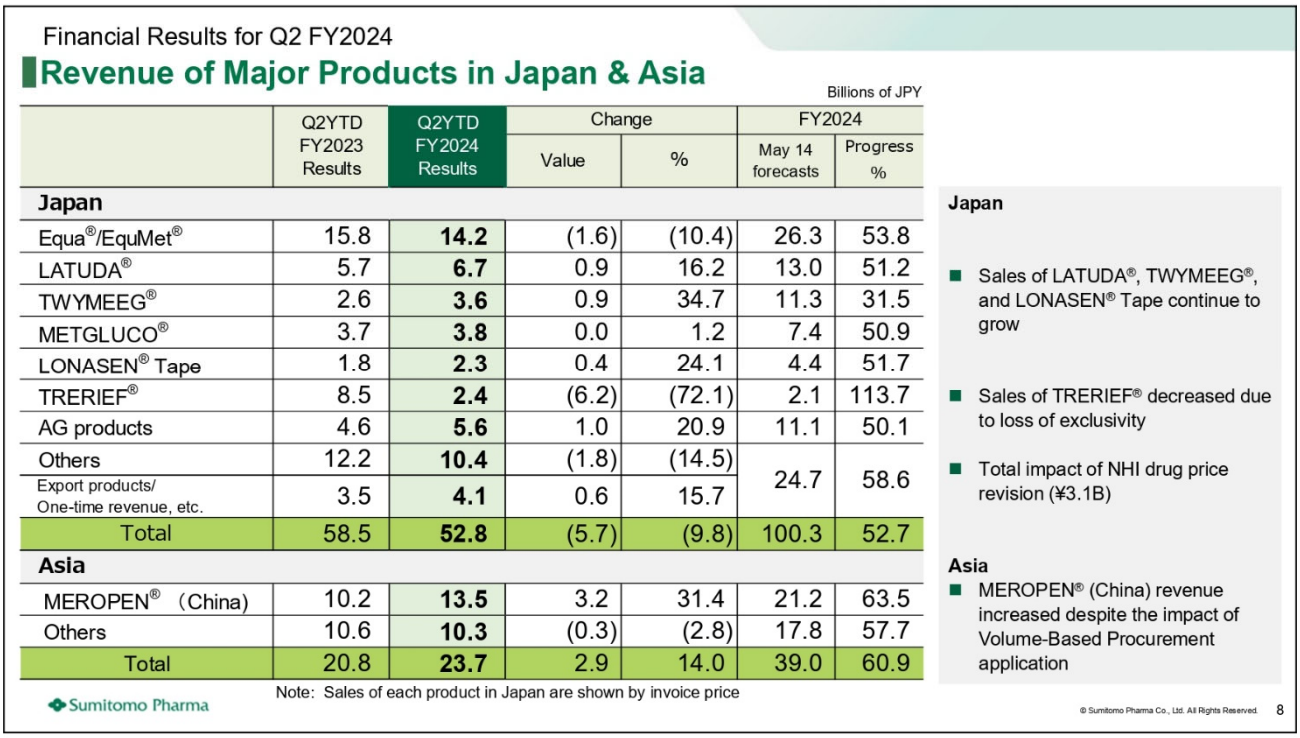
Here, we would like to explain the revenue of our main products in North America and Japan/Asia.

In North America, we are focusing on ORGOVYX, MYFEMBREE, and GEMTESA as our three key products, and the revenue of ORGOVYX is JPY35.5 billion, MYFEMBREE is JPY6 billion, and GEMTESA is JPY25.2 billion. In order to show you how these figures compare with our original plan, I am showing you a comparison with our plan up to Q2.

ORGOVYX is plus 26% and GEMTESA is plus 10%. Although MYFEMBREE is struggling a little, overall sales in North America amounted to JPY104.2 billion, a significant improvement from the previous fiscal year.



Financial Results for Q2 FY2024

Revenue of Major Products in Japan & Asia

Billions of JPY

	Q2YTD FY2023 Results	Q2YTD FY2024 Results	Change		FY2024	
			Value	%	May 14 forecasts	Progress %
Japan						
Equa®/EquMet®	15.8	**14.2**	(1.6)	(10.4)	26.3	53.8
LATUDA®	5.7	**6.7**	0.9	16.2	13.0	51.2
TWYMEEG®	2.6	**3.6**	0.9	34.7	11.3	31.5
METGLUCO®	3.7	**3.8**	0.0	1.2	7.4	50.9
LONASEN® Tape	1.8	**2.3**	0.4	24.1	4.4	51.7
TRERIEF®	8.5	**2.4**	(6.2)	(72.1)	2.1	113.7
AG products	4.6	**5.6**	1.0	20.9	11.1	50.1
Others	12.2	**10.4**	(1.8)	(14.5)	24.7	58.6
Export products/ One-time revenue, etc.	3.5	**4.1**	0.6	15.7		
Total	58.5	**52.8**	(5.7)	(9.8)	100.3	52.7
Asia						
MEROPEN® (China)	10.2	**13.5**	3.2	31.4	21.2	63.5
Others	10.6	**10.3**	(0.3)	(2.8)	17.8	57.7
Total	20.8	**23.7**	2.9	14.0	39.0	60.9

Note: Sales of each product in Japan are shown by invoice price

Japan

- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Sales of TRERIEF® decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥3.1B)

Asia

- MEROPEN® (China) revenue increased despite the impact of Volume-Based Procurement application

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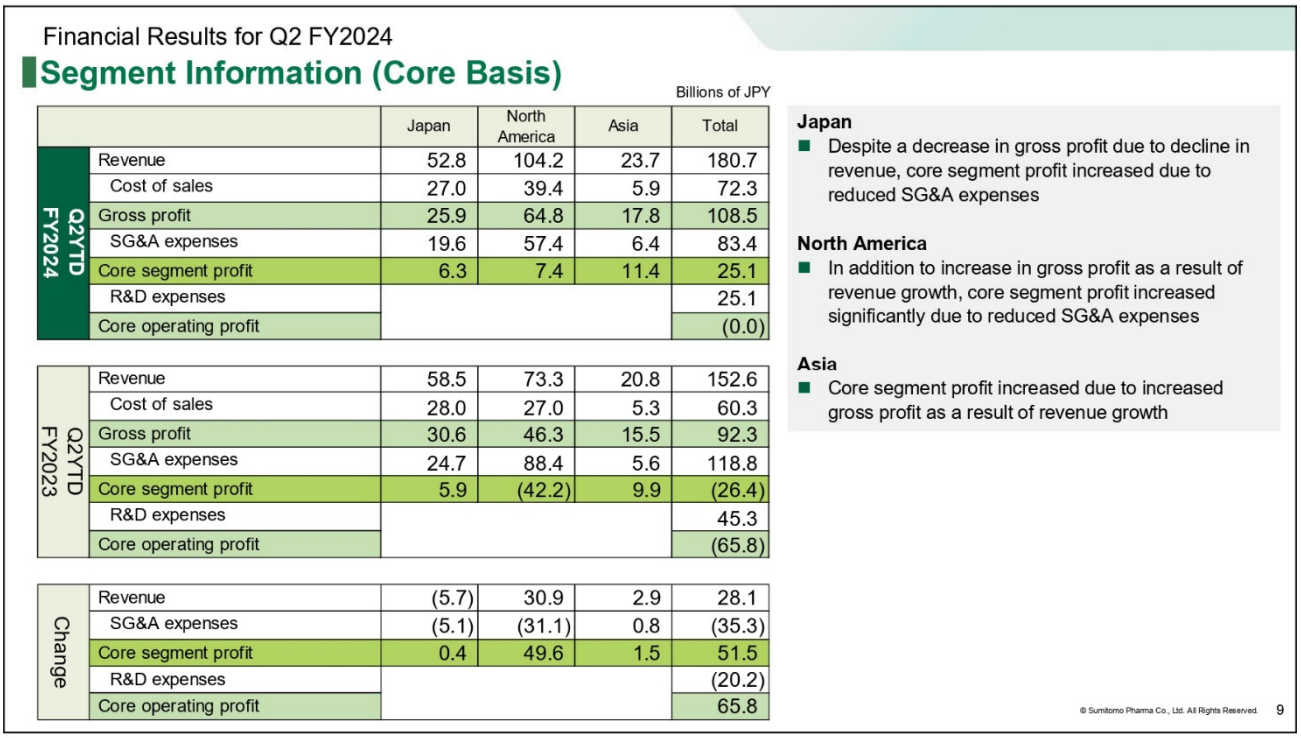
In Japan, revenue was JPY52.8 billion, slightly down from the previous fiscal year, but this is due to the end of the exclusive sales period for TRERIEF in June this year. In addition, there is a JPY3.1 billion impact of the NHI price revision on the segment as a whole, so this figure includes that.

On the other hand, TRERIEF is doing relatively well compared to our original plan. This reflects the progress against the annual plan, and as you can see, the domestic market is trending positively.

In Asia, MEROPEN in China is doing well, totaling JPY23.7 billion, up JPY2.9 billion from the previous fiscal year. This is 60.9% of the plan.



Financial Results for Q2 FY2024

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
Q2YTD FY2024	Revenue	52.8	104.2	23.7	180.7
	Cost of sales	27.0	39.4	5.9	72.3
	Gross profit	25.9	64.8	17.8	108.5
	SG&A expenses	19.6	57.4	6.4	83.4
	Core segment profit	6.3	7.4	11.4	25.1
	R&D expenses				25.1
	Core operating profit				(0.0)
Q2YTD FY2023	Revenue	58.5	73.3	20.8	152.6
	Cost of sales	28.0	27.0	5.3	60.3
	Gross profit	30.6	46.3	15.5	92.3
	SG&A expenses	24.7	88.4	5.6	118.8
	Core segment profit	5.9	(42.2)	9.9	(26.4)
	R&D expenses				45.3
	Core operating profit				(65.8)
Change	Revenue	(5.7)	30.9	2.9	28.1
	SG&A expenses	(5.1)	(31.1)	0.8	(35.3)
	Core segment profit	0.4	49.6	1.5	51.5
	R&D expenses				(20.2)
	Core operating profit				65.8

Japan
- Despite a decrease in gross profit due to decline in revenue, core segment profit increased due to reduced SG&A expenses

North America
- In addition to increase in gross profit as a result of revenue growth, core segment profit increased significantly due to reduced SG&A expenses

Asia
- Core segment profit increased due to increased gross profit as a result of revenue growth

