

Sumitomo Pharma Co., Ltd.

Conference on FY2024 Financial Results and Reboot 2027 - Reboot for a Strong Sumitomo Pharma-

May 13, 2025

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.	
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[Event Name]	Conference on FY2024 Financial Results and Reboot 2027 - Reboot for a Strong Sumitomo Pharma -	
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[Date]	May 13, 2025	
[Time]	14:00 – 15:27 (Total: 87 minutes, Presentation: 39 minutes, Q&A: 48 minutes)	
[Venue]	Webcast	
[Number of Speakers]	6	
	Toru Kimura	Representative Director, President and CEO
	Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Global Finance Administration External Affairs; Corporate Governance; IT Management & Data Analytics
	Tsutomu Nakagawa	Member, Board of Directors, Managing Executive Officer President and CEO, Sumitomo Pharma America, Inc. North America Business
	Yumi Sato	Managing Executive Officer Research and Development Division Senior Vice President, Head of Research and Development Division Chief Development Officer, Sumitomo Pharma America, Inc.
	Yutaka Wakemi	Executive Officer Global Corporate Strategy; Global Finance Vice President, Head of Global Corporate Strategy
	Koichi Kino	Vice President, Head of Corporate Governance

[Analyst Names]*	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Stephen Barker	Jefferies
	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities

Presentation

Kino: We would like to begin the briefing for analysts and investors on Sumitomo Pharma Co., Ltd. FY2024 financial results and Reboot 2027 - Reboot for a Strong Sumitomo Pharma.

I am moderator, Kino, Vice President, Head of Corporate Governance, Sumitomo Pharma.

Thank you very much for joining us today. This presentation is being delivered live from our Tokyo headquarters via Zoom webinar. Please change the participant information displayed on your Zoom screen to your company name and your name.

Today, we will begin with explanations in accordance with the presentation material posted on our website, followed by a question-and-answer period. The scheduled end time is 15:30.

In attendance today are Dr. Kimura, Representative Director, President and CEO; Mr. Sakai, Representative Director, Executive Vice President; Dr. Nakagawa, Member, Board of Directors, Managing Executive Officer; Ms. Sato, Managing Executive Officer; and Mr. Wakemi, Executive Officer.

Now, Dr. Kimura will explain our business performance in FY2024 and Reboot 2027 - Reboot for a Strong Sumitomo Pharma. Dr. Kimura, could you please?

Agenda

- Financial Results for FY2024
- Financial Forecasts for FY2025
- Research and Development

- Reboot 2027 - Reboot for a Strong Sumitomo Pharma -
 - I. Review of FY2023-2024
 - II. Reboot of Sumitomo Pharma
 - III. Business Strategy
 - IV. R&D Initiatives
 - V. Summary

- Q&A

Kimura: I am Kimura, President of Sumitomo Pharma. Thank you for attending this briefing today.

Today, as shown here, we will provide a summary of our 2024 financial results and our 2025 forecast, followed by Reboot 2027, and finally a Q&A session.

Financial Results for FY2024

Financial Results for FY2024 (Core Basis)

Billions of JPY

	FY2023 Results	FY2024 Results	Change			FY2024 Jan. 31 forecasts
			Value	FX impact	%	
Revenue	314.6	398.8	84.3	15.5	26.8	381.0
Cost of sales	126.6	153.2	26.6	4.4	21.0	147.5
Gross profit	188.0	245.6	57.7	11.1	30.7	233.5
SG&A expenses	236.4	167.7	(68.7)	6.7	(29.1)	167.0
R&D expenses	90.9	48.5	(42.4)	1.1	(46.7)	48.5
Others (core basis)	6.4	13.7	7.3	—	—	12.0
Core operating profit	(133.0)	43.2	176.1	3.3	—	30.0
Adjustments (negative number indicates loss)	(221.9)	(14.3)	207.5	—	—	(9.0)
Operating profit	(354.9)	28.8	383.7	—	—	21.0
Finance income/costs	31.7	(11.2)	(42.9)	—	—	(12.0)
Profit before taxes	(323.1)	17.6	340.7	—	—	9.0
Income tax expenses	(8.2)	(6.0)	2.2	—	—	(7.0)
Net profit	(314.9)	23.6	338.6	—	—	16.0
Net profit attributable to owners of the parent	(315.0)	23.6	338.6	—	—	16.0

Average rates:

FY2023 Results : 1US\$ = ¥144.59, 1RMB = ¥20.14
FY2024 Results : 1US\$ = ¥152.62, 1RMB = ¥21.11
FY2024 forecasts : 1US\$ = ¥152.00, 1RMB = ¥21.00

Period end rates:

As of the end of March 2024 : 1US\$ = ¥151.33, 1RMB = ¥20.84
As of the end of March 2025 : 1US\$ = ¥149.53, 1RMB = ¥20.59

- 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 and became profitable
- Adjustments:
 - FY2024: Business structure improvement expenses in Japan and North America; impairment loss on intangible assets
 - FY2023: Impairment loss on intangible assets and goodwill; business structure improvement expenses in North America

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Here are the financial results for FY2024. The results were almost in line with the revised forecast announced on April 28. Revenue was JPY398.8 billion, an increase of JPY84.3 billion from the previous year. Growth in three key products, mainly in the US, contributed to the increase.

We have been working to reduce R&D expenses as part of our efforts to cut costs through drastic business restructuring or as part of our selection and concentration efforts. As a result, selling, general, and administrative expenses decreased JPY68.7 billion to JPY167.7 billion, and R&D expenses decreased JPY42.4 billion from the previous year to JPY48.5 billion.

In the fiscal year under review, JPY13.7 billion was recorded in others, core basis, because we spun off part of our regenerative medicine/cell therapy business and transferred some of our shares to SUMITOMO CHEMICAL COMPANY, LIMITED. As a result, core operating profit was JPY43.2 billion, an increase of JPY176.1 billion compared to FY2023, which was a very difficult year.

The JPY14.3 billion recorded as adjustments includes restructuring costs in North America or Japan and a small impairment loss on TEYMEEG. As a result, operating profit was JPY28.8 billion, an increase of JPY383.7 billion from FY2023.

As for financial income/costs, we recorded a loss of JPY11.2 billion due to foreign exchange losses, interest, and others. As a result, net profit was JPY23.6 billion, and net profit attributable to owners of the parent increased by JPY338.6 billion compared to the previous year, far exceeding the figures announced at the Q3 results briefing on January 31.

Financial Results for FY2024

Revenue of Major Products in North America

	FY2023 Results	FY2024 Results	Change	FY2023 Results	FY2024 Results	Change		
						Value	FX impact	%
North America	Millions of USD			Billions of JPY				
ORGOVYX®	292	544	253	42.2	83.1	40.9	4.4	96.9
MYFEMBREE®	64	84	20	9.2	12.8	3.6	0.7	39.0
GEMTESA®	255	431	176	36.8	65.8	28.9	3.5	78.6
APTIOM®	235	258	23	34.0	39.4	5.5	2.1	16.1
RETHYMIC®	44	45	1	6.3	6.8	0.5	0.4	7.7
Others	61	80	18	8.9	12.2	3.3	0.6	37.4
Export products/ One-time revenue, etc.*	150	208	58	21.7	31.8	10.1	1.7	46.6
Total	1,100	1,650	550	159.0	251.8	92.8	13.2	58.3

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

FY 2023 Results	Deferred revenue from the collaboration with Pfizer	\$117M	FY 2024 Results	Deferred revenue from the collaboration with Pfizer	\$171M
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■ ORGOVYX® and GEMTESA® revenue have grown beyond initial forecasts

Million \$		
Initial Forecasts	Results	%
400	544	136.1
124	84	67.6
380	431	113.4

■ APTiom® revenue increased primarily due to the favorable price

■ One-time recognition of deferred revenue associated with the transition to independent commercialization of MYFEMBREE®

Average rates:
FY2023 Results : 1US\$ = ¥144.59
FY2024 Results : 1US\$ = ¥152.62

Revenue from sales of major products is shown here.

The numbers in the middle are yen-denominated figures. Revenues from ORGOVYX, MYFEMBREE, and GEMTESA increased 96.9%, 39%, and 78.6%, respectively, over the previous fiscal year, due in part to the slight impact of foreign exchange rates. Business in North America was very strong. Finally, revenue totaled JPY251.8 billion, up JPY92.8 billion, or 58.3%, from the same period last year.

A comparison between the forecast at the beginning of the period and the actual results is shown in the upper right corner. ORGOVYX and GEMTESA results exceeded initial forecasts. On the other hand, the results for MYFEMBREE, while growing compared to FY2023, were a little less favorable than we had expected.

With regard to MYFEMBREE, in January, we switched from co-marketing with Pfizer to sole marketing by the Company. If there is any remaining in the future, deferred revenue will be recorded in a lump sum. This is included in export products/one-time revenue, etc., at the bottom.

Financial Results for FY2024

Revenue of Major Products in Japan & Asia

Billions of JPY

	FY2023 Results	FY 2024 Results	Change	
			Value	%
Japan				
Equa®/EquMet®	30.6	24.9	(5.7)	(18.7)
LATUDA®	11.7	13.2	1.4	12.1
TWYMEEG®	4.6	7.6	3.1	66.9
METGLUCO®	7.3	7.3	0.0	0.6
LONASEN® Tape	3.8	4.6	0.8	20.2
TRERIEF®	15.5	3.7	(11.8)	(76.4)
AG products	9.7	11.4	1.8	18.2
Others	23.5	19.2	(4.2)	(17.9)
Export products/ One-time revenue, etc.	8.0	7.9	(0.1)	(1.3)
Total	114.7	99.8	(14.8)	(12.9)
Asia				
MEROPEN® (China)	21.3	26.3	5.1	23.9
Others	19.6	20.8	1.2	6.3
Total	40.9	47.2	6.3	15.5



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

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Japan

- Equa[®] revenue decreased due to its loss of exclusivity
- LATUDA[®], TWYMEEG[®], and AG products revenue continued to grow
- TRERIEF[®] revenue decreased due to its loss of exclusivity
- Total impact of NHI drug price revision (¥4.8B)

Asia

- MEROPEN[®] (China) revenue increased

In Japan, total revenue was JPY99.8 billion, down JPY14.8 billion from FY2023. As noted, the 12.9% decrease was due to the significant decline in sales of Equa and TRERIEF, whose exclusivity period ended during the fiscal year.

In Asia, Chinese MEROPEN remains strong. Total revenue in Asia and China was JPY47.2 billion, up JPY6.3 billion or 15.5% from FY2023.

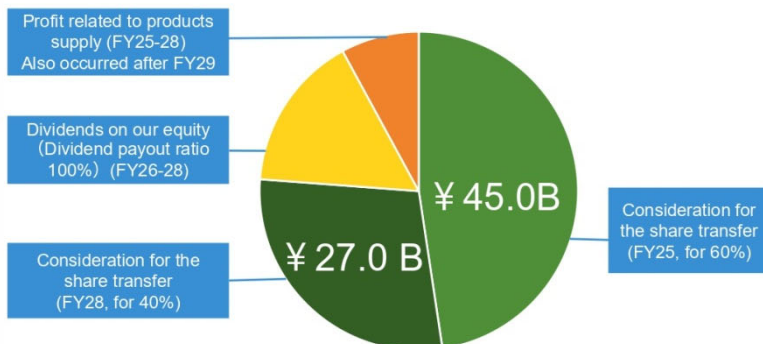
Joint Venture of Asia Business and Transfer of Frontier Business

Allocating the necessary growth investments for the Asia business and Frontier business is currently difficult
Strategic investments in growth areas will be strengthened

● Joint Venture of Asia Business

In addition to receiving the consideration of share transfer, the Company will continue to supply products to the joint venture company with Marubeni Global Pharma Corporation for a certain number of years, thereby contributing to patients in Asian countries

Profit from Joint Venture (Image)



● Transfer of Frontier Business

For further expansion and accelerated growth of FrontAct, the Company has decided to transfer its shares to Sawai Group Holdings, which has expertise in digital healthcare business



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I would like to explain about the joint venture of our Asian business and the transfer of our frontier business announced in March and April.

We are in a very difficult situation, and we desperately need to invest in growth at this time in order to further maintain and grow our Asian and frontier businesses in the future.

After internal discussions, we decided to concentrate on the US and Japan, which is the core markets for new drugs. The decision was made to transfer the Chinese and Asian operations, which have a much different pipeline and product mix, to a joint venture with Marubeni Global Pharma Corporation, which is expected to invest more in growth. The frontier business was transferred to Sawai Group Holdings, which focuses on the digital healthcare business.

We have not been able to explain to you the benefits of joint ventures, especially in Asia and China, so I am showing you the benefits here. The entire business will be transferred in two separate transactions.

First, 60% will be transferred in FY2025 and the remaining 40% in FY2028, receiving JPY45 billion and JPY27 billion at each timing. In the meantime, the joint venture's dividend payout ratio will be 100% in principle, and our share will be 40%. In addition, we will continue to supply products from our company, which will benefit us in the future. This is an image of the benefits of a joint venture.

