Conference on Q3 FY2024
(April 1, 2024 to December 31, 2024)
Financial Results

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Sumitomo Pharma Co., Ltd.

January 31, 2025

Sumitomo Pharma
Innovation today, healthier tomorrows

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This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties.

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Information concerning pharmaceuticals and medical devices (including those under development) contained herein is not intended as advertising or as medical advice.

Agenda

- Financial Results for Q3 FY2024
- Financial Forecasts for FY2024
- Research and Development
- Q&A

Financial Results for Q3 FY2024

Financial Highlights for Q3 FY2024

Revenue growth and cost-reduction efforts led to a significant improvement, turning to core operating profit to profitability

- Revenue
  - Increased by 24.7% YoY: Increased by sales expansion of ORGOVYX® and GEMTESA® in the U.S.
- Costs
  - SG&A expenses: (decreased by 29.6% YoY): Decreased by the restructuring of the group companies in North America and cost-reduction in Japan, etc.
  - R&D expenses: (decreased by 48.0% YoY): Decreased by the selection and concentration of the pipeline

Net income also turned to positive due to the strong performance and weaker yen

- Status of borrowings
  - The repayment date of the bridge loan: Extended to the end of March 2025
  - Ongoing discussions with financial institutions and Sumitomo Chemical regarding necessary refinancing

Financial Results for Q3 FY2024 (Core Basis)

Revised full-year forecasts (See P.11)

Billions of JPY

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

Average rates:
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
Q3 FY2024 Results : 1US$ = ¥152.64, 1RMB = ¥21.17
FY2024 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2024 : 1US$ = ¥151.33, 1RMB = ¥20.84
As of the end of Dec. 2024 : 1US$ = ¥158.15, 1RMB = ¥21.67

- Revenue increased primarily owing to sales expansion of three key products
- In addition to the effects of business structure improvements, Group-wide streamlining, such as reductions through selection and concentration of R&D investments, has led to a significant reduction in SG&A expenses and R&D expenses
- Core operating profit improved significantly, turning profitable
- Non-recurring items:
  - Q3 FY2024: Business structure improvement expenses in Japan and North America
  - Q3 FY2023: Business structure improvement expenses in North America

Revenue of Major Products in North America

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

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

Million $

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

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

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

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

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

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Revenue of Major Products in Japan & Asia

Billions of JPY

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

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

Japan

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

Asia

- MEROPEN® (China) revenue increased

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Segment Information (Core Basis)

Billions of JPY

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

Japan

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

North America

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

Asia

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

Financial Forecasts for FY2024

Financial Highlights for Revised Forecasts

Core operating profit revised up to 30 billion yen due to increased sales of three key products and the effects of cost management

- Revenue
  - ORGOVYX® sales in the U.S. exceeded initial expectations, and the effects of one-time recognition of deferred revenue related to MYFEMBREE® led to an upward revision, primarily in the North America segment
- Costs
  - SG&A expenses: Decrease largely attributable to cost-cutting measures, including business structure improvement in Japan
  - R&D expenses: Maintained reduced budget through selection and concentration
    Decrease mainly attributable to the integrated management (deconsolidation) of the regenerative and cell medicine business with Sumitomo Chemical
- Other operating income and expenses
  - Partial divestment of subsidiary S-RACMO and transfer of the Company's regenerative and cell medicine business, totaling 12 billion yen (initial forecast was 20 billion yen)

Financial Forecasts for FY2024 (Core Basis)

Billions of JPY

	FY2024 May 14 Forecasts	FY2024 Revised Forecasts	Change from Previous forecasts	
			Value	FX impact
Revenue	338.0	**381.0**	43.0	13.0
Cost of sales	138.0	**147.5**	9.5	5.0
Gross profit	200.0	**233.5**	33.5	8.0
SG&A expenses	169.0	**167.0**	(2.0)	6.0
R&D expenses	50.0	**48.5**	(1.5)	1.1
Other operating income and expenses (Core basis)	20.0	**12.0**	(8.0)	
Core operating profit	1.0	**30.0**	29.0	0.9
Non-recurring items (negative number indicates loss)	(1.0)	**(9.0)**	(8.0)	
Operating profit	0.0	**21.0**	21.0	
Finance income/costs	(18.0)	**(12.0)**	6.0	
Income tax expenses	(2.0)	**(7.0)**	(5.0)	
Net profit	(16.0)	**16.0**	32.0	
Net profit attributable to owners of the parent	(16.0)	**16.0**	32.0	
R O E	(10.8%)	**9.8%**		
R O I C	0.6%	**7.1%**		