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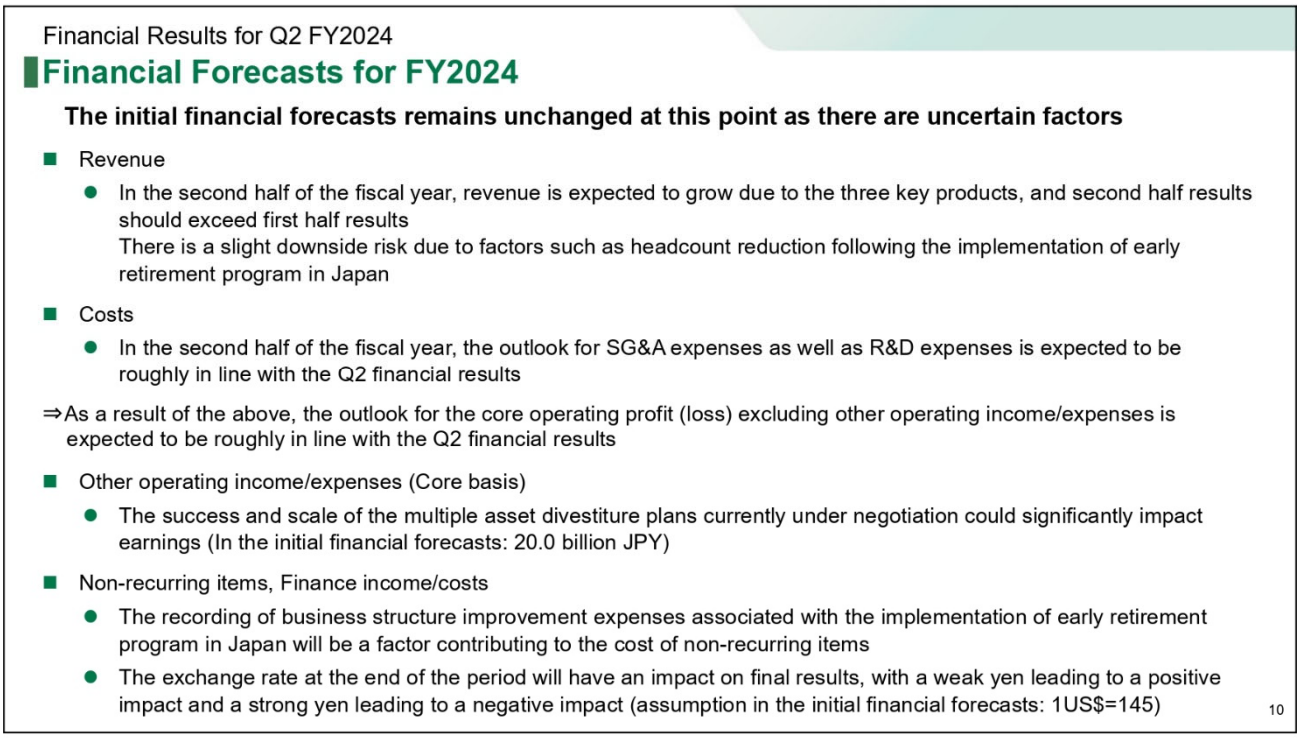
As a result, each segment, Japan, North America, and Asia, is performing very well compared to the original forecasts. Segment income was JPY25.1 billion: JPY6.3 billion in Japan, JPY7.4 billion in North America, and JPY11.4 billion in Asia.

At the bottom, we have compared the results with FY2023. In Japan, revenue has decreased slightly due to the reasons mentioned earlier, but effective control of SG&A expenses has led to a JPY400 million increase in core segment profit. In North America, while revenue has been growing very rapidly, the curbing of SG&A expenses has been effective, resulting in an improvement of approximately JPY50 billion.



On the other hand, while there were some criticisms regarding whether our initial forecasts could be achieved, we have been performing better than expected. However, for reasons I will explain shortly, we are maintaining our full-year performance forecasts at this time.

First, regarding revenue, we anticipate that our three key products will continue to grow steadily in H2 of this fiscal year. On the other hand, early retirement program offer is now being implemented in Japan. This will result in a very large reduction in personnel, including sales force, so we see a certain downside risk.

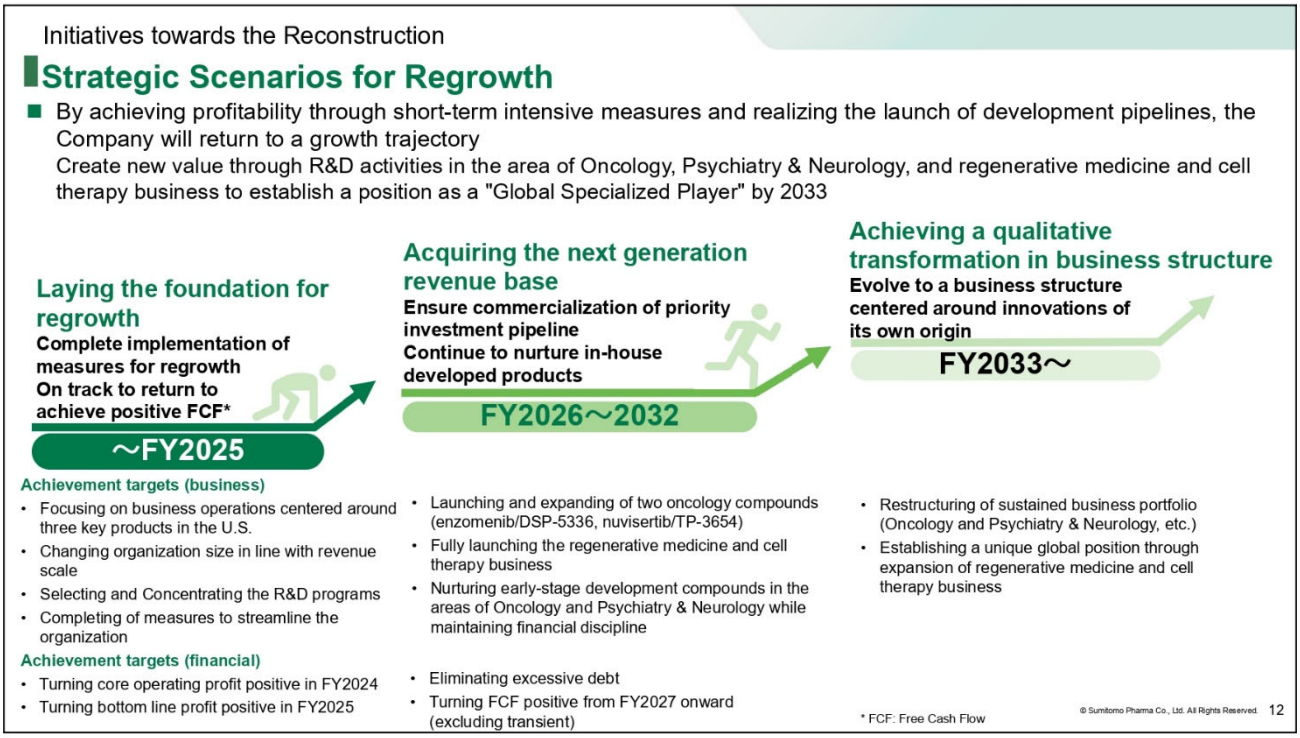
In terms of costs, we believe that both SG&A and R&D expenses can be kept at the same level as in Q2.

As a result, we believe that core operating profit, excluding other operating income and expenses, will be roughly on par with the Q2 results at the end of the fiscal year. On the other hand, the business transfer, for which we included JPY20 billion in the initial forecasts, is now zero by Q2. In fact, we are in discussions with several projects, each of which is of a certain scale, and earnings may fluctuate greatly depending on the success or failure of the project or the amount of money involved.

Our budget was originally a very small absolute value of JPY1 billion, so we are considering a very large swing. We cannot predict the confusion that might be caused by such fluctuations, and this is one of the reasons why we have left our earnings forecasts unchanged.

Regarding non-recurring items and financial income/costs, we have accounted for the business structure improvement expenses associated with the early retirement program offer for those who applied by September within Q2 of this fiscal period. However, those who applied in October will be accounted for in Q3, so there will be some remaining negative factors.

There are many uncertain factors regarding financial income/costs , as I explained earlier, such as very large movements in foreign exchange rates, so we have decided to leave our earnings forecasts unchanged at this time. We intend to provide a solid forecast in the Q3 financial results announcement.



I would like to continue by explaining our efforts to reconstruct.

We are in a situation where we must first rebuild our company, and I have presented a brief strategic scenarios for our regrowth.

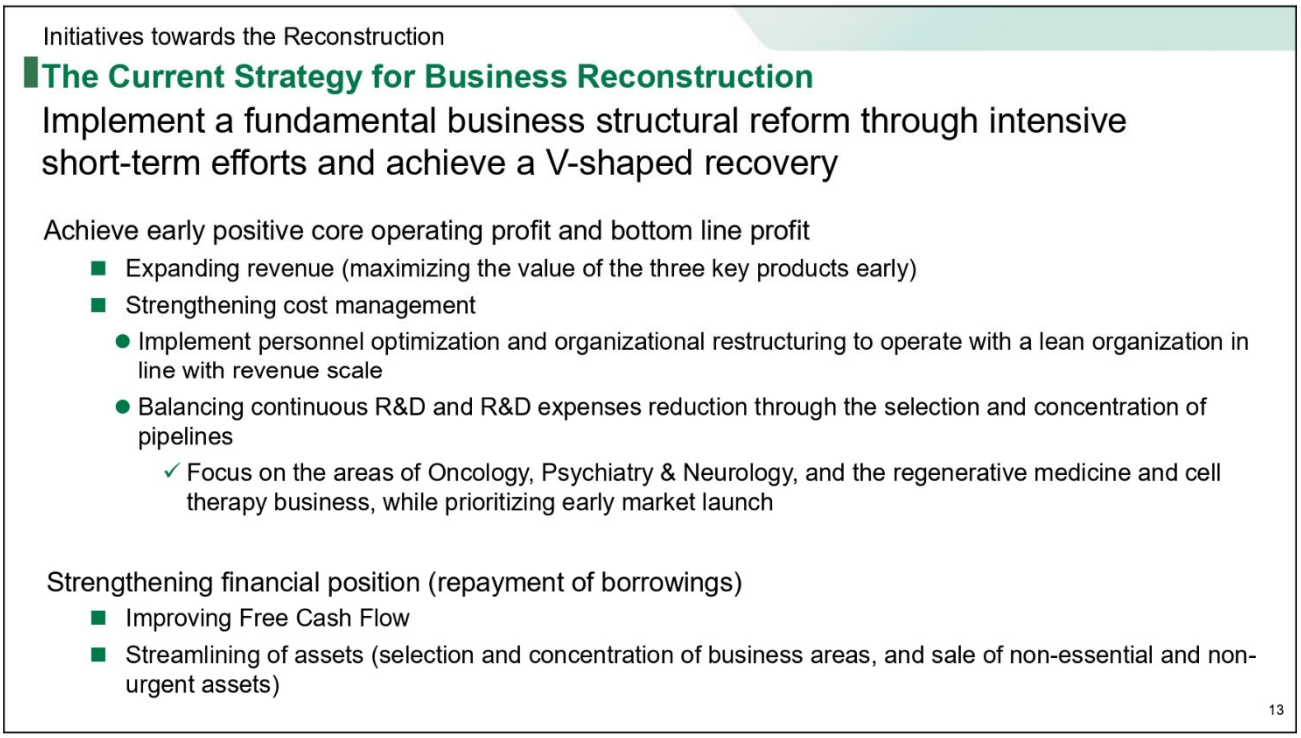
First of all, our goal is to achieve profitability through short-term intensive measures, and at the same time, we would like to put the Company back on track for growth by bringing new development pipelines to market.

In 10 years, we aim to firmly establish ourselves as a "Global Specialized Player." We will continue our research and development activities in the areas of Oncology, Psychiatry & Neurology, and regenerative medicine/cell therapies business, while also creating new value.

We have divided the period into three major periods, with the first goal of firmly laying the foundation for regrowth in the current and next fiscal years. First, we announced our goal to achieve positive core operating profit for this fiscal year, and to turn our bottom line profit positive by the next fiscal year. We will be moving forward with these objectives in mind.

After that, we have set aside a period of time to ensure the commercialization of R&D, especially priority investment pipelines, as the next generation revenue base.

