Sumitomo Pharma Co., Ltd.

Q3 Financial Results Briefing for FY2024

January 31, 2025

Event Summary

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[Number of Speakers]	6

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Presentation

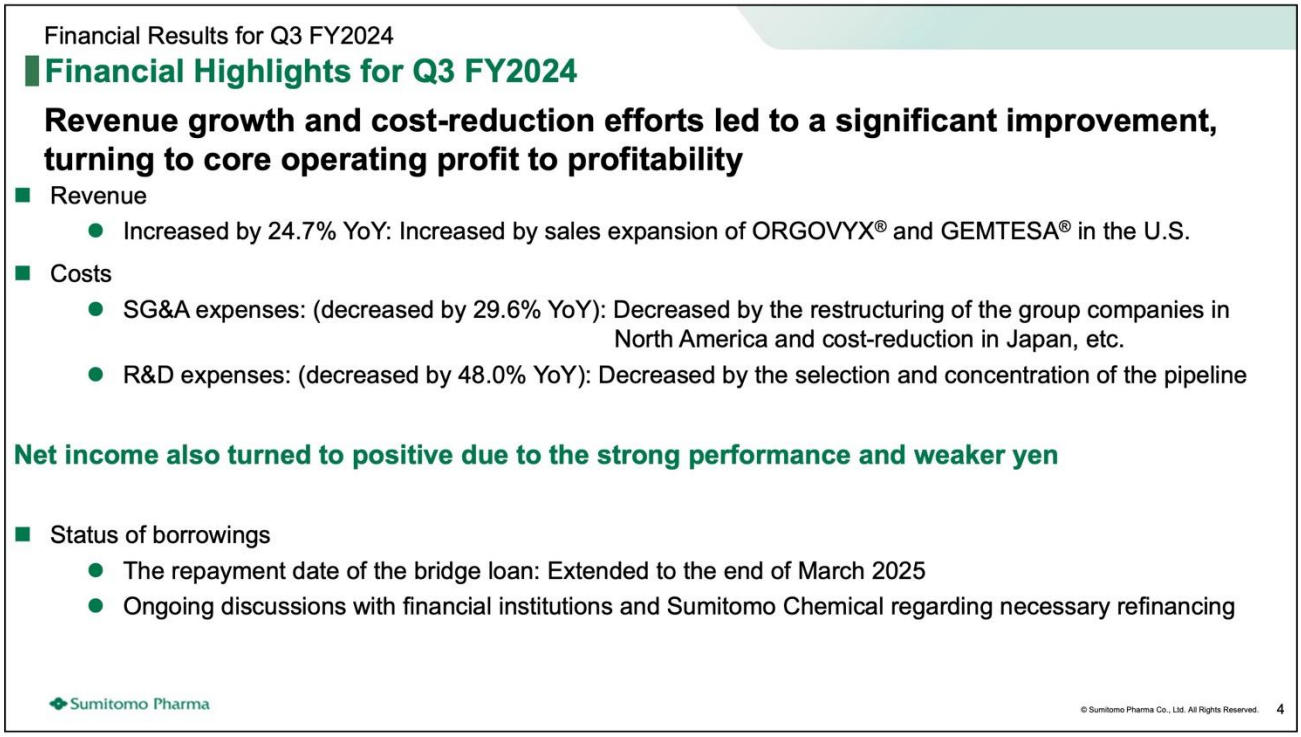
Ishida: It is now time to begin Sumitomo Pharma Co., Ltd., Q3 FY2024 financial results briefing for analysts and investors. Thank you very much for taking the time to join us today. This briefing will be conducted via a live Zoom webinar from our Tokyo headquarters. Following our presentation, which will be based on the materials available on our company website, we will hold a Q&A session.

Let me introduce today's participants. We have with us President and CEO Kimura; Executive Vice President Sakai; Executive Officer and Member of the Board Nakagawa; Managing Executive Officer Sato; Executive Officer Wakemi; and myself, Ishida, Vice President and Head of Finance & Accounting, who will serve as the moderator. Thank you all for your participation.

Now, Dr. Kimura will provide an overview of our Q3 FY2024 financial results and an update on clinical development. Dr. Kimura, please go ahead.

Kimura: This is Kimura, President and CEO. Thank you all for joining us today. The materials have already been made public, and I will now provide an explanation of this quarter's financial results based on those materials.

As outlined in the agenda, I will first go over the Q3 financial summary, followed by our FY2024 earnings forecast, and then discuss research and development. After that, we will open the floor for a Q&A session.



First, here is an overview of our Q3 financial results. In addition to revenue growth, our cost reduction initiatives have been effective, enabling us to return to profitability in terms of core operating profit. This is one of the key highlights of this quarter.

Revenue increased by 24.7% YoY, while both SG&A expenses and R&D expenses were significantly reduced. As a result, also supported by the impact of the weaker yen, we achieved profitability at the net income level as well.

Although I will not go into detail today, I understand that many of you are concerned about our borrowings. The repayment deadline for our bridge loan has already been extended to the end of March 2025. Additionally, we continue to discuss necessary refinancing measures with financial institutions as well as our parent company, Sumitomo Chemical.

Financial Results for Q3 FY2024

Financial Results for Q3 FY2024 (Core Basis)

Billions of JPY

	Q3YTD FY2023 Results	Q3YTD FY2024 Results	Change			FY2024	
			Value	FX impact	%	May 14 forecasts	Progress %
Revenue	235.0	**293.2**	58.2	12.9	24.7	338.0	86.7
Cost of sales	93.2	**113.5**	20.3	3.7	21.8	138.0	82.3
Gross profit	141.8	**179.7**	37.8	9.3	26.7	200.0	89.8
SG&A expenses	176.6	**124.4**	(52.2)	5.6	(29.6)	169.0	73.6
R&D expenses	68.0	**35.4**	(32.6)	0.9	(48.0)	50.0	70.7
Other operating income/expenses	6.4	**1.6**	(4.7)	—		20.0	
Core operating profit	(96.4)	**21.5**	117.9	2.8	—	1.0	—
Non-recurring items (negative number indicates net loss)	(21.4)	**(8.3)**	13.1			(1.0)	
Operating profit	(117.7)	**13.2**	131.0		—	0.0	—
Finance income/costs	12.6	**10.8**	(1.8)			(18.0)	
Profit before taxes	(105.2)	**24.0**	129.2		—	(18.0)	
Income tax expenses	12.5	**2.8**	(9.7)			(2.0)	
Net profit	(117.7)	**21.2**	138.9		—	(16.0)	—
Net profit attributable to owners of the parent	(117.7)	**21.2**	138.9		—	(16.0)	—

Average rates:
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
Q3 FY2024 Results : 1US$ = ¥152.64, 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 Dec. 2024 : 1US$ = ¥158.15, 1RMB = ¥21.67

Revised full-year forecasts (See P.11)

- Revenue increased primarily owing to sales expansion 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, turning profitable
- Non-recurring items:
  - Q3 FY2024: Business structure improvement expenses in Japan and North America
  - Q3 FY2023: Business structure improvement expenses in North America

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Next, here are the core-based financial figures for Q3. Revenue came in at JPY293.2 billion, representing an increase of JPY58.2 billion YoY. Looking at the rightmost column, you will see the May 14 forecast, which reflects our internal budget. At the end of Q3, our progress stood at 86.7% of this forecast.

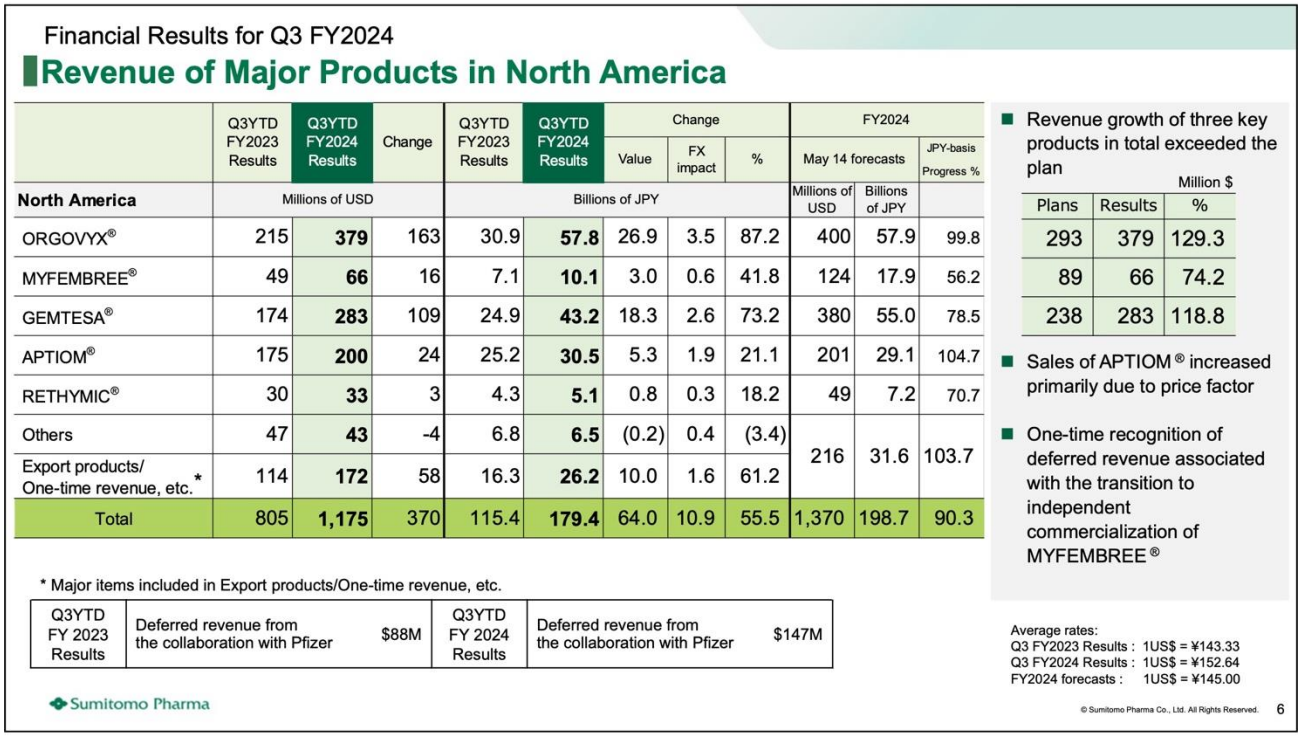
Gross profit reached JPY179.7 billion, an increase of JPY37.8 billion. As I mentioned earlier, SG&A expenses and R&D expenses were reduced by JPY52.2 billion and JPY32.6 billion, respectively. As a result, we posted a core operating profit of JPY21.5 billion.