FX rates:
FY2024 Previous forecasts :
1US$ = ¥145.00, 1RMB = ¥20.00
Revised forecasts :
1US$ = ¥152.00, 1RMB = ¥21.00

- **Revenue:** Revised upward by ¥43.0B
  (FX impact +¥13.0B)
  Excluding FX impact
  - Japan (¥0.5B) : TWYMEEG® revised down
  - North America +¥25.9B : ORGOVYX® revised up
  - China +¥4.6B : MEROPEN® (China) revised up
- **SG&A expenses:** FX impact +¥6.0B
  Cost reductions are anticipated in Japan
- **R&D expenses:** FX impact +¥1.1B
- **Other operating income and expenses:**
  Gain from the change in ownership ratio of S-RACMO and the transfer of the regenerative and cell medicine business
- **Non-recurring items:** Recorded business restructuring expenses related to the voluntary early retirement program in Japan

Financial Forecasts for FY2024

Revenue of Major Products in North America

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

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

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

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

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

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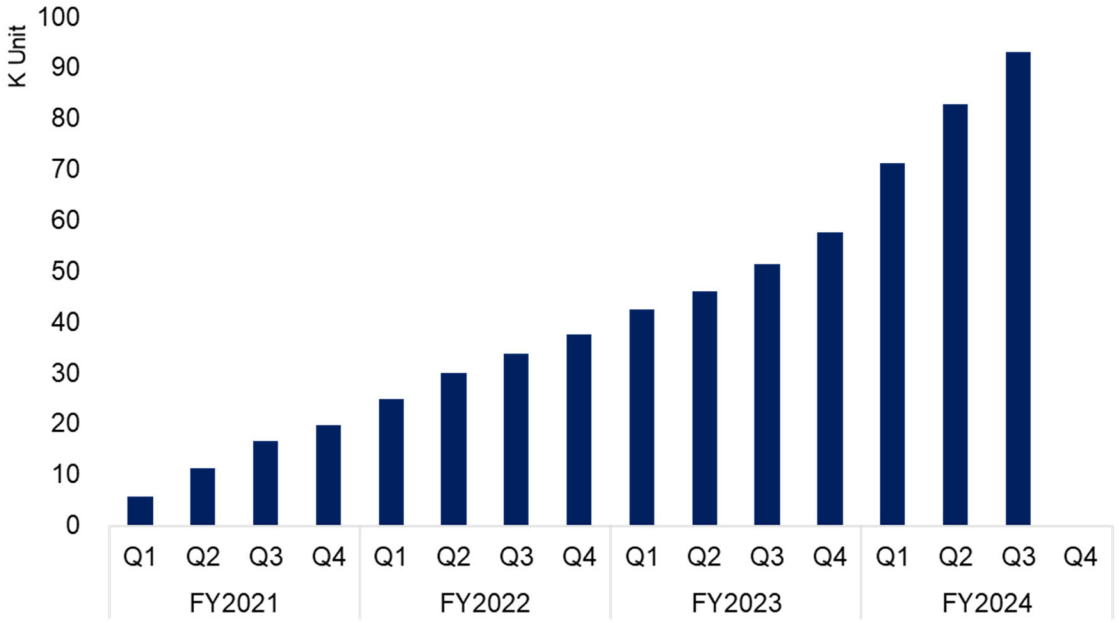
Financial Forecasts for FY2024

ORGOVYX®

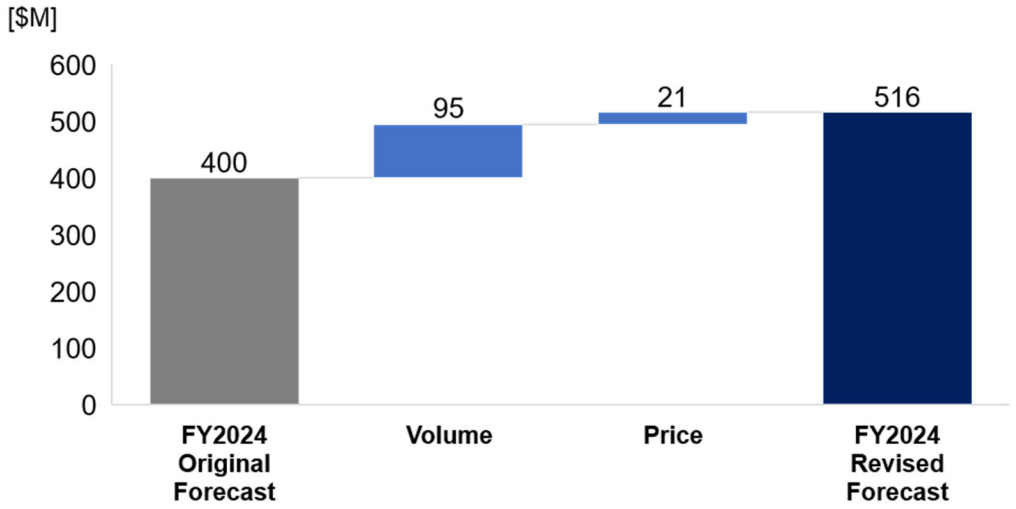
Plan for 3Q YTD FY2024	Actual for 3Q YTD FY2024	YoY comparison	Influence of volume and price against actual	
$293M	**$379M (129% to plan)**	**Approx. 76% increase**	Volume	$68M
			Price	$18M