After that, we have planned a three-phase approach to achieving our goal of becoming a "Global Specialized Player" through a business structure centered around innovations of our own origin.

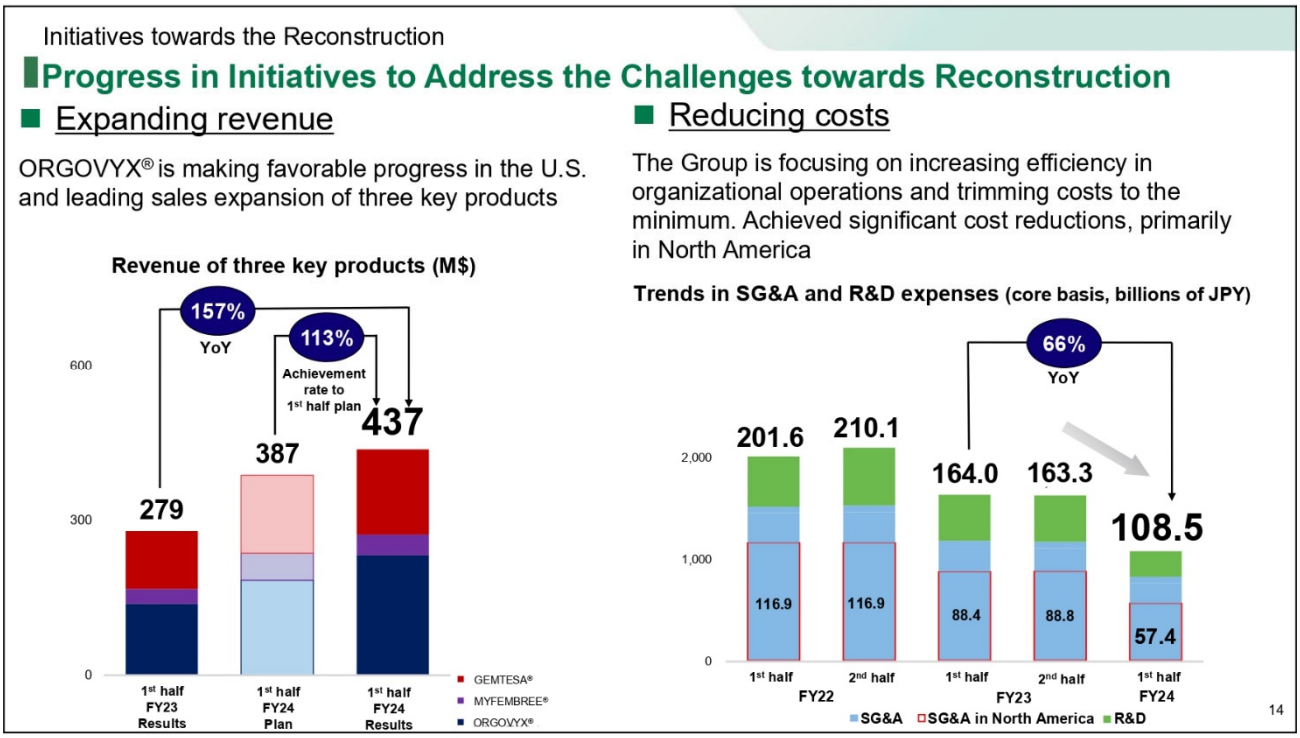


First of all, as I mentioned earlier, for the immediate business reconstruction, we are proceeding with the goal of achieving a V-shaped recovery by decisively implementing drastic structural reforms in a short-term and concentrated manner, and our target is to quickly return core operating profit and bottom line profit to profitability this fiscal year and next fiscal year. As I explained earlier, we believe that there is still room for growth in maximizing the value of the three key products at an early stage.

On the other hand, we will proceed with good cost management. At the same time, in our R&D efforts, we will focus on selecting and concentrating our pipelines, prioritizing early market launches, and dedicating resources to the areas of Oncology, Psychiatry & Neurology, and regenerative medicine/cell therapies business, as previously mentioned.

On the other hand, in terms of financial position, we have a very high level of borrowings, so we will improve free cash flow. At the same time, as we move forward with selection and concentration in our business areas, we will also streamline our assets by selling non-essential and non-urgent assets.

We would like to create the foundation for regrowth in the current and next fiscal years through a comprehensive, short-term, and concentrated approach.



Here is the progress of the project.

The first step is to expand revenue, particularly in the United States. We have shown the revenue of our three key products in the United States on a half of fiscal year basis. Compared to H1 of last fiscal year, it has increased by 157%, and when compared to our plan for H1 of this fiscal year, it is up by 13%. This indicates that we are progressing smoothly, as illustrated on the left.

On the other hand, as a result of Group-wide efforts to trim costs at all costs, SG&A and R&D expenses for H1 of this year were reduced from over JPY160 billion in the previous fiscal year to JPY100 billion, JPY108.5 billion, in H1 of this fiscal year. This will continue well into H2 of this fiscal year, as I mentioned earlier.

Initiatives towards the Reconstruction

ORGOVYX®

ORGOVYX (relugolix) 120mg tablets

Plan for Q2 YTD FY2024	Actual for Q2 YTD FY2024	YoY comparison	Breakdown of actual volume and price difference from plan	
$184M	**$232M (126% to plan)**	**Approx. 69% increase**	Volume	$37M
			Price	$12M

- Volume grew more than expected due to the changes in the medication benefit design for Medicare Part D
- Price was higher than expected due to the lower-than-anticipated returns and coverage gap

Quarterly Volume Trends*
(number of bottles, estimation)

Sales Forecasts and Marketing Topics

- Volume trend has accelerated since January 2024
- The further reduction in the patient's out-of-pocket cost cap scheduled for January 2025 is also expected to provide a tailwind, and revenue for this fiscal year is projected to exceed the initial plan

- New patient starts have continued to increase
- Strong demand growth continued in all account segments, with significant growth in Urology and Oncology Clinics with in-office dispensing as well as Academic Centers/Integrated Delivery Networks

* Internal calculation

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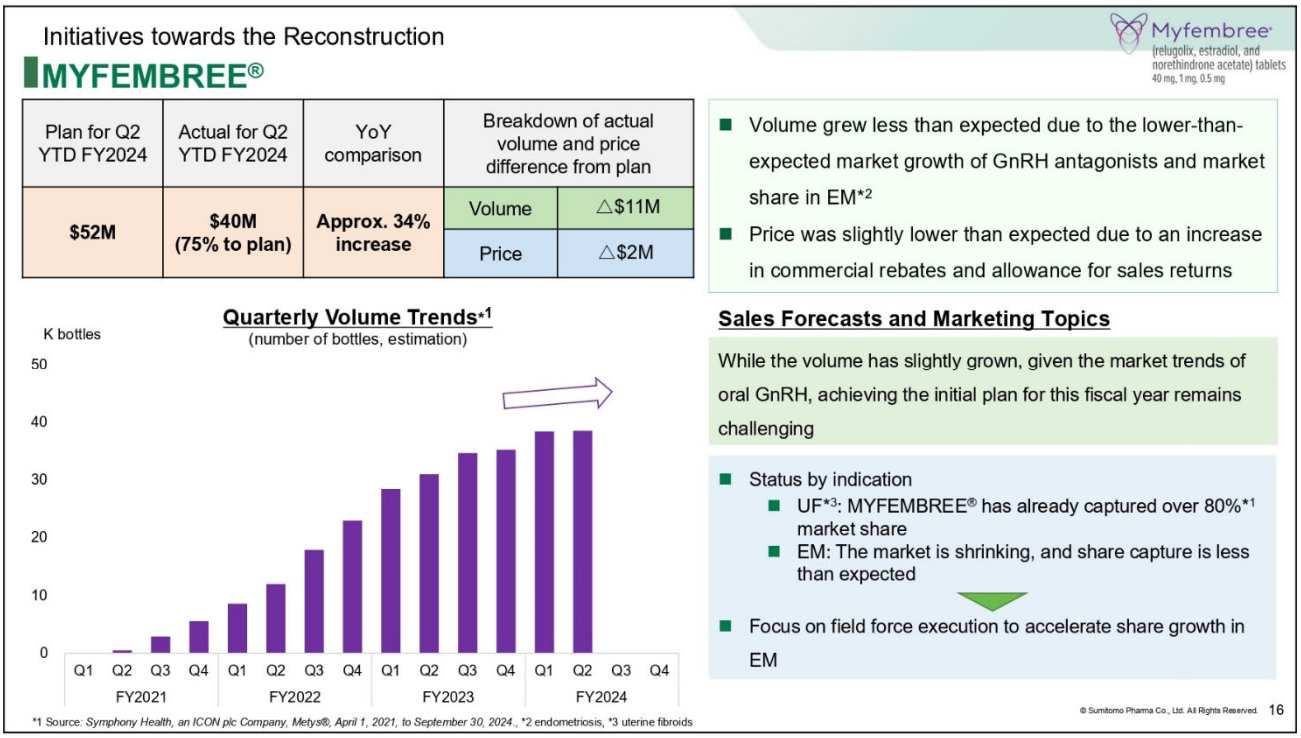
Here is the situation for each of the three key products.

ORGOVYX, a drug for prostate cancer, grew by 70% YoY, mainly in terms of shipping volume. The growth is primarily driven by an increase in volume. This growth has been supported by the new Medicare Part D and IRA drug reimbursement systems that have been implemented this year, which have provided a tailwind for us, resulting in increased volume. We have been doing very well since FY2021 and expect to continue to grow.

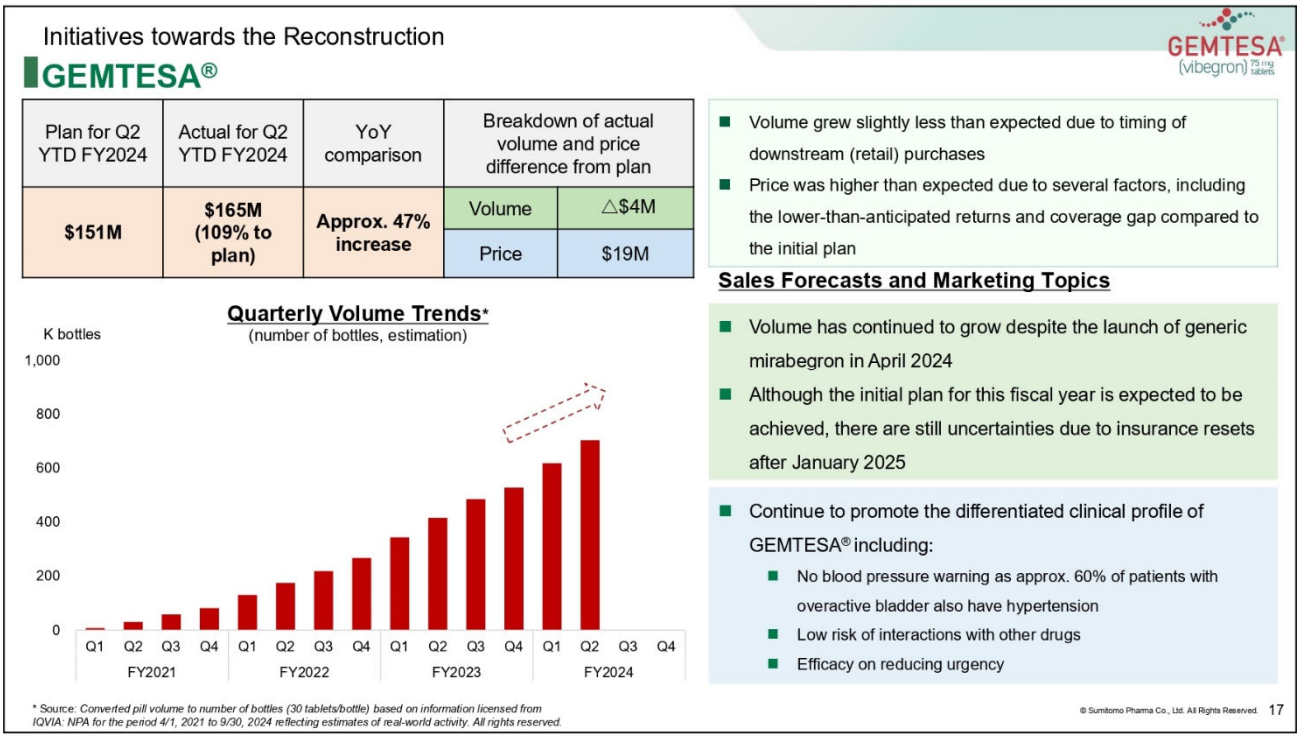


Next is MYFEMBREE.