Next, regarding non-recurring items, these include expenses related to our business restructuring efforts in Japan, as well as restructuring costs from the previous fiscal year in North America.

Consequently, operating profit stood at JPY13.2 billion. As for financial income and expenses, due in part to further yen depreciation, the figure was JPY10.8 billion.

This resulted in a quarterly profit attributable to owners of the parent of JPY21.2 billion, marking a significant improvement of JPY138.9 billion compared to the previous fiscal year.

Based on these results, we intend to revise our full-year earnings forecast, which I will explain later.



Financial Results for Q3 FY2024

Revenue of Major Products in North America

North America	Q3YTD FY2023 Results (Millions of USD)	Q3YTD FY2024 Results (Millions of USD)	Change (Millions of USD)	Q3YTD FY2023 Results (Billions of JPY)	Q3YTD 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	FY2024 JPY-basis Progress %
ORGOVYX®	215	**379**	163	30.9	**57.8**	26.9	3.5	87.2	400	57.9	99.8
MYFEMBREE®	49	**66**	16	7.1	**10.1**	3.0	0.6	41.8	124	17.9	56.2
GEMTESA®	174	**283**	109	24.9	**43.2**	18.3	2.6	73.2	380	55.0	78.5
APTIOM®	175	**200**	24	25.2	**30.5**	5.3	1.9	21.1	201	29.1	104.7
RETHYMIC®	30	**33**	3	4.3	**5.1**	0.8	0.3	18.2	49	7.2	70.7
Others	47	**43**	-4	6.8	**6.5**	(0.2)	0.4	(3.4)	216	31.6	103.7
Export products/ One-time revenue, etc. *	114	**172**	58	16.3	**26.2**	10.0	1.6	61.2			
Total	805	**1,175**	370	115.4	**179.4**	64.0	10.9	55.5	1,370	198.7	90.3

- Revenue growth of three key products in total exceeded the plan

Million $

Plans	Results	%
293	379	129.3
89	66	74.2
238	283	118.8

- Sales of APTIOM® increased primarily due to price factor
- One-time recognition of deferred revenue associated with the transition to independent commercialization of MYFEMBREE®

* Major items included in Export products/One-time revenue, etc.

Q3YTD FY 2023 Results	Deferred revenue from the collaboration with Pfizer	$88M	Q3YTD FY 2024 Results	Deferred revenue from the collaboration with Pfizer	$147M

Average rates:
Q3 FY2023 Results : 1US$ = ¥143.33
Q3 FY2024 Results : 1US$ = ¥152.64
FY2024 forecasts : 1US$ = ¥145.00

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Now, moving on to revenue by major products, this slide presents our North American revenue. For our three key North American products, ORGOVYX, MYFEMBREE, and GEMTESA, ORGOVYX generated JPY57.8 billion, MYFEMBREE JPY10.1 billion, and GEMTESA JPY43.2 billion, all of which represent significant YoY increases.

Comparing these figures to our initial budget, as seen in the rightmost column, expressed in US dollar terms, ORGOVYX achieved 129% of the target, GEMTESA 119%, while MYFEMBREE came in at 74%. Overall, the combined performance of these three products exceeded our budget by 17%.

Additionally, revenue from other products, including APTIOM and RETHYMIC, totaled JPY179.4 billion, marking an increase of JPY64 billion YoY. Compared to our budget, the progress rate currently stands at 90.3%, reflecting strong performance.

One additional note regarding MYFEMBREE: this product was previously co-marketed with Pfizer, but following discussions, we transitioned to a fully in-house sales model as of the end of December last year. As a result, we recorded a lump-sum recognition of JPY9.1 billion in deferred revenue, which is included in the JPY26.2 billion listed under exports and upfront payments at the bottom of the slide.

Financial Results for Q3 FY2024

Revenue of Major Products in Japan & Asia

Billions of JPY

	Q3YTD FY2023 Results	Q3YTD FY2024 Results	Change		FY2024	
			Value	%	May 14 forecasts	Progress %
Japan						
Equa®/EquMet®	24.6	**20.9**	(3.7)	(14.9)	26.3	79.6
LATUDA®	9.0	**10.2**	1.2	13.7	13.0	78.7
TWYMEEG®	3.5	**5.7**	2.2	62.7	11.3	50.3
METGLUCO®	5.7	**5.7**	(0.0)	(0.0)	7.4	76.7
LONASEN® Tape	2.9	**3.6**	0.6	21.8	4.4	81.3
TRERIEF®	13.1	**3.2**	(9.9)	(75.9)	2.1	150.4
AG products	7.1	**8.8**	1.7	24.1	11.1	79.0
Others	18.2	**15.1**	(3.1)	(17.2)	24.7	82.8
Export products/ One-time revenue, etc.	5.1	**5.4**	0.3	6.0		
Total	89.2	**78.5**	(10.7)	(12.0)	100.3	78.2
Asia						
MEROPEN® (China)	15.3	**19.7**	4.4	28.9	21.2	93.1
Others	15.2	**15.6**	0.4	2.8	17.8	87.6
Total	30.5	**35.3**	4.8	15.9	39.0	90.6

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

Japan

- Sales of LATUDA®, TWYMEEG®, and AG products continue to grow
- Sales of TRERIEF® decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥4.1B)

Asia

- MEROPEN® (China) revenue increased

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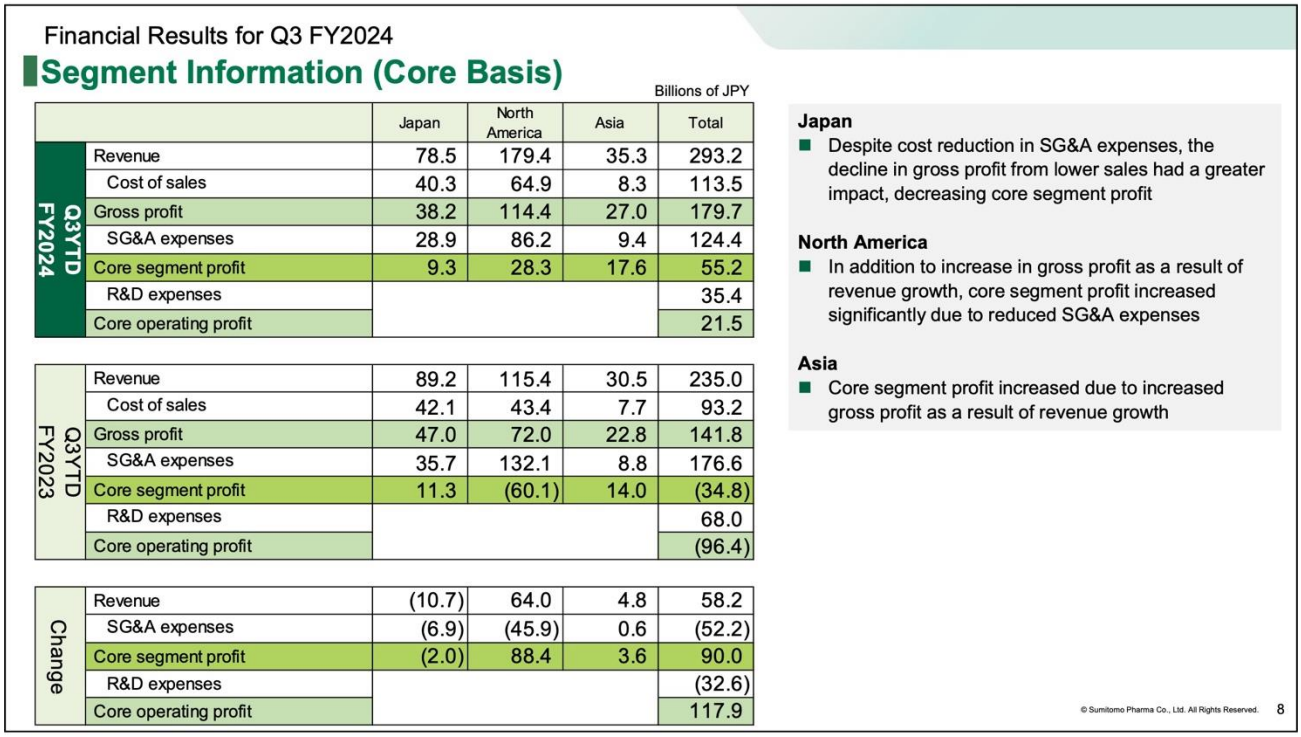
Here, we present the revenue by product for Japan and Asia. In Japan, Equa and EquMet, particularly Equa, saw a slight decline in sales due to its loss of exclusivity in December. As for TWYMEEG, it is slightly behind our initial budget expectations, but LATUDA, METGLUCO, and other products are progressing steadily.

On the other hand, TRERIEF's exclusivity period ended in June, leading to a significant decline in sales. Reflecting this, total revenue in Japan declined by JPY10.7 billion YoY to JPY78.5 billion. However, compared to our initial budget, sales have remained relatively strong.

Next, turning to Asia and China, MEROPEN continues to perform well, with total revenue reaching JPY35.3 billion, an increase of JPY4.8 billion YoY. Performance has also been strong compared to our budget.