- Volume grew more than expected across all segments due to improved affordability and strong tactical execution
- Price was higher than expected due to the lower-than-anticipated coverage gap and returns

Quarterly Demand Trends*
(number of bottles, estimation)



Analysis of FY2024 Original Forecast vs Revised Forecast



- Volume: Continued demand growth across all segments due to improved affordability and strong tactical execution
- Price: Favorable driven by lower than assumed Medicare Part D rebates related to IRA

Source: * Internal calculation

Financial Forecasts for FY2024

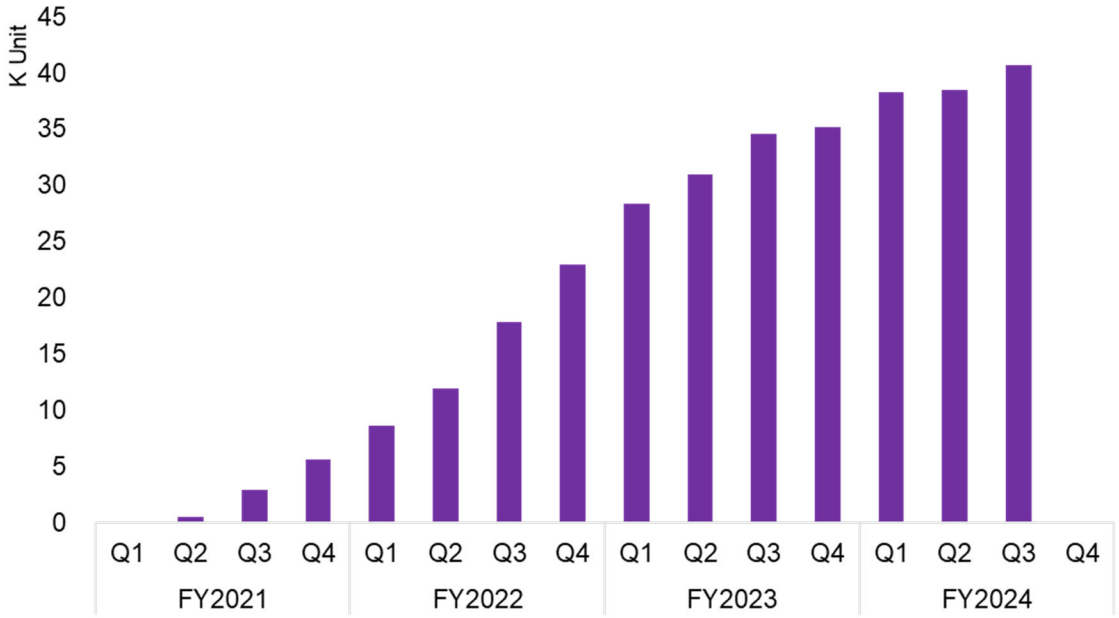
MYFEMBREE®

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

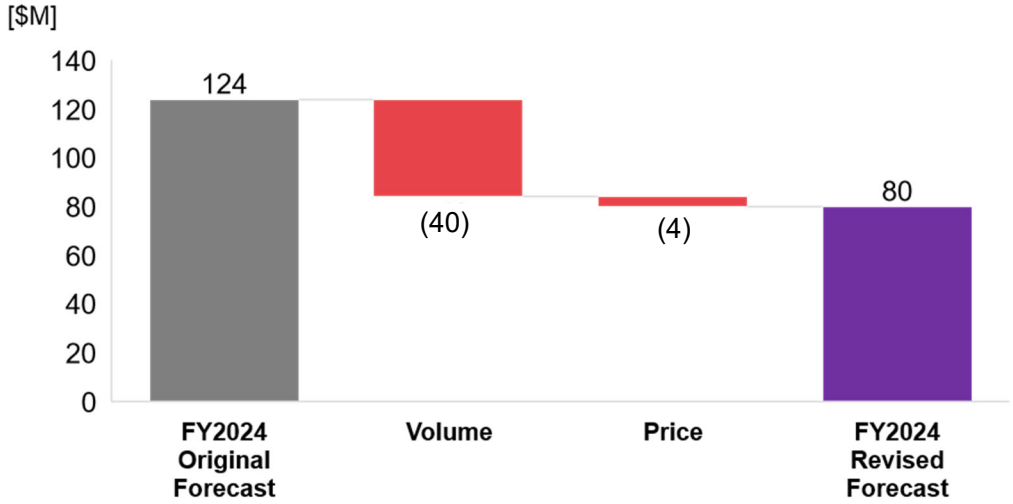
Plan for 3Q YTD FY2024	Actual for 3Q YTD FY2024	YoY comparison	Influence of volume and price against actual	
$89M	**$66M (74% to plan)**	**Approx. 33% increase**	Volume	($21M)
			Price	($2M)

- Volume grew less than expected due to the lower-than-expected market growth of oral GnRH antagonists and market share in EM*2
- Price was almost on track to expectation

Quarterly Demand Trends*1
(number of bottles, estimation)



Analysis of FY2024 Original Forecast vs Revised Forecast



