



Sumitomo Pharma Co., Ltd.

Q1 Financial Results Briefing for FY2024

July 31, 2024

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.	
[Company ID]	4506-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Q1 Financial Results Briefing for FY2024	
[Fiscal Period]	FY2024 Q1	
[Date]	July 31, 2024	
[Time]	17:00 – 18:12 (Total: 72 minutes, Presentation: 15 minutes, Q&A: 57 minutes)	
[Venue]	Webcast	
[Number of Speakers]	7	
	Toru Kimura	Representative Director, President and CEO
	Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Corporate Governance; Human Resources; Global Finance Administration
	Tsutomu Nakagawa	Member, Board of Directors, Executive Officer
	President and CEO, Sumitomo Pharma America, Inc.	
	Yoshiharu Ikeda	Managing Executive Officer Drug Research Division Head of Japan Business Unit
	Naoki Noguchi	Executive Officer Corporate Governance; Corporate Communications Vice President, Head of Corporate Communications
	Yutaka Wakemi	Executive Officer Global Corporate Strategy; Global Finance Vice President, Head of Global Corporate Strategy
	Koji Ishida	Vice President, Head of Global Finance
[Analyst Names]	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Seiji Wakao	JPMorgan Securities Japan
	Hidemaru Yamaguchi	Citigroup Global Markets Japan
	Fumiyoshi Sakai	UBS Securities Japan

Presentation

Noguchi: We will now begin the presentation of financial results for Sumitomo Pharma Co., Ltd. for Q1 of fiscal year 2024. Thank you very much for joining us today.

This presentation will be webcast live via Zoom webinar from our Tokyo headquarters.

After the presentation in accordance with the financial results briefing materials posted on our website, there will be time for a Q&A session.

First of all, I would like to make an announcement and request to all of you. Please help us by changing the attendee information displayed on your Zoom screen to your company name and name.

Let me now introduce today's attendees. Dr. Kimura, President and CEO; Mr. Sakai, Executive Vice President; Dr. Nakagawa, Member of Board of Directors, Executive Officer; Dr. Ikeda, Managing Executive Officer; Mr. Wakemi, Executive Officer; Mr. Ishida, Vice President, Head of Global Finance; and finally, I am Noguchi, the moderator. Thank you.

Dr. Kimura will now present the Q1 results for FY2024 and the current status of clinical development.

Dr. Kimura, thank you.

Kimura: Kimura here. I am pleased to present our financial results for Q1 of fiscal year 2024. Thank you for joining us today. I would also like to express my sincere appreciation for your continued interest in our Company's management.

Then, based on the presentation materials, I will report on the business performance and the current status of clinical development for Q1 of this fiscal year.

Business Operation Policies and Initiatives for Regrowth

- **Expanding revenue** In order to maximize the value of the three key products (ORGOVYX®, MYFEMBREE®, GEMTESA®) early, aim to achieve revenue of approx. 130 billion yen from the combined sales of the three key products in FY2024
⇒ Total revenue of the three key products shows strong progress towards meeting the plan as of Q1 FY2024
- **Reducing costs** The Group will make concerted efforts to accelerate streamlining by increasing efficiency in organizational operations and trimming costs to the minimum
 - ✓ North America segment: Structural reforms (workforce reduction) have been completed in FY2023
 - ✓ Japan segment: As part of the structural reform for Japan business reconstruction, the Company decided to implement an early retirement program⇒ SG&A and R&D expenses in each segment are progressing as planned as of Q1 FY2024
- **Securing seeds for future business growth**
 - ✓ Promote two development programs (TP-3654, DSP-5336) in the Oncology area and the regenerative medicine/cell therapy development program (CT1-DAP001/DSP-1083 for Parkinson's disease), which are expected to bring product creations to market during the period of the Mid-term Business Plan 2027
 - ✓ Continue to invest in HLCR011 for retinal pigment epithelium tear, SMP-3124 for solid tumors, DSP-3077 for retinitis pigmentosa, and other programs that are a part of seeds for future business growth⇒ Started NDA submission preparation for CT1-DAP001/DSP-1083 in Japan and signed a clinical collaboration agreement with GSK to evaluate the combination of nuvisertib (TP-3654) with momelotinib* in a Phase 1/2 study (refer to page 14 for details on Major Progress in Clinical Development)

* Therapeutic agent for myelofibrosis with inhibitory effects on JAK1, JAK2, and activin receptor type 1

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Please see page three. The following is a summary of our business operation policies and initiatives for regrowth, along with the progress made up to the end of Q1 of this fiscal year.

We consider turning core operating profit positive as a must-achieve goal in order for the Group to initiate regrowth in this fiscal year, and is implementing various measures with the entire Company united under the policies of (1) Expanding revenue, (2) Reducing costs, and (3) Securing seeds for future business growth. I am pleased to report that we have made progress Q1 of this fiscal year on the initiatives based on our three policies, as indicated by the green arrows in the chart.

First of all, the expanding revenue is progressing strongly against the plan, especially in ORGOVYX.

As for reducing costs, the Group is making concerted efforts to accelerate streamlining by increasing efficiency in organizational operations and trimming costs to the minimum. As announced today, we have also decided to offer an early retirement program in Japan.

I will explain about securing seeds for future business growth later in the R&D part.

Financial Results for Q1 FY2024

Financial Results for Q1 FY2024 (Core Basis)

The forecasts are not revised

	Q1YTD FY2023 Results	Q1YTD FY2024 Results	Change			FY2024	
			Value	FX impact	%	May 14 forecasts	Progress %
Revenue	75.7	90.7	15.0	7.2	19.8	338.0	26.8
Cost of sales	30.4	34.9	4.5	2.5	14.9	138.0	25.3
Gross profit	45.3	55.7	10.5	4.7	23.1	200.0	27.9
SG&A expenses	61.8	43.8	(18.0)	3.8	(29.2)	169.0	25.9
R&D expenses	22.8	12.8	(10.0)	0.6	(43.8)	50.0	25.6
Other operating income/expenses	5.9	(0.0)	(5.9)	—	—	20.0	—
Core operating profit	(33.5)	(0.9)	32.6	0.0	—	1.0	—
Non-recurring items (negative number indicates net expense)	(18.1)	(2.2)	15.9	—	—	(1.0)	—
Operating profit	(51.6)	(3.1)	48.5	—	—	0.0	—
Finance income/costs	20.5	20.3	(0.2)	—	—	(18.0)	—
Profit before taxes	(31.1)	17.2	48.3	—	—	(18.0)	—
Income tax expenses	7.8	1.3	(6.5)	—	—	(2.0)	—
Net profit	(38.9)	15.9	54.8	—	—	(16.0)	—
Net profit attributable to owners of the parent	(38.9)	15.9	54.8	—	—	(16.0)	—

- Revenue increased due to the growth of three key products, etc.
- SG&A expenses and R&D expenses decreased significantly due to the effects of business structure improvements and reductions through selection and concentration of R&D investments
- Other operating income/expenses:
 - Q1 FY2023: Share transfer of Sumitomo Pharma Animal Health Co., Ltd.
- Non-recurring items:
 - Q1 FY2024: Business structure improvement expenses in North America
 - Q1 FY2023: Business structure improvement expenses in North America

Average rates:
Q1 FY2023 Results : 1US\$ = ¥137.50, 1RMB = ¥19.57
Q1 FY2024 Results : 1US\$ = ¥155.86, 1RMB = ¥21.48
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 June 2024 : 1US\$ = ¥161.03, 1RMB = ¥22.05

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Next, page four. We are pleased to report our Q1 financial results. This is shown on an IFRS core basis.

First, revenue was JPY90.7 billion, a YoY increase of JPY15 billion. Revenue increased due to growth in sales of three key products in North America and the effect of foreign currency translation resulting from the yen's depreciation.