Financial Forecasts for FY2025

Financial Forecasts for FY2025 (Core Basis)

	FY2024 Results	FY2025 Forecasts	Change		
			Value	FX impact	%
Revenue	398.8	355.0	(43.8)	(13.8)	(11.0)
Cost of sales	153.2	146.0	(7.2)	(5.8)	(4.7)
Gross profit	245.6	209.0	(36.6)	(8.0)	(14.9)
SG&A expenses	167.7	153.5	(14.2)	(6.3)	(8.5)
R&D expenses	48.5	44.0	(4.5)	(1.2)	(9.3)
Others (core basis)	13.7	44.5	30.8		
Core operating profit	43.2	56.0	12.8	(0.6)	29.8
Adjustments (negative number indicates loss)	(14.3)	(2.0)	12.3		
Operating profit	28.8	54.0	25.2		87.5
Finance income/costs	(11.2)	(14.0)	(2.8)		
Income tax expenses	(6.0)	0.0	6.0		
Net profit	23.6	40.0	16.4		
Net profit attributable to owners of the parent	23.6	40.0	16.4		69.2
R O E	14.5%	21.1%			
R O I C	9.4%	11.8%			

Average rates:
FY2024 Results : 1US\$ = ¥152.62, 1RMB = ¥21.11
FY2025 Forecasts : 1US\$ = ¥145.00, 1RMB = ¥20.00

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- **Revenue:**
 - Japan (¥14.1B) : LOE of Equa®/EquMet®
 - North America (¥3.6B) : Despite the revenue increase in USD, it is expected to decrease in JPY due to impact of exchange rates
 - Asia (¥26.1B) : Impact of business transfer (Assume JV formation at the end of July 2025)
- **Cost of sales:**
 - Potential tariff impact was not taken into account
- **SG&A expenses:**
 - Expected to decrease due to the effect of business structure improvement in Japan and transfer of Asian business
- **R&D expenses:**
 - Despite the increase in oncology area to accelerate programs, total expense is expected to decline due to the shift of regenerative medicine and cell therapy-related expenses to JV
- **Others (core basis):**
 - Expected income from the Asian business transfer (Gain on transfer about ¥45.0B)
- **Adjustments:**
 - No major expenses are expected

Here you see forecasts for FY2025.

See the middle of the table. Revenue forecast is JPY355 billion, a decrease of JPY43.8 billion including the impact of foreign exchange, and a decrease of JPY30 billion excluding the impact of foreign exchange, compared to FY2024.

Since the China and Asia business will be transferred to the joint venture, its sales will no longer be recorded from August of this fiscal year. In North America, APTIOM will soon face LOE, and its sales will decrease significantly. The period of exclusivity for Equa/EquMet will end in Japan as well. These are the main reasons for the decrease in revenue.

SG&A expenses and R&D expenses will be reduced in the same manner as the fiscal year under review, or even more so where possible. However, most of the decrease in revenue is due to the impact of foreign exchange rates.

The JPY44.5 billion recorded as others, core basis, is due to the JPY45 billion in income expected from the transfer of the Asian business. Core operating profit is expected to be JPY56 billion, an increase of JPY12.8 billion from the fiscal year under review.

There will be no adjustment, and operating profit is expected to be JPY54 billion. Financial costs are expected to be JPY14 billion, including foreign exchange losses due to the difference between the actual exchange rate of JPY152.62 for the fiscal year under review and the projected exchange rate of JPY145 for FY2025. As a result of the above, net profit attributable to owners of the parent is expected to be JPY40 billion, an increase of JPY16.4 billion.

Financial Forecasts for FY2025

Segment Information (Core Basis)

		Billions of JPY			
		Japan	North America	Asia	Total
FY2025 Forecasts	Revenue	85.7	248.2	21.1	355.0
	Cost of sales	46.0	92.1	7.9	146.0
	Gross profit	39.7	156.1	13.2	209.0
	SG&A expenses	32.2	115.8	5.5	153.5
	Core segment profit	7.5	40.3	7.7	55.5
	R&D expenses				44.0
	Core operating profit				56.0
FY2024 Results	Revenue	99.8	251.8	47.2	398.8
	Cost of sales	51.8	90.8	10.6	153.2
	Gross profit	48.0	161.0	36.6	245.6
	SG&A expenses	36.6	118.4	12.7	167.7
	Core segment profit	11.4	42.6	23.9	77.9
	R&D expenses				48.5
	Core operating profit				43.2
Change	Revenue	(14.1)	(3.6)	(26.1)	(43.8)
	SG&A expenses	(4.4)	(2.6)	(7.2)	(14.2)
	Core segment profit	(3.9)	(2.3)	(16.2)	(22.4)
	R&D expenses				(4.5)
	Core operating profit				12.8

Japan

- Despite the SG&A expense reduction, core segment profit is expected to decrease given the decline of gross profit

North America

- Profit is expected to be kept flat on USD basis. On JPY basis, however, the profit decreases due to the impact of exchange rate

Asia

- Profit decreases due to business transfer

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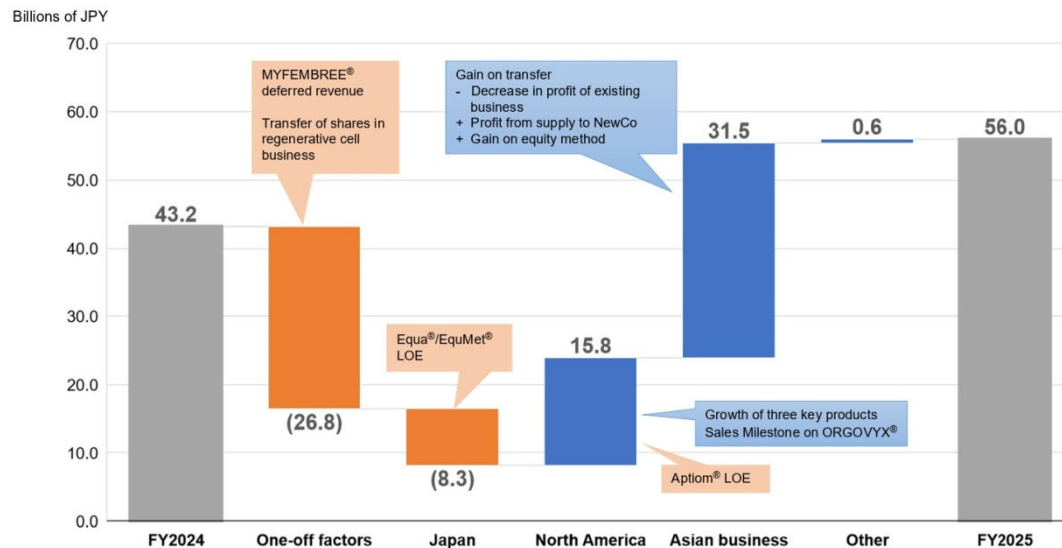
The forecast by segment is shown here.

Since we will basically only be supplying drugs for our Asian operations from August onward, we anticipate a very large decrease in revenue and profits in Asia.

In North America, APTIOM will face LOE. Although our strategy is to offset this with growth in the three products, we do not expect to be able to completely absorb the foreign exchange loss.

Financial Forecasts for FY2025

Core Operating Profit Increase/Decrease Factors



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This shows a breakdown of the changes in forecasted core operating profit.

The actual amount for the fiscal year under review was JPY43.2 billion. Core operating profit for the current fiscal year will no longer include the one-time recognition of deferred revenue from MYFEBREE and a gain of JPY26.8 billion from a change in equity interest in the regenerative medicine/cell therapy business. In addition, the termination of the exclusivity period of Equa/EquMet will reduce gross profit in Japan by JPY8.3 billion.

In contrast, gross profit in North America will increase, but on the other hand, the exclusivity period for APTIOM will end. Subtracting these items will result in a positive figure. In Asia, the Company will record a gain of JPY45 billion on the transfer, but will lose sales after August. On the other hand, there are equity method profits and profits from the supply of products after the transfer of the business. Net amount related to the transfer will be JPY31.5 billion. As a result of the above, core operating profit forecast for FY2025 is JPY56 billion.

Financial Forecasts for FY2025

Revenue of Major Products in North America

	FY2024 Results	FY2025 Forecasts	Change	FY2024 Results	FY2025 Forecasts	Change		
						Value	FX impact	%
North America	Millions of USD			Billions of JPY				
ORGOVYX®	544	710	166	83.1	103.0	19.9	(5.4)	24.0
MYFEMBREE®	84	85	1	12.8	12.3	(0.5)	(0.6)	(3.8)
GEMTESA®	431	572	141	65.8	82.9	17.1	(4.4)	26.1
RETHYMIC®	45	45	0	6.8	6.5	(0.3)	(0.3)	(4.5)
APTiom®	258	33	(225)	39.4	4.8	(34.6)	(0.3)	(87.8)
Others	80	267	(21)	12.2	38.7	(5.3)	(2.0)	(12.0)
Export products/ One-time revenue, etc.	208			31.8				
Total	1,650	1,712	62	251.8	248.2	(3.6)	(13.0)	(1.4)

- ORGOVYX® and GEMTESA® revenue are expected to increase significantly
- APTiom® revenue is expected to decline due to loss of its exclusivity
- One-time revenue includes the deferred revenue recognized all at once in FY2024. Sales milestone is expected in FY2025

FX rates:

FY2024 Results : 1US\$ = ¥152.62
FY2025 Forecasts : 1US\$ = ¥145.00

The revenue forecasts for our main products are shown here. Our focus is on ORGOVYX, MYFEMBREE and GEMTESA. In particular, revenues from ORGOVYX and GEMTESA are expected to increase by JPY19.9 billion and JPY17.1 billion, respectively, over the fiscal year under review. We expect these to continue to be our growth drivers.

On the other hand, since MYFEMBREE is to be sold solely by the Company, although we do not expect an increase in revenue, we expect the profit from the product to improve so much that it to be profitable as a stand-alone item in the current fiscal year. This will be explained again later. We expect revenue of JPY248.2 billion for North America as a whole.

In the next fiscal year, we will receive 100 million sales milestone from Pfizer, which is also included in the JPY38.7 billion.

Financial Forecasts for FY2025



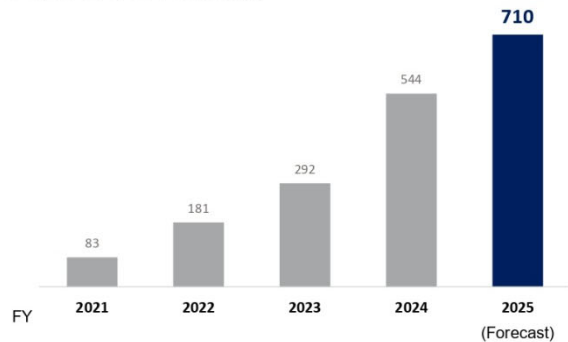
FY2024 Performance

FY2024 Initial Forecast	FY2024 Results	Year-over-year comparison
\$400M	\$544M (Achievement: 136%)	Approx. 87% Increase

- Volume: Significantly outperformed by \$112M more than Forecast due to the implementation of patient out-of-pocket cap in Medicare Part D as part of the Inflation Reduction Act, and reduction of the cap started January 2025
- Price: Outperformed by \$32M more than Forecast due to Medicare Part D Coverage Gap trueups, less returns, and favorable Medicare Part D Rebates starting in 2025

Note: Overachieved even to revised forecast (\$516M) primarily driven by strong demand

FY2025 Forecast (\$M)



Sales Strategy

Drive demand and brand preference across Urology and Oncology

- Urology: Establish firm position in Androgen Deprivation Therapy
- Oncology: Expand market share supported by clinical differentiation
- Patients: Disseminate educational resources regarding changes in out-of-pocket costs due to Medicare Part D drug benefit modifications

Note: Forecast represents product sales only and does not include sales milestone

The following is a brief explanation of each product. First, ORGOVYX achieved an 87% increase in sales in FY2024 compared to FY2023. The figures in the chart below are in dollar terms. In FY2025, we project a 24% increase over the previous fiscal year to USD710 million.

Financial Forecasts for FY2025

MYFEMBREE®

Myfembree®
(relugolix, estradiol, and
norethindrone acetate) tablets
40 mg, 1 mg, 0.5 mg

FY2024 Performance

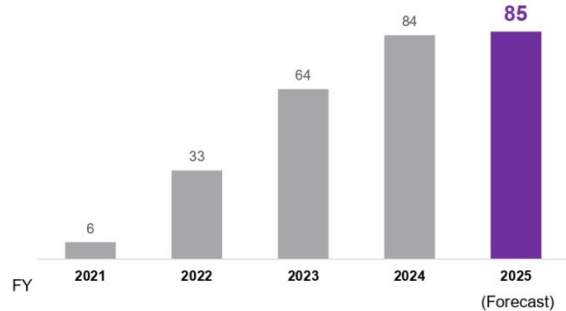
FY2024 Initial Forecast	FY2024 Results	Year-over-year comparison
\$124M	\$84M (Achievement: 68%)	Approx. 32% Increase

□ Volume: Underperformed by \$37M due to the slower growth for oral GnRH in the women's health sector and slower market share growth in endometriosis

□ Price: Almost as expected (slightly underperformed by \$3M)

Note: Both volume and price were almost as expected to revised forecast (\$80M)

FY2025 Forecast (\$M)



Sales Strategy

Ensure profitability under independent sales structure

- Organizational optimization: Launched new Community Care team in April by integrating Legacy Women's health team with Legacy GEMTESA® Primary care team
- Mitigation of impact by Pfizer partnership conclusion: Maintained high-potential prescribers previously covered by Pfizer
- Endometriosis: Lead HCP promotion with safety and efficacy of MYFEMBREE® in treating moderate to severe pain associated with endometriosis

MYFEMBREE revenue was up 32% in FY2024 compared to FY2023, but revenue is expected to be almost flat in FY2025. The plan is to increase profitability and profit while covering the termination of the partnership through our own sales activities alone.