- Volume grew less than expected due to the lower oral GnRH antagonists market size and anticipated market share in EM
- Price was slightly below plan due to an increase in commercial rebates and an increase in return risk

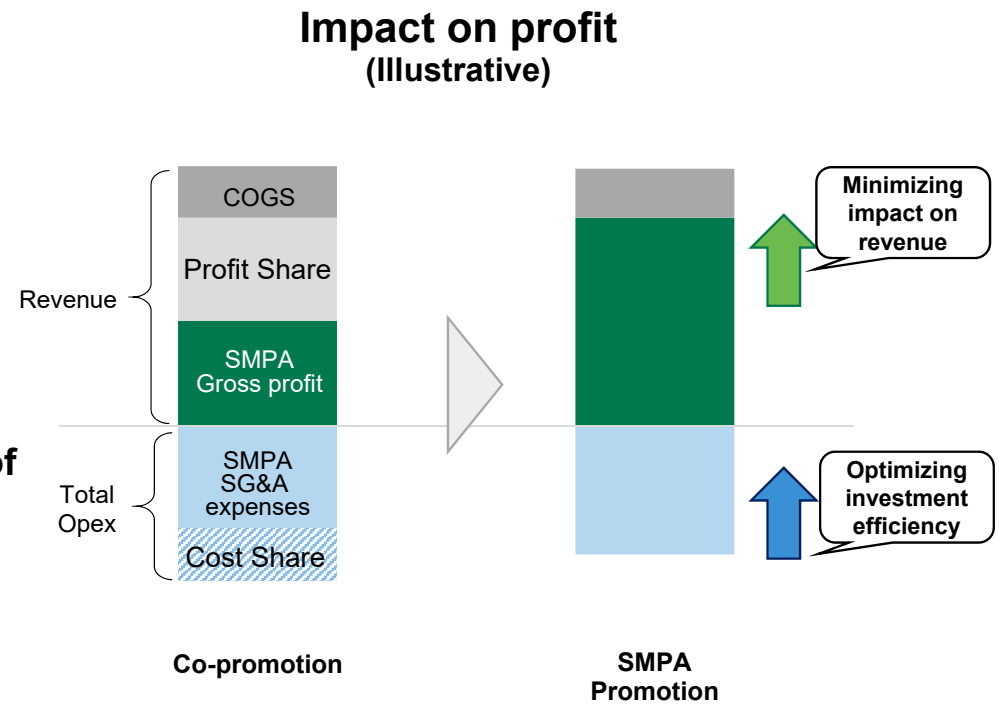
*1 Source: Symphony Health, an ICON plc Company, Metys®, April 1, 2021, to December 31, 2024., *2 endometriosis

MYFEMBREE®| Shift to independent sales and development

- Co-promotion / co-development agreement with Pfizer for MYFEMBREE® was concluded at the end of December 2024
- Since January 2025, **SMPA started sales and marketing activities in the US individually**

Future plan and expected financial impact

- **Pursuing product profitability improvement through**
  - ① Integration of MYFEMBREE® and GEMTESA® PCP sales teams for more **efficient and effective sales execution to minimize the impact on sales revenue**
  - ② **Elimination of profit share**, resulting in **gross profit improvement**
  - ③ **Efficient promotional investment to minimize the impact of loss of cost sharing**
- **Quicker strategic decision-making and flexible operations**
- Continued execution of the **clinical development plan** for MYFEMBREE® by SMPA