SG&A and R&D expenses decreased YoY by JPY18 billion and JPY10 billion, respectively. This is due to the effects of business structure improvement in North America and reduced R&D investment.

Core operating loss was JPY900 million, a significant YoY decrease. This is due to increased revenues and decreased expenses. This figure improved YoY by JPY32.6 billion.

Due to a decrease in business structure improvement expenses associated with the reorganization of group companies in North America, which were recorded as non-recurring items in the previous fiscal year, operating loss improved significantly YoY, resulting in an operating loss of JPY3.1 billion. This represents an improvement of JPY48.5 billion.

Profit before taxes for the quarter was JPY17.2 billion due to a foreign exchange gain of JPY21.5 billion resulting from the depreciation of the yen.

As a result, quarterly net profit attributable to owners of the parent also improved significantly, with a figure of JPY15.9 billion.

Since these are the financial results as of the end of June 2024, please understand that the actual net profit may differ slightly from what was explained today due to exchange rate fluctuation.

As for the annual forecast, revenue is expected to increase in H2 of fiscal year, while SG&A and R&D expenses are expected to decrease from the previous fiscal year.

On the other hand, we are also moving forward with our early retirement program in Japan and are considering business transfers. In addition, due to uncertain factors such as foreign exchange rates, our current policy is to leave the earnings forecast announced at the beginning of the fiscal year unchanged and not to revise the full-year forecast.


Financial Results for Q1 FY2024

Financial Results for Q1 FY2024 (Core Basis) - vs. Q1 FY2024 Plans

Billions of JPY

	Q1YTD FY2024 Plans	Q1YTD FY2024 Results	Change			
			Value	%	FX impact	% (w/o FX)
Revenue	81.2	90.7	9.5	111.7	4.4	106.2
Cost of sales	31.5	34.9	3.4	110.8	1.7	105.4
Gross profit	49.7	55.7	6.1	112.2	2.7	106.7
SG&A expenses	47.2	43.8	(3.4)	92.7	2.3	87.9
R&D expenses	13.3	12.8	(0.5)	96.5	0.4	93.7
Other operating income/expenses	—	(0.0)	(0.0)		—	
Core operating profit	(10.9)	(0.9)	10.0	—	(0.1)	—

Average rates:
 Q1 FY2024 Results : 1US\$ = ¥155.86, 1RMB = ¥21.48
 FY2024 Plans : 1US\$ = ¥145.00, 1RMB = ¥20.00

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Please continue to page five, which shows our performance against the plans for the current Q1 of fiscal year.

Revenues were JPY90.7 billion, representing an achievement rate of 111.7%, or 106.2% in real terms excluding exchange rate differences. All segments, including North America, Japan, and Asia, attained the figures of plans.

SG&A expenses amounted to JPY43.8 billion, representing an achievement rate of 92.7%, or 87.9% in real terms, excluding foreign exchange.

R&D expenses were JPY12.8 billion, 96.5% of the achievement rate, 93.7% in real terms, and below the plan in both SG&A and R&D expenses.

As a result, there was a core operating loss of JPY900 million, a significant improvement over the plan.

Financial Results for Q1 FY2024

Revenue of Major Products in North America

	Q1YTD FY2023 Results	Q1YTD FY2024 Results	Change	Q1YTD FY2023 Results	Q1YTD FY2024 Results	Change			FY2024			
						Value	FX impact	%	May 14 forecasts		JPY-basis Progress %	
North America	Millions of USD			Billions of JPY						Millions of USD	Billions of JPY	
ORGOVYX®	68	108	40	9.3	16.8	7.4	2.0	79.7	400	57.9	29.0	
MYFEMBREE®	13	19	6	1.8	3.0	1.2	0.4	67.7	124	17.9	16.8	
GEMTESA®	63	78	15	8.7	12.1	3.4	1.4	39.3	380	55.0	22.1	
APTIOM®	58	65	7	7.9	10.2	2.2	1.2	27.9	201	29.1	34.9	
RETHYMIC®	11	11	(0)	1.5	1.7	0.2	0.2	13.4	49	7.2	23.6	
Others	12	20	7	1.7	3.1	1.4	0.3	80.2	216	31.6	25.5	
Export products/ One-time revenue, etc. *	33	32	(1)	4.5	5.0	0.5	0.6	11.1				
Total	258	332	75	35.5	51.8	16.4	6.1	46.1	1,370	198.7	26.1	

(Ref.) Achievement rate against Q1 YTD plans for three key products

Million of USD		
Plans	Results	%
86	108	125.5
22	19	88.4
79	78	98.2

- Revenue of three key products increased generally as planned
- Sales of APTIOM® increased due to true-up of rebates, etc.

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

Q1 FY2023	Deferred revenue from the collaboration with Pfizer of \$29M	Q1 FY2024	Deferred revenue from the collaboration with Pfizer of \$29M

Average rates:
Q1 FY2023 Results : 1US\$ = ¥137.50
Q1 FY2024 Results : 1US\$ = ¥155.86



Next, page six, revenue for the North America segment.

In the North America segment, sales of three key products, ORGOVYX, MYFEMBREE, and GEMTESA, as well as APTIOM, increased. In yen terms, sales were JPY51.8 billion, a YoY increase of JPY16.4 billion.

For the three key products, the achievement rate for the current Q1 of fiscal year is shown in the upper right-hand corner. We can see that ORGOVYX is far ahead of plan.

The main breakdown of upfront and milestone income is shown at the bottom of the slide.

I will now give you a few details about the three key products: ORGOVYX, MYFEMBREE, and GEMTESA.

Financial Results for Q1 FY2024



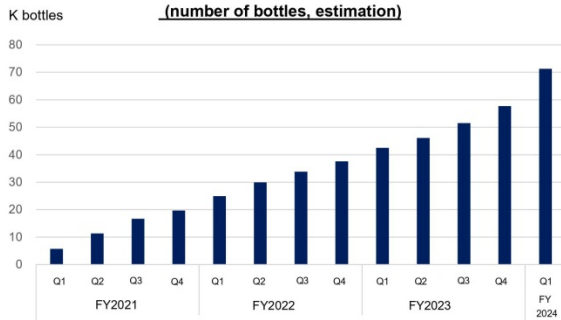
ORGOVYX®

Plan for Q1 YTD FY2024	Actual for Q1 YTD FY2024	YoY comparison	Influence of volume and price against actual (VS plan)	
\$86M	\$108M (125% to plan)	Approx. 59% increase	Volume	\$15M
			Price	\$7M

■ Share in ADT Market¹
 Products Share June 2024: 7% (March 2024: 6%)

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

Quarterly Volume Trends²
 (number of bottles, estimation)



Topic for Sales and Marketing

- Recorded the highest number of new patients starts in May 2024
- Prescription growth has been confirmed in all account segments, with significant growth in Urology Clinics with in-office dispensing and Academic Centers/Integrated Delivery Networks (Oncology)
 - ✓ Continued communication to patients and HCPs about the changes in the medication benefit design for Medicare Part D from Jan. 2024
 - ✓ Focused on driving awareness and education on the updated NCCN guidelines that recognize ORGOVYX® as a recommended ADT option for advanced prostate cancer patients

¹ Internal calculation based on information licensed from IQVIA: NSP Volume for the period 3/1 to 3/31, 2024 and 6/1 to 6/30, 2024 reflecting estimates of real-world activity. All rights reserved.
² Internal calculation

Page seven covers ORGOVYX.

The actual result was USD108 million, compared to a plan of USD86 million. The result is 125% of the figure of plan, with Q1 volume and price impacts as noted. The figures were strong both on a volume and price basis.

As shown in the figure on the bottom left of the slide, volumes continue to expand, mainly due to the impact of changes in the medication benefit design for Medicare Part D.