We are struggling a bit here. Although only 75% of the JPY52 million planned for H1 was achieved, this is still an increase of more than 30% compared to the previous fiscal year.

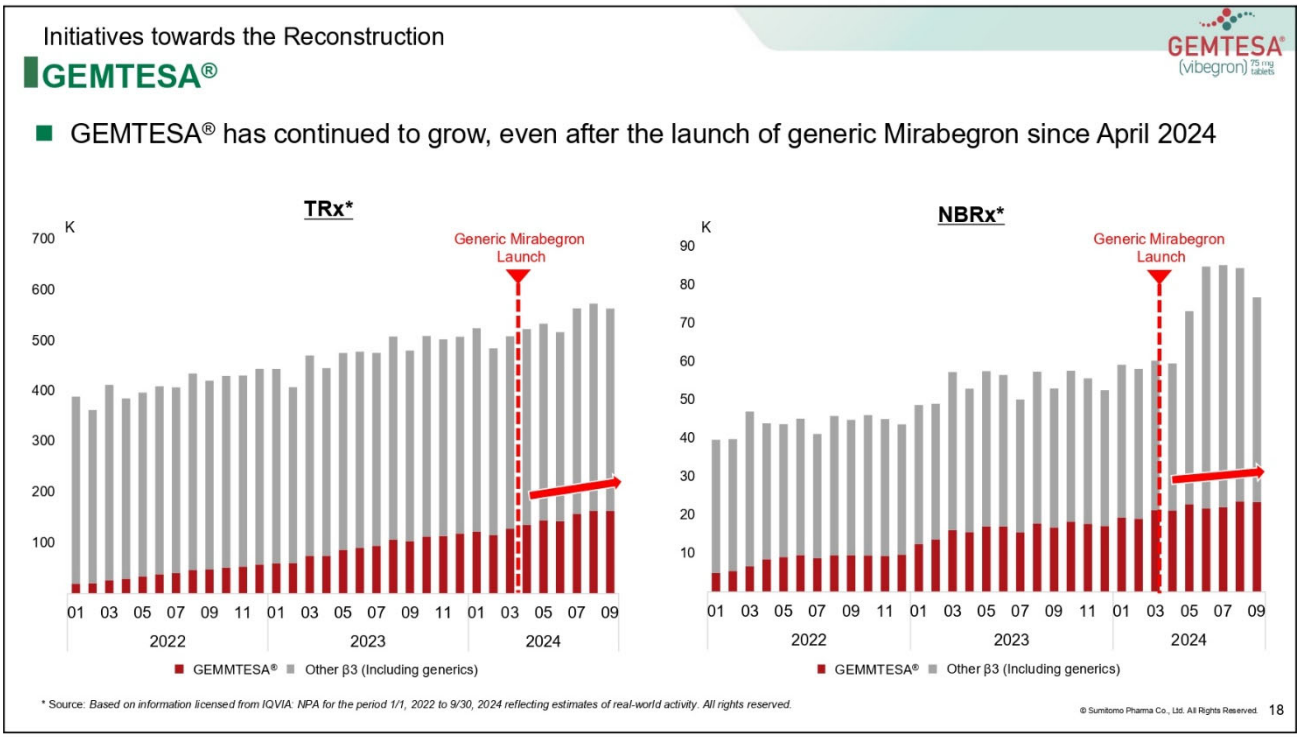
The main challenge we face is the difficulty in achieving substantial volume growth. We have two indications: endometriosis and uterine fibroids. In the case of endometriosis, we have not been able to expand our market share as anticipated. However, we are seeing some growth, and we will continue to carefully monitor market trends moving forward.

On the other hand, it has become very difficult to achieve our initial plan, so we are somewhat giving up on this fiscal year's targets.



On the other hand, GEMTESA is performing well, with a 9% increase over the plan and a 47% increase over the previous fiscal year.

In particular, in terms of pricing, we have experienced a tailwind from the lower burden of the coverage gap compared to our forecasts at the beginning of the fiscal year, and we have exceeded our plan. We were concerned about the introduction of a competing generic product, and we have received some questions from our stakeholders, but so far there has been no impact.



Two graphs are shown around this area: the number of prescriptions, or how many prescriptions were prescribed to completely new patients.

In the red dotted line below, the market environment has changed dramatically due to the launch of competing generic products in these dotted areas. Our product is growing steadily.

On the other hand, sales of beta 3, a drug with similar efficacy, have increased all at once when generics came out, but you can see that ours are increasing steadily regardless of the sales of generics.

Next to that, it indicates that the new structure will start in December.

We have implemented the early retirement program in Japan. As a result, the structure and organization have become leaner, and the essence of the R&D and the Sales & Marketing divisions, a particularly large organization, is shown here.

Until now, we had three divisions: the Drug Research Division for research and non-clinical testing, the Development Division for clinical development, and the Technology Research & Development Division for CMC or reviewing manufacturing process. We took this opportunity to undertake a major organizational reform by combining the three divisions into one and making the entire organization leaner, while creating an R&D structure that would allow us to proceed with everything from research to development and launch in a single integrated manner.

Previously, when transitioning between divisions, there were often delays and miscommunication. This time, with an integrated operation, we aim to be somewhat leaner while significantly increasing productivity compared to before.

Our strategy is to first focus on the two Oncology compounds that are close to market launch, as well as on the development programs for the regenerative medicine and cell therapy. Following that, we aim to solidly advance the development programs for small molecules in Oncology and Psychiatry & Neurology to support the next generation.

The Sales & Marketing Division is the foundation of our domestic business. However, the early retirement program has made the organization very lean. We would like to reorganize division's functions and branches to improve productivity with an efficient organization. 19 departments will be reduced to 10 departments and

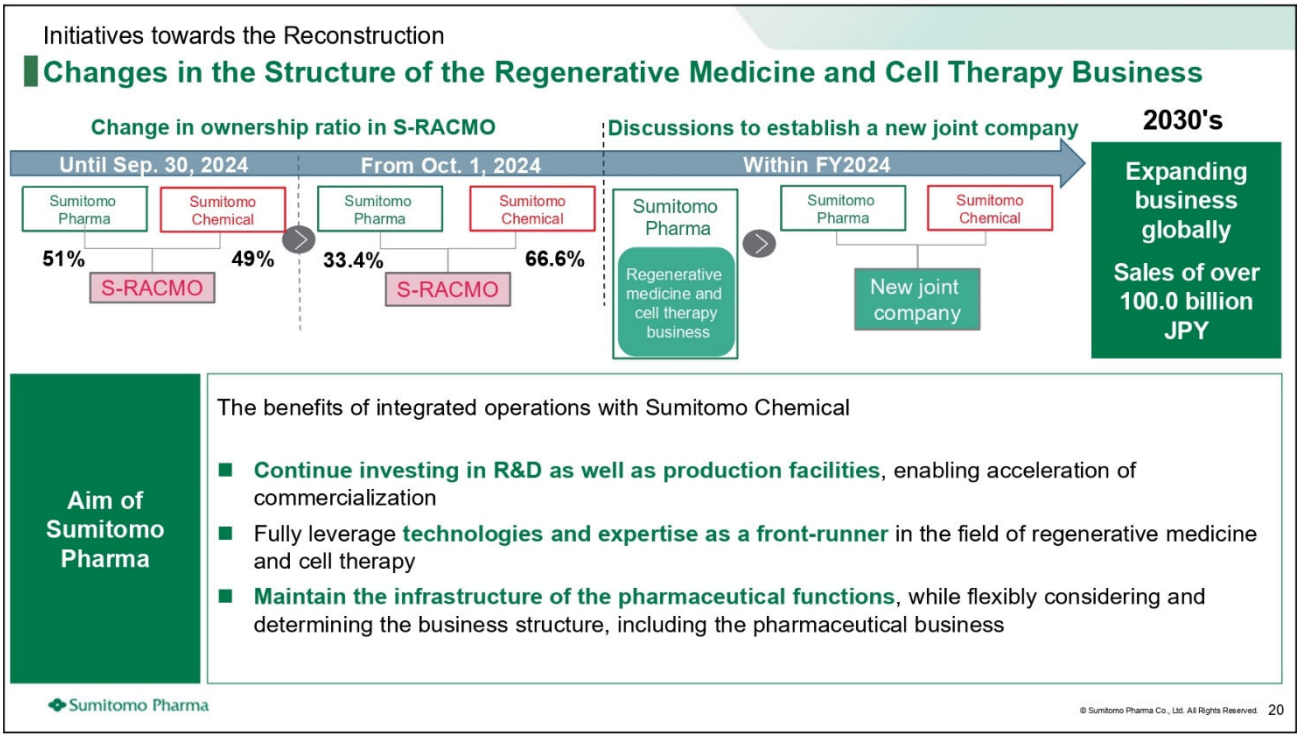
12 branches nationwide will be reduced to 7 branches. The number of sales representatives, which used to exceed 1,000, is to be reduced to 620, and the number of MRs, which currently stands at 770, is to be reduced to 450, resulting in a considerably slimmer structure.

In order to cover the entire country, we have been using a disease area system, with MRs specializing in CNS being assigned to CNS, and MRs specializing in diabetes being assigned to diabetes. So in some hospitals, different SMP MRs have come and gone depending on the department, but we will change to an area system because the number of MRs will be reduced.

For example, in Shinagawa, Tokyo, representatives will cover a broader area, allowing them to handle both CNS and diabetes responsibilities. This marks a significant change in our approach.

We believe that we can provide information that meets the needs of our customers and that our MRs, who are very enthusiastic and excellent, are capable of providing information on any drug, although it is difficult to expand the scope of their areas.

The Corporate Departments, which I have not detailed, will be streamlined and made more efficient by merging related functional departments and reducing the number of departments from 18 to 13.



The other is a change in the structure of the regenerative medicine and cell therapy business.

We have had various discussions with Sumitomo Chemical, and we believe that under our current financial position, it will be very difficult to expand our regenerative medicine and cell therapy business while continuing to focus on the areas of Oncology and Psychiatry & Neurology. We must not slow down in any of the areas, and especially in regenerative medicine and cell therapy, where there are significant synergies with

Sumitomo Chemical, the Sumitomo Chemical Group will firmly develop it into a global business of more than JPY100 billion by the 2030s, as we had originally planned. To that end, we plan to increase Sumitomo Chemical's stake in the S-RACMO CDMO business. Additionally, while we are still discussing and have not made an announcement yet, we intend to advance drug discovery and development in regenerative medicine and cell therapy through a joint venture with Sumitomo Chemical, similar to S-RACMO, and we are currently working on the organizational design for this initiative.