Continued strong partnership with Pfizer for ORGOVYX® for advanced prostate cancer patients

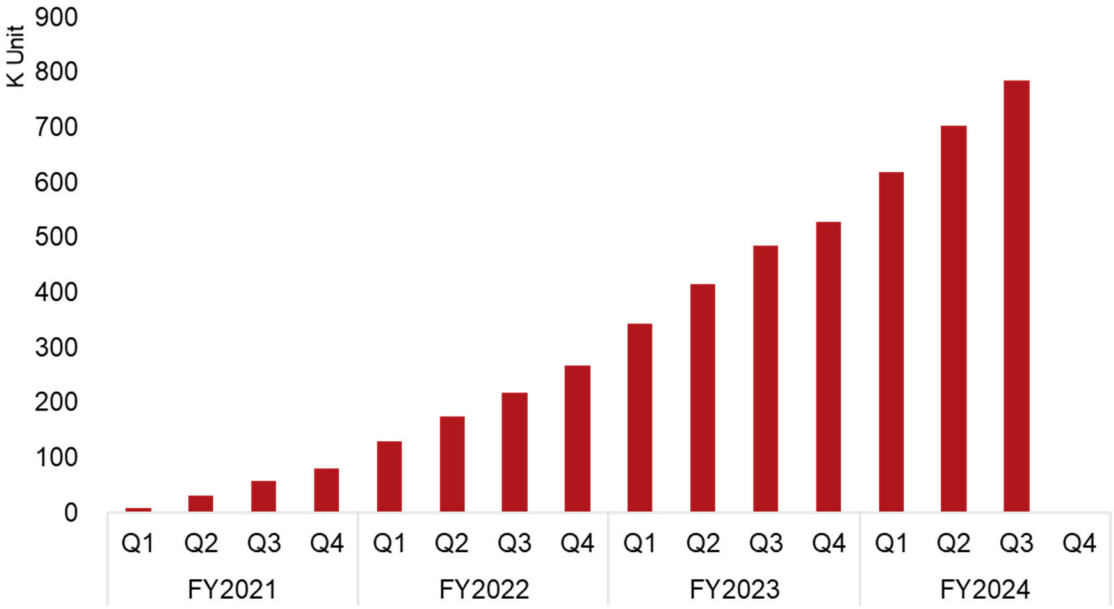
Financial Forecasts for FY2024

GEMTESA®

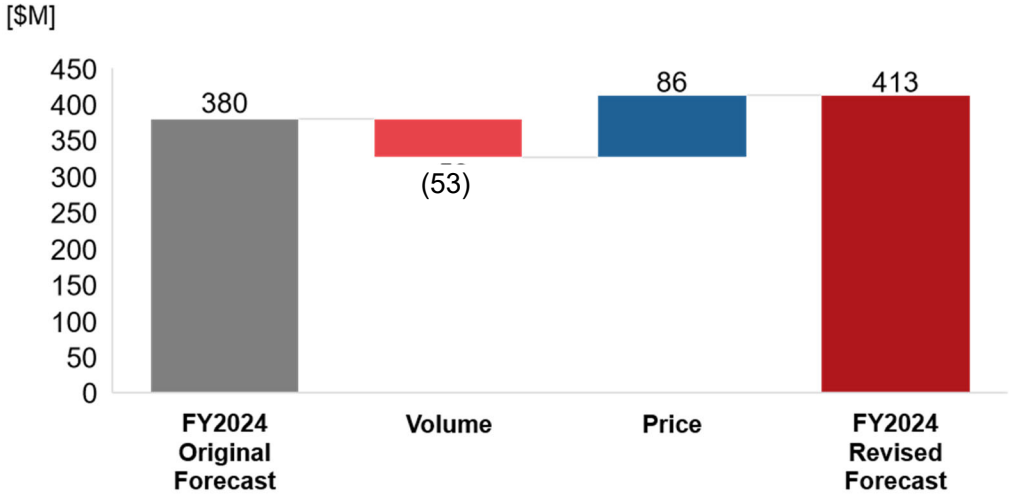
Plan for 3Q YTD FY2024	Actual for 3Q YTD FY2024	YoY comparison	Influence of volume and price against actual	
$238M	**$283M (119% to plan)**	**Approx. 63% increase**	Volume	($6M)
			Price	$51M