Regarding the topics of sales and marketing, we are currently focusing on providing information on the revised NCCN guidelines. We are aiming to further increase the volume at academic centers and integrated delivery networks, which account for 50% of the market share for androgen deprivation therapy.

Financial Results for Q1 FY2024



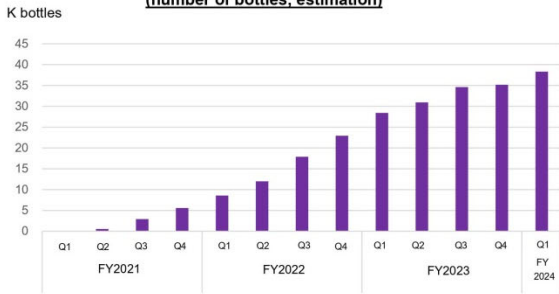
MYFEMBREE®

Plan for Q1 YTD FY2024	Actual for Q1 YTD FY2024	YoY comparison	Influence of volume and price against actual (VS plan)	
\$22M	\$19M (88% to plan)	Approx. 46% increase	Volume	(\$3M)
			Price	\$1M

- Rx Share in Oral GnRH antagonists Market*¹ June 2024
- ✓ TRx 47% (UF²: 87% EM³: 22%)
(Mar. 2024: 44%, 84%, 20%)
- ✓ NBRx 50% (UF: 92% EM: 21%)
(Mar. 2024: 47%, 91%, 20%)

■ Volume grew less than expected due to the lower-than-expected market growth of GnRH antagonists and market share in EM
Price was favorable due to the lower-than-expected Co-pay cards costs

Quarterly Volume Trends⁴
(number of bottles, estimation)



Topic for Sales and Marketing

- Strategy remains focused on attaining share leadership; achieved NBRx share leadership (combined UF and EM) for first time in oral GnRH antagonist market in May 2024
- Launched consumer advertising campaign to coincide with endometriosis awareness month in Mar. 2024 which resulted in a sharp increase in consumer EM-related search and MYFEMBREE® website activity

*1 Source: Symphony Health, an ICON plc Company, Metyls®, June 1, 2024, to June 30, 2024 and March 1, 2024 to March 31, 2024. *2 uterine fibroids, *3 endometriosis, *4 Source: Symphony Health, an ICON plc Company, Metyls®, April 1, 2021, to June 30, 2024.

Page eight covers MYFEMBREE.

We saw a result of USD19 million against a plan of USD22 million for Q1 of fiscal year, 88% of the figure of plan. The figure in terms of volume and price is as described here. The goal has not been achieved in volume terms.

Regarding the topic of sales and marketing, we would like to focus on increasing our market share, especially for endometriosis.

As you can see, on a per-quarter basis, the volume has continued to increase.

Financial Results for Q1 FY2024

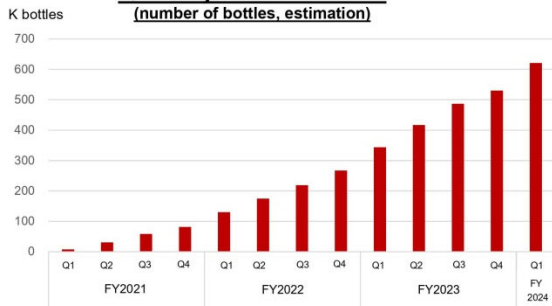


Plan for Q1 YTD FY2024	Actual for Q1 YTD FY2024	YoY comparison	Influence of volume and price against actual (VS plan)	
\$79M	\$78M (98% to plan)	Approx. 23% increase	Volume	(\$3M)
			Price	\$2M

■ Rx Share in β3 Market*1 June 2024
 TRx 28%, NBRx 26% (March 2024: 25%, 35%)

- Volume was generally as planned, but slightly lower-than-expected in non-pharmacy channels
- Price was favorable due to the lower-than-anticipated returns and coverage gap

Quarterly Volume Trends²
 (number of bottles, estimation)



Topic for Sales and Marketing

- GEMTESA[®] volume has continued to grow, reaching all time highs in May 2024 despite the launch of generic mirabegron in Apr. 2024 (No revision to FY2024 forecast as of Q1 FY2024)
- Promoted the fact that GEMTESA[®] has no warnings regarding hypertension because approx. 60% of patients with overactive bladder also have hypertension

*1 This is based on information licensed from IQVIA: NPA for the period 3/1 to 3/31, 2024 and 6/1 to 6/30, 2024 reflecting estimates of real-world activity. All rights reserved.
 *2 Converted pill volume to number of bottles (30 tablets/bottle) based on information licensed from IQVIA: NPA for the period 4/1, 2021 to 6/30, 2024 reflecting estimates of real-world activity. All rights reserved.

Page nine covers GEMTESA.

We saw a result of USD78 million against a plan of USD79 million for Q1 of fiscal year, so the achievement rate is 98%. The figure in volume and price terms is as described here, and we have not attained the plan in volume terms.

Regarding the topic of marketing, as you know, a generic version of mirabegron was launched in April 2024, but no significant impact on sales has been seen as of Q1, with GEMTESA recording record volume in May.

We have not revised our forecast for the current fiscal year because while we expect a decrease in volume due to generics of mirabegron in the future, we expect an upside in price. We will continue to closely examine the impact of generics of mirabegron.

As we have shown in the lower left-hand corner, the increase in volume passed on to the patients has continued on a per-quarter basis.

Financial Results for Q1 FY2024

Revenue of Major Products in Japan & Asia

Billions of JPY

	Q1YTD FY2023 Results	Q1YTD FY2024 Results	Change		FY2024	
			Value	%	May 14 forecasts	Progress %
Japan						
Equa [®] /EquMet [®]	8.2	7.4	(0.8)	(10.0)	26.3	28.0
LATUDA [®]	2.8	3.4	0.5	18.3	13.0	25.9
TWYMEEG [®]	1.2	1.7	0.6	49.6	11.3	15.3
METGLUCO [®]	1.9	1.9	0.0	0.5	7.4	25.9
LONASEN [®] Tape	0.9	1.1	0.2	26.3	4.4	25.5
TRERIEF [®]	4.4	1.5	(3.0)	(67.0)	2.1	69.8
AG products	2.3	2.8	0.5	20.2	11.1	25.3
Others	6.8	5.1	(1.6)	(23.9)	24.7	29.1
Export products/ One-time revenue, etc.	1.9	2.1	0.2	10.4		
Total	30.4	27.0	(3.4)	(11.2)	100.3	26.9
Asia						
MEROPEN [®] (China)	4.4	6.4	1.9	43.0	21.2	30.0
Others	5.4	5.5	0.1	2.3	17.8	31.1
Total	9.9	11.9	2.0	20.6	39.0	30.5

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

Japan

- Sales of LATUDA[®], TWYMEEG[®], and LONASEN[®] Tape continue to grow
- Sales of TRERIEF[®] decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥1.7B)

Asia

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



Page 10 shows revenue from sales in the Japan and Asia segment.

In the Japan segment, revenue decreased by JPY3.4 billion YoY to JPY27 billion. Sales of LATUDA, TWYMEEG, and LONASEN Tape increased, but overall segment sales decreased due to the end of the exclusivity period for TRERIEF and the NHI price revision.

Progress against the full-year forecast is 26.9%, which means that the segment as a whole is almost in line with expectations.

In the Asia segment, overall segment sales increased by JPY2 billion YoY due to the impact of increased sales of MEROPEN in China. Progress against the full-year forecast as a percentage is high at 30.5%.