Financial Forecasts for FY2025



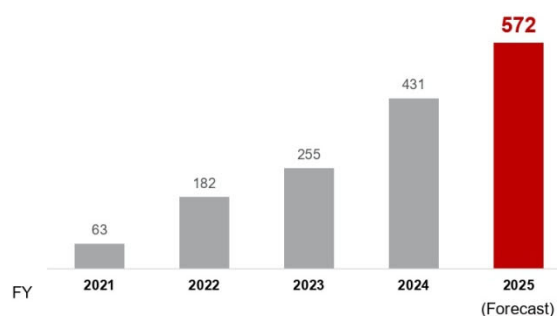
FY2024 Performance

FY2024 Initial Forecast	FY2024 Results	Year-over-year comparison
\$380M	\$431M (Achievement: 113%)	Approx. 69% Increase

- Volume: Underperformed relative to initial forecast by \$48M, due to changes in Medicare Part D coverage starting in 2025
- Price: Significantly outperformed by \$99M driven by Medicare Part D Coverage Gap trueups and reduced Medicare Part D rebates starting in 2025

Note: Overachieved even to revised forecast (\$413M) primarily due to price impact

FY2025 Forecast (\$M)



Sales Strategy

Establish standard of care OAB treatment for men and women with overactive bladder

- Keep emphasizing clinical differentiation: Simple dosing regimen, no blood pressure warning in the label, no drug-drug interactions with CYP2D6 substrates, and crushable tablet
- Expansion of prescriptions for men: Increase awareness in male patients by leveraging new indication (overactive bladder in men being pharmacologically treated for benign prostatic hyperplasia)
- Optimize the balance between price and volume: Implement balanced pricing strategies in response to market changes

Next, let me explain about GEMTESA.

GEMTESA revenue was very strong in FY2024 with a 69% increase. We plan to continue to increase revenue by 26% to USD572 million in the current fiscal year.

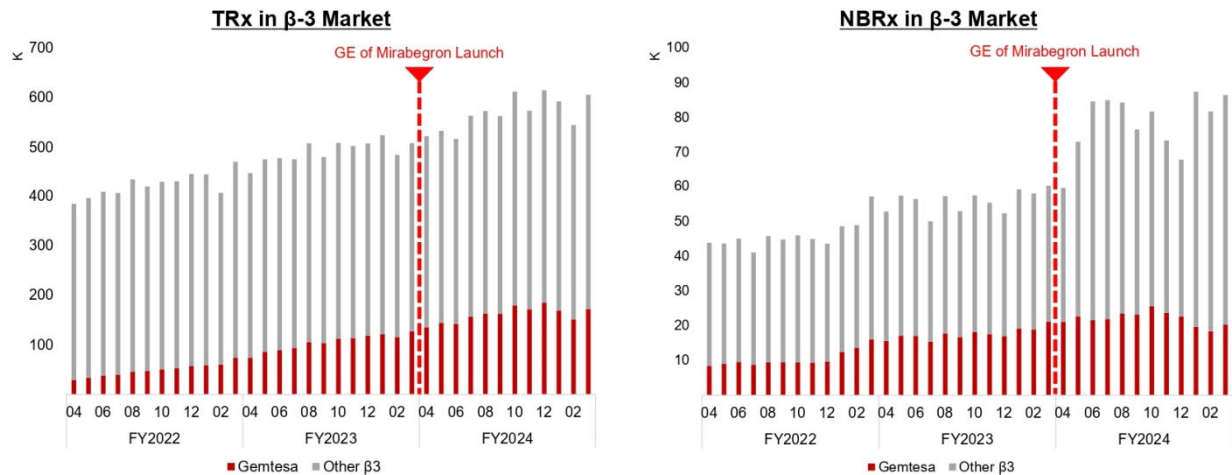
On the other hand, the addition of new indications for OAB/BPH, overactive bladder with prostatic hypertrophy, was decided late last year, and a new differentiating factor from other competing products has emerged. We will continue our sales activities to make it the standard treatment of choice for both male and female patients.

Financial Forecasts for FY2025

GEMTESA®



- Despite the launch of Mirabegron generics in April 2024, the total number of GEMTESA® prescriptions and new prescriptions continued to increase. However, since January 2025, there has been a slightly decline due to changes in Medicare Part D coverage and other factors



* Source: Based on information licensed from IQVIA. NPA for the period 1/1, 2022 to 3/31, 2025 reflecting estimates of real-world activity. All rights reserved.

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We have been paying attention to the generic version of MIRABETRIC, a competitor that came out in the middle of the last fiscal year. The red area shows the trend of GEMTESA, which is increasing without receiving impact.

The number appears to have decreased slightly since this calendar year. This is due to the impact of our price negotiations with payers, where we were bullish because of the new indications, but we received a proposal to lower the price, so once we started activities to have them removed from the formulary. We have already seen a large payer return to us, so we are optimistic that performance will return soon.

Major Topics in Clinical Development

● Psychiatry & Neurology (Regenerative medicine/cell therapy)

■ Allogeneic iPS cell-derived dopaminergic neural progenitor cells (Japan, collaboration with RACTHERA)

- Parkinson's disease

Preparing for NDA submission in FY2025 based on the data from the investigator-initiated study by Kyoto University.

Aiming to obtain approval in Japan in FY2025.

Release of the results of the investigator-initiated study by Kyoto University (For details, page 19)

● Oncology

■ enzomenib (DSP-5336) (U.S., Japan)

- Agreed with FDA on the study package for NDA submission

■ nuvisertib (TP-3654) (U.S., Japan)

- The latest efficacy and safety data from the monotherapy cohort to be presented at EHA 2025 (June 2025)

● Others

■ TWYMEEG® (Japan)

- Revision of Package Insert: Based on the results of Phase 4 study, the range of patients with renal impairment eligible for TWYMEEG® has been expanded (The range of patients with renal impairment for whom administration is not recommended has been changed from those with an eGFR of less than 45 mL/min/1.73m² to those with an eGFR of less than 10 mL/min/1.73m²)
- Focusing on prescription proposal activity for elderly type 2 diabetes patients, with a higher percentage of impaired renal function compared to younger patients

■ fH1/DSP-0546LP(Europe)

- Universal Influenza Vaccine Interim analysis result of Phase 1 study will be available in FY2025

Next, let me talk about research and development.

The progress since the Q3 results in January this year is shown here. In the CNS area, or regenerative medicine/cell therapy, we have made a major change in the form of our business for dopamine neural progenitor cells derived from other iPS cells, which will be now conducted in collaboration with RACTHERA. However, the program itself is proceeding as usual. Data from a physician-initiated clinical trial at Kyoto University made headlines when it was published in Nature on April 17.

We are already in the process of conducting a SAKIGAKE Comprehensive Evaluation Consultation with the PMDA and hope to obtain approval in FY2025, preferably by the end of the year.

In the area of oncology, as we have repeatedly explained, we are focusing on two products, enzomenib and nuvisertib. Regarding enzomenib, we recently agreed on a study package with the FDA in April for submission and have started a pivotal study.

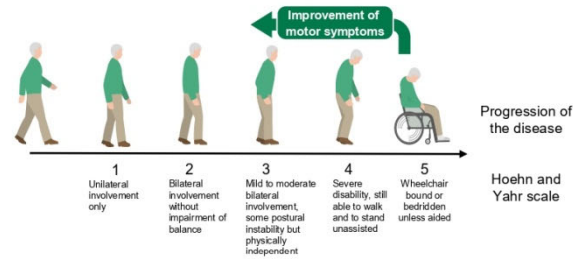
As for nuvisertib, we will soon be presenting the latest data on the efficacy and safety of the single-agent cohort at the European Hematology Congress, so please stay tuned.

TEYMEEG was marketed in the form of a cautiously administered dose for patients with kidney problems, but data have emerged showing no effect on renal function. Here are the criteria. The drug can now be administered to patients with CKD 3B or 4, making this drug even more reliable.

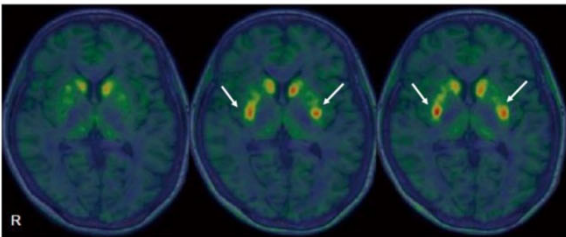
We expect to know the results of the interim analysis of the universal influenza vaccine by the end of this year. All human administration and immunization studies in clinical trials have been completed.

Research and Development

Regenerative Medicine/Cell Therapy: Allogeneic iPS cell-derived dopaminergic neural progenitor cells(CT1-DAP001/DSP-1083) Results of the Investigator-Initiated Study(Announcement by Kyoto University Hospital)



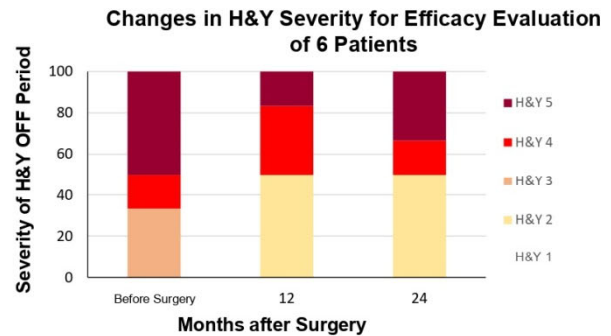
Newly Observed Dopaminergic Neuronal Activity Post-Transplant* (Arrow)



Engraftment of transplanted cells and increased dopamine production confirmed by ^{18}F -DOPA PET

* Nature, 587, Fig. 3e, 123-130, 2025, Springer Nature

Modified by the Company from Sawamoto et al. Nature 2025



Improve OFF period scores for 4 out of 6 efficacy evaluation patients using the Hoehn & Yahr Severity Classification, which assesses PD pathology in five stages

Hoehn & Yahr Severity Classification (H&Y) 3~5 correspond to patients with designated intractable diseases in Japan

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Let me explain each product in a little more detail.

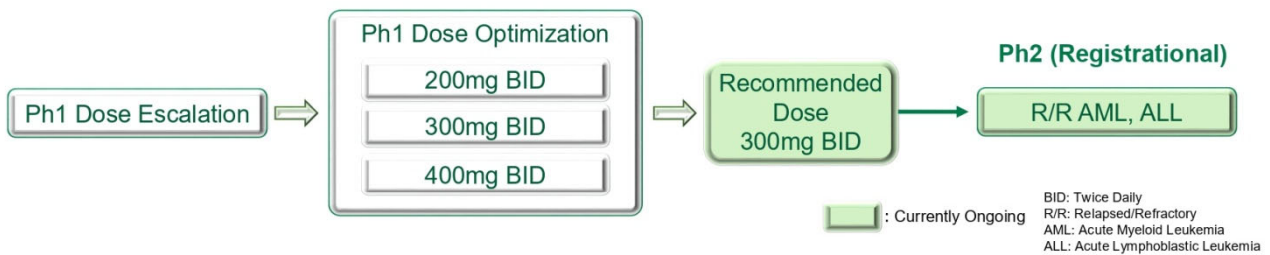
I will explain about allogeneic iPS cell-derived dopaminergic neural progenitor cells for regenerative medicine/cell therapy. In the lower left corner, there are three round, egg-like objects in a row. This is a PET image of the brain, and the red area is where dopamine is made. Two large red dots appear, one on each side, as indicated by the arrows, which were not there before the surgery. It can be seen that the transplanted cells made dopamine well.

There is a rating index called the Hoehn & Yahr scale for patients' symptoms. In this index, as noted in the upper right corner, a person living in bed or wheelchair without assistance is classified as 5, while a person with tremors or stiffness of limbs on only one side of the body is classified as 1.

In Japan, people with Hoehn & Yahr's 3 to 5 are eligible for designated incurable diseases. All six patients who underwent surgery were designated as intractable. After 12 and 24 months, half of the patients moved to index 2. I think you can see that this is very impactful for patients.

Patient with 3 walks in small increments and shows sagging legs. In index 2, tremors in both limbs and muscle stiffness remain, but overall movement is normal. Indicators 3 and 2 have this difference.

Oncology: enzomenib (DSP-5336) Acute Leukemia



Advance of Clinical Development

- Agreed with FDA on the study package for NDA submission
- Plans to consult with PMDA (FY2025 Q2)
- Plans to complete patient enrollment for Phase 2 part (FY2025 Q4)

Presentation at Academic Conference

- Continuous data presentations and workshops utilizing the Japanese Society of Hematology, European Hematology Association, and American Society of Hematology

As for enzomenib, as I mentioned earlier, approval trials have begun. We are considering consulting with PMDA in Q2, as well as accelerating patient enrollment for the Phase II part.