- Volume was almost on track to expectation
- Price was higher than expected due to the lower-than-anticipated Medicare and coverage gap rebates

Quarterly Demand Trends
(number of bottles, estimation)



Analysis of FY2024 Original Forecast vs Revised Forecast

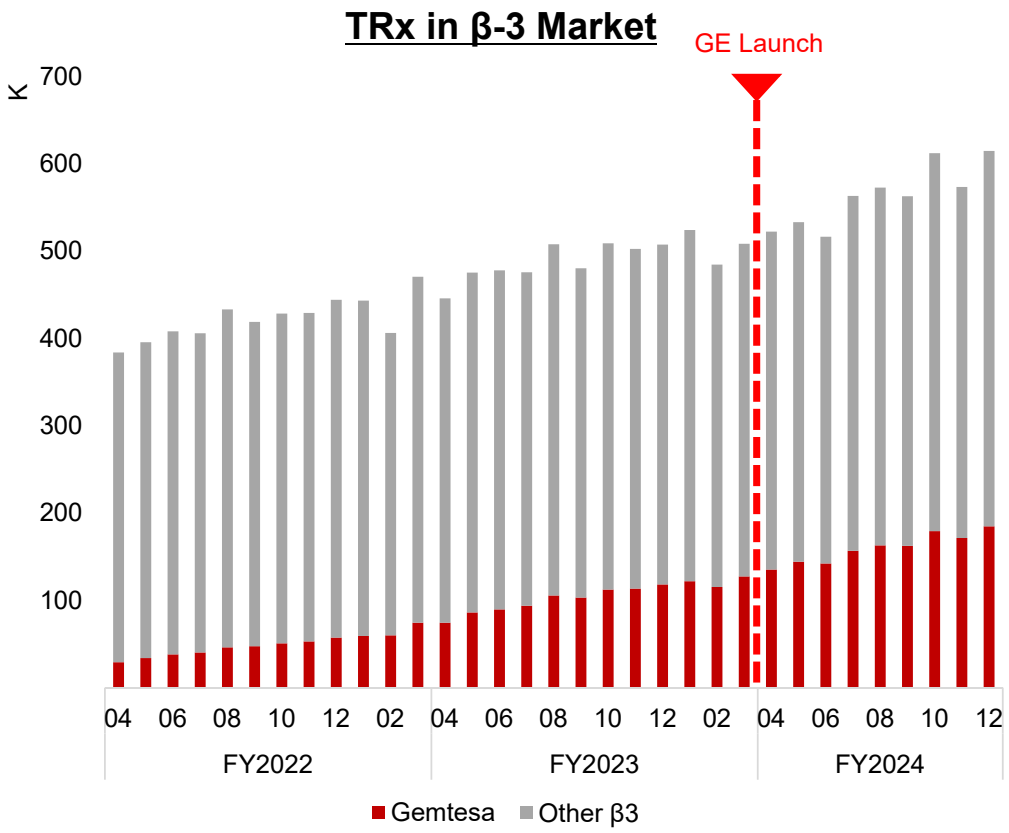


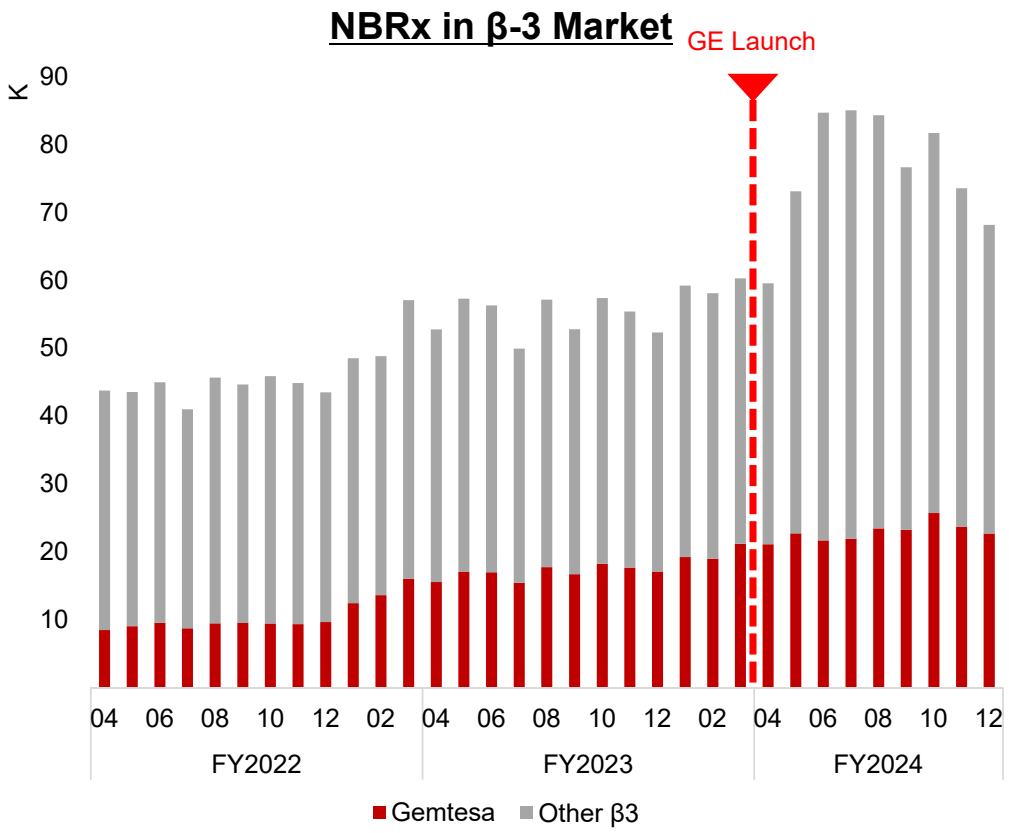
- Volume: Lower volume growth forecast due to Medicare Part D coverage changes starting from January 2025
- Price: Increased due to change of the Medicare Part D mix and lower Part D coverage gap rebates