Financial Results for Q1 FY2024

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
Q1YTD FY2024	Revenue	27.0	51.8	11.9	90.7
	Cost of sales	13.2	18.5	3.2	34.9
	Gross profit	13.8	33.3	8.7	55.7
	SG&A expenses	9.7	31.1	3.0	43.8
	Core segment profit	4.0	2.1	5.7	11.9
	R&D expenses				12.8
	Core operating profit				(0.9)

		Japan	North America	Asia	Total
Q1YTD FY2023	Revenue	30.4	35.5	9.9	75.7
	Cost of sales	14.7	13.0	2.7	30.4
	Gross profit	15.6	22.5	7.1	45.3
	SG&A expenses	12.8	46.2	2.8	61.8
	Core segment profit	2.8	(23.7)	4.3	(16.6)
	R&D expenses				22.8
	Core operating profit				(33.5)

		Japan	North America	Asia	Total
Change	Revenue	(3.4)	16.4	2.0	15.0
	SG&A expenses	(3.1)	(15.1)	0.2	(18.0)
	Core segment profit	1.2	25.9	1.4	28.5
	R&D expenses				(10.0)
	Core operating profit				32.6

Japan

- Despite a decrease in gross profit due to decline in revenue, core segment profit increase due to decrease in selling, general and administrative expenses

North America

- In addition to increase in gross profit resulted from revenue growth, core segment profit increased significantly due to decrease in selling, general and administrative expenses

Asia

- Core segment profit increased owing to increased gross profit due to increased revenue

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Page 11 summarizes financial results by segment.

In the Japan segment, core segment profit increased by JPY1.2 billion to JPY4 billion as a decrease in SG&A expenses in personnel costs exceeded the decrease in gross profit due to lower sales.

In the North America segment, core segment profit increased by JPY25.9 billion to JPY2.1 billion due to an increase in gross profit from growth in three key products and a decrease in SG&A expenses.

In the Asia segment, core segment profit increased by JPY1.4 billion to JPY5.7 billion due to the significant impact of higher gross profit from increased sales.

I would like to continue with an explanation of research and development.

Research and Development

Development Pipeline (as of July 31, 2024)

 : Psychiatry & Neurology
 : Oncology
 : Others

Revisions since the announcement in May 2024 are shown in red

Area	Phase 1	Phase 2	Phase 3	NDA submitted
Japan	DSP-0187 (Narcolepsy)	nuvisertib (TP-3654) (Myelofibrosis)	Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated study)	
	DSP-0378 (Dravet syndrome, Lennox-Gastaut syndrome)	enzomenib (DSP-5336) (Acute leukemia)		
		DSP-0390 (Glioblastoma)		
		SMP-3124 (Solid tumors)		
		KSP-1007 (Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia)		
U.S.	DSP-0038 (Alzheimer's disease psychosis)	nuvisertib (TP-3654) (Myelofibrosis)	Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated study/ Company-sponsored clinical study)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)
	DSP-3456 (Treatment resistant depression)	enzomenib (DSP-5336) (Acute leukemia)		
	DSP-2342 (To be determined)	DSP-0390 (Glioblastoma)		
		SMP-3124 (Solid tumors)		
	KSP-1007 (Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia)			
China			vibegron (Overactive bladder)	
Europe	fH1/DSP-0546LP (Influenza)			

Please see page 13. This section provides an overview of development.

This is a list of the development stages of our development programs, and the changes since May are explained on the next page.

Major Progress in Clinical Development

- **Allo iPS cell-derived products (dopaminergic neural progenitor cells)**
Japan: Parkinson's disease (Phase 1/2)
 - Obtained study results in the investigator-initiated study by Kyoto University, and preparing for NDA submission
- **nuvisertib (TP-3654)**
 - Signed a clinical collaboration agreement with GSK to evaluate the combination of nuvisertib (TP-3654) with momelotinib* in a Phase 1/2 study
- **enzomenib (DSP-5336)**
 - At the European Hematology Association (EHA) 2024 Congress in June 2024, presented the new clinical data from the ongoing Phase 1/2 study as an oral presentation (more details on the next page)
 - Received Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with mixed lineage leukemia rearrangement (MLLr) or nucleophosmin 1 mutation (NPM1m) in June 2024
- **SMP-3124**
Japan: Started Phase 1/2 study for solid tumors

* Therapeutic agent for myelofibrosis with inhibitory effects on JAK1, JAK2, and activin receptor type 1

Page 14 summarizes the progress of clinical development.

In the area of Psychiatry & Neurology, we have obtained the data for the investigator-initiated study for Parkinson's disease conducted by Kyoto University using dopaminergic neural progenitor cells, and are currently preparing to submit an NDA. This program has been designated for “sakigake” rapid review, and we are aiming to obtain approval by the end of the fiscal year.

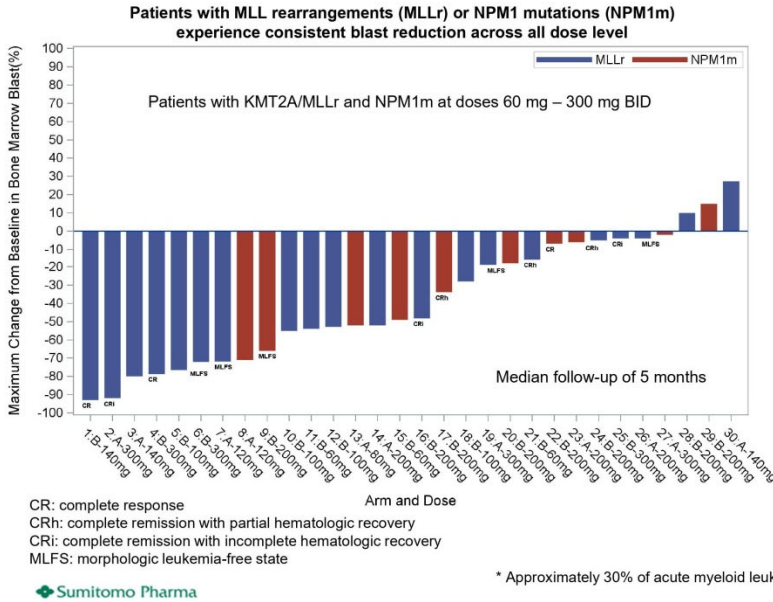
In the Oncology area, we entered into a clinical collaboration agreement with GSK to evaluate TP-3654 in combination with momelotinib in a Phase I/II study.

New clinical data from the Phase I/II study of DSP-5336 were presented orally at the European Hematology Association 2024 Congress held in June this year. Details are explained on the next page.

In June 2024, we received Fast Track Designation from the FDA for the treatment of relapsed or refractory AML with MLL rearrangement or NPM1 mutation.

TP-3654 and DSP-5336 now have generic names and are introduced here. TP-3654 is nuvisertib and DSP-5336 is enzomenib. They are a little hard to say, but I will get used to it.

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



Safety (57 patients)

- ✓ Well-tolerated with no dose limiting toxicity (DLT)
- ✓ No significant cardiac signal nor treatment-related discontinuations or deaths
- ✓ No differentiation syndrome (DS) prophylaxis was needed, and 5.7% (3/57 patients) of DS reported was manageable and did not result in death or discontinuation of enzomenib

Efficacy (21 patients (received 140 mg twice-daily or higher, with enzomenib target mutations (MLLr or NPM1m*)) (excludes patients with prior menin inhibitor treatment))

- ✓ Objective response was observed with 57% (12/21 patients)
- ✓ Complete remission or complete remission with partial hematologic recovery (CR/CRh) observed in 24% (5/21 patients)

Future Plan

- ✓ The pivotal part of the monotherapy study is scheduled to start in FY2024

* Approximately 30% of acute myeloid leukemia (AML) patients have NPM1m and 5-10% of AML patients have MLLr

Last but not least, please see page 15.

The interim results of the Phase I/II study of DSP-5336 as a single agent in acute leukemia, which was presented orally at the European Hematology Association 2024 Congress, are shown in the slide.

The safety profile was well tolerated, with no dose-limiting toxicity (DLT) observed. No treatment-related cardiotoxicity findings, discontinuations, or deaths have been observed.