In this way, Sumitomo Pharma can continue to invest in R&D and production facilities and further accelerate commercialization, and we, as the front runner, can make maximum use of our technology and expertise for business expansion.

Maintaining such infrastructure functions is crucial. While doing so, we will also have the flexibility to discuss and arrange future business structures with Sumitomo Chemical. The benefits of having Sumitomo Chemical as a partner are significant, and we are eager to move forward with this collaboration.

Research and Development

Development Pipeline (as of October 30, 2024)

No revisions since the announcement in July 2024

Area	Generic name/Product code	Mechanism of action, etc.	Proposed indication	Region	Development stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT_{2A} receptor antagonist and serotonin 5-HT_{1A} receptor agonist	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Selective orexin 2 receptor agonist	Narcolepsy	Japan	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator	Dravet syndrome, Lennox-Gastaut syndrom	Japan	Phase 1
	DSP-2342	Serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist	To be determined	U.S.	Phase 1
	CT1-DAP001/DSP-1083	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study	Japan	Under preparation for the NDA
	CT1-DAP001/DSP-1083	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company-sponsored clinical study	U.S.	Phase 1/2
	HLCR011	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Japan	Phase 1/2
Oncology	nuvisertib/TP-3654	PIM1 kinases inhibitor	Myelofibrosis	U.S., Japan	Phase 1/2
	enzomenib/DSP-5336	Menin and MLL inhibitor	Acute myeloid leukemia	U.S., Japan	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	U.S., Japan	Phase 1
	SMP-3124	CHK1 inhibitor	Solid tumors	U.S., Japan	Phase 1/2
Others	vibegron (Brand name: GEMTESA®)	ß3 adrenergic receptor agonist	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	sNDA submitted in February 2024
	vibegron	ß3 adrenergic receptor agonist	Overactive bladder (OAB)	China	Phase 3
	KSP-1007	β-lactamases inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	U.S., Japan	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Europe	Phase 1

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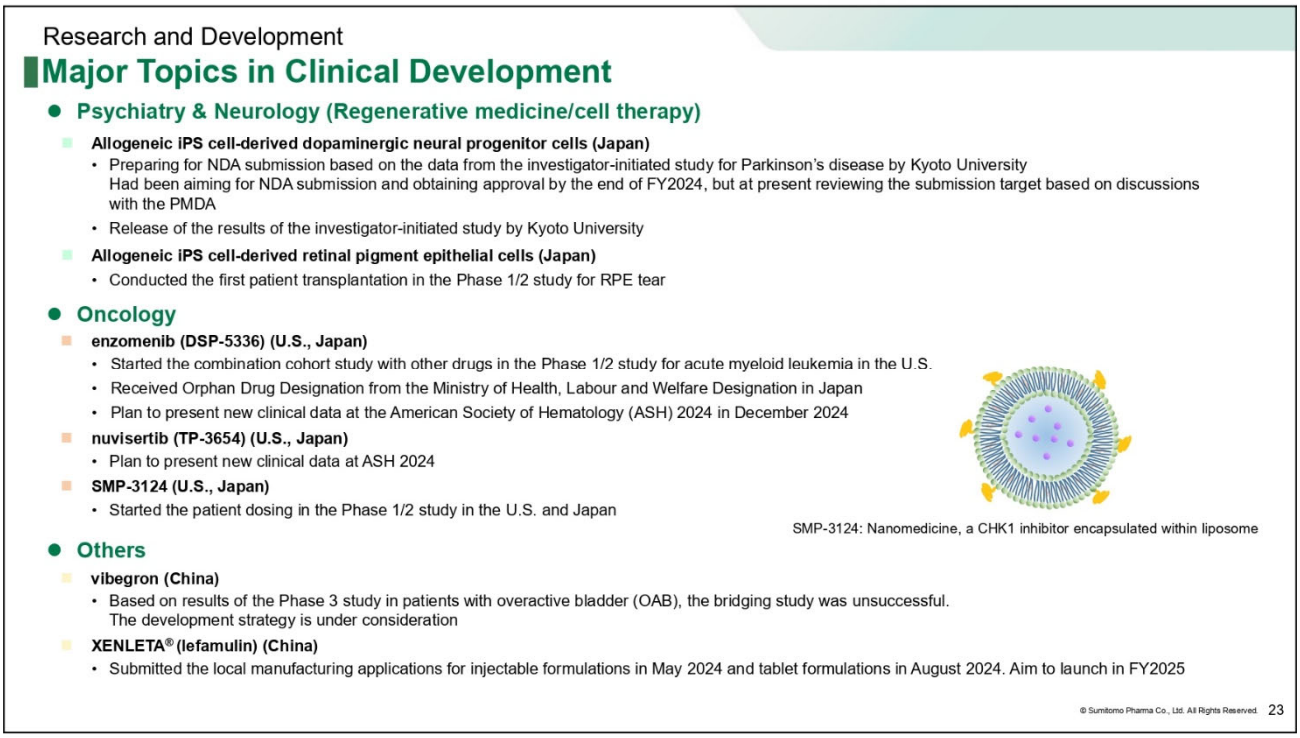
Next is R&D.

This is the list of major developments, but there are no changes, so we will move on.



The main topics of clinical development are listed here.

In the area of Psychiatry & Neurology , which also includes the field of regenerative medicine and cell therapy, one example is allogeneic iPS cell-derived dopaminergic neural progenitor cells, and another is regenerative therapy for Parkinson's disease. The investigator-initiated study at Kyoto University has concluded, and we are preparing for the application based on that data. While we initially aimed for NDA submission and obtaining approval within FY2024, we have begun to review our submission target in light of recent discussions with the PMDA.

Meanwhile, the results of the investigator-initiated study are being prepared for publication in a paper from Kyoto University, so you will be able to see the data at the same time as the paper. Please ask Kyoto University about this.

On the other hand, the first transplant of retinal pigment epithelial cells into a patient in Japan was successful.

In the Oncology area, we have been calling it DSP-5336, but it now has a generic name, enzomenib. A cohort study with other drugs has been started in the U.S., and the Ministry of Health, Labour and Welfare has given us orphan drug designation. In December, we will be presenting our clinical data at the American Society of Hematology. The target disease is acute myeloid leukemia.

What we called TP-3654 has the generic name nuvisertib. We are making good progress and plan to present the latest clinical data at the American Society of Hematology in 2024.

A new Oncology compound, SMP-3124, is now in the clinical study and is being administered to patients in the U.S. and Japan. This SMP-3124 is not just a low molecular compound, but a liposome-encapsulated

nanomedicine, in which the compound is encapsulated in liposomes. This contains an inhibitor of CHK1, a protein kinase that we are targeting, and we expect that this will reduce side effects and increase efficacy.

On the other hand, in China, we were conducting a Phase 3 study (bridging study) of vibegron, but unfortunately the bridging study was unsuccessful, so we are now considering our development strategy.

Also in China, regarding lefamulin, we have submitted the local manufacturing applications in May and August 2024, so we hope to be able to put the product on the market next fiscal year.

This is the end of the presentation. Thank you very much for your kind attention.

Noguchi: Thank you, Dr. Kimura.

Question & Answer

Noguchi [M]: I would now like to move on to the question and answer session.

Kusaka [Q]: My name is Kotaro Kusaka from Daiwa Securities.

I would like to ask a question from a credit perspective. The phrase "elimination of excessive debt" appears at the bottom of page 12. I don't think there are currently any loans that will mature after 2026, so I understand that as a declaration of intent for a first call on the subordinated debt. Am I correct in my understanding?

Kimura [M]: Mr. Sakai, go ahead.

Motoyuki Sakai [M]: I'm sorry, what do you mean by "declaration of intent?"

Kusaka [Q]: Excuse me. I think the only interest-bearing debt maturing between 2026 and 2032 is subordinated debt.

Motoyuki Sakai [A]: Yes, that's right. It is in 2027 and 2030.

Kusaka [Q]: So we can take this as a repayment, or rather a first call, of this subordinated debt?

Motoyuki Sakai [A]: There are various conditions for making a call, so I naturally believe that allowances must be made within the scope of those conditions.

Kusaka [Q]: Thank you very much.

Next, on page 13, it says "strengthening financial position (repayment of loans)." Does this mean that you are referring to extended bridge loans or something else?

Motoyuki Sakai [A]: Are you talking about page 13? It is not necessarily the case that we are referring to that specifically.

Kusaka [M]: I understand. Thank you very much.

Kimura [A]: I would like to add something regarding the first part of your question on eliminating excessive debt. We are currently scheduled to repay the subordinated debt you asked about, but we will also create a repayment plan for the money we are borrowing now, so we will repay the debt during this period again.

Noguchi [M]: Mr. Wakao from JPMorgan Securities Japan.

Wakao [Q]: Seiji Wakao, JPMorgan Securities Japan. Thank you very much.

First of all, regarding asset sales, is it likely that the JPY20 billion projected at the beginning of the term can be achieved during the remainder of the term? Can you tell us a little more about your current progress?

Kimura [A]: First of all, the JPY20 billion itself was included for a certain sense of scale, but we are currently discussing a variety of ways to make the scale of the asset sales more substantial, so please understand that a reasonable amount of the asset sales will be included in Q4.

However, since we have a counterparty and the amount will not be determined until a contract is signed, we have not included anything at this time.

Wakao [Q]: So it will be in the January to March period? By Q4?

Kimura [A]: We have multiple projects. Some are up to Q4 and some are just by end of Q4.

Wakao [Q]: I understand.

For something of that size, would it be correct to assume there will be a press release? Regarding this JPY20 billion, would it be correct to say that the feeling of the certainty of achieving the asset sales has not changed from the beginning of the period?

Kimura [A]: Kimura here. In terms of scale and asset sales, the accuracy has not changed.

Wakao [Q]: I understood that there is no specific delay. Thank you very much.

In that case, in Q1, I think you said that there was an upward revision of JPY10 billion against the internal plan, but I would like to know how much the cumulative total of H1 of this fiscal year is above the internal plan, and what are the savings.

And if that does not change the outlook for H2, is the Company making good progress with respect to the top line? If we think on a net basis, if we think the asset sales will go well, can we assume that there is a possibility of an upward revision at some point on a core basis, such as in Q3? Is that correct?

Motoyuki Sakai [A]: First of all, I would like to remind you of our forecasts for the full year, and we said that core operating profit would be JPY1 billion, but we added JPY20 billion for the sale of businesses and other items, which has been the topic of discussion. In other words, we had factored in a considerable amount of negative impact in other areas, amounting to less than JPY20 billion yen.

As Dr. Kimura explained earlier, the first-half results are zero, not including gains on sales of businesses, so you can imagine from that figure.

Regarding the sale of the business, as Dr. Kimura explained earlier, there is a specific project that we are negotiating. The scale of the projects varies, so if a contract is signed for a project that falls within the scale that should be disclosed, we will naturally announce what needs to be announced. In light of this, if it is necessary to revise performance in Q3, we will naturally do so.

Wakao [Q]: Thank you very much.

What I wanted to know is, I think you mentioned that the Q1 figure was JPY10 billion, the core operating profit, was up in Q1. I wanted to know how this was going to be as of Q2. If everything went well, can I understand it as an upward revision?