Financial Results for Q3 FY2024

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
Q3YTD FY2024	Revenue	78.5	179.4	35.3	293.2
	Cost of sales	40.3	64.9	8.3	113.5
	Gross profit	38.2	114.4	27.0	179.7
	SG&A expenses	28.9	86.2	9.4	124.4
	Core segment profit	9.3	28.3	17.6	55.2
	R&D expenses				35.4
	Core operating profit				21.5
Q3YTD FY2023	Revenue	89.2	115.4	30.5	235.0
	Cost of sales	42.1	43.4	7.7	93.2
	Gross profit	47.0	72.0	22.8	141.8
	SG&A expenses	35.7	132.1	8.8	176.6
	Core segment profit	11.3	(60.1)	14.0	(34.8)
	R&D expenses				68.0
	Core operating profit				(96.4)
Change	Revenue	(10.7)	64.0	4.8	58.2
	SG&A expenses	(6.9)	(45.9)	0.6	(52.2)
	Core segment profit	(2.0)	88.4	3.6	90.0
	R&D expenses				(32.6)
	Core operating profit				117.9

Japan
- Despite cost reduction in SG&A expenses, the decline in gross profit from lower sales had a greater impact, decreasing core segment profit

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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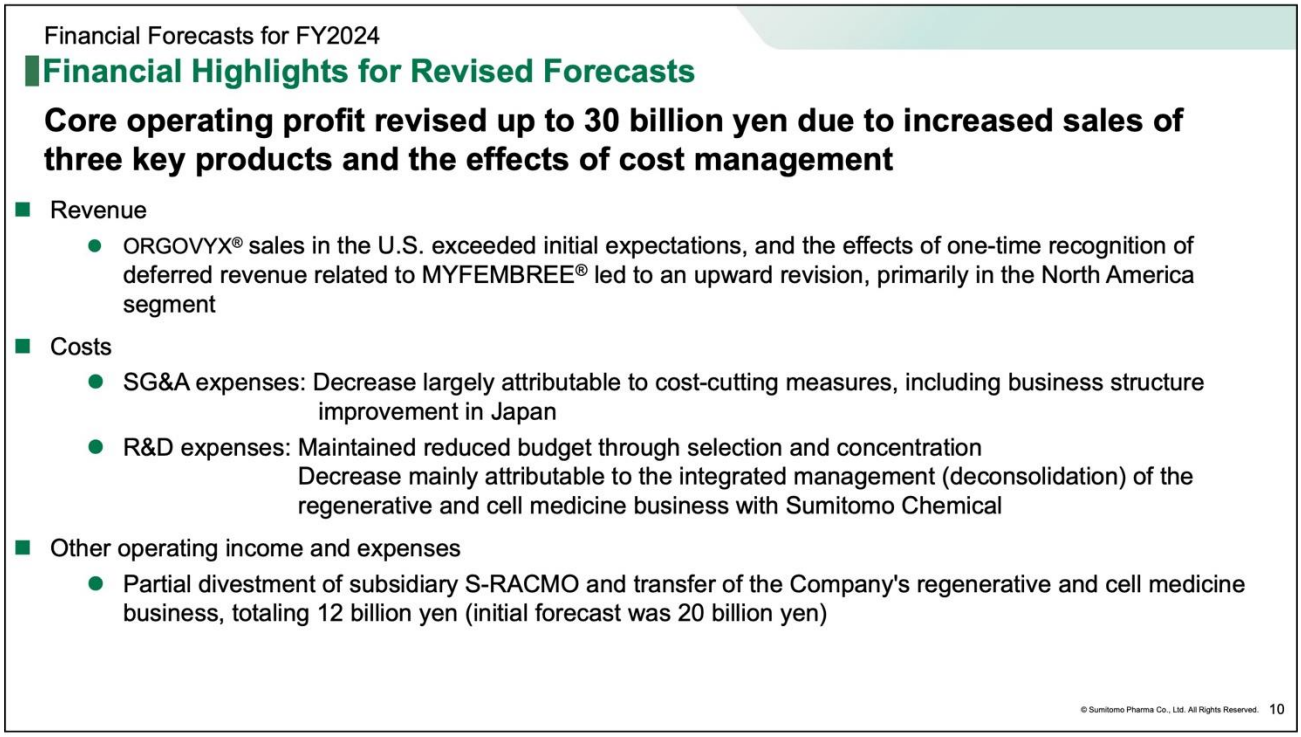
Here, we present the operating results by segment. Across Japan, North America, and Asia, core segment profit has returned to positive territory, with a total profit of JPY55.2 billion. Even after deducting R&D expenses, core operating profit remains positive at JPY21.5 billion.

At the bottom of the slide, you can see the YoY changes. In Japan, TRERIEF's loss of exclusivity had an impact, leading to a JPY2 billion decline in core segment profit. Meanwhile, North America performed strongly, with core segment profit increasing by JPY88.4 billion compared to the previous year.

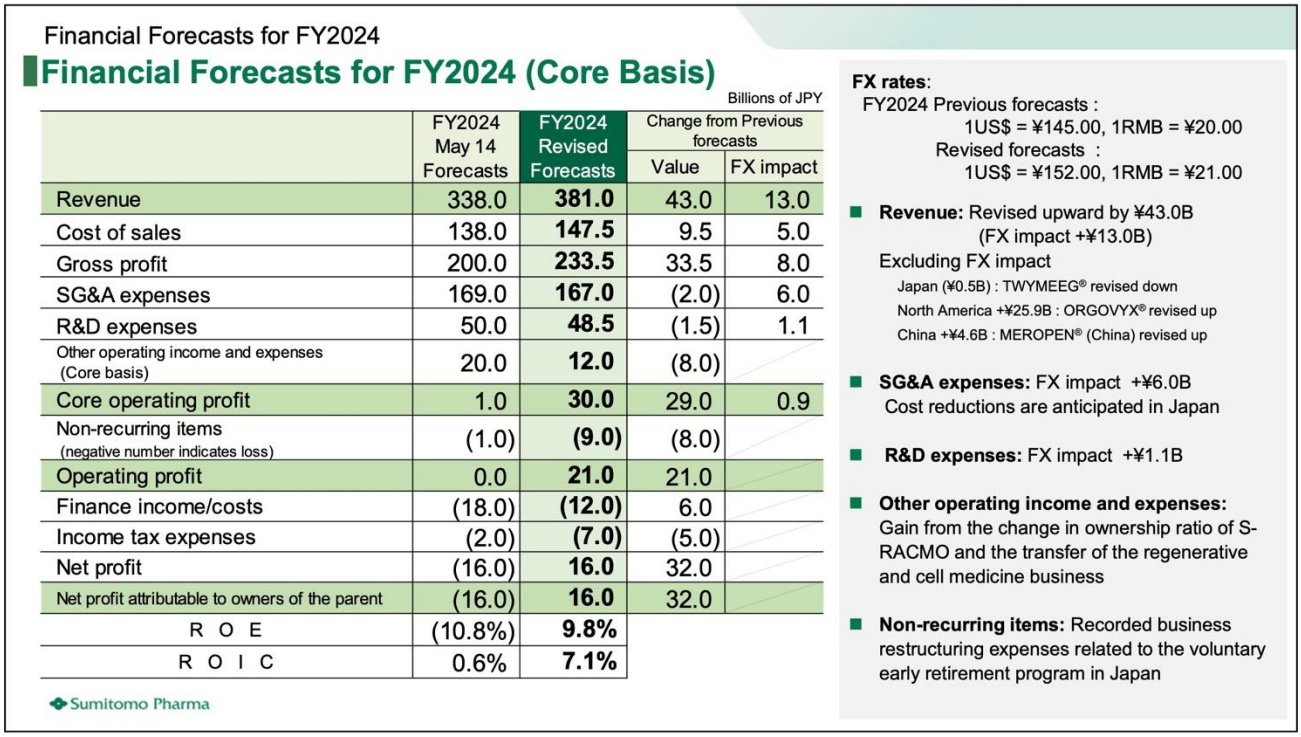


With these results, we have decided to revise our earnings forecast. The expansion of sales for our three key products, along with the effects of cost management, has led us to raise our core operating profit forecast to JPY30 billion.

As I have explained, sales in the US, particularly for ORGOVYX, have been strong. Additionally, the lump-sum recognition of deferred revenue for MYFEMBREE has also contributed significantly to the upward revision for North America.

On the cost side, expenses have decreased due to business restructuring in Japan. At the same time, we have been prioritizing and focusing our R&D investments, continuing to control our budget. Furthermore, as part of the integration of the regenerative and cell medicine business with Sumitomo Chemical, from February onward, this segment will no longer be consolidated, which will contribute to further reductions in expenses.

Regarding other costs, we plan to transfer the regenerative and cell medicine business to Sumitomo Chemical by establishing RACTHERA, which we expect to generate a gain of JPY12 billion. Meanwhile, we have already recorded JPY1.6 billion in Q3 from the transfer of our stake in S-RACMO to Sumitomo Chemical.



As a result, here we present our revised earnings forecast for FY2024. The leftmost column represents our original budget based on our May 14 projections, while the middle column shows our revised forecast.

We now expect revenue of JPY381 billion, gross profit of JPY233.5 billion, SG&A expenses of JPY167 billion, and R&D expenses of JPY48.5 billion. Core operating profit is projected at JPY30 billion.

As for non-recurring items, as I explained earlier, business restructuring costs are included in our forecast, and we now expect operating profit of JPY21 billion. This means that for the first time in a while, we anticipate achieving positive operating profit this fiscal year.

In addition, financial income and expenses have seen some minor adjustments due to foreign exchange fluctuations. Ultimately, we are forecasting net income attributable to owners of the parent at JPY16 billion.

Financial Forecasts for FY2024

Revenue of Major Products in North America

	FY2024 May 14 Forecasts	FY2024 Revised Forecasts	Change	FY2024 May 14 Forecasts	FY2024 Revised Forecasts	Change		
						Value	FX impact	%
North America	Millions of USD			Billions of JPY				
ORGOVYX®	400	**516**	116	57.9	**78.5**	20.6	3.6	35.6
MYFEMBREE®	124	**80**	(44)	17.9	**12.2**	(5.7)	0.6	(31.8)
GEMTESA®	380	**413**	33	55.0	**62.8**	7.8	2.9	14.2
APTIOM®	201	**241**	40	29.1	**36.6**	7.5	1.7	25.8
RETHYMIC®	49	**50**	1	7.2	**7.6**	0.4	0.4	5.6
Others Export products/ One-time revenue, etc. *	216	**248**	32	31.6	**37.7**	6.1	1.7	19.3
Total	1,370	**1,548**	178	198.7	**235.4**	36.7	10.8	18.5

- Sales of ORGOVYX® and GEMTESA® revised upward
- Sales of MYFEMBREE® revised downward
- Sales of APTIOM® revised upward
- One-time revenue includes the deferred revenue recognized all at once

* Major items included in Export products/One-time revenue, etc.