Non-clinical data do not indicate that prevention of differentiation syndrome is necessary. Differentiation syndrome was observed in 5.7% of patients. However, all of these cases are manageable and have not resulted in death or discontinuation of treatment.

As for efficacy, patients with the target mutation of DSP-5336 showed a consistent decrease in blasts, as you can see in the graph on the left side. We hope to commence a single-agent pivotal part by the end of this fiscal year.

This concludes my presentation. Thank you very much.

Question & Answer

Noguchi [M]: Thank you very much, Dr. Kimura. I would now like to move on to the question-and-answer session.

We will take questions from analysts and institutional investors first, and then move on to questions from the press.

If you have any questions, please let us know by pressing the “raise your hand” button on Zoom. Also, please change the participant information displayed on your Zoom screen to your company name and name.

The moderator will call out your name in turn and we will unmute the microphone. Please state your name and company name, followed by your question.

Mr. Muraoka of Morgan Stanley MUFG Securities, please go ahead.

Muraoka [Q]: Thank you very much. Morgan Stanley, Muraoka. Thank you.

First, I would like to ask about the financial results. I think there was a comment about an upswing, but I think three months ago you were talking about reducing the deficit with each passing quarter, and at the end of the quarter, the figure would be in the black.

Since you are doing very well in reducing costs, does it seem likely there will be a core operating profit surplus in Q2? Or might we see a rebound dip in Q2?

It would be helpful if you could just sort out a few ideas in that area.

Kimura [A]: This is Kimura. As you just mentioned, I would like to say that we are in the black, but one issue is the end of the market exclusivity period for TRERIEF in June. We are not at a stage today where we can say for sure whether we will be able to turn core operating profit into the black or not, since we are considering the impact of this change.

Muraoka [Q]: Thank you very much. Even if it is unlikely in Q2, with overseas growth in play, how about Q3 and Q4? I assume there has been no change in your thinking there?

Kimura [A]: Yes, sales of overseas products are expected to grow in the future, but on the other hand, I am sorry to say that APTIOM's LOE is coming up, so we are considering reducing our sales force a little.

One of the key points in our North American business in the future will be how that area will be affected.

On the other hand, as I mentioned, the three key products are moving strongly, and we have high expectations for them.

We are seeing very good results with GEMTESA, and we have not seen any impact, but we are at the stage where we will be able to predict the future transition in more detail when the data on the transition between drugs and other data become available around August.

Muraoka [Q]: Thank you very much. I would like to ask about GEMTESA. I may be looking at the data the wrong way, but if you look at the sales per quarter in US dollar terms, which I found at the back of the Supplementary Financial Data, the January-March sales were USD81 million, while the April-June sales were

USD78 million, and the volume you are showing in the chart now is a significant increase from January-March to April-June.

This gives the impression that the unit price has fallen by quite a lot. I wondered at first if this was due to mirabegron. I thought that maybe there was a negative impact on the unit price due to generics, but I think I am probably mistaken, so if I am wrong about something, I would appreciate some clarification.

Kimura [A]: Thank you. There is a coverage gap effect, which is why one quarter was a little higher than the other, or Q1 of the calendar year.

So it appears that there is a slight drop in Q1 of FY2024, compared with Q1 of the calendar year. Gross to net is worsening slightly.

However, we are not too worried about this because we believe that the price transition will be strong in the future.

Muraoka [Q]: Thank you very much. When you say “slightly worsening gross to net,” is that due to the generics of mirabegron, or some other factors? Thank you.

Kimura [A]: We have been able to negotiate with the insurance company about the shipping price for this year, and we think that the price will not go down that much. Dr. Nakagawa, President and CEO, Sumitomo Pharma America, do you have any information to add on this?

Nakagawa [A]: This is Nakagawa. Thank you. As Dr. Kimura just mentioned, we see an upward trend in prices for this fiscal year, and although we expect the impact of generic mirabegron to be negative in terms of volume, we believe it will be positive in terms of price.

Muraoka [Q]: Thank you very much. When will the price be decided for the next year? I guess it would be around November or December.

Nakagawa [A]: It depends on the other parties. Some are currently under negotiation, and I expect that they will be decided gradually after this summer or in the fall.

Muraoka [Q]: Okay. Thank you very much. Just one more thing, sorry, about the TP-3654 study that you are doing with GSK, I think this is like a research collaboration, but should I assume that you are not talking about getting lump sums of money or anything like that?

Kimura [A]: Yes, it is not a licensing agreement, but rather a clinical study using the other party's drug and our compound in combination, so we are cooperating with each other. I am not in a position to give details, but I can say that this is not an initiative that promises future licenses or other commitments.

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

Noguchi [M]: Thank you very much. Next question, Mr. Wakao from JP Morgan.

Wakao [Q]: Wakao, JP Morgan. Thank you very much. There are several, the first of which is ORGOVYX.

I think the Q1 numbers were very good, but I would like to know more about the factors behind this strong performance, and whether the key point was the publication in the guidelines.

And is it safe to assume that this strong trend in Q1 will continue in Q2 and beyond?

Kimura [A]: I have mentioned several times before about the NCCN guidelines. We believe that this will have an impact for the better, but the strong sales this time are due to IRAs, and the fact that the burden on patients has been reduced this year, which has led to a very strong increase in administration. In this sense, we believe we have made a very good start in increasing future sales.

Wakao [Q]: So, you are saying that this trend will continue in Q2 and beyond?

Kimura [A]: Yes, that is what we are hoping for.

Wakao [Q]: Okay. Understood. And will ORGOVYX receive or be affected by the Medicare Part D reform, which starts in January 2025? I think I heard something about GEMTESA not being accepted the other day. Could you comment on this?

Kimura [A]: The IRA will have a positive impact on us because the maximum amount of out of pocket of patient will be lowered next year.

Wakao [Q]: Wouldn't that be a deteriorating factor for your company's gross to net?

Kimura [A]: For our part, we do not envision that at this time.

Nakagawa [A]: Although we will naturally have to negotiate with payers in this area, we believe that the appeal of our products' prices is relatively strong, so we believe that this will have a positive effect on the total.

Wakao [Q]: Okay. If so, does that mean that your company expects to see further volume growth starting next January, or that the trend will be even stronger?

Nakagawa [A]: Yes. We hope so.

Wakao [Q]: Okay. Does this mean that sales, even if your company's burden increases slightly, will grow on a net basis, or will the trend be even stronger in the next fiscal year?

Nakagawa [A]: That's right.

Wakao [Q]: Okay. Understood. One more thing, please tell us about your early retirement program. I understand that the number at present is 700, but is it correct to say that this is regardless of the department? How should we look at the impact on SG&A expenses for the next fiscal year if 700 people decide to retire early?

Now, I think your company in Japan alone has about 2,900 employees, so if you had 700, you would lose about 25% of your staff. Is it correct to simply think that the fixed costs would fall by that amount as well?

Kimura [A]: First of all, the subject excludes the manufacturing division. As for the decrease in SG&A expenses, it depends on who quits, but we expect SG&A expenses to decrease by about JPY7 billion.

However, this will also lead to a decrease in the number of MRs, so we expect a slight negative impact in terms of sales.

Wakao [Q]: Okay. If so, I believe that the SG&A expenses in Japan for the current fiscal year is JPY46.6 billion, so should we expect SG&A expenses of less than JPY40 billion for the next fiscal year?

Kimura [A]: Yes, that will be the case under the current system, but as Sumitomo Chemical has announced, there will be externalization of regenerative medicine and joint ventures, so I hope you will consider the impact of this on the next fiscal year.

However, the details have not been finalized yet, so we will report back when the details are finalized.

Wakao [Q]: In terms of scale, is the impact big or not that big? What kind of impact should we expect?

Kimura [A]: Yes, of course, we are not working on regenerative medicine as a whole company, so it is not that big of a thing, but I think it will be more than 100 people.