Oncology: nuvisertib (TP-3654) Myelofibrosis



Advance of Clinical Development

- Promotion of patient enrollment for the Dose Escalation cohort
- Collection of efficacy, safety, and pharmacokinetic data for the determination of recommended doses for monotherapy and combination therapy

Presentation at Academic Conference

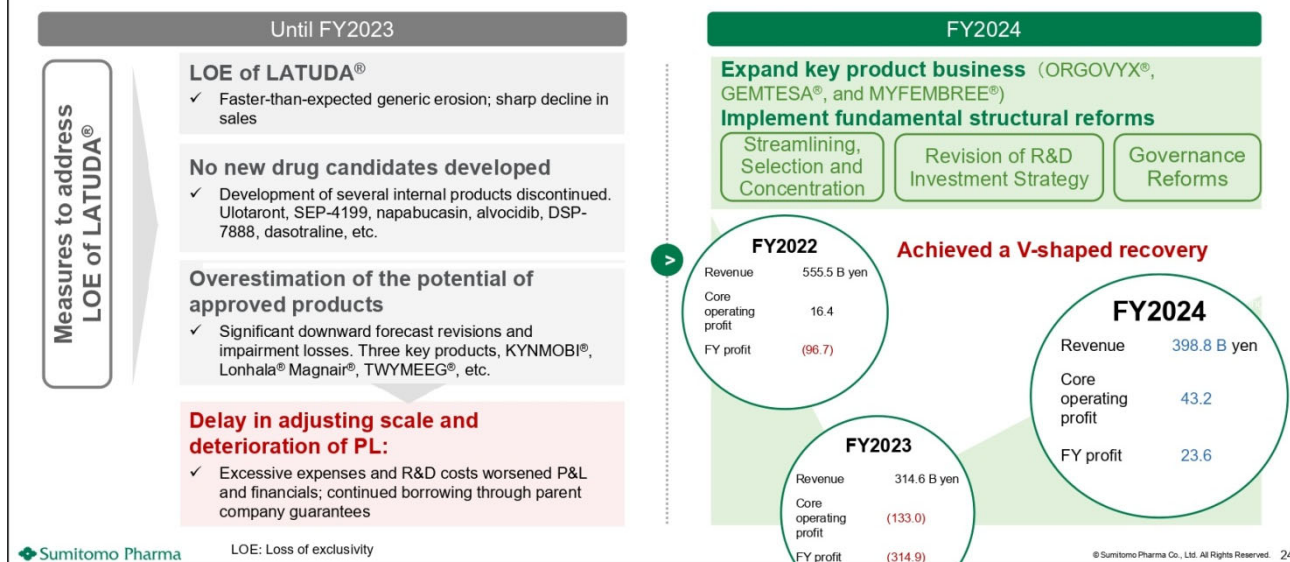
- Presentation of the latest data from the monotherapy cohort at the European Hematology Association
- Continuous data presentations and workshops utilizing the Japanese Society of Hematology, European Hematology Association, and American Society of Hematology

For nuvisertib, we are proceeding with a cohort of patients receiving nuvisertib as a single agent or in combination with a JAK inhibitor. There is a European hematology conference coming up soon, and I heard that the abstracts will be published on May 14. We will be able to explain the contents tomorrow or the day after.

We are in the process of accelerating to determine the recommended clinical dose as soon as possible so that we can move to the next stage.

1. Review of FY2023-2024

Insufficient and unsuccessful measures to address the LOE of LATUDA® led to a significant decline in performance in FY2023. Core operating profit and final profit returned to profitability in FY2024 by formulating and implementing fundamental structural reforms



Next, let me briefly explain about Reboot. This is our immediate action plan to restart a strong Sumitomo Pharma.

With the announcement of this plan, the current mid-term management plan, called Mid-Term Management Plan 2027, which no longer fits the current situation, has been withdrawn.

First, let's look back at FY2023 and FY2024. As we have explained many times, our performance in FY2023 was very difficult, and we achieved a V-shaped recovery in FY2024. In fact, in North America, we have already undertaken a very large and fundamental structural reform in FY2023.

In Japan and the US, we have been promoting rationalization, selection and concentration, review of R&D investments, and governance reforms.

2. Initiatives for FY2023-2024 (PL Management through Fundamental Structural Reforms)

Implemented PL management through significant company-wide cost reductions and revision of R&D investment strategy

- Streamlining, Selection and Concentration**

A) Thorough cost reduction and significant workforce reduction
 Japan*: -1,200 people (3,000→1,800)
 U.S.: -1,000 people (2,200→1,200)
End of FY2022 → End of FY2024

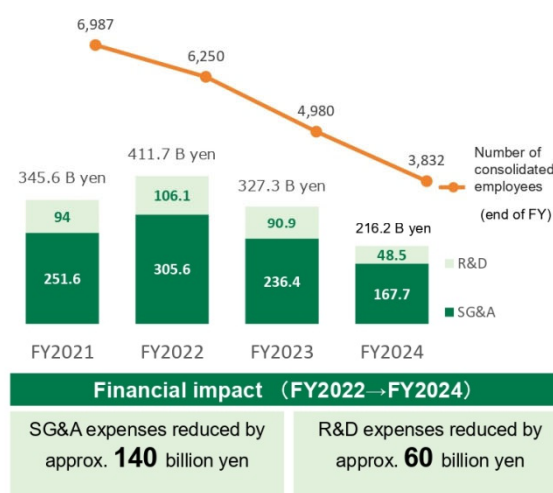
B) R&D spending cap management
 110 billion → 50 billion yen (FY22 → FY24)

C) Sale of assets and businesses
 Sale of Roivant shares, Asia business joint venture formation, etc. (Total sales amount: 250 billion yen)

Revision of R&D Investment Strategy

A) Selection and Concentration of Programs
 Prioritized and reduced programs
 Focused investment in two oncology compounds

B) Established framework for cooperation with Sumitomo Chemical in the regenerative medicine/cell therapy business
 Reduced our initial costs and acquire greater flexibility in R&D strategy



The initiatives for FY2023 and FY2024 are shown here.

We have thoroughly cut costs and implemented a workforce reduction of 1,200 employees in Japan and the US. In addition, we are conducting cap management on R&D expenses and reduced those from JPY110 billion to JPY50 billion. At the same time, a gain of JPY250 billion was recorded from the sale of the entire stake in Roivant and the conversion of our Asian operations into joint ventures, etc. In addition, we promoted selection and concentration of programs in R&D, too.

In order to ensure that our financial situation does not hinder us from expanding our regenerative medicine/cell therapy business, we have established a new joint structure with Sumitomo Chemical as a member of the Sumitomo Chemical Group. As a result, from FY2023 to FY2024, we achieved a JPY140 billion reduction in SG&A expenses and a JPY60 billion reduction in R&D expenses compared to FY2022. With this Reboot, Sumitomo Pharma is now restarted as the new Sumitomo Pharma.

1. Reboot 2027

Reboot for a “Strong Sumitomo Pharma”

Work to strengthen our platform as an R&D-driven pharmaceutical company while continuing with selective, focused investment and governance reforms

Pave the way for revival by rebuilding the Value Creation Cycle based on internal innovation

“Reboot 2027” is an initiative beginning in FY2025

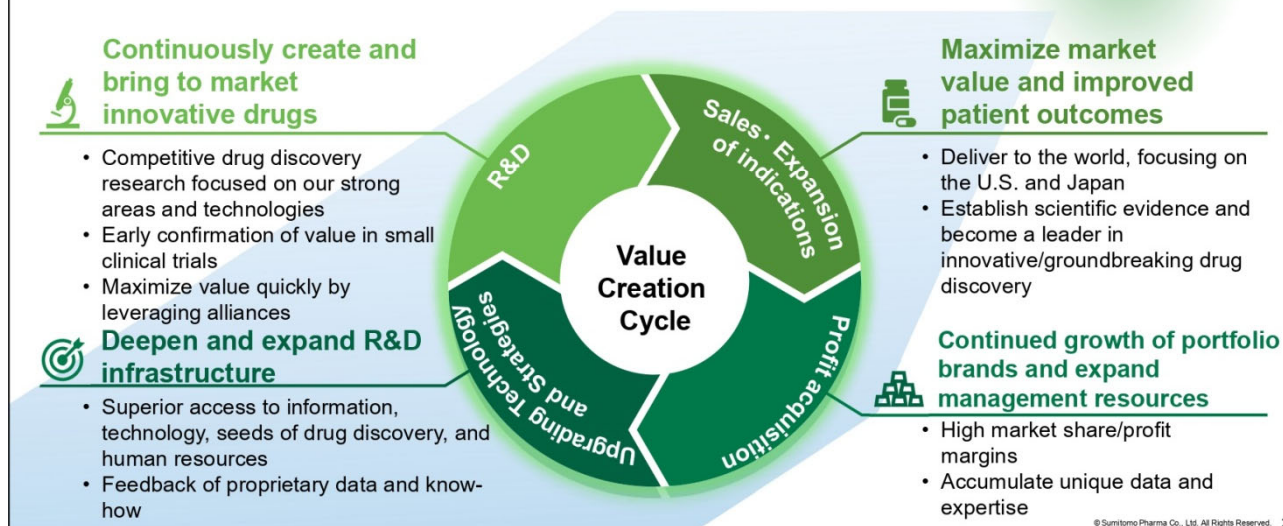


Despite the difficult situation, Sumitomo Pharma is determined to rebuild its foundation as an R&D-oriented pharma. We will rebuild our value creation cycle based on our own innovations and make a strong start.

2. Our Vision: Global Specialized Player (GSP)

Continue to create and implement innovations in society by strongly turning the Value Creation Cycle in specific fields and technologies. Establish the “Sumitomo Pharma” brand worldwide by contributing to healthy and fulfilling lives

GSP



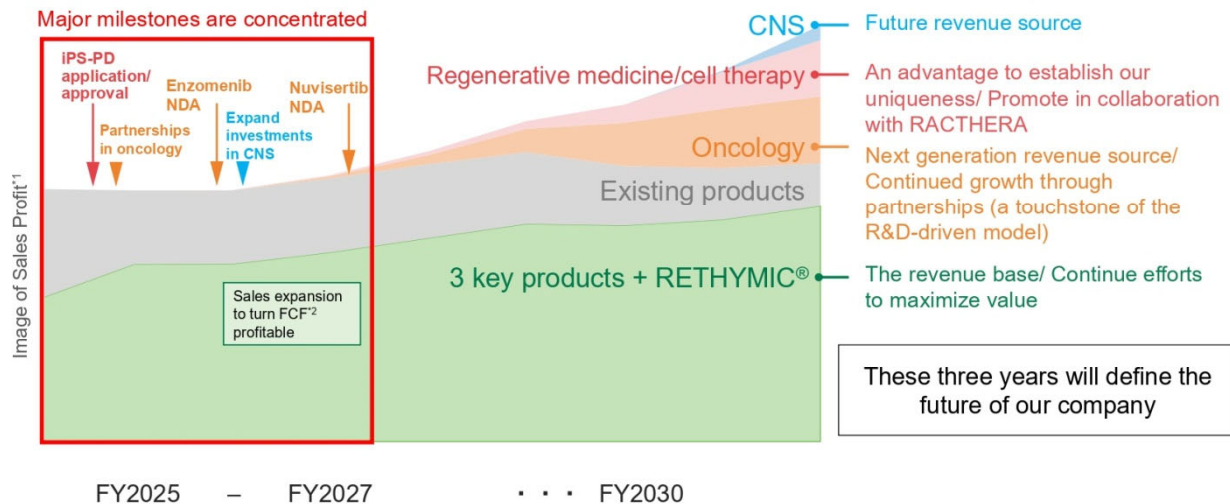
We would like to emphasize the value creation cycle as a keyword within our company. Not only must we continuously bring innovative drugs to market through research and development, but we must also maximize their market value afterwards to contribute to better medical care and lead them to the stage of expanded sales and indications.

The resulting product branding and expansion of the next set of management resources will allow for further new strategies or new research. We have named this cycle the Value Creation Cycle.

All company functions are responsible for one of these. We would strongly encourage each person or department to contribute to this cycle.

3. To Rebuild the Value Creation Cycle

Major milestones in the rebuilding of the Value Creation Cycle will be concentrated over the next three years. The entire company will work together to achieve these milestones through selection and concentration, as well as through external partnerships.



As a result, we would like to rebuild the Company as a global R&D-oriented company, which is our ideal, albeit in a limited area, as a global specialized player.

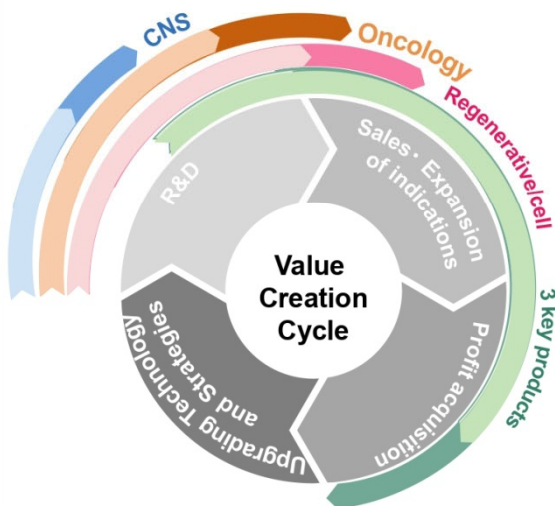
In this regard, research and development have not been very successful so far. However, the next two to three years will bring major milestones in regenerative medicine such, as iPS, Parkinson's, and cancer, that will feed us in the future.

For the time being, the three key products plus RETHYMIC will provide solid support for earnings, while we nurture the next buds.