FY2024 May 14 Forecasts	Deferred revenue from the collaboration with Pfizer	$117M	FY2024 Revised Forecast	Deferred revenue from the collaboration with Pfizer	$169M

FX rates:
FY2024 Previous forecasts : 1US$ = ¥145.00
Revised forecasts : 1US$ = ¥152.00

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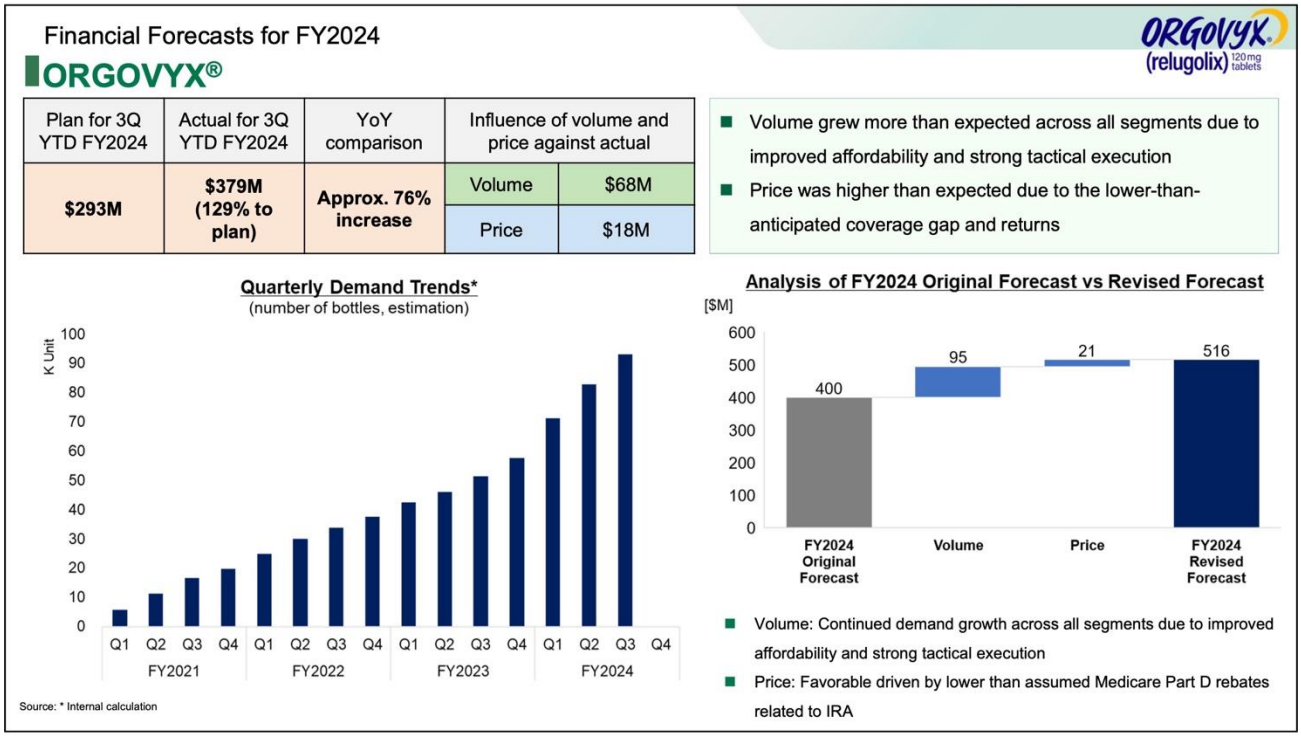
Given these circumstances, we have revised our sales forecast for key products, as shown here.

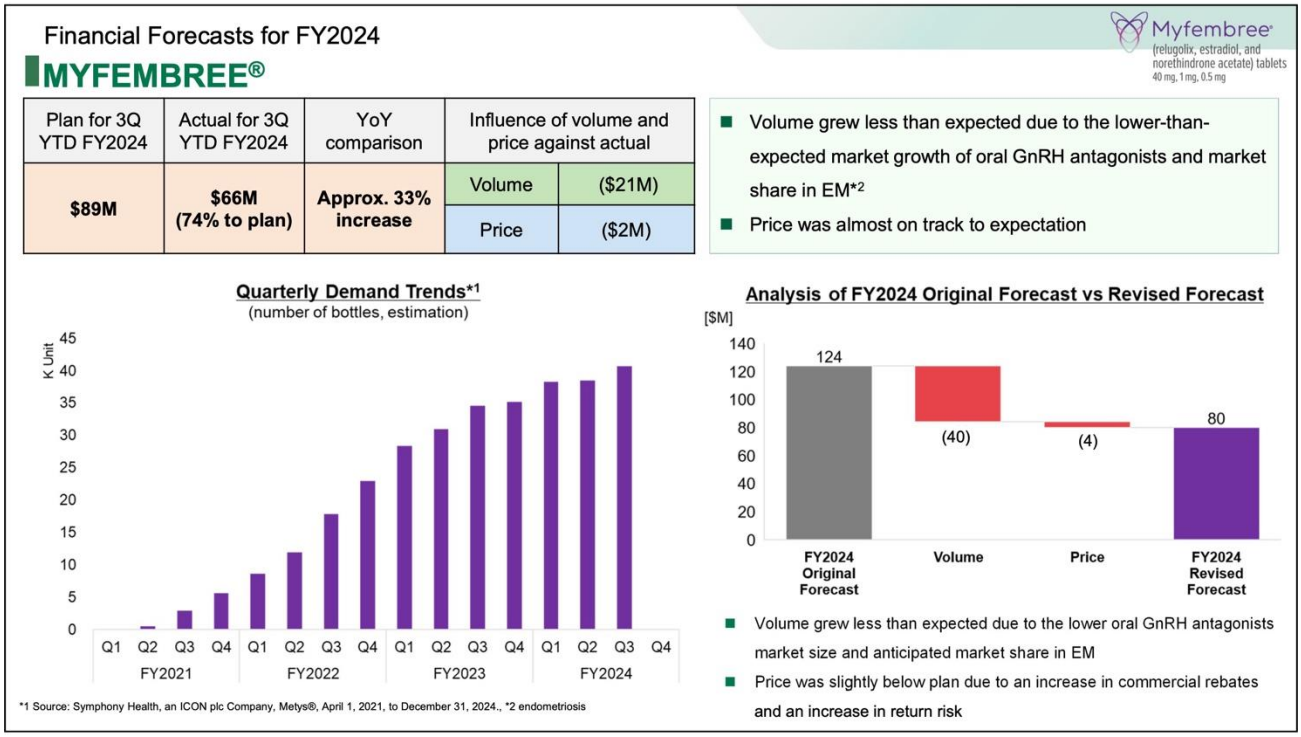
ORGOVYX continues to perform well, and we expect this trend to continue, leading to an upward revision of JPY20.6 billion, bringing the forecast to JPY78.5 billion. MYFEMBREE has faced some challenges, but we are forecasting JPY12.2 billion. GEMTESA has also been revised upward from our initial forecast to JPY62.8 billion. APTIOM has also been performing strongly this fiscal year, with a forecast of JPY36.6 billion. Initially, we had projected total sales of JPY198.7 billion for these products, but after revising our estimate upward by JPY36.7 billion, we now forecast JPY235.4 billion.



Now, let me go into detail about each product. First, ORGOVYX. Our initial plan projected cumulative sales of USD293 million through Q3. However, actual sales have reached USD379 million, a 129% increase over our forecast and a 76% increase year over year.

The primary driver of this growth has been volume. In addition to reducing the financial burden on patients, our promotional strategies have been effective, leading to higher-than-expected demand across all segments.

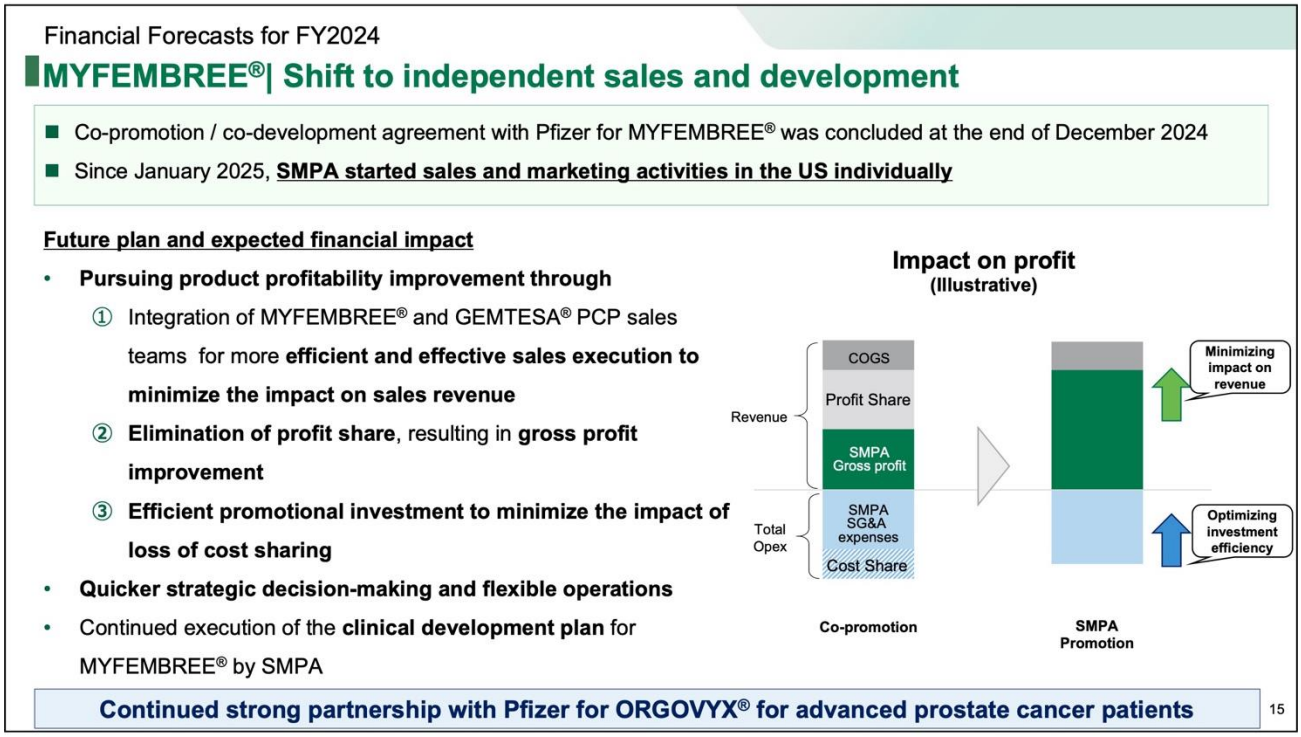
Looking at the revised forecast in the lower right, the key factor behind this adjustment is the significant impact of increased volume.



Next, MYFEMBREE. MYFEMBREE's achievement rate stands at 74%, with current sales at USD66 million. However, this still represents a 33% increase year over year.

The reason behind this performance is that sales volume did not grow as much as we had expected. The expansion of the oral GnRH market and MYFEMBREE's market share growth in endometriosis have fallen below our initial expectations, leading to these results.

As shown below, the key difference between our original FY2024 forecast and the revised forecast is the impact of volume. Accordingly, we have lowered our sales forecast from USD124 million to USD80 million.