Source: *Converted pill volume to number of bottles (30 tablets/bottle) based on information licensed from IQVIA: NPA for the period 4/1, 2021 to 12/31, 2024 reflecting estimates of real-world activity.*

GEMTESA®

- Despite the launch of the Generic mirabegron in April, GEMTESA® 's TRx and NBRx continues to grow





* Source: Based on information licensed from IQVIA: NPA for the period 1/1, 2022 to 12/31, 2024 reflecting estimates of real-world activity. All rights reserved.

Financial Forecasts for FY2024

Segment Information (Core Basis)

Billions of JPY

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

Japan

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

North America

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

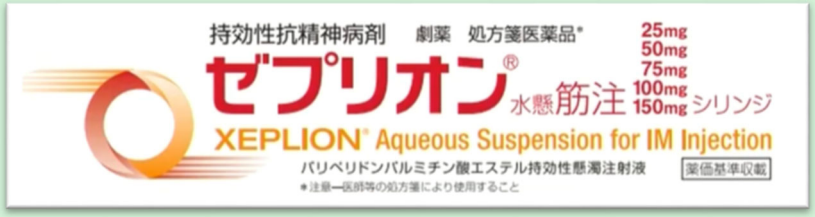
Asia

- Profit increased due to the upward revision of revenue

Agreement on Co-Promotion of Long-Acting Antipsychotic Medications "XEPLION®" and "XEPLION TRI®" with Janssen Pharma in Japan

- ✓ By acquiring the option of injectable formulations and expanding the range of information provided, we aim to enhance our presence in the field of psychiatry and become a trusted medical partner for healthcare professionals
- ✓ Synergies with LATUDA® and LONASEN® Tape are also expected (the atypical LAI market is approximately 36 billion yen annually)*

Injection: Long Acting Injectable (LAI)



Oral

Latuda®

Tape

Lonasen® Tapes

*Source: Internal calculation based on external data

Research and Development

Development Pipeline (as of January 31, 2025)

Revisions since the announcement in October 2024 are shown in red

Area	Generic name/Product code	Mechanism of action, etc.	Proposed indication	Region	Development stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT_{2A} receptor antagonist and serotonin 5-HT_{1A} receptor agonist	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Selective orexin 2 receptor agonist	Narcolepsy	Japan	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator	Dravet syndrome, Lennox-Gastaut syndrom	Japan	Phase 1
	DSP-2342	Serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist	To be determined	U.S.	Phase 1
	CT1-DAP001/DSP-1083	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study	Japan	Under preparation for the NDA
	CT1-DAP001/DSP-1083	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company-sponsored clinical study	U.S.	Phase 1/2
	HLCR011	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Japan	Phase 1/2
	DSP-3077	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	U.S.	Phase 1/2
Oncology	nuvisertib/TP-3654	PIM1 kinases inhibitor	Myelofibrosis	U.S., Japan	Phase 1/2
	enzomenib/DSP-5336	Menin and MLL inhibitor	Acute myeloid leukemia	U.S., Japan	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	U.S., Japan	Phase 1
	SMP-3124	CHK1 inhibitor	Solid tumors	U.S., Japan	Phase 1/2
Others	KSP-1007	β-lactamases inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	U.S., Japan	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Europe	Phase 1

Major Topics in Clinical Development

Psychiatry & Neurology (Regenerative medicine/cell therapy)

Allogeneic iPS cell-derived dopaminergic neural progenitor cells (Japan)

- Parkinson's disease

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

Allogeneic iPS cell-derived retinal sheet (U.S.)