4. Rebuilding the Value Creation Cycle from FY2025 to FY2027

Stabilize the revenue base by expanding the business of the three key products (operating base not dependent on one-time revenues)

Rebuild the Value Creation Cycle by commercializing regenerative medicine/cell therapy and oncology



Three key products

Establish the Group's revenue base through sales expansion
Expand to 250 billion yen (FY2027)

Regenerative medicine/cell therapy

Start the iPS cell-based drug business with the approval and launch of iPS-PD
Expand the business in collaboration with RACTHERA

Oncology

Dedicate resources as a top priority and promote the fastest development (by leveraging partnerships)
enzomenib launch, nuvisertib NDA submission (FY2027)

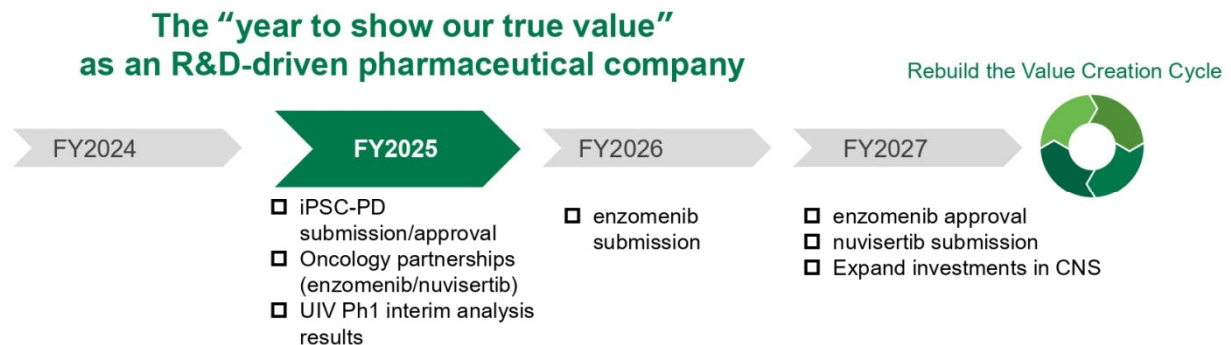
CNS

Resume development using accumulated expertise and key technologies
Expected to become a revenue base after LOE of the three key products

In this context, if we apply this value creation cycle, CNS is still in the research and development stage, as we have suspended the development of a major late-stage product. As for cancer, we are finally starting to see sales, and the same is true for the regenerative medicine/cell therapy. We will strive to maximize them as soon as possible by putting them on the value creation cycle that we will be strengthening.

5. Milestones for FY2025

Advance the development of two oncology compounds, possibly through partnerships, and submit and obtain approval for iPSC-PD in Japan. FY2025 is the “year to show our true value” as we work to achieve the goals to reinvigorate ourselves as an R&D-driven pharmaceutical company



Our revival as an R&D-driven pharmaceutical company by achieving the FY2025 milestones

Formulation of comprehensive growth strategy after reviewing the progress of the two oncology compounds

In order to implement this, we have positioned FY2025 as the year in which we will demonstrate our true value as an R&D-oriented pharma company, as shown in the previous diagram.

The results I have shown you here, and have emphasized many times before, will be concentrated in this fiscal year, and we hope to regain momentum through them. We currently believe that the success of this will allow us to draw up a more concrete strategy for future growth.

6. Financial Targets

By FY 2027

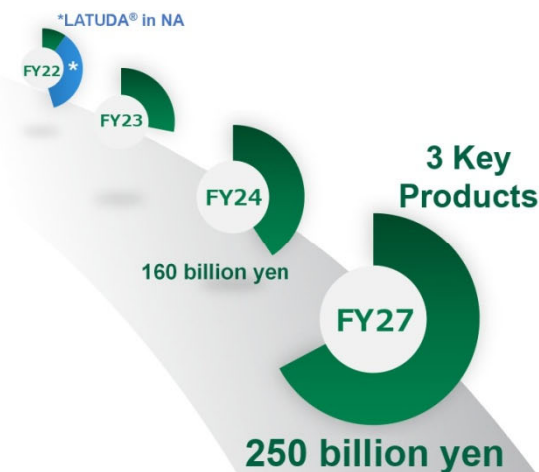
PL	Sales of 3 key products	Expand to 250 billion yen*
	Core operating profit	Consistently more than 25 billion yen, excluding one-time factors (from FY2027)
CF	Free cash flow	Maintain profitability(FY2025-2027) → Return to profitability excluding sales-related income (FY2027)

As early as possible

Interest-bearing debt	Reduce interest-bearing debt to less than 200 billion yen
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Dividend policy	Prioritize the repayment of interest-bearing debt for the time being and aim to resume dividend payments at an appropriate time
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Sumitomo Pharma *: Converted at the rate of 150 yen per dollar



Financial targets.

These figures do not factor in the fact that sales are currently very strong and that a major milestone in research and development will come this year. We will achieve revenue of JPY250 billion for the three key products. Core operating profit will not fall below JPY25 billion after FY2027.

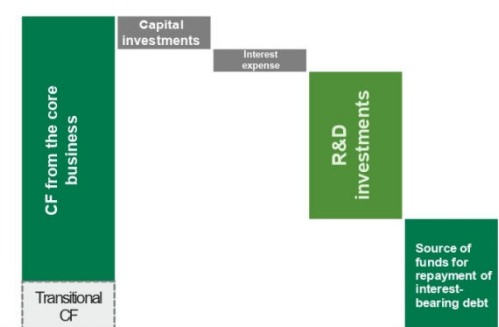
On the other hand, sales-related revenues account for the bulk of current cash flow and operating profit. One of our goals for free cash flow is to quickly get the Company into a position where it can generate a profit without sale-related revenues. In addition, we hope to quickly reduce interest-bearing debt to less than JPY200 billion and resume dividend payments as soon as possible. For the time being, we believe that repayment of loan debt must be our priority.

6. Financial Targets (2)

The management of interest-bearing debt through FY2027 will depend on the transfer income from the Asia business. Stable free CF from the core business is expected to return to profitability during the period, but key financial events lie ahead

→ Seeking further financial improvement by leveraging external partnerships in the program to return dividends to shareholders and resume strategic investments

Cash Allocation Chart:
FY2025-2027 3-year Cumulative Total



Financial Issues

A) Repayment of interest-bearing debt

In FY2024-2025, repayment will depend only on the sale of assets and businesses. By FY2027, free CF will be stabilized by core business revenues to accelerate repayment

B) Response to financial events

In FY2027, in addition to refinancing, the first repayment of subordinated debt (60 billion yen) will be made in September

C) Resumption of shareholder returns and strategic investments

Need to return profits to shareholders (resumption of dividends) in response to recovery from the emergency
Shift to a strategy of strengthening the portfolios through strategic investments

Measures

Accelerate growth through program collaboration with strategic partners

Maintain internal programs from a portfolio strategy perspective
Achieve both rapid development and value maximization while reducing cost burdens through partnerships

Financial targets.

This image shows cash allocation. We intend to use cash flow from our core business and one-time cash flow effectively, mainly for R&D investment or repayment of interest-bearing debt.

In addition to the repayment of interest-bearing debt, the recent refinancing will become due in FY2027, and the first redemption of the existing subordinated debt will also arrive. We also see shareholder return and strategic investment as issues to be addressed.

On the other hand, to start up with a focus on R&D, aggressive investment in development will be necessary, but there is a possibility that we may not be able to fully finance the cost of such investment. We would like to place maximizing our profits through external partnerships in our development programs at the center of our strategy.

We do not sell our pipeline to outside parties throughout-licensing. We partner to maximize our value.

1. Overview of Business Strategies

Establish a P&L base by maximizing the value of existing products, with a focus on the three key products, and thorough cost management

Maintain free CF and acquire the next revenue base by selection and concentration of the development pipelines



Maximize the value of existing products

- North America: Maximize sales and product P&L of the **three key products**
- Japan: Contribute steadily to revenue by **expanding sales of existing products + XEPLION®**

Thorough cost management



Strengthen the portfolios by selecting internally developed pipelines and pursuing partnering opportunities

- **Focus on the two oncology compounds:** Establish the next revenue base after the three key products
- **Seek partnering opportunities:** Maximize value, develop as quickly as possible, reduce investment capital
- **Collaboration with RACTHERA:** Promote the regenerative medicine/cell therapy business and develop it into the Group's core business

The business strategy overlaps with what I have already explained.

The overall picture is to first maximize the value of existing products. Thorough cost control will also continue in the future. We intend to strengthen our portfolio by selecting our in-house development pipeline and pursuing partnership opportunities.

First, we will focus on two oncology products and regenerative medicine/cell therapy, followed by strategies in the CNS and neurology fields, which are our foundation.

2. For the Early Launch of the Two Oncology Products

This will be given a top priority as the flagship program for realizing the R&D-driven pharmaceutical company. Given financial constraints, maximize value by developing the products as quickly as possible through leveraging partnerships



Promote focused development

- ✓ Prioritized investment in the two oncology compounds
- ✓ A touchstone for the R&D-driven pharmaceutical company



Maximize value through partnerships

- ✓ Maintain development speed and compete with competitors' products
- ✓ Manage the investment burden



Achieve early launch

enzomenib

NDA submission in FY2026,
Launch in FY2027

nuvisertib

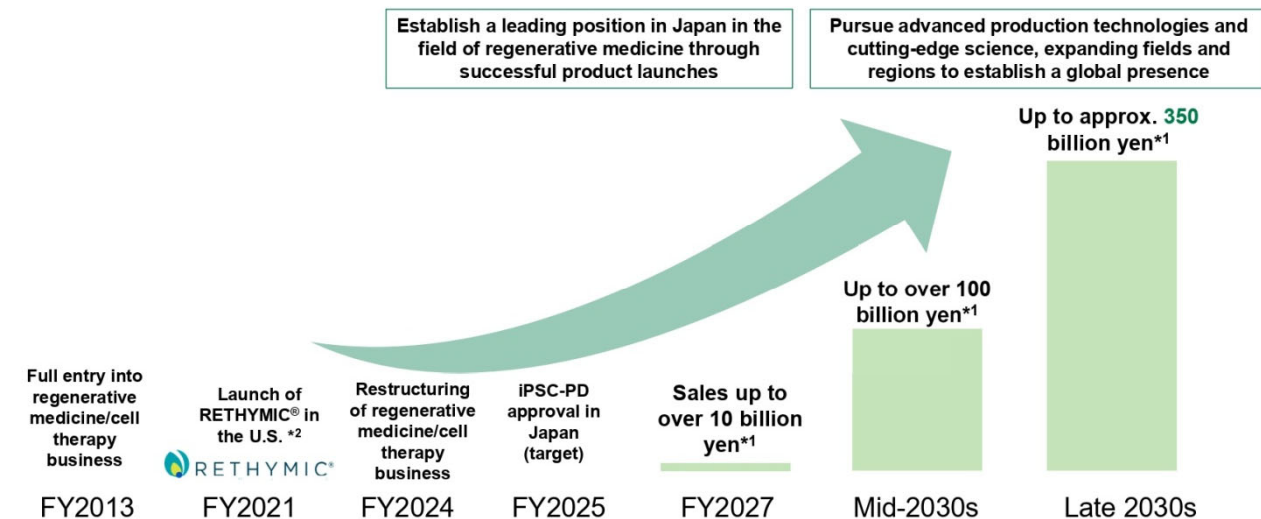
NDA submission in FY2027

As we work toward the launch of the two oncology products, I would like to reiterate that we will give priority to the development of three products and look for a development partner as soon as possible to maximize their value. We are currently planning to file for enzomenib in FY2026 and launch it in FY2027. For nuvisertib, we plan to file in FY2027, although there will be a slight delay. By adhering to this schedule, we will move forward with the realization of the early market launch shown on the right side.

3. Expansion of the Regenerative Medicine/Cell Therapy Business

As a “front-runner” in regenerative medicine/cell therapy, create new value that can only be realized through regenerative medicine

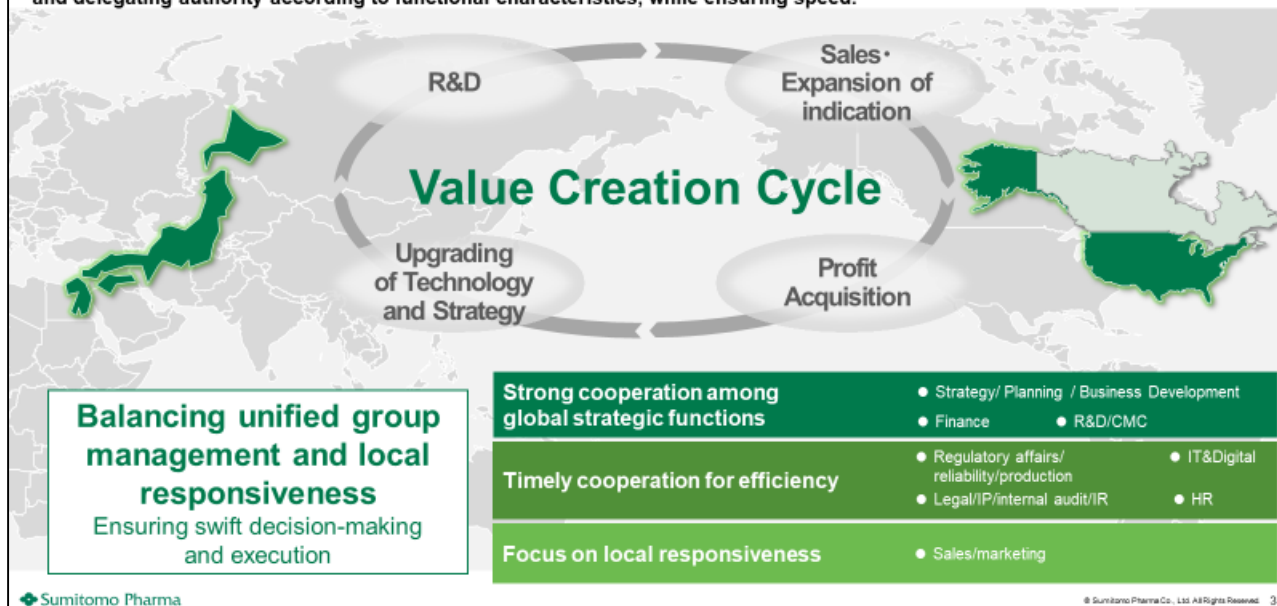
Aim to expand sales to a maximum of approximately 350 billion yen*1 in the second half of the 2030s



As for regenerative medicine/cell therapy, as I have repeatedly mentioned, we have only launched RETHYMIC in the United States. We aim to obtain approval for iPSC, Parkinson's disease drugs, as soon as possible this year, and to start selling them in the next fiscal year. We will continue to develop the product in the US to become one of the world leaders in this field. We aim to make this a JPY100 billion business by the mid-2030s and JPY350 billion thereafter.