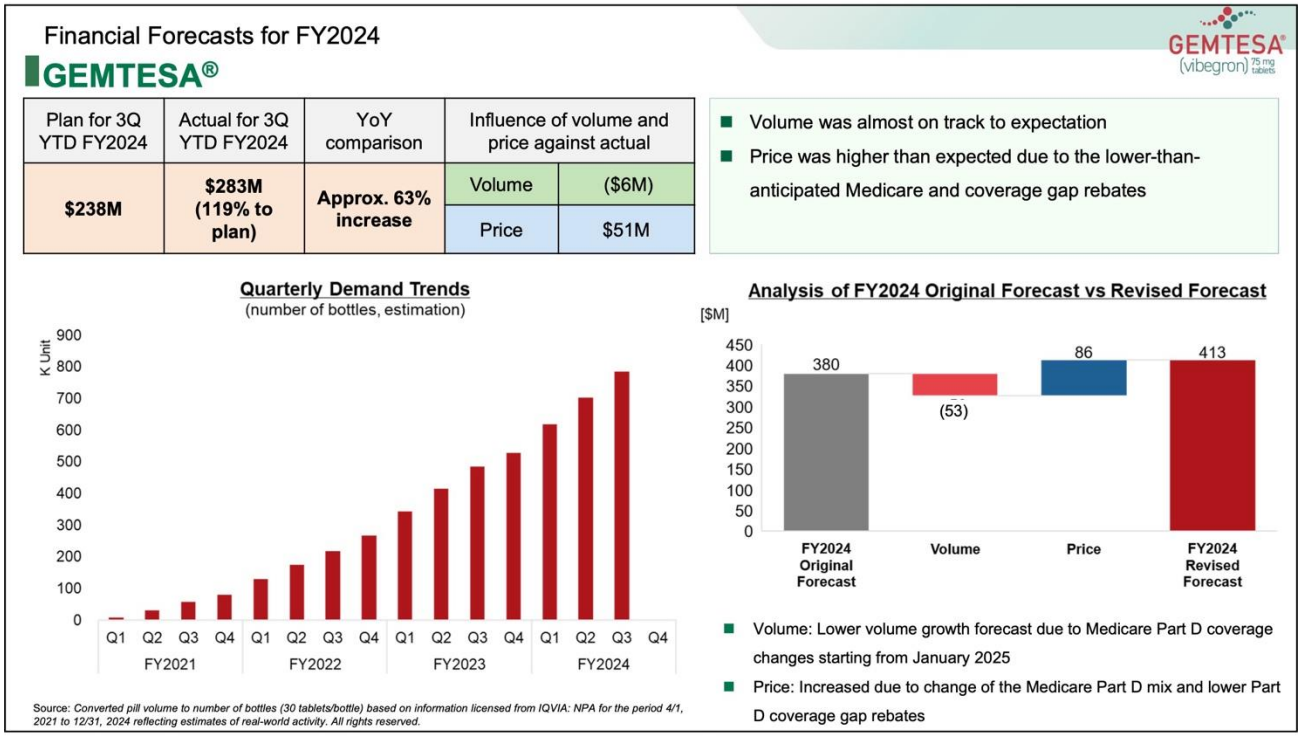


Next, I would like to explain our transition to fully in-house commercialization of MYFEMBREE, which I briefly mentioned earlier, including our intent and the expected impact.

As of the end of December, we ended our co-commercialization agreement with Pfizer. From January onward, Sumitomo Pharma America (SMPA) has been handling the sales and marketing of MYFEMBREE independently. Looking at the impact on our earnings, we view this transition positively, as fully in-house sales allow us to improve the product's profitability. Furthermore, having sole control over sales strategy enables us to respond more flexibly and dynamically, which we see as a major advantage.

To illustrate this, I will briefly explain the diagram in the lower right. Until December, we shared gross profit with Pfizer after deducting the cost of goods sold from revenue. With this transition, that entire portion of the profit will now be retained by us. On the other hand, in terms of SG&A expenses, we previously shared some costs with Pfizer rather than bearing the full burden ourselves. With this change, our share of costs will increase, but we aim to streamline our in-house sales operations to offset this increase. As you can see from the chart, we view this transition as a net positive.

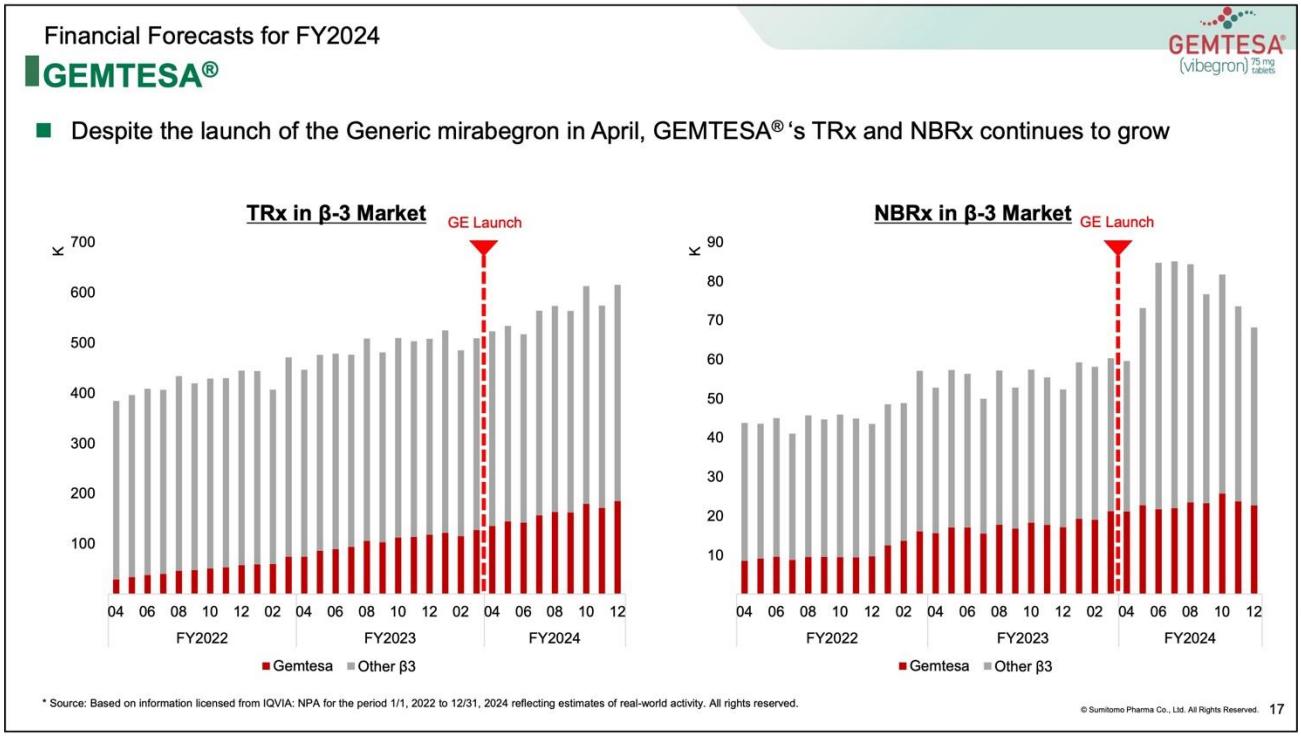
Meanwhile, ORGOVYX continues to perform very well, and we will maintain our partnership with Pfizer to further expand its market presence.



Now, moving on to GEMTESA. The achievement rate for GEMTESA is at 119%, with sales increasing by nearly 20%. Compared to the same period last year, revenue is up 63%.

Breaking this down, the primary driver has been pricing. Prices have remained higher than we initially expected, which has contributed positively to performance. Compared to our initial forecast, factors such as lower-than-anticipated product returns and reduced financial burdens related to the Coverage Gap have led to an increase in average selling price.

We had originally forecast sales of USD380 million for GEMTESA, but given these pricing benefits, we have now revised our projection upward to USD413 million.



Here, we present data on GEMTESA, specifically regarding the impact of generic versions of mirabegron, a competing product, which became available starting in April. I believe you are all aware of this development.

This chart shows how total prescription volume and new prescription volume have been affected since the launch of these generics.

The red section represents GEMTESA, and as you can see, there has been no significant change in prescription trends following the introduction of mirabegron generics.

Financial Forecasts for FY2024

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
FY2024 Revised Forecasts	Revenue	99.8	235.4	45.8	381.0
	Cost of sales	51.8	85.4	10.3	147.5
	Gross profit	48.0	150.0	35.5	233.5
	SG&A expenses	38.4	116.2	12.4	167.0
	Core segment profit	9.6	33.8	23.1	66.5
	R&D expenses				48.5
	Core operating profit				30.0
FY2024 May 14 Forecasts	Revenue	100.3	198.7	39.0	338.0
	Cost of sales	52.7	76.3	9.0	138.0
	Gross profit	47.6	122.4	30.0	200.0
	SG&A expenses	46.6	109.9	12.5	169.0
	Core segment profit	1.0	12.5	17.5	31.0
	R&D expenses				50.0
	Core operating profit				1.0
Change	Revenue	(0.5)	36.7	6.8	43.0
	SG&A expenses	(8.2)	6.3	(0.1)	(2.0)
	Core segment profit	8.6	21.3	5.6	35.5
	R&D expenses				(1.5)
	Core operating profit				29.0

Japan
- Profit expected to increase due to reduction in SG&A expenses

North America
- Profit expected to increase significantly due to the impact of the upward revision of revenue