Wakao [Q]: Okay. Incidentally, I think this 700 employees is the same level that you had in mind when you announced the revised plan in May, when you suggested that restructuring and business reorganization would be carried out in Japan. Or is it even larger than the figure at that time?

Kimura [A]: No, it was only recently that we decided to do it, but we have been considering the scale, including the timing, for several months now, so the scale is consistent with what we said at the press conference in May.

Wakao [Q]: Okay. Thank you very much. I apologize for the length of this question, but I was wondering if you could tell me a little bit about borrowing. I think there is no more problem with the part where the parent company has guaranteed the debt, but I was thinking that long-term debt will mature in the current and next fiscal years, JPY60 billion and JPY65 billion respectively. What will happen with this?

I believe that the situation with regard to debt has improved, or at least that is how it is written in the Summary of Consolidated Financial Results. Could you comment on this point? What is the outlook for this?

Kimura [A]: Unfortunately, it has not gotten better, but we are of course planning repayment. We are currently discussing a repayment plan with the bank, which will determine how the loan will be repaid.

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

Kimura [A]: I'm sorry, in the additional explanation I gave earlier, I mentioned the manufacturing division, but the department in charge of regenerative medicine is also excluded from the scope of the early retirement program. We are also assuming that we will create a new company and have to strengthen the company in the near future, so we are excluding this department from the scope of the early retirement program. I am sorry for the additional explanation.

Wakao [M]: Yes, understood. Thank you very much.

Noguchi [M]: Yes, thank you. Next, Mr. Yamaguchi from Citigroup, please go ahead. Mr. Yamaguchi.

Yamaguchi [Q]:

First, I would like to ask about your results exceeding the plan in Q1. This has just been Q1, but given that you have exceeded the plan, I would like to know if this excess could continue over the full year.

If there is an excess of JPY10 billion per quarter, it would be a big change. Of course, JPY10 billion for the full year would also be a big change. Since it is only the first quarter, it seems there are many potential scenarios here, so could you say a few words on this?

Kimura [A]: When we announced our forecast, analysts questioned whether we could reduce expenses this much, but both SG&A and R&D expenses have been reduced further than our plan. Since we can control these expenses, I believe this situation will continue throughout the fiscal year.

On the other hand, as I mentioned earlier, there are uncertainties regarding sales, and while we expect sales to be strong, we would like to monitor the situation more carefully.

Yamaguchi [Q]: Thank you very much. We have heard some things about a cliff for TRERIEF and a few other things about sales, and also the past true-up of rebates of Medicare, but were these things already included in the forecast?

Kimura [A]: Yes, that was included, but regarding GEMTESA, our internal assumption was that generics of mirabegron would be launched at the beginning of the new year, so it came more than six months early.

Yamaguchi [Q]: Okay. Thank you very much. Regarding Medicare Part D for ORGOVYX, you mentioned that the number of patients who use the drug has increased due to the reduced out of pocket of patient. What kind of segments are you getting new patients from? For example, are they switching from Leuplin, or are they new patients?

Kimura [A]: Yes, it is true that we are getting a lot of new patients, but as you just mentioned, we would like to revise our forecast to include the switch from other competing drugs.

Yamaguchi [Q]: Okay. Lastly, regarding iPS, there seems to be no announcement from Kyoto University, but your company has obtained data from seven people and is preparing to submit an NDA. I don't think I would prepare an application if the data is not good, and I was wondering if you can tell us anything about the top line?

Kimura [A]: Yes, Kyoto University is currently preparing the data itself, including the publication of the paper, so I would say that Kyoto University will be responsible for the data. Sorry to be so vague, but the data is as expected.

Yamaguchi [Q]: Okay. Is this business separate from the regenerative medicine spin-off?

Kimura [A]: No, we are thinking of spinning off the regenerative medicine business, including this business, but in reality, it would be nearly impossible for the new company to take on this entire business, so we will cooperate with the new company, including in sales activities.

Yamaguchi [M]: Yes, I understand. Thank you very much.

Noguchi [M]: Yes, thank you very much. Next, Mr. Sakai of UBS Securities.

Sakai [Q]: Sakai, UBS. I would like to ask two questions.

In the balance sheet section, on page seven of the Supplementary Financial Data, you always disclose the breakdown of patent rights, but I think that this time there was an increase in those denominated in the U.S. dollars due to the impact of exchange rates and the depreciation of the yen.

If we separate goodwill and intangible assets, there is a huge amount of money on the balance sheet, and this part will be dealt with in the so-called restructuring plan that you are working on now. In the case of intangible assets, I think we are talking about amortizing them as soon as the products are sold.

In the case of goodwill, I'm not sure from the outside, so I'm wondering what your thoughts are on that right now. Could you comment on this?

Kimura [A]: Regarding patent rights, as you mentioned, we are thinking of gradually amortizing them, and since there was a significant impairment last year, we think that an impairment like last fiscal year, or rather FY2023, is very unlikely to occur for some time to come.

Goodwill was impaired last fiscal year, but as our sales continue to grow, we believe that future impairment of goodwill is highly unlikely.

Sakai [Q]: In the case of impairment, or goodwill, if the status quo is maintained, I would say that there is no impairment at all, or that it is not treated as an expense, but is recorded as is on the balance sheet, and that is the direction you are taking now.

Kimura [A]: Yes, yes. There is no amortization, which means we keep it. As I said, we believe there is no more impairment.

Sakai [Q]: Okay. Also, I would like to ask one more question to you personally. I have seen you being interviewed in various places by the media and talk about your future management policy.

You mentioned that Q1 was good, or rather, exceeded expectations, but what do you think is necessary for the momentum to continue into Q2 and beyond?

Even if you achieve the guidance for this fiscal year, next fiscal year, you will lose the exclusivity of some products, such as APTIOM in the U.S., but also Equa and EquMet in Japan, so I think the situation in Japan will become even more difficult. Could you say a few words on this?

Kimura [A]: Yes, thank you. First, I will answer based on North America and Japan separately. As you know, North America underwent two major restructurings last fiscal year, and the number of employees in North America has been reduced from 2,200 to about 1,200. We have managed to achieve these results there in Q1 at this time when there is a burden on staff.

We are also working to reduce costs, but I think one of the challenges is whether or not we can continue to build momentum in the future, and I think this is an issue for management in North America. Fortunately, the products is performing well, so we need to continue to support that and get everyone working hard.

In Japan, as you mentioned, the product composition is a serious issue. Unless something new product is introduced, sales will not increase that quickly, even with the launch of regenerative medicine products. This is why we are offering the early retirement program to employees in Japan this time.

Because of that situation, it will be a very large-scale early retirement program, which will be a blow to the organization. In terms of solidly rebuilding, and setting new goals, I would say that the situation in Japan is about a year behind of that in North America, and I think that is the biggest risk.

Of course, our borrowings are significant, so we are imperatively working on this issue.

Sakai [Q]: Okay. So I get the impression there are still areas where the Company's cash flow cannot fully cover everything. Page 18 of the presentation materials shows the cash flow section.

Kimura [A]: Yes, with time, we will be able to address this, and the question at the moment is to what extent we cover this through financial institutions.

Sakai [M]: Yes, I understand. Thank you very much.

Noguchi [M]: Yes, thank you very much. Okay, Mr. Hashiguchi, please go ahead.

Hashiguchi [Q]: Thank you very much. Hashiguchi, Daiwa Securities. I have two questions.

The first question is a continuation of the previous one, but I wonder if you could tell us a little more about your vision of how Sumitomo Pharma aims to position itself as a pharmaceutical company among the many pharmaceutical companies in Japan.

Three months ago, I was told that it would take more time to formulate the Mid-term Business Plan, so perhaps it will take a little longer to develop a firm vision.