4. Regional Strategies

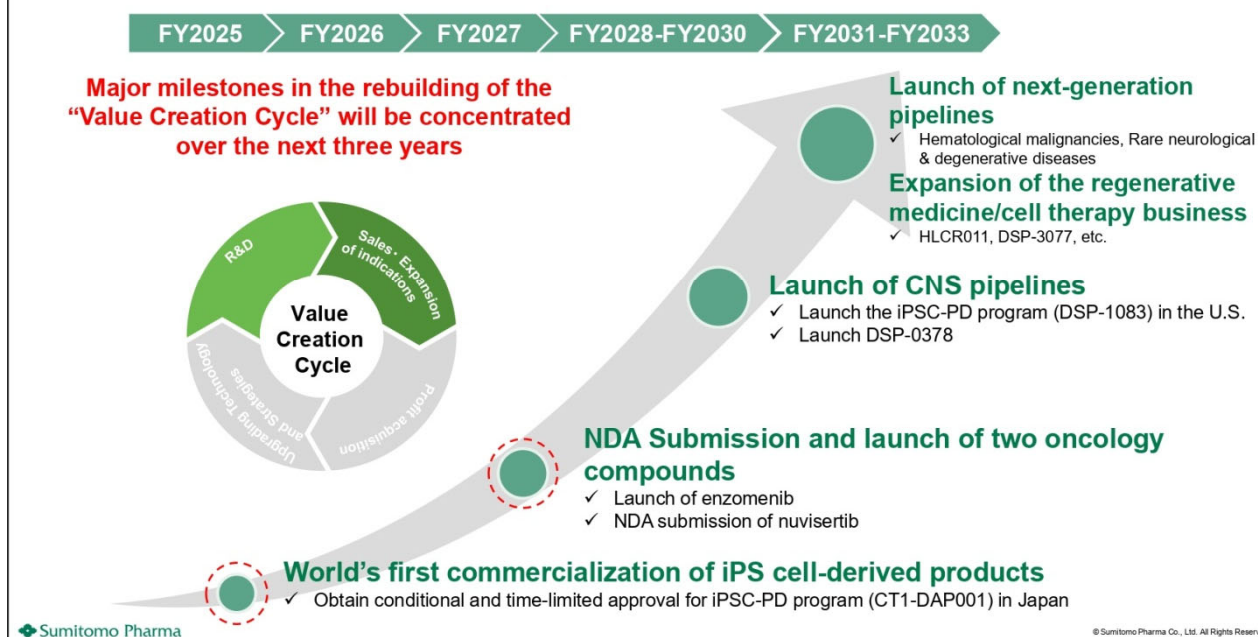
Focus on Japan, which has the pharmaceutical business platform including drug discovery research, and North America, the largest market. For the organizational operations in Japan and the US, consider the balance between strengthening cooperation and delegating authority according to functional characteristics, while ensuring speed.



This is the regional strategy of our value creation cycle.

Until now, we have focused on Japan, the US, China, and Asia. Our business in China and Asia, which has not been in the form of a new drug market, will be transferred to a joint venture with Marubeni Corporation, and we will establish our business with a focus on the US and Japan. The global strategy function, or R&D, will be promoted firmly on a global basis, while sales and marketing will be managed with an emphasis on localization.

1. Value Creation through R&D Activities



I will explain our R&D efforts in more detail, but since most of these overlap with the previous explanations, I will skip some points. First, milestones for the restructuring of the value creation cycle are concentrated in the next three years, especially in the current fiscal year. Our top priority is the commercialization of iPSC cell-derived products and the launch of two products, which will be followed by other products.

2. Promote Stable Development of the Two Oncology Products

- Launch of enzomenib and NDA submission of nuvisertib by FY2027
- We are confidently promoting development of the two oncology compounds for the following three reasons



Right target (Drug target relevance)

- ✓ Targets clearly associated with disease and accumulated internal and external clinical evidence



Right plan (Development strategy and clinical trial design)

- ✓ Focus on hematological malignancies, which have a high probability of successful development within the oncology area
- ✓ Select a patient population in which the treatment is more likely to be effective
- ✓ Efficacy endpoints are objective measures* and will continue to be used in confirmatory clinical trials



Right action (Clinical development operations)

- ✓ Promote development steadily by conducting single-arm, open-label studies while reviewing data step by step
- ✓ Promote small-scale confirmatory clinical trials in a conscientious and elaborate manner

Accelerate indication expansion through external alliances to maximize value faster

I hear a lot of different voices about the two cancer products. It is said that we have done many things before. We will continue to move forward with the strategy of Right target, Right plan, Right action to maximize value as soon as possible, with more concrete confirmation.

3. To Increase the Likelihood of R&D Success

Focus on diseases where the Company can maximize its strengths and promote R&D stepwise with a compact development strategy

	Key Success Factors	Review of the past	Current/future actions
1	Generate development candidates with high certainty Right target	<ul style="list-style-type: none"> Attempted to work on drug targets with uncertain disease relevance Selected a broad range of diseases within oncology/CNS (dispersed R&D resources) 	<ul style="list-style-type: none"> Carefully select more disease-relevant drug targets Focus on hematological malignancies, Rare neurological & degenerative diseases (improve R&D continuity) <p>Early development pipelines are becoming richer and their quality is improving</p>
2	Drive clinical development to success Right plan Right action	<ul style="list-style-type: none"> Accepted risks and moved into late-stage development Promoted large-scale confirmatory clinical trials 	<ul style="list-style-type: none"> Confirm efficacy signals early in studies with patients (initial POC*) Obtain First approval through promoting small-scale confirmatory clinical trials in a conscientious and elaborate manner
3	Improve the Company's overall execution capability (become the Company that can get things done)	<ul style="list-style-type: none"> Focused on fulfilling the role of each one's own department 	<ul style="list-style-type: none"> Integrated R&D Management (3→1 Division) Pursue the results creation throughout the Company, centered on the integrated R&D organization

The policy of Right target, Right plan, Right action applies not only to cancer but also to CNS. Until now, for example, when verified in a large comparative study, the results were not known until the unblinding. Rather, we will continue our research and development in areas other than oncology, while firmly confirming efficacy signals even in small diseases. At the same time, the unification of the R&D and Technology Research Divisions into a single entity was a major highlight of the December structural reform. We would like to pursue efficiency and results creation.

4. To Maximize the Value of Internal Portfolios

- Maximize the value of internal portfolios through appropriate means, whether developed internally or through external partnerships
- Continually nurture pipelines while reducing the company's cost burden

1. Partnerships to maximize value utilizing internal development capability (co-development, etc.)

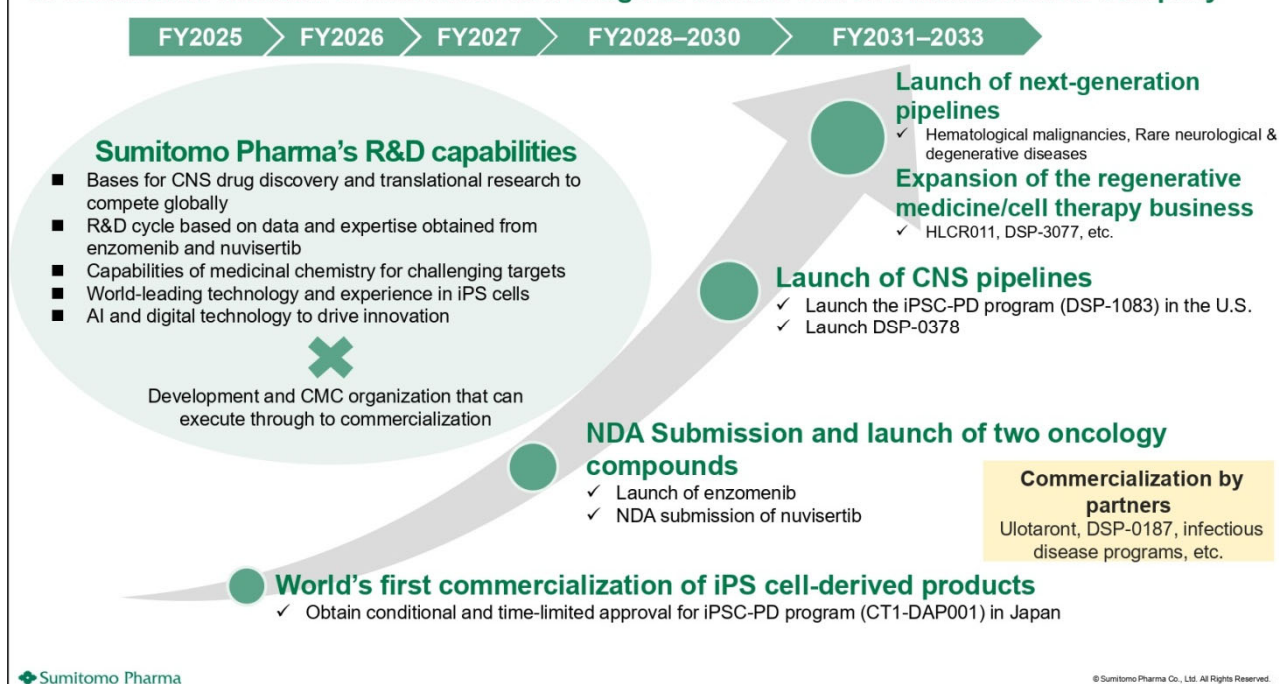
Areas	Disease Focuses (or businesses)	Policies
Oncology	Hematological malignancies	<ul style="list-style-type: none">• Achieved initial POC for the two oncology compounds• Maximizing product value through partnerships
CNS	Neurological rare/degenerative diseases	<ul style="list-style-type: none">• Aiming to obtain initial POC with a compact development strategy• Considering partnerships to maximize product value
	Regenerative medicine/cell therapy business	<ul style="list-style-type: none">• Reorganization with Sumitomo Chemical has been completed<ul style="list-style-type: none">✓ Secure stable funding for R&D and capital investments✓ Proactively participate in development and accelerate commercialization through group synergies

2. Alliances leveraging partner's late-stage development capabilities (out-licensing, etc.)

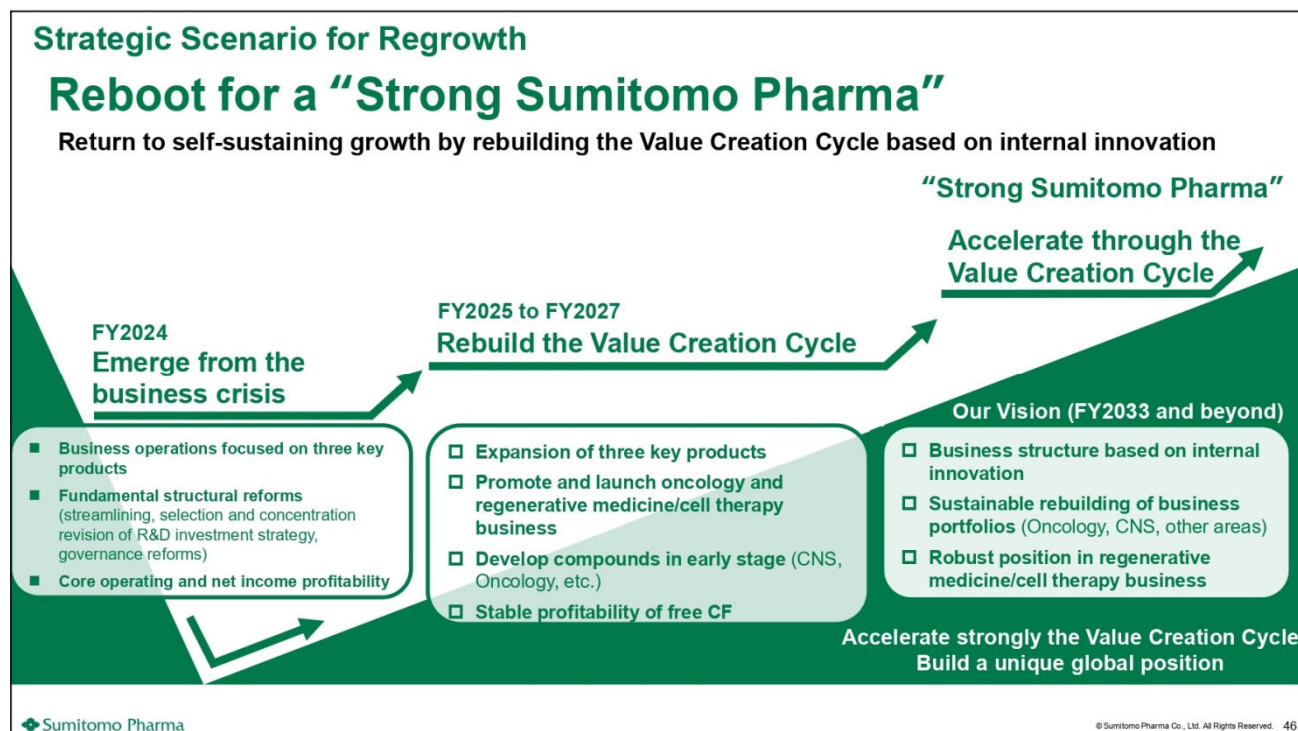
Infectious diseases, existing pipelines outside disease focuses, etc

We show you how to maximize the value of our portfolio in oncology, CNS, and regenerative medicine. This has already been mentioned, so I will skip it.