Kimura [A]: I talked it about in Q1, so I will not give you the target for core operating profit for Q2, but on page six, there is a figure for the percentage of progress toward the May 14 forecasts for FY2024.

Although we have not included figures for core operating profit, I hope you can see from our current situation that sales, especially for the three key products in North America, are growing. Revenue from sales in H1 was 53.5% of total sales.

On the other hand, we are determined to keep SG&A and R&D expenses at half in H1 and at the same level in H2, as we assumed.

Wakao [Q]: Got it. So the part from the sale of the asset is added to the profit. Thank you very much.

Finally, I would like to ask about Orgovyx and Gemtesa. I think your company assumed that the impact of next year's Medicare reform would be positive, especially with regard to Orgovyx. Is there any change from your original assumption? Also, I believe that you are currently in payer negotiations for the portion of gross to net that will be covered by your company from the next fiscal year. How is the progress there? I would like to know if it is likely to settle as your company expects, or if there are any changes, positive or negative.

Kimura [A]: The market is as strong as we expected, or even stronger. Dr. Nakagawa, who is in charge of North America, will be with you.

Nakagawa [A]: There was a change that you just asked about, which is that patients' out of pocket will be limited to a certain degree starting this January. Since this amount will be further reduced starting next January, we believe that this will work to the advantage of Orgovyx, and this remains the case.

Payer negotiations are progressing, they are not going contrary to our expectations, and we believe they will progress as we expect.

Wakao [Q]: Thank you very much.

Then, with regard to the part of the chart that you have just provided, there is no particular change from your company's assumption. So, when I looked online, I understood that the volume will increase in the next fiscal year and will grow even more. Thank you very much.

Also, I just want to know one more thing. Since Orgovyx is performing very solidly, I am concerned about the possibility that the milestone may come in sooner than expected. Can you comment on this? Should I assume that it will be in the next fiscal year?

Nakagawa [A]: I'm not sure if it is too early, but we originally decided on a calendar year in this contract, and our current assumption is that we will receive the milestone from Pfizer in fiscal year 2025.

Noguchi [M]: Next, Morgan Stanley, Mr. Muraoka.

Muraoka [Q]: Morgan Stanley, Shinichiro Muraoka. Thank you.

I would like to ask about Meropen in China. I think the Company absorbed the negative VBP. This has happened a few times before, but always at the beginning of the period, there would be talk of it being tough. This time, now that you have a good upswing in the interim, what should we be thinking about for the next fiscal year and beyond? This is also relevant as Asia is now the most profitable in terms of segment profit.

Kimura [A]: Indeed, we were very concerned about Meropen when it was first included in the volume-based procurement. On the other hand, the price of the drug has not decreased as much as we had expected because it is recognized as a very necessary drug for Chinese society and public health.

Since the volume-based procurement will review prices on a regular basis, every three years or so, we expect to see a slight decrease in prices the next time a review takes place. It is not that we had very pessimistic expectations, but that we were lucky.

Muraoka [Q]: Thank you. And the review is on a three-year cycle? Will the next one be 2025? I'm sorry, I don't know the details of this.

Kimura [A]: The last time was in June 2022, so the next time will be next fiscal year or the fiscal year after. The basic policy is for a review once every three years, but the authorities have a deal of discretion, and we have an expectation that we will not be on the list for FY2025.

Muraoka [Q]: I understand. If it is the next fiscal year, that means that as of next May, we will have to look at this conservatively, right?

Kimura [A]: Yes, that's right. If it starts next fiscal year, yes, but we have already discussed our forecasts for the next fiscal year, and it has not appeared in that forecasts, so it may be shifted a little more than one year.

Muraoka [Q]: I understand. Thank you very much.

I am sorry to have to talk about the next fiscal year, but based on the current momentum, I understand that you have indicated that core operating profit will be in the black next fiscal year and I know that what you have written down is a positive in bottom line profit even without asset sales. Is it correct to say that you are looking at returning all four quarters to profitability?

Kimura [A]: I am not going to go so far as to say each quarter, but if we can maintain the momentum of this fiscal year, we believe that we can achieve profitability in core operating profit next fiscal year even without asset sales.

Muraoka [Q]: Got it. Thank you very much.

Finally, with regard to iPS cells for Parkinson's, what more specific points have surfaced, and why do you think that the timing of the submission is now out of sight?

Kimura [A]: It is difficult to give specifics at this time, but as we have repeatedly stated, we initially said that we would obtain approval with a conditional and time-limited approval in this fiscal year. However, in talking with the PMDA, it seems we have some tasks to do. We are going to do further work to publish evidence supporting the efficacy and possibilities of this treatment technique. As we do that, we are continuing discussions with the PMDA, and have decided to withdraw the target submission date of the end of this fiscal year.

We are currently considering what kind of schedule we will follow in the future. If our plan progresses quickly, it will mean next fiscal year, and we will announce that again after we have made our plans.

Muraoka [Q]: Thank you very much. In other words, is it my understanding that as early as next fiscal year, it is not a matter of the quality or size of the clinical data, but that it is taking a little longer in other areas?

Kimura [A]: The clinical data is as expected in a very small study with only seven cases. The discussion is about how to interpret the conditional and time-limited approval.

Noguchi [M]: Next, Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi [Q]: I would like to confirm the facts about the bridge loan. Is it correct that the deadline has now been extended to the end of December 2024 for JPY145 billion? Am I correct in understanding that, together with the JPY60 billion in loans originally due at the end of December 2024, the repayment of JPY205 billion is currently due at the end of December 2024?

Motoyuki Sakai [A]: Yes, that's right.

Hashiguchi [Q]: How should we understand the reason for this extension? I think it is possible to interpret this in various ways, but I understand that your company originally intended to refinance the loan. It is not impossible to interpret that the financial institutions did not agree to refinance the loan. If that is the case, could you please explain a little more about why it was extended, such as that your company's reconstruction plan is necessary more elaboration or you are waiting for a third party's decision related to this?

Motoyuki Sakai [A]: I am not sure if I can give you a full answer to your question. Basically, we are going to enter into a new loan agreement that includes the bridge loan of JPY145 billion and the loan for repayment in December 2024, as you pointed out. We are currently discussing with the parent company and the financial institutions to conclude a new borrowing agreement, although we will need to consult with the financial institutions to determine how long the loan will be stable or how long it will last.

We have sold our shares in Roivant and have surplus cash from that sale. We are currently discussing with the financial institutions what kind of formation it will take and how it will finance us in the future, taking into consideration the repayment of those funds.

This will not be decided straight away. Therefore, we have postponed the bridge loan until December 2024, and are currently discussing how to proceed with the next round of borrowing.

I'm sorry if that does not completely answer your question.

Hashiguchi [M]: Understood. Thank you very much. That is all.

Kimura [A]: To add one more thing, I understand that the reconstruction plan, with the current figures I explained today, have been favorably received.

Noguchi [M]: Next, Mr. Sakai of UBS Securities Japan.

Fumiyoshi Sakai [Q]: Fumiyoshi Sakai, UBS. I have one question.

I would like to ask you about S-RACMO in the field of iPS cells. I would like to ask you about the overall recombination rather than individual projects. I understand that it has gone from majority to minority, and that Sumitomo Chemical has taken the majority. Is this in the form of a capital increase, or has your company sold shares to Sumitomo Chemical? Will there be any financial impact from this change?

I also heard for the first time that a new company will be established in the new fiscal year. I was wondering if the investment ratio itself will remain the same even after the new company is established. For example, would the Company increase its capital or take other measures in order to add high value-added businesses? I think Sumitomo Chemical is expressing its intention not to give up its production capacity and technology for iPS cells technology. In what ways will you be involved in this area as a minority?

Thank you.

Kimura [A]: Thank you for your question.

In terms of capital relationship alone, we are in the minority and Sumitomo Chemical manages all operations. The Company itself is managed as an independent company.

Regarding regenerative medicine, S-RACMO in particular is a CDMO contract manufacturer. The Company was set up three or four years ago, and has been consistently growing and profitable. Sumitomo Chemical is also engaged in the small molecule business of bulk pharmaceuticals, CDMO, and we believe that our business is similar to that of Sumitomo Chemical. Sumitomo Chemical is growing in the area of small molecule business, such as CDMO for pharmaceutical atoms.

On the other hand, the new company, which you mentioned for the first time, has already been announced by Sumitomo Chemical on April 30 in its future restructuring plan. We have indicated here that it will be implemented by the end of this fiscal year.

Sumitomo Chemical will probably be the major player here, while we will be in the minority, but Sumitomo Pharma has the knowledge, know-how, and technology to handle cells. In addition, as explained earlier, we will also be responsible for the pharmaceutical functions, becoming a kind of center of that functionality, so we will continue to be responsible for the main part of the activities.

On the other hand, S-RACMO, the new company, and the SMP itself must be organically connected in order to proceed, so we will proceed with this with the understanding of Sumitomo Chemical.

On the other hand, in order to expand regenerative medicine and cell therapy business in the future, research and development expenses and investment in production facilities will continue to increase. If Sumitomo Chemical is the majority company, we will be able to exclude it from our PL, reducing the burden on us. That is an important benefit, and the Company itself is continuing with the policy.

Fumiyoshi Sakai [Q]: Just to confirm, is it my understanding that the recapitalization of S-RACMO will have no impact on cash transfer or PL, and that the two companies will continue to exist in parallel with the transition to the new company? Thank you.

Kimura [A]: Yes, that's right. First, the two companies will continue to exist in parallel.

Regarding the establishment of S-RACMO, we had been holding 51% of the shares of S-RACMO to Sumitomo Chemical's 49%. On October 1, we changed our shareholding by transferring more than 10% of the shares to Sumitomo Chemical

Fumiyoshi Sakai [Q]: So the financial impact of that will be reflected in H2?

Kimura [A]: Yes, that's right. As it was October 1, it was not in this quarter.

Fumiyoshi Sakai [Q]: So that will be disclosed later?

Kimura [A]: It is not a large amount, so we may or may not disclose the amount, but it will be included.

Fumiyoshi Sakai [M]: Understood. Thank you very much.

Noguchi [M]: Thank you very much.

Next, Mr. Yamaguchi from Citigroup.

Yamaguchi [Q]: Hidemaru Yamaguchi, Citi. Thank you very much.

This is a bit of similar with Mr. Wakao's question, but I would like to ask one more time about the relationship between the original setup for the full year and the sale of the business. Since progress is solid at the moment, it looks as if you will be able to achieve your original plan of JPY1 billion in the core business. In other words, although you originally included the sale of the business, it appears from the outside that the original Company forecasts could be achieved without it.

Regarding the handling of the sale of the business, you mentioned that it is a matter of whether or not you can do it, or whether or not it is a matter of who you are dealing with. In terms of achieving the forecasts for this fiscal year, is there room for a decision to be made that you do not have to do it now but can leave it for later? Or is there no possibility of that?

Kimura [A]: None whatsoever. We have already started to discuss the specifics of the plan, and we have been working on improving our business performance while moving forward with the plan.

Yamaguchi [Q]: Understood. Thank you very much.

And one more point, a simple answer is fine, but I understand the number of MRs has been reduced considerably. It means that you can change the way you do things, but I think the number of calls will inevitably decrease because you are still holding quite a few diabetes drugs and other drugs that require call volume.

If this happens, I think there is a possibility that domestic sales strength will be a little weakened. Is that something that can't be helped, or are you devising various ways to cover it, including digital? I believe the Company plan is also based on the original number of calls, so what do you mean by downside in that area?