I suppose this was something you were considering when setting the numbers for the early retirement program. For example, your company maintained the number one position in the area of diabetes. What are your current views on positioning in the future?

Kimura [A]: Yes, as you mentioned, we had a foundation for marketing products for lifestyle-related diseases such as diabetes and, a little while ago, hypertension.

On the other hand, we believe that it will be very difficult to cover the entire area if we implement this measure. In terms of our future business in Japan, we must establish a sales system that can deliver products with special characteristics to patients who need them, and we must change our business structure from the one that covers the entire country.

Hashiguchi [Q]: Yes, thank you. My second question is for you, Mr. Sakai.

Since you recently moved from Sumitomo Chemical to Sumitomo Pharma, what role do you think you can play in the future? What kind of issues do you feel you are facing as a member of this group? Conversely, I would like to ask you, Mr. Sakai, to comment on what you feel the future growth potential of Sumitomo Pharma is.

Sakai [A]: Yes, thank you for your question. This is a difficult question. I worked for Sumitomo Chemical and my last job was as a division head of a business division. Originally, I had about 30 years of experience in management, finance, and corporate planning at Sumitomo Chemical. As you know, we are in a difficult financial situation, and I think that my past experience at Sumitomo Chemical could help me to contribute to the Company in this respect.

As you know, Sumitomo Chemical is in the equipment industry, so it is a business with large loans that operates in a certain way, and the type of business is quite different from that of the pharmaceutical industry, or Sumitomo Pharma. I believe that the experience I gained during my time at Sumitomo Chemical helps supplement some aspects of the Company's human resources, because of our different backgrounds.

As you know, one of our immediate challenges is that we have not been able to adequately control costs in relation to revenue, for example. I have set cost reduction as a priority.

As some of you have pointed out, we are committed to repaying our borrowings, as a matter of course, but we also believe that it is very important to do so properly.

I think that in the short term, it will be very difficult to balance these financial issues and our desire to do our best as a research and development-oriented pharmaceutical company. I feel that continuing to walk that line and deliver on both of these things is my number one job right now.

I am sorry to be so long winded, but to be honest, I am not that knowledgeable about the pharmaceutical industry, so I am still in the process of learning about what kind of products are being developed since I joined our company.

As you are probably more familiar with, we are proud to be at the forefront of the development of cancer drugs and the regenerative medicine/cell therapies. I think there is a lot of potential in these areas, and I want us to do more.

It would be very sad if we are unable to get out of the current financial crisis and are then unable to do proper research because of funding limitations. We will make every effort to prevent that from happening. I hope I answered your question.

Hashiguchi [M]: Thank you very much.

Noguchi [M]: Yes, thank you very much. This concludes the Q&A session with analysts and institutional investors. Analysts and institutional investors are welcome to leave Zoom at their convenience.

We would now like to start taking questions from the media. If you have any questions, please press the “raise your hand” button. We will call your name and unmute the microphone. Please provide your affiliation and name followed by your question.

First, Mr. Ishii of the Iyaku Tsushinsha, go ahead.

Ishii, the Iyaku Tsushinsha [Q]: Ishii, the Iyaku Tsushinsha. Regarding DSP-5336, I would like to know your future outlook due to the Fast Track Designation by the FDA.

Kimura [M]: Future prospects, you mean.

Ishii [M]: Yes, it is designated, so could you tell me how development will be accelerated?

Ikeda [A]: Yes, Ikeda here, thank you for your question. I will take it. Since it has been designated as Fast Track, it will be very easy for us to discuss various clinical studies that will go on to Phase II or beyond. In addition, we believe that it is be very beneficial for the future development of the project that we can consult individually, rather than submitting all the application materials as a package.

Ishii [Q]: Wouldn't that make the application period much earlier?

Ikeda [A]: This will not speed up the application process, but on the other hand, the FDA has designated the Syndax's compound, which has the same mechanism of action, as Fast Track and is reviewing it.

I think the Syndax's compound could receive approval this year. However, because our compound has the same mechanism of action, and our compound is also fast-tracked, the FDA has seen all the data, so I think we have a good chance to work hard to get approval as soon as possible while receiving good suggestions from the FDA.

Ishii [M]: Thank you very much.

Noguchi [M]: Yes, thank you very much. Next, YAKUJINIPPO, Kuriyama.

Kuriyama, YAKUJINIPPO [Q]: Kuriyama, YAKUJINIPPO. I would like to ask about the number of early retirees. You mentioned 700, specifically. This is not 300, not 1,000, you gave us a figure of 700. Could you explain the rationale behind 700? Do you know how many of these will be MRs?

Kimura [A]: Kimura here. As I mentioned earlier, we manage profit and loss by segment for each region, namely, North America and Japan. In this situation, we have set the number of applications sought at 700, based on the assumption that the Japan segment will be able to remain profitable only with its own products for some time in the future, and as a result of considering the reduction of labor costs in SG&A expenses.

On the other hand, it would be a big problem if we, as an organization and as a pharmaceutical company, could not sell our current products well, so we have decided to set the number at 700, to balance these issues.

As I mentioned earlier, we are currently accepting the early retirement applications for all divisions except the manufacturing division and the Regenerative Medicine/Cell Therapy business departments, so we do not have individual figures for what will happen to the sales & marketing division or the head office as a result. Therefore, I am not able to give you an answer as to how many people will be in the sales & marketing division at this time.

Kuriyama [Q]: Thank you very much. Just one more question, please. You mentioned briefly in your talk that you are also considering business transfers. What kind of business transfer is envisioned? Would you be considering the transfer of a large part of Japan business itself, or is that not what you meant? Can you tell us about that?

Kimura [A]: Yes, we are considering the transfer of various items, but the transfer of Japan business is not in our focus.

As I have just mentioned, the Japan business, through this measure, will be firmly transformed into a profitable structure.

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

Noguchi [M]: Yes, thank you very much. Next, the Asahi Shimbun, Seii.

Seii, the Asahi Shimbun [Q]: Seii, the Asahi Shimbun. I would also like to ask you first about the early retirement program. I know that your company has offered the early retirement program three times in the past, but would it be correct to say that 700 employees is the largest number so far?

Kimura [A]: Yes, I think there have been three previous occasions, but this is the largest scale.

Seii [Q]: The reason why you had to go to such a large scale was to achieve and maintain the profitability of the Japan business, as you mentioned earlier, is that correct?

Kimura [A]: Yes, the period during which we can sell products in Japan, which are products sold through sales tie-ups, is gradually disappearing, and in this sense, profitability has deteriorated greatly.

Seii [Q]: Am I correct in understanding that you needed to streamline the products in light of the expiration of some patents and so on?

Kimura [A]: Yes, you are right.

Seii [Q]: Okay. Sorry, one more point, there was an additional policy rate hike today on the part of the Bank of Japan. The figure of 0.25% has been announced, but I would like to know your opinion on this and what impact it will have on the Company.

Kimura [A]: My personal feeling is that what is possible has just arrived, but in terms of the impact on our profit and loss, the yen-denominated loans to our overseas subsidiaries are very expensive, so if the yen appreciates against the U.S. dollar, we will lose JPY2 billion in net profit for the fiscal year.

Core operating profit is also slightly affected, but I think it is only a JPY100 million increase.

Seii [Q]: Regarding the loans, the ones you are borrowing now, is there any impact on the interest rate increase?

Kimura [A]: There is no impact on borrowings.

Seii [Q]: Is it your understanding that you have already borrowed at the stipulated interest rate and that it will never move?

Kimura [A]: I'm sorry, I was only thinking about the exchange rate, but in terms of interest rates going up, it means that borrowing rates will also go up, so there will be a negative impact in terms of interest going up and borrowing rates going up.

Seii [Q]: I see. Since you have a very large amount of debt in relation to the size of your business, should we consider this to be a negative factor for your business?