Asia
- Profit increased due to the upward revision of revenue

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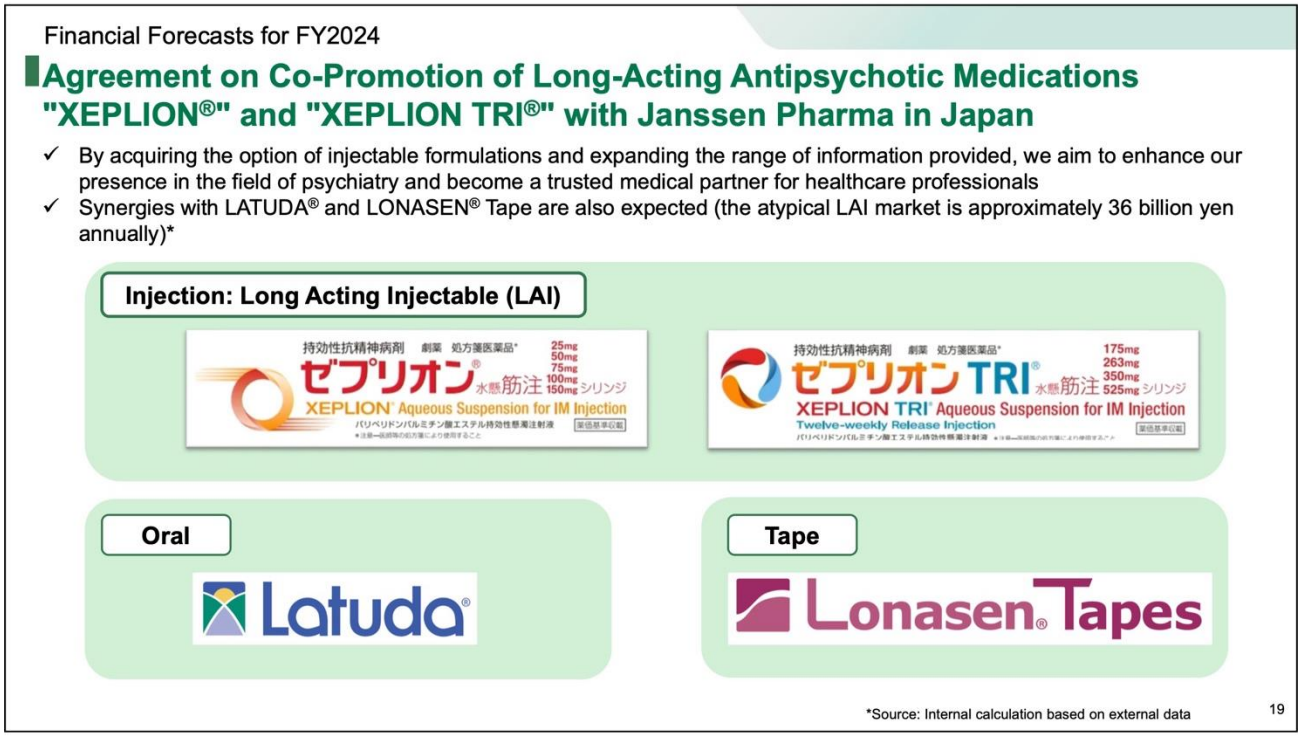
Here, we present the core-based earnings forecast for FY2024. If you look at the comparison between the previous and revised forecasts, shown at the bottom of the slide, you can see that core segment profit has improved by JPY8.6 billion in Japan, JPY21.3 billion in North America, and JPY5.6 billion in Asia, for a total improvement of JPY35.5 billion. Please refer to the top of the slide for a regional breakdown.



Another recent announcement we made is that we have entered into a co-promotion agreement with Janssen Pharma in Japan for the long-acting injectable (LAI) antipsychotic medications XEPLION and XEPLION TRI.

By securing an injectable treatment option for schizophrenia, we aim to expand the breadth of our information provision and enhance our presence in the psychiatric field. Adding an LAI formulation to our pipeline, which already includes LATUDA in tablet form and LONASEN Tape, is expected to generate significant synergies.

Research and Development

Development Pipeline (as of January 31, 2025)

Revisions since the announcement in October 2024 are shown in red

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
	DSP-3077	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	U.S.	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	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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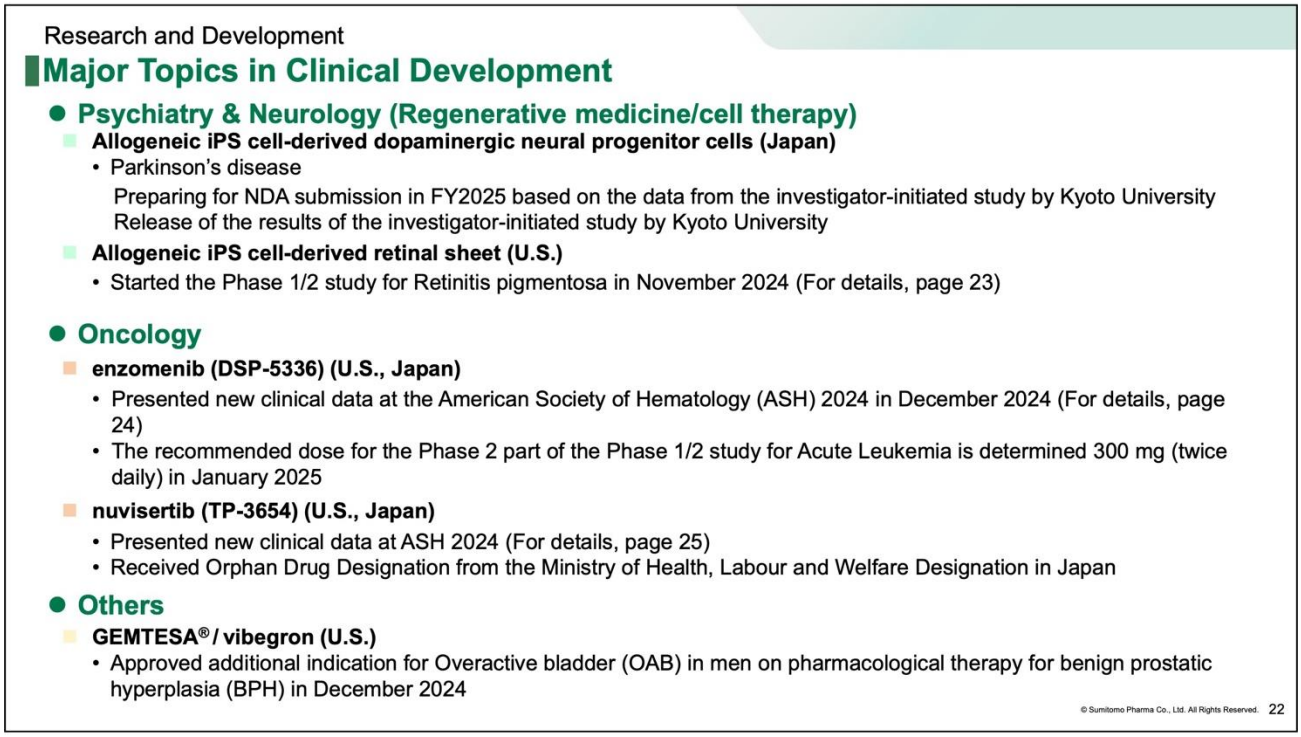
Next, I will provide an update on research and development. In terms of new progress, as indicated in red on the slide, we have initiated a Phase I & Phase II trial in the US for DSP-3077, an allogeneic iPS cell-derived retinal sheet for the treatment of retinitis pigmentosa.

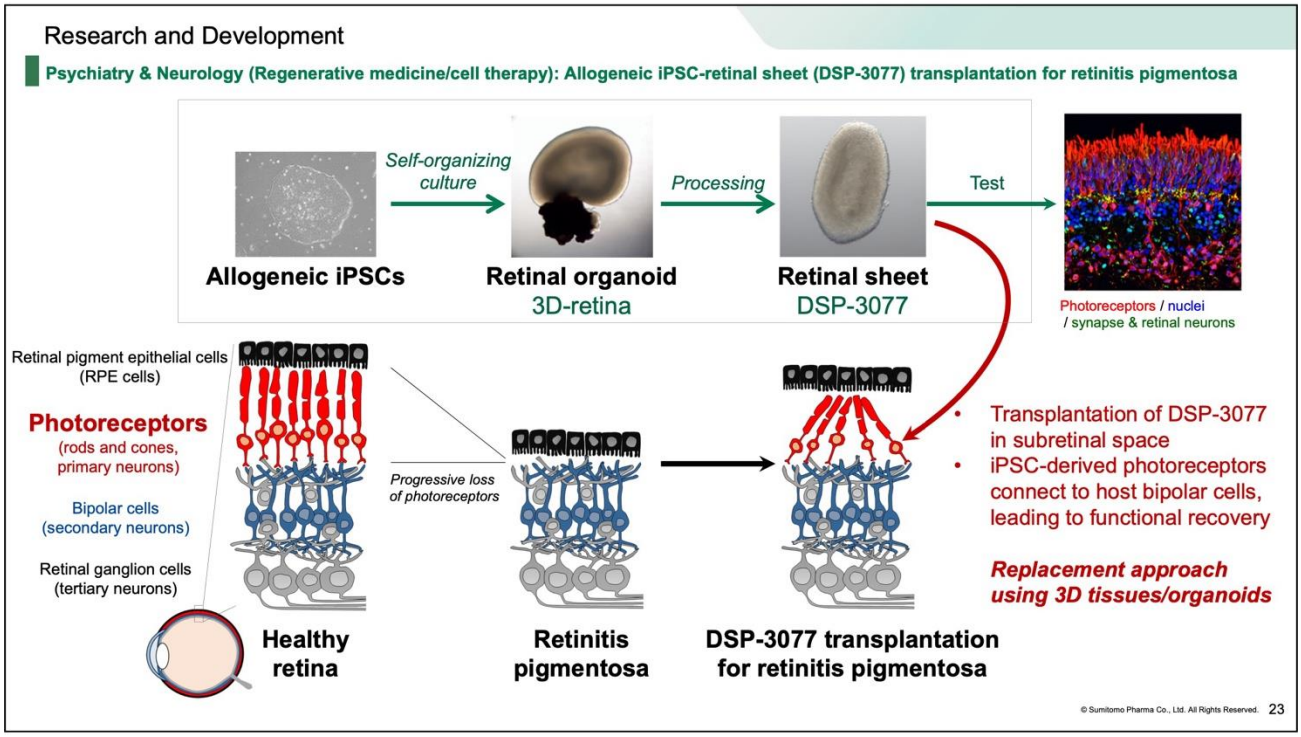


Here are some key topics. In the field of regenerative and cell medicine, including psychiatric disorders, we previously announced during our Q2 earnings presentation that we were reviewing our domestic regulatory strategy for Parkinson's disease regenerative therapy. We have now established a new timeline and have resumed activities with the goal of submitting for approval in FY2025. In addition, we understand that the results of the physician-led clinical trial will soon be announced by Kyoto University.

Meanwhile, as mentioned earlier, we initiated a new clinical trial in the US in November.

For oncology, both enzomenib and nuvisertib continue to show promising data. At the American Society of Hematology (ASH) conference in December, enzomenib received very high praise, and interest in nuvisertib is also growing.

Another key update is that in December, GEMTESA received additional approval in the US for the treatment of overactive bladder (OAB) in patients with benign prostatic hyperplasia (BPH) undergoing drug therapy.



Here, we present an illustration of the new clinical trial we have initiated for DSP-3077. Retinitis pigmentosa is a progressive eye disease in which the photoreceptor cells responsible for detecting light, as shown in red on the diagram, gradually degenerate and disappear, leading to vision loss.

The diagram illustrates how light enters from below and is detected in the red-marked area at the top, representing the retinal structure. For patients with this condition, we are conducting a Phase I/II clinical trial at Mass Eye and Ear, an ophthalmology affiliate of Harvard University, to evaluate the transplantation of an iPS cell-derived retinal sheet, which we believe could help restore light perception.