5. Continuous Creation of Innovative New Drugs as an R&D-Driven Pharmaceutical Company



As an R&D-oriented firm, we will do our best.



Finally, we are considering three steps in the restart toward a strong Sumitomo Pharma.

First of all, we have almost achieved our goal of getting out of the business crisis. Next, while reforming the Company to ensure that the value creation cycle rotates strongly, we will work to expand our three key products along with R&D in oncology and regenerative medicine from now until FY2027. After that, we would like to firmly establish our positioning as a global specialized player, which is what we are aiming for. We are considering restarting in these three phases.

I have explained Reboot 2027 above. As I have just mentioned, we will withdraw the current medium-term management plan, and at the same time, we would like to continue the restructuring of the Company in the direction I have explained today.

On the other hand, sales in North America have been very strong. We have a major milestone ahead of us this year, in FY2025. Once these are clarified, we would like to prepare a more elaborate mid-term management plan and present it to you.

That is all I have to say.

Kino: Thank you very much, Dr. Kimura.

Question & Answer

Yamaguchi [Q]: I am Yamaguchi from Citigroup Global Markets. I would like to briefly ask you a few questions.

You told us about the mid-term management plan, the partnership in enzomenib, and the prompt launch, which is likely to move the corporate value in the short-term. Regarding the partnership, you have a sales team in the US, and of course, I don't think you are going to go into partnership for all products. Could you first tell us what you are aiming to achieve through this alliance in Japan and the US, and how you plan to distribute profits as a result?

Kimura [A]: Naturally, it depends on the partner, but we would like to share the up-front and R&D costs in the alliance. On the other hand, in terms of commercialization, as you have just mentioned, our target markets are Japan and the US, so we would like to sell our products there. We hope to have such partnership.

Yamaguchi [Q]: Is the timing set already? I believe it was described as the current fiscal year.

Kimura [A]: Our R&D expenditures are sufficient for our current activities, but as you know, our R&D investment will continue to grow. We would like to do R&D with partners in the next year and beyond. We are aiming for the end of this fiscal year or H2 of this fiscal year. However, we need to consider the convenience of the other party, so we are considering the possibility of a slight extension.

Yamaguchi [Q]: I understand. This time, you spoke about the next three years. We have received the figures for the fiscal year ending March 31, 2026, but what will happen in the three years through the fiscal years ending March 31, 2027, and 2028? In particular, you said that fundamentals are expected to be positive in the fiscal year ending March 2026, but there will be temporary ups and downs. It is probably a little early to ask this, but beyond that, will there be no one-time revenue, and profit will grow mainly through the core business in the US? Or are the ups and downs expected to continue?

Kimura [A]: Thank you very much. We believe that the sale of the Asian business will be the last major one-time proceeds from the sale. So, we intend to make a good profit from our own products in the fiscal year ending March 2027. Sales of the three products are performing very well compared to our initial forecast, which we hope would make up for it.

Yamaguchi [Q]: Thank you. Finally, could you briefly tell me about the relationship between dividends and interest-bearing debt, which was mentioned on the same slide? Is one threshold when interest-bearing debt falls below JPY200 billion, or is that not necessarily the case?

Kimura [A]: They are not linked. We want to reinstate dividends and reduce interest-bearing debt, both of which are independent of each other. First of all, we would like to strike a balance by discussing with our shareholders what priorities we should give to the banks from which we have borrowed money, as well as to other parties.

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

Wakao [Q]: My name is Wakao from JPMorgan. Thank you for your explanation. First of all, please tell us about the results for the three key products in the Q4 and the forecast for this fiscal year.

I believe there has been a positive impact of Medicare Part D from in Q4. I would love to know how the gross-to-net is improving. Especially in light of the performance in Q4, I would say that the forecast for ORGOVYX

for the current fiscal year is somewhat underwhelming, and I believe perhaps it has the potential to go a bit higher.

For GEMTESA, on the other hand, it is difficult to understand actual revenue from the prescription trend. I believe that the high earnings forecast probably had a lot to do with the improved gross-to-net. In light of these points, could you please tell us about your projections for the three key products?

Kimura [A]: First, I will give a brief explanation, then Dr. Nakagawa will elaborate.

Regarding ORGOVYX, as you mentioned, the insurance system, a very perfect measure for us, will be implemented this year, which will reduce the burden on patients.

There has been a significant change in the trend since January, and I think the difference can be read quantitatively. Dr. Nakagawa will comment on this later.

For GEMTESA, the current figure is mainly due to the improvement of GTN. We are not particularly concerned about the lack of volume growth because Medicare coverage is now temporarily reduced. Dr. Nakagawa, do you have any additions?

Nakagawa [A]: I am Nakagawa, in charge of North America. I cannot go into more detail at this stage than Dr. Kimura has just explained. There will be no major changes to the pricing strategy for ORGOVYX in Q4, or before, or in FY2025.

Certain improvements resulting from changes in IRAs are, of course, working in our favor starting in January 2025. While maintaining this, we would rather take advantage of the ease of use of this drug. The characteristics we have been advocating have led to more and more prescriptions, and the number of new patients has been increasing very steadily. Basically, we calculated a strong sales forecast for FY2025 based on such volume strength.

On the other hand, the change in the IRA for GEMTESA, which began in January of this year, is working in our favor in terms of price. In this regard, we are considering whether to focus on price, being listed in the formulary, volume, or market share in order to achieve the best balance.

We would like to refrain from disclosing detailed figures. Through such strategies, we hope to achieve the significant increase in sales in FY2025 that I explained earlier.

As we have informed you, the various effects of the Executive Order are naturally not taken into account at this time. We have determined that nothing can be considered from the information available at this time.

Wakao [Q]: Thank you very much. Could you tell us quantitatively how much the gross-to-net is improving?

Nakagawa [A]: I am sorry. We have always refrained from giving such figures by quarter. We would like to keep that information within the Company.

Wakao [Q]: Regarding ORGOVYX, if the gross-to-net is improving and the trend of the volume in Q1, which was quite strong, continues, your plan looks conservative. If there is anything wrong with that concept, could you please point it out? As for GEMTESA, what is your volume forecast for this fiscal year?

Nakagawa [A]: First of all, ORGOVYX was very strong, at least in Q4. We are also seeing some very good figures in April, although still at the preliminary level. I don't think the FY2025 forecast is conservative, but I would like to review it at the appropriate stage based on the latest information.

You asked about the volume of GEMTESA. As I mentioned earlier, we will be looking at the situation and making a strategic decision on whether we should pursue price or volume.

Of course, we have included certain figures in our budget, but we would like to refrain from disclosing them. Rather than just increasing market share and volume, as I mentioned earlier, we would like to consider a variety of options, including price. This is not a straightforward answer, but we hope you understand the situation.

Wakao [Q]: Thank you very much. The second is a similar theme. According to Dr. Kimura's explanation earlier, the JPY250 billion in the medium-term management plan does not factor in the recent strong performance. So, can you expect to exceed the JPY250 billion if the current situation continues?

Nakagawa [A]: I will answer this as well. Yes, when we made this plan, we did not fully factor in the very strong January to March situation. We will make every effort, both strategically and operationally, to somehow surpass this.

Wakao [Q]: Thank you very much. Finally, in terms of changes in the external environment, I would like to ask about the impact of US tariffs. For example, if a 25% tax rate were applied to pharmaceuticals, what would be the expected impact? What will be the impact regarding yesterday's Executive Order? In fact, I believe the three key products are much higher than their original prices, is that understanding correct?

Kimura [A]: I will answer your question. First of all, it is difficult to make a decision related to tariffs, as the situation changes in many ways. Assuming the 25% condition you just mentioned, it could have an impact of about JPY1.5 billion, as we are actually doing all kinds of things for our supply chain. That would not be a very significant impact. Therefore, we have not incorporated the impact of tariffs in our forecast for FY2025.

As for the Executive Order, as you said, we are analyzing it, but it is very vague and abstract. We will keep a close eye on when and in what form this will be implemented and how it will affect our business.

He seems to comment that prices are high in the US or low in Japan and Europe. We will keep a close eye on the future trend. In terms of actual selling price, the price at which the drug is passed on to the patient in the US may be somewhat higher, but that is not something that the drug companies can control. I think this is a very difficult problem to solve.

Wakao [Q]: I understand. It seems that within the next 30 days, each pharmaceutical company will receive some sort of notice. In response to this, are there any factors that your company can work on in the short term regarding price?

Kimura [A]: We don't have, specifically. In our business in the US, we determine the publicly listed wholesale price ourselves, which is called the WAC price, but then there are costs for middlemen and large rebates. Therefore, I would like to mention that prices are never changed by a single voice of a pharmaceutical company.

Wakao [M]: I understand very well. Thank you very much. That is all.

Muraoka [Q]: I am Muraoka from Morgan Stanley. In your earlier explanation about tariffs, you said that even if a 25% tariff were applied, it would only affect by about JPY1.5 billion. Does this mean that the three key products are mainly manufactured in the US, and some materials are imported from outside the US?

Kimura [A]: This is very complicated and difficult to explain in a few words. We import raw materials, etc., to the US, but we do not import products. We also have products that are manufactured in the United States.

Muraoka [Q]: Yes. So, in a nutshell, you can say that the ratio of US manufacturing is quite high.

Kimura [A]: Yes. That's it in a nutshell. Although the percentage of sales in the US is very high, the impact of tariffs on our company is very small.

Muraoka [Q]: By the way, what has been the Medicare to Medicaid ratio for ORGOVYX and especially GEMTESA, and what do you expect it to be this year? There may have been several references to this in the past.

Kimura [A]: I have explained the payer mix briefly so far. Roughly speaking, Medicare accounts for around two-thirds of the total for both ORGOVYX and GEMTESA.

Muraoka [Q]: Is the Medicaid ratio small?

Kimura [A]: The Medicaid ratio is very small.

Muraoka [Q]: I understand. Thank you very much. Let me confirm about slide 32. I have read that you are saying that core operating profit will be more than JPY25 billion in FY2027 and beyond. Or is it FY2028?

Kimura [A]: You got that right. It means that we will reach JPY25 billion in FY2027 and will not fall below at least that amount after that. In the sense that we will not repeat the very severe performance of the year before last, FY2023, we have indicated that we would like to set a standard of JPY25 billion to manage the financial performance.

Muraoka [Q]: I understand. Is the statement that the dividend will be resumed at the appropriate time an implication that the dividend will be resumed after FY2027, although it will be difficult to resume by FY2027?

Kimura [A]: We do not intend to make such a strong statement. We have indicated that we would like you to be patient in FY2025, but that we would like to consider very seriously reinstating the dividend in FY2026 and beyond, whether it is feasible or not.

Muraoka [Q]: I understand. The basic assumption for this is JPY250 billion for the three key products. I have asked several times before, but it appears that the milestone that is triggered when the second round of ORGOVYX achieves USD1 billion is not included in this JPY25 billion.

Although that figure is included in FY2028 and beyond, given the strong performance in January to March and April, is it possible that a second milestone will be added in FY2027?

Kimura [A]: Thank you for your very perceptive point. The next major milestone is the promise to Pfizer of USD1 billion in a calendar year. This is USD325 million, which, of course, depends on the exchange rate, but in yen terms it is around JPY50 billion.

We have not included it in our current plans, but we will work to make that happen as soon as possible. Looking at how well the last couple of months have been going, I don't think it is unrealistic to imagine that this can be accomplished quickly. As I said, we would like to plan based on a clear assessment of what the trend will be and incorporate those figures when we announce what we would call a medium-term management plan.

Muraoka [Q]: I understand. Sorry, just one last question. So, there may be upside in FY2027, but in FY2026, which is not mentioned here, there will be rebounds of various factors, and profits will decrease slightly?

Kimura [A]: We would like to avoid that, but we are expecting a gain of JPY45 billion from the sale of our Asian business in the current fiscal year, and we think it will be difficult to make a profit of JPY45 billion from something in the next fiscal year. So, while profits will probably decrease a little, we will make every effort not to decrease them significantly.

Muraoka [M]: I understand. Thank you very much. That is all.

Barker [Q]: I'm Stephen Barker from Jefferies. Thank you very much.