Kimura [A]: It is not a plus, but the interest rate is not that high, so I don't think the 0.25 interest rate will have a direct impact on our business strategy.

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

Noguchi [M]: Yes, thank you very much. Next, Nihon Keizai Shimbun, Kurose?

Kurose, Nihon Keizai Shimbun [Q]: Kurose, Nihon Keizai Shimbun. Thank you. I would like to ask you about the early retirement program.

I understand that you are excluding the manufacturing division and the regenerative medicine/cell therapy business departments, but may I ask what kind of people are in the manufacturing division and why they were excluded?

Kimura [A]: Yes, you can think of the manufacturing division as the factory that makes the products we sell. We have been extremely busy, mainly with MEROPEN, an antibiotic preparation sold in China, and TWYMEEG, a diabetic agent whose sales are increasing in Japan. Since there is absolutely no room for restructuring in such areas as manufacturing in three shifts, we have decided to exclude them from this measure.

Kurose [Q]: Thank you very much. I'm sorry, this is a bit long, but I have three questions.

The first one is regarding last year's workforce reduction in the U.S. Your company restructured in stages. Is there still a possibility of additional headcount reductions in Japan during FY2024, other than the 700 employees in the current early retirement program? Or is the idea to do it all at once already this time?

Kimura [A]: In the case of the U.S., it is not that we divided it into two parts, but that we did the second part because an unexpected event occurred. The target departments were completely different.

As I mentioned earlier, we are offering the early retirement program throughout the Company in Japan, and further reductions will affect our day-to-day business activities in terms of how we conduct our business, so we are not considering any further reductions.

Kurose [Q]: Thank you very much. Next, you mentioned business transfers. Is it correct that you are thinking about this during FY2024?

Kimura [A]: Yes, we expect to have something to report on business transfers by the end of FY2024.

Kurose [Q]: Thank you very much. Last question.

In an earlier question, you mentioned that personnel reductions have been made three times in the past, so is this the fourth time? How different is the background of the past three times from the current one?

Kimura [A]: The third was in 2017, so it was seven years ago. The situation was quite different. We were Sumitomo Dainippon Pharma, the company resulting from the merger of Sumitomo Pharmaceuticals and Dainippon Pharmaceutical. It is strange to say this, but most mergers of pharmaceutical companies were followed by structural reforms with restructuring.

In our case, we have been proceeding with natural reduction for a long time. So, in 2016 and 2017, we streamlined the system a little bit.

As I mentioned, the situation is slightly different this time, as we are facing a very serious problem in the product composition and the profitability of the Japanese business itself.

Kurose [M]: Thank you very much. Sorry it took so long, thank you very much.

Noguchi [M]: Yes, thank you very much. Next question, MIX, Kamio.

Kamio, MIX [Q]: Kamio, MIX. I too would like to ask you a few questions about the early retirement program and the sales & marketing in Japan.

First of all, the number of MRs is on page nine of the Supplementary Financial Data. The total number is 950, and excluding managers and others, the figure is 860. I think that the early retirement program is done in anticipation of the scale of the change here. What are your thoughts on the number of MRs that will remain after the early retirement program? For example, will it be in the 400s or 500s, or something in this area?

Kimura [A]: Thank you for your question. As I mentioned earlier, we are offering the early retirement program throughout the Company, so naturally the sales & marketing division, which has the largest number of employees, will probably receive the most applicants. However, as a result, we do not anticipate that we will be able to limit the target to any particular amount, and I am not at liberty to discuss this at this time.

Kamio [Q]: Okay. Also, I think it was a question with an analyst earlier, but you mentioned that you think that MRs will have to convert or switch from covering the entire country. If that is the case, could you please explain a little more about, for example, how you would market TWYMEEG, for example, using digital marketing, or if you cannot cover the whole country, how you would market diabetes products, so that it is still available?

Kimura [A]: Yes, that is an issue for us as well. We are in the process of increasing sales of TWYMEEG and we have many other diabetes products. I think that the number of MRs will considerably reduce, so the MRs will have to be very creative in their activities.

On the other hand, as I mentioned in my answer to another question, I believe that we must be prepared for a decline in sales to some extent due to the decrease in the number of employees.

Kamio [Q]: Okay. Also, one more thing, in a previous answer, you mentioned that you need to set new targets for Japan sales and move forward with them. Do you mean by that a reduction in sales? Or are you referring to another action plan or some new and different KPI? Thank you.

Kimura [A]: There are two ways. First, once we determine how the sales & marketing division will remain in the future, we will set new goals and have the sales & marketing division work accordingly. Second, in order to minimize the impact of the reduction in the number of employees, we will have the sales & marketing division work in a different way than before.

On the other hand, in the mid- to long-term, SMP's sales activities will focus on delivering products with more distinctive features and shifting to products that can generate sales without the 1,000-person workforce that

we have had up to now. I'm sorry if that was a little difficult to follow. We will provide more information on this.

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

Noguchi [M]: Thank you very much. Since we have 10 minutes remaining, we would like to ask each of you to limit your questions from this point on to one question per person. Next, the Chemical Daily, Tsubokura.

Tsubokura, the Chemical Daily [Q]: Thank you. I think you mentioned earlier that for APTIOM, there is a possibility of reducing the sales force because the LOE that is in sight. I would like to know a little bit about when this LOE for APTIOM in North America will be, and if there is a possibility of further reducing the head count in North America.

Nakagawa [A]: Nakagawa here. I was a bit incorrect in saying that the LOE is coming, but we already know when the generics are coming in, which is next May. We are planning to reduce the number of sales reps in H2.

Tsubokura [Q]: Okay. So, in addition to the reduction of the North American workforce to date, there will also be a reduction in the number of sales reps to some extent?

Nakagawa [A]: The number of sales reps in charge of APTIOM will be reduced. This has already been announced internally, so it is planned.

Tsubokura [M]: Yes, I understand. Thank you very much.

Noguchi [M]: Yes, thank you very much. Next, NHK, Obi?

Obi, NHK [Q]: Obi, NHK. Thank you very much for your explanation. I'm sorry, but I couldn't hear you during the session because of the signal, and I'm very sorry if this is a duplicate of what you have said so far.

In April of this year, President Iwata of Sumitomo Chemical announced the optimization of 4,000 employees, and I understand that you are not planning to add to that number this time.

Kimura [A]: Yes, I don't mean to add. I believe that this figure of 4,000 people covers the Sumitomo Group as a whole.

Obi [Q]: Okay. If so, I'm sorry if this is a second related question, but do you think that your company will outsource some of its sales activities in the future, or do you think that you have no choice but to do so with your limited staff?

Kimura [A]: Currently, many pharmaceutical companies are outsourcing a large portion of their MRs, or what do you call it, using contracted MRs, and we are currently doing so and will continue to do so in the future. Of course, as necessary.

Obi [Q]: So I guess we have to be moderate there, or rather, we have to deal with the situation from time to time.

Kimura [A]: Yes, there are times when it is necessary to take a lot of work, so we are flexible in handling such cases.

Obi [M]: Thank you very much.

Noguchi [M]: Yes, thank you very much. Next, Jiho, Chiboshi.

Chiboshi, Jiho [Q]: Jiho, Nikkan Yakugyo, Chiboshi. Regarding the early retirement program of the 700 employees, I would like to ask for a message to the employees in the Company about the situation that led to this decision.

Kimura [A]: I think it is a very important mission for management to protect the employment of our employees. We have been thinking about how we can do that, but as I mentioned earlier, we have had to ask nearly 700 employees to leave the Company through the early retirement program. However, as I mentioned earlier, we are very sorry that we have had to do this, and we would like to do all we can under the current circumstances to help those employees who are leaving.

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

Noguchi [M]: Yes, thank you very much. This concludes the presentation of Sumitomo Pharma's financial results for Q1 of fiscal year 2024.

Thank you very much for your participation today.

[END]