Research and Development

From data presented at ASH 2024

Oncology Area: Phase 1/2 Study of enzomenib (DSP-5336) for Acute Leukemia

- ✓ **CR/CRh rate, the important efficacy measure, was 30.4% in the MLLr patient group (with 40.0% in the 300 mg BID group) and 47.1% in the NPM1m patient group**
- ✓ **Enzomenib was well tolerated in terms of safety, including QTc prolongation and differentiation syndrome**

Efficacy

- ✓ **Complete remission or complete remission with partial hematologic recovery (CR/CRh): 30.4% in the MLLr patient group (with 40.0% in the 300 mg BID group) and 47.1% in the NPM1m patient group**
- ✓ Objective Response Rate (ORR): 65.2% in the MLLr patient group and 58.8% in the NPM1m patient group
- ✓ No impact on efficacy was observed with or without the concomitant use of azole antifungal agents

Safety

- ✓ **QTc prolongation was Grade 3 in 1% (1/84) of patients**
- ✓ **Differentiation syndrome was observed in 10.7% (9/84) of patients but did not result in deaths or permanent discontinuations of the treatment**
- ✓ No dose-limiting toxicities (DLTs) were reported
- ✓ The main related adverse events were gastrointestinal toxicities, with Grade 3 or higher in 1% (1/84) of patients

Data Cut-Off: October 22, 2024	*MLLr*			*NPM1m*		
	200 mg BID n = 8	300 mg BID n = 15	Total n = 23	200 mg BID n = 10	300 mg BID n = 7	Total n = 17
Objective Response Rate (CR + CRh + CRi + MLFS)	50% (4/8)	73.3% (11/15)	65.2% (15/23)	60% (6/10)	57.1% (4/7)	58.8% (10/17)
Composite CR (CR + CRh + CRi)	37.5% (3/8)	53.3% (8/15)	47.8% (11/23)	50% (5/10)	42.9% (3/7)	47.1% (8/17)
CR + CRh	12.5% (1/8)	40.0% (6/15)	30.4% (7/23)	50% (5/10)	42.9% (3/7)	47.1% (8/17)

CR: Complete Remission, CRh: Complete Remission with Partial Hematologic Recovery, CRi: Complete Remission with Incomplete Blood Count Recovery, MLFS: Morphologic Leukemia-Free State, BID: Twice Daily, BID: Twice Daily

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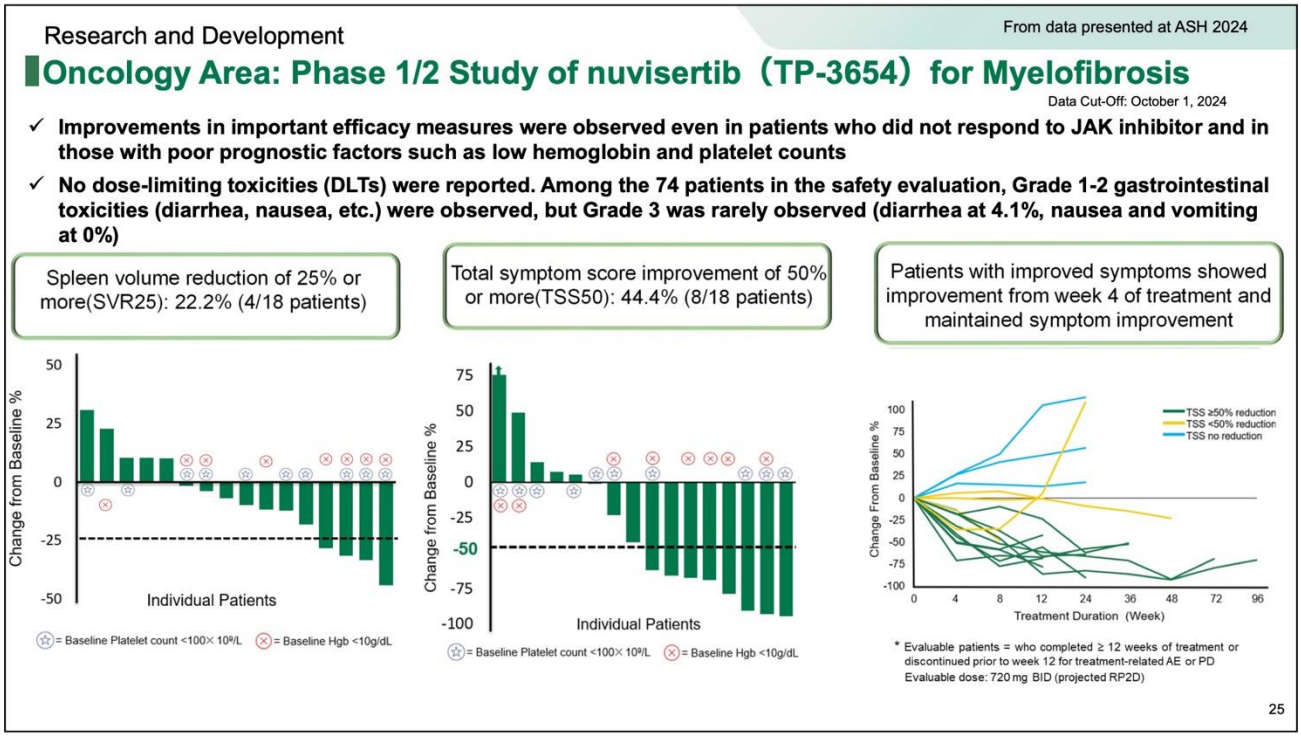
Next, we summarize the key findings from the Phase I/II trial of enzomenib (DSP-5336). Both efficacy and safety data continue to be positive.

Regarding efficacy, the drug has demonstrated a high response rate, with complete remission or partial hematologic recovery observed in 30% of patients with MLL rearrangement and 47% of patients with an NPM1 mutation, indicating strong clinical potential.

One of enzomenib's key advantages is its safety profile. While some patients have exhibited QT prolongation, the incidence rate remains very low.

Another potential challenge for this class of drugs is differentiation syndrome, which has been observed in approximately 10% of patients. However, no cases have led to severe outcomes such as death or treatment discontinuation. Given its strong efficacy and favorable safety profile, enzomenib is being evaluated as a potential best-in-class treatment.



Next, moving on to nuvisertib. So far, 22% of patients have experienced a reduction in spleen size of 25% or more, while 44% have shown an improvement of at least 50% in their total symptom score, indicating very promising results.

As shown on the right, patients who experienced symptom improvement began to show positive changes around the fourth week, and these improvements have been sustained over time.

That concludes my explanation. I would now like to move on to the Q&A session. Thank you.

Ishida: Thank you, Dr. Kimura.

Question & Answer

Moderator [M]: We will now begin the Q&A session. Mr. Wakao from JPMorgan Securities, please proceed with your question.

Wakao [Q]: This is Wakao from JPMorgan. I'd like to ask about the outlook for your three key products. I believe they have been performing very well, and I'm keen to understand how things will develop from here, so I'd like to get some insights. In particular, I'd like to hear about ORGOVYX and GEMTESA; what assumptions you are working with and what the current situation looks like.

With the start of Medicare Part D changes in Q4, as well as similar developments in Japan, I assume you have factored in improvements to gross-to-net and the effects of APLIV. How is that playing out? Also, just looking at recent prescription trends, perhaps due to the year-end and New Year holiday impact, it seems that both drugs have weakened somewhat since January. How do you evaluate this?

Nakagawa [A]: Nakagawa here. I'll take this question. First, regarding ORGOVYX, we expect the very strong demand growth to continue. As you pointed out, insurance system changes took effect in January, and we view this as another positive factor for us. So, we expect strong results in Q4 as well.

On the other hand, with GEMTESA, we anticipate that the growth pattern seen through December will shift slightly starting in January. This is the result of our negotiations with various payers under Medicare Part D. That said, while we do expect demand growth to slow somewhat, we see the pricing impact working positively in our favor. As a result, we believe we can still achieve our sales targets and maintain the overall trend we've seen so far through Q4.

Wakao [Q]: As a follow-up; so, if I understand correctly, ORGOVYX will continue its growth trajectory without much change. But looking at your forecast, Q4 sales are projected at USD132 million, whereas Q3 was USD147 million, meaning QoQ it appears to decline. Based on your explanation, it seems like the figure should actually be growing a bit more. Could you clarify that point?

Also, regarding the Medicare Part D coverage changes for GEMTESA, should I understand this as simply meaning that while coverage is reduced, gross-to-net improves, so the net impact is positive?

Nakagawa [A]: If you just do the math, as you pointed out, it might look like ORGOVYX's Q4 sales are slightly lower than in Q3. But the thing is, month-to-month and QtoQ, there is always a certain degree of fluctuation. In particular, December tends to see a surge in demand ahead of the holiday season, which was a factor in Q3 performing exceptionally well.

Then, looking at January, February, and March, there's the effect of what you might call a reset in insurance coverage, so those factors come into play as well. Rather than seeing a perfectly smooth upward trajectory every single month, there are some fluctuations along the way. But in terms of the broader trend, we believe it is indeed on an upward trajectory, and we think that's the right way to interpret the situation.

Ishida [M]: Regarding the question on GEMTESA, could you please repeat it once more?

Wakao [Q]: I'd like to clarify the meaning here. I didn't fully understand, so could you explain? When you say that changes in coverage will lead to a decrease in volume, does that mean that the number of payers covering GEMTESA is decreasing, and that's why volume will decline? On the other hand, since gross-to-net is improving, does that mean that, in net terms, revenue will actually increase? Is that the correct

interpretation? What exactly do you mean when you say that a change in coverage will lead to a decline in volume?

Nakagawa [A]: Yes, that understanding is generally correct.

Wakao [Q]: So, when we look at recent prescription trends and see that GEMTESA appears to be somewhat weaker, is that being affected by this?

Nakagawa [A]: Yes, that understanding is correct.

Wakao [Q]: It's not that it's losing out to generic versions of mirabegron or anything like that, right?

Nakagawa [A]: That's correct. We don't believe that's the case. We see this as moving in line with our expectations.

Wakao [Q]: By the way, how much has gross-to-net improved since January?

Nakagawa [A]: That information is not disclosed.

Wakao [Q]: My second question is about enzomenib. As Dr. Kimura mentioned, I also believe this has the potential to be best-in-class. Since DLT hasn't been granted yet, I was wondering if there was a possibility of increasing the dose. But in the end, I understand that you're proceeding to the Phase II portion with a 300 mg dose. Why didn't you increase the dose? I'm not sure whether this decision was made at Phase I or later, but I'd also like to know when we can expect the next update.

Also, how far do you think you can go with this on your own? Do you see the potential to take it all the way to the first-line setting?