Kimura [A]: We had a disease area system in place, but we are now using an area system, where certain areas are assigned to certain MRs to facilitate their activities. We are aiming to keep the number of calls per MR as high as possible, but if the number of calls actually decreases, it will be unavoidable. As a result, we expect that domestic earnings will decline to some extent in H2.

This is one of the reasons why we are taking a cautious approach to H2, despite the favorable first half. However, I don't think there will be as much of a decrease as in the number of calls, as we have some very talented employees who have remained with us.

Yamaguchi [M]: Understood. Thank you very much. That is all.

Noguchi [M]: Thank you very much.

Next, Mr. Tsuzuki of Mizuho Securities, please go ahead.

Tsuzuki [Q]: Shinya Tsuzuki, Mizuho Securities. Thank you very much.

I would also like to ask about DSP-1083. I personally think that in the seven patients data, the Kyoto University side also showed improvement in the motor scale score at some conferences, symposiums, and so on. I am not sure if this is the case. Considering that, the background for delaying the application this time is that you are looking at historical data in the historical record, for example, since it is an unblinded study, or only in the dosing group, or at the manufacturing, and I have the impression that additional clinical data is not required, but I am not sure what the situation is here. Since you originally said that you were aiming for an application for approval by the end of September, I was wondering if you could give us some more information on timing.

Kimura [A]: I have heard that Kyoto University has only presented the data at a very informal overseas meeting of specialists. That was a closed meeting, so I'm not sure if they have presented data more formally. Please check with the university. I have no knowledge of that.

Regarding the application, I would like to refrain from mentioning specifics about timing or the content of the project at present. However, I would like to repeat that, based on the discussions, we have decided to drop the March target, and are considering what to do in the future based on our discussions.

However, we are very positive about the data itself, and I am sure that everyone will be able to see the data presented by Kyoto University in the near future. We will also be working on new submission target in parallel.

Tsuzuki [Q]: Thank you very much.

I would like to clarify that no further clinical trials or repeat trials are necessary.

Kimura [A]: We believe that we have sufficient data for conditional and time-limited approval, but in terms of formal approval, we are aware that we will eventually have to implement something on a larger scale.

Tsuzuki [Q]: Understood. Thank you very much.

One other point was that there will be a data presentation at ASH on TP-3654. I was wondering if you could tell us here what we should look out for, in terms of new data.

Kimura [A]: Thank you for your question.

The clinical study is progressing well, and additional cases and others are being added. I believe that this data will help us to present data that will convince everyone of the safety and efficacy of our compound.

Tsuzuki [M]: Thank you very much.

Noguchi [M]: Thank you very much.

Noguchi [M]: Mr. Wada from SMBC Nikko Securities, please go ahead.

Wada [Q]: Hiroshi Wada. I would like to ask two questions. I was under the impression you would revise the Mid-term Business Plan by the end of this year or this fiscal year, and that this would be based on sales performance of your three key products and actual SG&A expenses. When do you anticipate that this revision will take place?

Also, talking about the pipeline, the development of protein-protein interactions for menin inhibitors, I think there is enzomenib, which is a small molecule drug targeting this protein-protein interaction, and I wonder if it can be made into a platform as a technology for this. I was wondering if your company has the technology to obtain other compounds that target protein-protein interactions.

Kimura [A]: First of all, the current Mid-term Business Plan 2027 is very far from the actual situation. We are currently working on a medium- to long-term plan, which we are calling the Long Range Plan, and we are considering internally how to present it to you. I am considering presenting it to you in some form by the end of this fiscal year. I think it will have to be in the form of a rather compact Mid-term Business Plan, but that is the way we are thinking.

Unfortunately, we do not have a specific platform technology for enzomenib, which is a protein-protein interaction inhibitor, but we are challenging this area by making full use of our organic synthesis technology and have produced good compound. I believe that we can use this as a platform for other examples. What is about the specific basic technology for protein-protein interaction inhibitors? Dr. Ikeda, could you say a few words on this?

Ikeda [A]: There are a variety of technologies available today to specifically inhibit protein-protein interactions. However, these are not the technologies used for DSP-5336.

However, since we have DSP-5336, we naturally have the technology to create and analyze the structure of the target protein on a computer and to analyze its crystal structure.

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

Noguchi [M]: That concludes our Q&A session with analysts and institutional investors.

From here, we would like to take questions from the media.

First of all, I would like to ask the members of the media at the Tokyo venue to raise their hand if they have any questions. After you have been designated, a staff member will bring the microphone to you. Please state your affiliation and name followed by your question.

Please go ahead.

Kozaki, KOKUSAI SHOGYO Publishing [Q]: My name is Kozaki from KOKUSAI SHOGYO Publishing. Thank you very much.

In the oncology area of the main topics of clinical development, there are various other drugs in the early Phase 1 development stage. What is the reason why you chose SMP-3124? I would like to know what percentage of cancers have CHK1 as a driver gene, if you have any figures.

Ikeda [A]: In the Oncology area, there are three compounds listed here, and there are several others, but these are the ones that are most advanced in development. Based on the current data, we have high expectations for them.

As for SMP-3124, although it is a liposome formulation, we believe that it can be a platform technology for our company. If the concept of this agent is proven, we will be able to develop various compounds by changing what we put in the agent. We actually already have some candidates. If we are able to achieve this, we will be in a position to talk more about other candidates in the future.

There are various equivalent tasks for CHK1, such as ART and WEE1, but each of them has its own characteristics, good points and bad points, and we are currently targeting CHK1 among them.

Kozaki [M]: I understand. Thank you very much.

Kimura [A]: Sorry, let me correct one thing.

This section lists the topics where progress has been made in Q2.

Kozaki [Q]: And you are pushing for this in particular?

Kimura [A]: No, we are pushing for it, but what I have done here is not to show how much we are pushing for it, but to organize the progress that has been made in the past three months.

Kozaki [M]: Thank you.

Noguchi [M]: Yes, go ahead.

Yoshimizu, Iyakukeizai [Q]: My name is Yoshimizu from Iyakukeizai. I have two questions.

First of all, regarding the number of the early retirements announced today, the number of 700 employees is 100 below the initial estimate. Are you considering any re-recruitment?

Kimura [A]: We had announced the number as 700, but in fact, we assumed that during that period, there would be some retirees and voluntary retirees, so the number is almost 700, including such employees. Therefore, we are not thinking of re-recruiting.

Yoshimizu [Q]: If you include that, you attained the target accurately. If you include retirement and such.

Kimura [A]: Indeed. We believe we have achieved this goal.

Yoshimizu [Q]: I understand. Secondly, there is a lot of talk about whether or not our parent company, Sumitomo Chemical, will sell or not sell, but is it correct to say that the current various plans are based on the premise that the Company will continue to operate as a member of the Sumitomo Chemical Group?

Kimura [A]: The current plan, as you say, is realizing a goal to exist independently as Sumitomo Pharma. I have heard that Sumitomo Chemical did discuss this. For us, we would like to be open about everything and consider whether or not there are any advantages for us, but I would like to reiterate that we have presented a plan to proceed independently.

Yoshimizu [Q]: I understand. On page 20 of the presentation material, how should I interpret the phrase, "while flexibly considering and determining the business structure, including the pharmaceutical business"?

Kimura [A]: Is this referring to regenerative medicine? We may, for example, increase or decrease our share depending on the situation, but if Sumitomo Chemical is the counterparty, we will be able to discuss various options, including increasing our share. Of course, I am not denying the possibility of a third party coming in at this point in time.

Yoshimizu [M]: I understand. Thank you very much. That's all for now.

Noguchi [M]: Thank you very much.

Go ahead.

Ando, Nihon Keizai Shimbun [Q]: My name is Ando from Nihon Keizai Shimbun.

As was mentioned earlier in the explanation of the Parkinson's disease iPS cells project, what we are discussing most is how to ensure that the conditional and time-limited approval can be transferred to the formal approval process, which has not been done in the past by other companies. Is it correct to say that it has taken some time to discuss how to do this, taking into consideration the guidelines that have recently been established?

Kimura [A]: There are several points for discussion, but one is that the PMDA is now thinking very hard about how to grant this approval, assuming approval with a conditional and time-limited.

Ando [Q]: Can you say anything about the other points?

Kimura [A]: I am not able to get into specifics here, but we think the data is good, and we will continue to discuss it with the PMDA as we have everyone look at it and discuss it broadly. Until now, we had a policy of discussing data while not releasing it, but we have reorganized our approach so that we will proceed with publication as publication, and applications as applications.

Ando [Q]: I'm not sure if it's just that Kyoto University won't release the data, or publish, or that things won't move forward unless they are released as data, or papers, or that one is waiting for the other. Could you clear this up for me?

Kimura [A]: Sorry, there is no link between the two. I was simply referring to the timing issue. Assuming an initial approval at the end of March, we planned for the approval to go ahead first, and then we would present the data after. However, the publication of the data is proceeding as originally planned, so please understand that the situation is now reversed.

Ando [Q]: If it is the kind of discussion we just had, I have a feeling that it won't take that much time, but I was wondering if you are talking about next fiscal year, or next fiscal year at the earliest, with the possibility of taking a year or more, depending on the case. I wonder if you are considering the possibility that it may take a year or longer.

Kimura [A]: We are hoping to achieve this as soon as possible, but we are considering various tactics and strategies as we look ahead.

Ando [Q]: I understand.

Also, in the area of R&D, R&D expenses have decreased by 40% and the number of personnel has decreased from 560 to 440. With such decreases in resources, it seems that research capability will be limited somewhat. Could you comment on this situation?

Kimura [A]: We are in a situation where we have to be very patient with the departments and employees in charge of research and development. As I mentioned on another occasion, the amount of JPY50 billion, down 40% from the JPY90 billion or so in the previous fiscal year, is due in large part to the dissolution of the late-stage clinical development system in North America itself because of the failure of the ulotaront project. It is true that we have strict control over R&D expenses, but it is also true that they are not as large as they appear.

Ando [Q]: Thank you very much.

As for the division of roles, S-RACMO, as you mentioned earlier, is a CDMO-like company. Will the new company also do research and development?

Kimura [A]: Yes, that is exactly the image I have. We intend to entrust the business of regenerative medicine and cell therapy to this new company in the future. However, at the start, it will really be an R&D-only company, but in the long run, if all goes well, we are discussing the direction I just mentioned.

Ando [Q]: Would that mean that a significant portion of the R&D personnel that remain at the head office now would also be transferred here?

Kimura [A]: Regarding regenerative medicine and cell therapy, a considerable amount of human resources is moving in this direction. On the other hand, in the case of drugs, especially regenerative medicine, employees from various fields are involved, such as reguratory affairs and CMC. It is practically impossible to bring all of them to the new company, so we are currently building cooperation with the main body of the Company organically, as mentioned elsewhere.

Ando [M]: I understand. Thank you very much.

Noguchi [M]: Thank you very much. Next question.

Mitani, NHK [Q]: Mitani, NHK. Thank you.

I have another question about Parkinson's disease. First of all, I would like to ask you how you perceive the revised timing for the application for approval. I would like to know whether you recognize that the schedule has been delayed from the beginning, whether you think this level is still within the expected range, or whether you think the situation is becoming increasingly difficult to predict. What is your perception of the current situation?

Kimura [A]: In a nutshell, I think it is later than originally expected.

Mitani [Q]: Thank you very much.