I would like to ask about the joint venture of the Asian business on page seven. In this pie chart, the overall value appears to be about JPY100 billion, of which the orange portion to be about JPY15 billion. How should this be interpreted? Does this mean that the Company expects to generate about JPY15 billion in profits from exports to Asia over the next three years?

Kimura [A]: This is just an image, so it is hard to explain quantitatively. We naturally place a margin on the supply of our products, and we expect to receive some income from this. Depending on sales, we believe profit will be generated. I don't think this appears to be JPY15 billion, but if it appears to be JPY15 billion, I think I owe you an apology.

Barker [Q]: So, you are saying that it will not reach JPY15 billion?

Kimura [A]: No, that is not what I meant. This is just an image.

Barker [Q]: I understand. On page six of the Supplementary Financial Data, the sales forecast for the Asia segment for this fiscal year is about JPY21.1 billion. I assume that business will remain the same until H1, but please tell us what kind of sales we can expect from product supply in H2 and beyond. This is about the contents of the JPY21.1 billion.

Kimura [A]: I can't give you any details because it would cause trouble for the customer if you knew the price of the product supply. The four-month forecast for April, May, June, and July includes the sales of products as they are under the current business structure. We hope you understand that from August onward, we disclose the projected amount of product supply.

Barker [M]: I understand. Thank you very much. That is all.

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Thank you. First of all, I think you mentioned that over the past year or so, you have been discussing what kind of company you would like to become in the future, given that the number of people has decreased considerably and the number of pipelines has also decreased.

On page 46, you show us what you are aiming for in FY2033 and beyond. Am I correct in understanding that what is written here has not changed much from what your company has always aimed for, and that you are in a condition that you are able to continue to aim for that?

Kimura [A]: Qualitatively, it is as you just said. We would like to establish a firm positioning in certain areas and products not only in Japan but also overseas.

For example, we have given up on our presence in China and Asia. In terms of cutting the development pipeline, the number of products that can demonstrate positioning may also be slightly reduced. However, qualitatively, we want to be a company that has a strong presence in the US and Japan as an R&D-oriented pharma company.

Hashiguchi [Q]: Although the number of pipelines has been reduced as you rebuild the value creation cycle, do you ultimately aim to become a pharmaceutical company with a certain depth of pipeline of projects from early to late stage, as you once did?

Kimura [A]: Yes, that's right. We aim to be a company that can do everything in-house from early to late stage. We believe that it will be difficult to run a number of late-stage programs in-house, especially at this size. So,

we would like to use the two cancer products as a touchstone and combine them with a partnering strategy. We will do the initial development in-house.

There are some programs that we have not been able to introduce to the outside world, and are now forcing us to stop. We have a number of very promising non-clinical programs at the late stage lined up. We are maintaining that and hope to bring it back as soon as possible.

Hashiguchi [Q]: Thank you very much. Second, I would like to confirm the definition of core operating profit of JPY25 billion for FY2027. You mention excluding one-time factors; what do they include? I don't think it's something like the JPY45 billion gain from the transfer of the Asian business this quarter, for example.

Are the sales milestones coming in from Pfizer not a one-time factor? For example, I would appreciate it if you could sort out to some extent which of the pipelines that are in the late stage are temporary factors and which are not.

Kimura [A]: To give an example from this quarter, The lump-sum recognition of deferred revenue for MYFEMBREE is a one-time factor, and the sale of the business is also a one-time factor. Sales milestones are also a temporary factor.

I hope you understand that excluding one-time factors here means, for example, the gains from ORGOVYX, GEMTESA, and MYFEMBREE.

Hashiguchi [Q]: I understand very well. Thank you very much. Finally, I would like to ask you about the data in the paper published in Nature this time regarding the iPS cell-derived products for Parkinson's disease. I believe Nature also published the results of a clinical trial of a very similar concept of ES cell-derived product.

I don't think it is fair to compare them, since the number of cases is still quite small in both cases. However, the numbers looked better in terms of efficacy and safety, and the other side is already conducting tests on frozen cells. In that sense, I felt that that might have a slight advantage in terms of development progress. What do you think of your company's competitiveness against the product with such similar concepts that other groups are developing?

Kimura [A]: It is a very similar-sized clinical trial as you mentioned. This is being implemented by an American venture called BlueRock, and at first glance, the effect looks good. But in reality, the demographics of the enrolled patients are different. The Kyoto University trial is targeting patients who are considered by experts to be less likely to benefit.

For example, I am now showing you imaging data that indicates whether dopamine is being produced in the brain. The Kyoto University trial has such very solid data, but the trial of the other part has not yielded very good data.

I don't think it is easy to decide between the two, but if you look at the details, I believe that the Kyoto University trial has better results in terms of safety. In any case, it is not that one is better or worse than the other, since enrolled patients are very few.

We are currently running clinical trials in North America for both live and frozen cells. We would like to look at that and make a firm decision on which is more advantageous. It is true that frozen cells are easier to distribute, but our stance is that it is necessary to carefully assess whether it is advantageous or not.

Hashiguchi [Q]: Do you mean that there is a possibility that frozen cells are not necessarily advantageous in a commercial sense?

Kimura [A]: Yes, that's right. I would like to say out loud that I would only say this with the word "not necessarily." Frozen cells have a lower rate of viable cells, and the thawing required for actual use is not as easy. If someone unfamiliar with the process does this, it can cause problems. Therefore, I think it is necessary to conduct a thorough verification, including actual clinical use, in the future.

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

Fumiyoshi Sakai [Q]: My name is Sakai from UBS. Regarding the balance sheet, at the end of March, you had about JPY260 billion in long-term debt and JPY46 billion in short-term debt remaining. In Dr. Kimura's explanation of financial targets, he said that this figure is just an image. In other words, you will reduce roughly JPY100 billion by FY2027. It says that it will be reduced to less than JPY200 billion, although I am not sure how much less.

Now, there was talk of a lump sum or a gain on the sale. Will the JPY100 billion be repaid in the normal cash flow?

In addition, the redemption of subordinated debt is expected in FY2027. Is this JPY200 billion figure after redemption of subordinated debt?

Kimura [A]: Thank you for your question. I will explain first, and then Mr. Sakai would like to add a few more details.

First, you are correct that there is a JPY100 billion difference between the JPY200 billion and the current JPY300 billion. Our goal is to reduce that JPY100 billion over the next three years.

However, this by no means that we will do that only with non-temporary income. Every cash-in will be utilized for it. One thing that can explain the current situation is the gain from the sale of the China and Asia businesses that will be recorded this fiscal year. Many of those items would also be used to repay loans. Mr. Sakai, do you have anything to add?

Motoyuki Sakai [A]: Regarding funding sources, as Dr. Kimura just explained. The income from the sale of businesses that have already been sold, or those that have not yet technically been sold but will be sold in the future, will also be used as a source of funds. As I mentioned earlier in relation to the R&D theme, we believe that the cash returned by the partnership could also be a source of funds.

JPY200 billion or less means total interest-bearing debt of JPY200 billion or less. So, it is not intended here what to return, including subordinated debt. We want to reduce interest-bearing debt to less than JPY200 billion.

We additionally assume that at that level, the debt-to-equity ratio will also be below one.

Fumiyoshi Sakai [Q]: I understand. Does that mean that that will be one of the benchmarks for resumption of dividends in the foreseeable future?

Kimura [A]: If we say that it is a benchmark, analysts will write the timing of the resumption of dividends based on it, so I would like to refrain from saying that. Naturally, the amount of debt would be one indicator for considering the timing of resumption of dividends, but we would also consider other factors, such as how stable the business situation is. I hope you understand that this is by no means the only indicator.

Fumiyoshi Sakai [Q]: I understand. Dr. Kimura is an expert, so I dare to ask this. After various failures with anti-cancer drugs in the past, you are now in a situation where two drugs are about to move forward.

Has anything changed significantly in your company's R&D, especially in drug discovery, during this process? After all, I think that the development of anticancer drugs is still a process that requires very detailed exploration.

Is there some kind of learning effect that is visible and shared within the Company? You mentioned earlier that you have changed the structure. Does that mean that research and development are now integrated?

Kimura [A]: It is very difficult to answer in what way. To put it crudely, in the past, we have run as fast as we could to get a big hit. Now, as written, we are thoroughly considering the results of individual patients or individual trials in detail and thinking scientifically, with experts, without wishful interpretation.

In particular, enzomenib, one of the two cancer products, is, fortunately or unfortunately, a target with which several companies are competing. It is by no means the wrong target. In looking at the data objectively, there is data from industry people and clinical doctors, and of course, there are websites where multiple agents are compared under clinical doctors, and such information can be taken into account.

Regarding nuvisertib, we are working with GSK on one of the current combination studies. The evaluation is being conducted not only by our own eyes, but also by the eyes of experts from other companies. The movements of individual patients are also naturally checked. There is no way to explain it other than that we are doing it in such a pragmatic way.

I can tell you that replacing the leadership of cancer development has had a very significant impact on the culture and other aspects of the Company. I apologize that all of this information is qualitative.

Fumiyoshi Sakai [Q]: I understand. I have the impression that it was tightened up because you are doing it on a tight budget. I hope you will be able to achieve results.

One thing, is the Medicare percentage for MYFENBREE zero?

Kimura [A]: I have heard that Medicare patients do not use MYFEMBREE very often. Dr. Nakagawa, do you have anything to add?

Nakagawa [A]: I think you are right. Medicare is for patients 65 years of age and older, and patients with endometriosis and uterine fibroids, which are the indications for MYFENBREE, are much younger. So, while it is not zero, you can assume that the percentage is close to zero.

Fumiyoshi Sakai [M]: Thank you very much.

Wakao [Q]: My name is Wakao from JPMorgan. For the second time, I would like to ask questions. Tell us about your development products. First, enzomenib and nuvisertib are included in the list of drugs with which you have external partnerships. By partnership in nuvisertib, do you mean the partnership with GSK? Or do you mean that you will sign a contract with GSK as the development progresses?

Kimura [A]: First of all, one of the two combination studies we are running with nuvisertib is with momelotinib, which we are doing with GSK. We are working with GSK on this.

Naturally, GSK will see that data very quickly, but there will be no obligations about future development policies and partnership strategies. Naturally, partnering with GSK is one possibility, but it is not limited to GSK.

Wakao [Q]: I understand. Thank you very much. Another question is about iPS. I was under the impression that it was proven to be safe after all. On the other hand, it seems difficult to say that it is highly effective because of the small number of cases compared to existing drugs.

I would like to ask what kind of iPS positioning you are aiming for. Also, what is the current status of this in Japan? I believe that you will now apply for approval with conditions and time limits. Have there been no prior consultations with the MHLW and PMDA? Let me confirm this point.

Kimura [A]: I will answer your second question first. Strictly saying, a SAKIGAKE Comprehensive Evaluation Consultation is currently underway. You can find out what a SAKIGAKE Comprehensive Evaluation Consultation is. This is a sort of pre-screening process.

After that is done, the application is submitted, and if all goes well, it will be approved. The SAKIGAKE Designation System has a time clock of six months, so you can get your application approved sooner than usual.

On the other hand, we will communicate with them in advance through a SAKIGAKE Comprehensive Evaluation Consultation. Although this is not a review, a procedural step similar to a review will proceed.

Regarding the position of regenerative medicine for Parkinson's disease, all existing drugs or therapies for Parkinson's disease lose their effectiveness as the patient's dopamine nerves degenerate and drop out. All of them are. Ultimately, the patient suffers from a very difficult situation.

Cell transplantation is, in principle, the process of transplanting another dopaminergic nerve when it is dying or has died. As the patient's symptoms are alleviated, the medication becomes more effective again. The description in the Nature article is also very technical and difficult to follow. The patient's symptoms improve significantly when the drug is not present, and at the same time, the patient's symptoms improve again when the drug is added.

That does not cure everything, and it varies from patient to patient. This is a new treatment option offering, totally different in nature. Once administered, the effect lasts for years. The trial has been following patients for two years, and the drug has been effective for patients for the entire two years.

Wakao [Q]: Thank you very much. I thought I understood the concept itself, but I was under the impression that it would not end up replacing it because its effectiveness was not necessarily high. I understood it very well.

After all, has the publication in Nature this time advanced the steps toward applying for the SAKIGAKE Comprehensive Evaluation?

Kimura [A]: I think it was a tailwind in the sense that many people became interested in it after it was published in Nature, or expectations were very high, including from patients.

However, the review itself does not review Nature papers. Nature's data is data we have known for more than a year, and I believe a rigorous review will proceed based on it.

Wakao [Q]: I honestly wasn't sure if there were any changes in the consultation, since the data itself seems to be the same all the time. Steadily, you are advancing various discussions regardless of Nature.

Kimura [A]: Yes, that's right. However, because the approval was conditional and time-limited, the Japanese PMDA was highly criticized by foreign regulatory authorities and professional journals, particularly Nature. So, Nature was the spearhead of the criticism. I imagine that it must have been psychologically very significant for the authorities to have that Nature magazine look at the results of the other Japanese trial besides ours and say something like, although the number of cases is insufficient, it shows one scientific suggestion.

Wakao [M]: I understand. Thank you very much. That is all.

Kino [M]: This concludes the presentation on Sumitomo Pharma's FY2024 financial results and Reboot 2027 - Reboot for a Strong Sumitomo Pharma. Thank you very much for your participation today.

[END]