Sato [A]: This is Sato. Regarding the recommended dosage, we have decided on 300 mg, as reported in our latest update. The 300 mg data is included in today's presentation materials and has also been presented at scientific conferences. We did consider testing a higher dose, but after evaluating the data, we determined that 300 mg was sufficient in terms of efficacy, and that is why we settled on this dose. We plan to begin dosing in the Phase II portion within this fiscal year.

As for whether we can advance this to the first-line setting, no decision has been made at this time.

Wakao [Q]: Given your current capabilities, do you think you can handle this yourself? From an R&D budget perspective and the current state of your development team, I imagine that moving into the first-line setting would be much more challenging than later-line indications. Do you have the capability to do this?

Kimura [A]: I do believe we have the capability to take this forward, but including nuvisertib, we want to continue assessing the data carefully and consider how best to approach our development strategy.

Wakao [Q]: I assume licensing out is also something you are considering. The data looks quite strong, but if you were to license it out, what kind of timing would you be looking at?

Kimura [A]: Rather than saying we are actively looking to license it out, I would say that if both drugs continue to perform well, we will also need to consider how to accelerate and expand their development further. In that case, bringing in a partner could be one possible approach. However, I believe we still need more data before making that decision. For now, we intend to continue development in-house.

Wakao [Q]: Lastly, I had asked earlier about when we can expect an update; when will the next update be? Can we expect anything this year? This is regarding enzomenib.

Kimura [A]: I believe we will have an update once we enter Phase II. I don't think it will be too far off. As for data updates, we will consider the best timing based on upcoming conferences and other opportunities.

Wakao [Q]: So, the data that will be presented at conferences will be an update on the Phase I portion?

Kimura [A]: Yes, I believe the Phase I summary data will be one of the key milestones.

Ishida [M]: Mr. Muraoka from Morgan Stanley MUFG Securities, please go ahead.

Muraoka [Q]: This is Muraoka from Morgan Stanley. I'd like to get a clearer picture of how you're thinking about the outlook beyond next fiscal year. Given that your full-year guidance this time is showing profitability even without asset sales, should we assume that next fiscal year will see further profit growth without relying on asset sales? And looking further ahead, will you be able to expand in FY2026? I imagine that from that point onward, the deferred revenue from Pfizer that was discussed earlier will also start to decline, so how should we interpret the outlook based on your company's current snapshot?

And while it may be too soon to ask this, are you considering resuming dividend payments?

Kimura [A]: First, regarding the last point on dividend resumption; while our business performance has been strong, as you know, our financial situation remains quite challenging, so we need to carefully consider the timing.

Another point I'd like to mention is that our FY2024 earnings revision includes a lump-sum recognition of JPY7.8 billion in deferred revenue from MYFEMBREE. If you don't account for that, it would be an overestimation of our actual performance.

All three of our key products are growing steadily. However, we should also consider that APTIOM has undergone salesforce restructuring and is now essentially selling on an as-is basis. Furthermore, it will lose exclusivity in June this year. In Japan, following Equa, EquMet will also lose exclusivity, which is another negative factor.

While the fundamental earning power of the business is increasing, there is a possibility that future earnings may not fully reflect the strong momentum that the current numbers suggest. That said, we believe we have taken solid steps toward recovery.

Muraoka [Q]: I completely understand that it may be difficult to give a precise answer, but just to confirm, looking at next fiscal year and then another year ahead into FY2026, do you expect core operating profit to continue rising from this year's JPY30 billion, even if we subtract the JPY7.8 billion from MYFEMBREE's deferred revenue? Or should we expect some volatility along the way?

Kimura [A]: First, a correction. APTIOM's LOE is actually in May, not June. As for core operating profit, we still expect to achieve our previously stated goal of maintaining net profitability next fiscal year. However, since MYFEMBREE's deferred revenue will no longer be gradually recognized, there will be an impact from that.

So rather than expecting a perfectly smooth upward trend, I think it's more realistic to assume some fluctuations along the way while generally moving in a positive direction. In terms of quantitative details, we will provide more specifics once we have a clearer picture after this fiscal year's financial results.

Muraoka [Q]: Also, there was quite a bit of discussion earlier about GEMTESA. Looking at page 17 of your materials, while TRx is increasing, new prescription volume seems to have slowed down recently. Based on the earlier discussion, I assume this is because of coverage changes, but since gross-to-net is improving, the expectation is that even if this trend continues, the price recovery will offset it, and the net impact will be positive. Is that the correct interpretation? Sorry if this is a bit of an oversimplified way of putting it.

Kimura [A]: I believe you're referring to the trends in November and December. If you look at past two fiscal years, you'll see that October, November, and December tend to be seasonally weak periods. So from that perspective, we are not particularly concerned about this trend.

That said, as I mentioned earlier, we do expect volume to decrease starting in January. However, at the same time, the improvements in gross-to-net will help support revenue. So overall, we remain confident in the upward trend for sales moving forward.

Ishida [M]: Mr. Stephen Barker from Jefferies Securities, please proceed with your question.

Barker [Q]: This is Stephen Barker from Jefferies Securities. Looking at page six, regarding revenue related to Pfizer, at the end of December last year, it was USD88 million, and this term, it's USD147 million. Is the difference entirely due to deferred revenue from MYFEMBREE?

Kimura [A]: Yes, that's correct. The USD59 million difference comes from the lump-sum recognition of deferred revenue from MYFEMBREE.

Barker [Q]: Regarding MYFEMBREE, how much deferred revenue was recognized each year, and how will that decline moving forward?

Kimura [A]: The deferred revenue was approximately USD30 million per year, but starting next fiscal year, that will no longer be recognized.

Ishida [M]: Mr. Hashiguchi from Daiwa Securities, please proceed with your question.

Hashiguchi [Q]: This is Hashiguchi. As you continue discussions on your mid-to-long-term business plan, what are the key discussion points? And how do you plan to present this information to us going forward? Also, regarding the refinancing of the bridge loan, I understand that discussions are ongoing, but what are the main issues being negotiated, and what kind of adjustments need to be made?

Additionally, I recall that around last spring, there was mention of a mid-to-long-term management strategy, something akin to a medium-term plan; I don't quite remember the exact wording your company used at the time. I believe you had mentioned an intention to announce something within this fiscal year. How is that progressing, and when can we expect to see something presented to us?

Kimura [A]: I will first address the mid-term plan, and then Sakai will provide an update on the refinancing situation. First, we already have a plan in place, which we have been discussing with our banks. However, the next step is to clarify the direction the Company will take moving forward. Also, as you are aware, since December, we have undergone a significant workforce reduction, particularly in Japan. In light of this, we are currently working on structuring our personnel policies within the Company.

So rather than preparing a large-scale medium-term management plan, we are instead focusing on formulating and sharing our internal vision first. How we will communicate this externally is something we are actively discussing right now. As for the timing, we are aiming for around this spring.

Sakai, please provide an update on the refinancing situation.

Motoyuki Sakai [A]: This is Sakai. At present, we are in discussions with our primary banks, as well as Sumitomo Chemical, regarding refinancing. However, as these negotiations are still ongoing, it is difficult to provide specifics at this stage.

As I have mentioned before, each financial institution has its own unique circumstances. Naturally, with a number of participating banks involved, we are currently working on adjusting the terms and conditions of the refinancing agreement. I would appreciate your understanding on this point.

Hashiguchi [Q]: Earlier, Dr. Kimura mentioned the timing of the plan as being around spring; does that mean it will be shared internally around spring, or will it also be shared externally during that timeframe?

Kimura [A]: That is exactly what we are currently discussing. For now, we are working toward an initial target of the end of March this fiscal year. From there, we are deliberating on how best to present it externally. I apologize for not having a more concrete answer at this moment.

Ishida [M]: Mr. Yamaguchi from Citigroup Securities, please go ahead with your question.

Yamaguchi [Q]: This is Yamaguchi from Citigroup. Regarding ORGOVYX, GEMTESA, and MYFEMBREE, your three key products currently being sold in the US, are they manufactured in the US? My understanding is that they are produced overseas and then imported into the US, but could you confirm whether they are made in the US or not, including whether they are subject to import duties?

Kimura [A]: Within our supply chain, some production does take place in the US, but a significant portion is manufactured overseas. The current situation is that, from the US perspective, most of the production is done outside the country. We are aware of recent discussions regarding import duties on pharmaceuticals, and we are currently assessing the potential quantitative impact. At this stage, that is about all the information we can provide.

Ishida [M]: Mr. Sakai from UBS Securities, please proceed with your question.

Fumiyoshi Sakai [Q]: This is Sakai from UBS. Dr. Kimura, since you come from an R&D background, I'm sure you are well aware of this issue, but I wanted to ask about your development pipeline. Looking at your portfolio of development programs, considering the number of projects, the therapeutic areas, and your annual R&D budget, which currently stands at JPY48.5 billion; do you believe that this budget is sufficient to sustain the pipeline?

From an outsider's perspective, it seems quite challenging. Realistically, won't you have to start making tough choices, potentially even dropping promising candidates? If so, at what point do you see those decisions being made? Or do you believe that with this JPY50 billion level of R&D spending, you can manage the pipeline as it stands? I'd appreciate your insights on this.

Kimura [A]: This is indeed a difficult issue. The reason we currently have so many projects in our pipeline is that most of them are still in the early stages. That's why we are able to handle this number of programs at the moment. However, as these projects progress to Phase IIB or Phase III, even if we obtain strong data across the board, we will inevitably have to make strategic choices and concentrate our resources.

At that point, partnering with other companies or out-licensing some assets will become viable options. Ultimately, once we start seeing even partial clinical proof of concept (POC), potential partners will also begin to recognize the value of these programs. I believe that will be a key decision-making point. Since most of our pipeline is at a similar stage, I don't expect significant discrepancies in timing when we assess these programs.

As you pointed out, the reality is that with JPY50 billion in annual R&D spending, we simply do not have the capacity to develop all these programs in-house.

Fumiyoshi Sakai [Q]: So, in other words, you expect R&D spending to remain at current levels for now, and you will manage development accordingly?

Kimura [A]: Yes, that's correct. For the next two to three years, we plan to maintain R&D spending at this level. Beyond that, as our US business grows and our company becomes more streamlined and financially stronger, there may come a time when we can allocate more resources to R&D. But for the next two to three years, we expect this situation to continue, and we are prepared to operate within our current R&D budget.

Ishida [M]: If there are no further questions, we will now conclude the Q&A session. That brings us to the end of Sumitomo Pharma's Q3 FY2024 financial results briefing. Thank you very much for your participation today.

[END]