On the other hand, you said earlier that the seven patients you have now are showing what you expected, and that you are getting good data. However, the fact that the PMDA does not agree means that you do not agree on the interpretation, or in other words, that it is difficult to obtain conditional and time-limited approval. Or is it an issue of clearing hurdles in preparation for the formal approval? I wonder if you could tell us a little bit more about what the discussion is about.

Kimura [A]: Since this is a discussion with the PMDA, we would like to refrain from giving too many specifics, but I think there is a difference in the position of the regulatory authority and the developer.

Mitani [Q]: A difference in position?

Kimura [A]: It's about different interpretations of the same data. Or to put it another way, what kind of possibilities exist based on the data presented.

Mitani [Q]: So your company has not changed its view that the current data is sufficient in this situation?

Kimura [A]: Yes, that's right. Ourselves and the Kyoto University professors who conducted the clinical study, who I believe are the world's leading experts in this field, share exactly the same understanding.

Mitani [Q]: One last point. Then, how can we break out of this situation in the future? What do you think about where we can find a landing point, a point of agreement, or what strategies are possible?

Kimura [A]: That is exactly what we are considering.

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

Noguchi [M]: Thank you very much. Next, please go ahead.

Sakata, YAKUJINIPPO [Q]: Sakata, YAKUJINIPPO.

I am sorry to revisit this topic again. This is about iPS cells. I understand that there are guidelines published from the Ministry of Health, Labour and Welfare in March. Does this mean that the interpretation of that evaluation is required to be very strict in comparison to the data that is now available, certified or historical data? Based on that, when you look at the next round of approval, is it correct to understand that you are asking for a very rigorous clinical study plan and evaluation of efficacy?

Kimura [A]: With very little data, we have seven patients, so I think the point is not so much about one or two points, but about how to think about it comprehensively. I will refrain from discussing the specifics, as it is difficult to discuss without data.

Noguchi [M]: Thank you very much.

Kurose, Nihon Keizai Shimbun [Q]: Kurose, Nihon Keizai Shimbun. Thank you for your time today.

I am also very sorry to be so detailed in the section on iPS cells, but would it be correct to say that plan for application for approval within FY2024 will be withdrawn?

Kimura [A]: Yes, that's right. We are currently reviewing the application and considering the timing for application.

Kurose [Q]: Regarding the establishment of the new company with Sumitomo Chemical, is there any particular impact on future plans in the regenerative medicine and cell therapy related area, and any particular impact on the schedule?

Kimura [A]: Indeed. We do not believe that this will have any impact on the schedule, especially in that area. Specifically, there are some internal procedural things that may delay the process by a couple of weeks, but both parties have confirmed that there will be no major impact.

Kurose [Q]: Thank you very much.

One more point is regarding President Iwata's comments at Sumitomo Chemical's Management Priorities and Business Strategies today. With regard to Sumitomo Pharma, President Iwata has said that a new framework is necessary for the sustainable growth of Sumitomo Pharma, and that President Iwata is considering various options, such as finding a partner, or a third party. With regard to this partner search, is it correct to say that Sumitomo Chemical is not alone in this search? Is Sumitomo Pharma also making some moves in this search for partners?

Kimura [A]: We are not thinking of making a move on our own, but if there is a candidate for such a partner, we will consider the merits of such a move. If there is a partner, we will consider what the benefits would be to us, we will discuss it with in advance. I'm sure that Sumitomo Chemical would take the same approach in the process. Thank you.

Kurose [M]: Thank you very much.

Noguchi [M]: Now, Mr. Ishii of the Iyaku Tsushinsha, who is joining us via Zoom, please go ahead.

Ishii, the Iyaku Tsushinsha [Q]: Ishii, the Iyaku Tsushinsha. From the Company's experience with early retirement in the U.S., are there any lessons that can be applied to domestic sales in Japan?

Kimura [M]: Dr. Nakagawa, would you like to take this question?

Nakagawa [A]: As Dr. Kimura mentioned earlier, many of the remaining employees have a solid level of engagement with the Company. Our current focus is providing these employees with motivation to work hard to sell these products. The products themselves have not changed, so even though we have a smaller number of MRs, we will consider and implement the most efficient strategy that shows off the strong points of our products. We are asking them to do their best with a high level of engagement in response.

In the U.S., we have reduced the number of employees considerably, but as I explained today, we have achieved a certain level of sales. I believe that we will be able to achieve the same level of sales in Japan.

Ishii [M]: Thank you very much.

Noguchi [M]: Kamio, MIX, please go ahead.

Kamio, MIX [Q]: Kamio, MIX. Thank you.

You mentioned that the early retirement this time reduced the number of employees by 600, or 700 in total, but how much will this reduce SG&A expenses by JPY20 million, starting in December. How much will it reduce personnel costs in FY2025? I thought I heard someone from Sumitomo Chemical mention a figure of JPY10 billion, is that correct?

Kimura [A]: I think that number is almost correct. In addition to labor costs, there are inevitably costs associated with the headcount involved in the project, and we estimate that the total cost will be around JPY10 billion.

Kamio [Q]: Understood. Also, I'm afraid this is a bit detailed, but I'd like to talk about domestic sales. You mentioned that the system will be based on an area system in order to cover the whole country with a system of about 450 people. What is your image of the area system, if any?

Kimura [A]: Up until now, the system has been based on the disease area system, which means that CNS MRs have been visiting CNS-related hospitals in a certain region, a relatively large region. There were also MRs working in the diabetes area going around in the same community. Of course, the hospitals are different. We

have fixed the scope of coverage in each region, and one MR is now in charge of CNS, diabetes, and other drugs in a given region.

Kamio [Q]: Understood. Also, will the number of sales offices remain the same?

Kimura [A]: We are also reducing the number of branches, which means that the number of sales offices will also decrease. I understand that there will be approximately 50 sales offices. The figure will be 50 sales offices for the time being.

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

Noguchi [M]: Thank you very much. Next, Yomiuri Shimbun, Matsuda.

Matsuda, Yomiuri Shimbun [Q]: Matsuda, Yomiuri Shimbun. Thank you very much. Regarding Parkinson's disease, just to confirm, the timing of your company's application for approval is not linked to the publication of the Kyoto University paper. Is it correct to say that the publication of the Kyoto University paper is likely to come first?

Kimura [A]: Maybe I didn't word it right, but I think that the Kyoto University announcement will be earlier than our approval. The Kyoto University is in the process of submitting the paper, so please understand that it has not yet decided on what date it will be published. I understand that it has already been posted and is in the process of being revisited.

Matsuda [Q]: Is it your understanding that there is likely to be an announcement from Kyoto University prior to obtaining approval?

Kimura [A]: So, I don't know if you know anything about the timing of that area, and it is normal for some of the top scientific journals to take years to revise, but we are not making that assumption.

Matsuda [Q]: Understood. Also, one more point: this time, will the delay in the timing of application and acquisition have any impact on the clinical study in the U.S.?

Kimura [A]: There is no impact. On the other hand, we are considering further acceleration in the U.S., taking into account the slight delay in Japan. Two clinical studies are already running.

Matsuda [Q]: I understand that the clinical study led by the university, the University of California, San Diego, is going to transplant the first patient by the end of this fiscal year, is that correct?

Kimura [A]: Yes, that has not changed.

Matsuda [Q]: And you have not yet set a date for this fiscal year.

Kimura [A]: It has not been decided yet.

Matsuda [M]: I understand. Thank you very much.

Noguchi [M]: Thank you very much. Next question, Chiboshi, Jiho.

Chiboshi, Jiho [Q]: Chiboshi, Jihosha Nikkan Yakugyo. I would like to ask two questions. First of all, regarding domestic sales, you mentioned that you are slimming down the domestic business through early retirement. I think you had mentioned before that you were considering introducing products to rebuild the domestic business. However, now that the business is going to be streamlined considerably, will the consideration of whether or not to introduce the product be put on hold?

Kimura [A]: We would like to introduce it if the opportunity arises. We are considering a sales tie-up of some kind, and are currently negotiating with various parties.

On the other hand, the change from the MRs of 770 to 450 will inevitably limit the number of details, so I think there will be differences in potential projects in this area.

Chiboshi [Q]: Thank you very much. In that case, when you say introduction, would it still be in the area of CNS or diabetes or something like that?

Kimura [A]: I think we can be more flexible in terms of disease areas, partly because we have moved to an area system.

Chiboshi [Q]: Thank you very much. One more point, on regenerative and cellular medicine. I have not been able to confirm whether or not your company has or will establish a base in the Nakanoshima Qross in Osaka, but I assume that you will be opening a base there, and I wonder what you feel the positive effects on your business will be.

Kimura [A]: We have established a base. For us, Nakanoshima Qross is very attractive, but we are based in Esaka, which is nearby, so we are thinking more in terms of a satellite shop.

Chiboshi [Q]: I understand.

Then again, it may be that it is too close and not that beneficial, but is there anything you can tell us about it as an attraction?

Kimura [A]: I think Nakanoshima Qross has the advantage of providing a place where people can easily consult with venture companies and medical institutions, including those related to Kyoto University, at various stages of their projects, as well as a place where seminars and lectures can be held. I think it will become a center for regenerative medicine in the Kansai region. We can easily get there from Esaka, so we are considering commuting there whenever we have the chance.

Chiboshi [M]: Thank you. That is all.

Noguchi [M]: Thank you very much. Next, Asahi Shimbun, Seii.

Seii, Asahi Shimbun [Q]: Seii, Asahi Shimbun. Sumitomo Chemical announced its financial results today, and I understand that the small molecule drug discovery business of Sumitomo Pharma has been removed from the Group's priority companies as of October 1, 2024. I have heard that there was a statement that this is not included in the Group's long-term vision. What kind of conversations have taken place within the Group on this topic, and what are the views of the head of the Group on this? Thank you.

Kimura [A]: I can't comment on that because I didn't hear about it myself, but I know that within Sumitomo Chemical's business fields, the new company and the main body of SMP, including CDMO for regenerative medicine and cell therapy, are classified in different areas.

I believe that this is simply a direct link to the business of the main body of Sumitomo Chemical. As I mentioned earlier, regenerative medicine is a business that is very unique in terms of production technology, so I was wondering if there is a relationship with Advanced Medical Solutions.

On the other hand, small molecule pharmaceuticals are exactly where the pharmaceuticals are, and there are no other companies besides Sumitomo Chemical that are engaged in pharmaceuticals. However, from our point of view, as I have said repeatedly, the two cannot operate unless they are organically connected, so I guess it depends on how each of us views the other.

Seii [Q]: In other words, within the Group, Sumitomo Chemical is not focusing its efforts there, and Sumitomo Pharma is focusing its efforts there, and by doing that, you can coexist. Is that your view?

Kimura [A]: Yes, that's right. It is true that Sumitomo Chemical has provided and will continue to provide solid support to Sumitomo Pharma, including debt guarantees, but in terms of business synergies, Sumitomo Pharma is independent.

Seii [Q]: Just to confirm again, there was no particular discussion with Sumitomo Chemical about removing this as a priority business, was there?

Kimura [A]: No, no, that's not how I see it. We have not talked about it, but I am aware that we are not in any particular dispute and are getting along well with each other. Mr. Sakai, would you like to add anything here?

Motoyuki Sakai [A]: I agree with Dr. Kimura's assessment.

Seii [M]: Thank you very much. That is all.

Noguchi [M]: This concludes the presentation of Sumitomo Pharma's financial results for Q2 of FY2024. Thank you very much for your participation today.

[END]