- Started the Phase 1/2 study for Retinitis pigmentosa in November 2024 (For details, page 23)

Oncology

enzomenib (DSP-5336) (U.S., Japan)

- Presented new clinical data at the American Society of Hematology (ASH) 2024 in December 2024 (For details, page 24)
- The recommended dose for the Phase 2 part of the Phase 1/2 study for Acute Leukemia is determined 300 mg (twice daily) in January 2025

nuvisertib (TP-3654) (U.S., Japan)

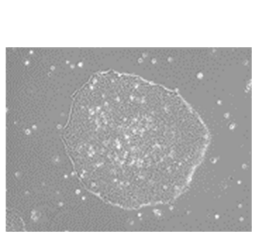
- Presented new clinical data at ASH 2024 (For details, page 25)
- Received Orphan Drug Designation from the Ministry of Health, Labour and Welfare Designation in Japan

Others

GEMTESA® / vibegron (U.S.)

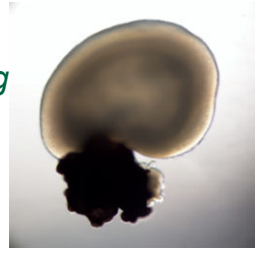
- Approved additional indication for Overactive bladder (OAB) in men on pharmacological therapy for benign prostatic hyperplasia (BPH) in December 2024

Psychiatry & Neurology (Regenerative medicine/cell therapy): Allogeneic iPSC-retinal sheet (DSP-3077) transplantation for retinitis pigmentosa



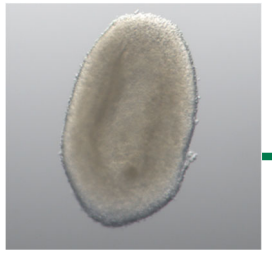
Allogeneic iPSCs

Self-organizing culture



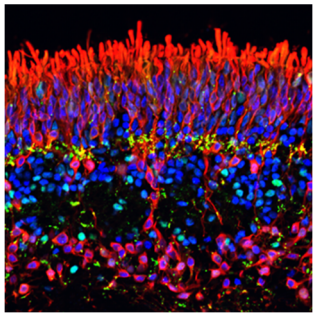
Retinal organoid
3D-retina

Processing



Retinal sheet
DSP-3077

Test



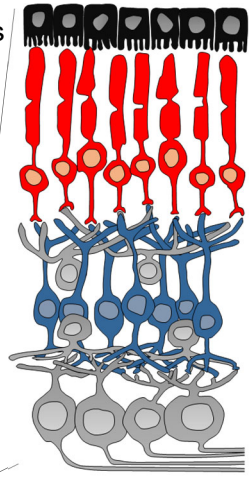
Photoreceptors / nuclei / synapse & retinal neurons

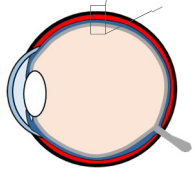
Retinal pigment epithelial cells (RPE cells)

Photoreceptors
(rods and cones, primary neurons)

Bipolar cells (secondary neurons)

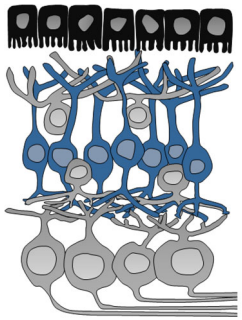
Retinal ganglion cells (tertiary neurons)



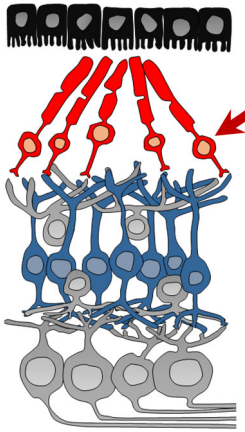


Healthy retina

Progressive loss of photoreceptors



Retinitis pigmentosa



DSP-3077 transplantation for retinitis pigmentosa

- Transplantation of DSP-3077 in subretinal space
- iPSC-derived photoreceptors connect to host bipolar cells, leading to functional recovery

Replacement approach using 3D tissues/organoids

From data presented at ASH 2024

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

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

Efficacy

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

Safety

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

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

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

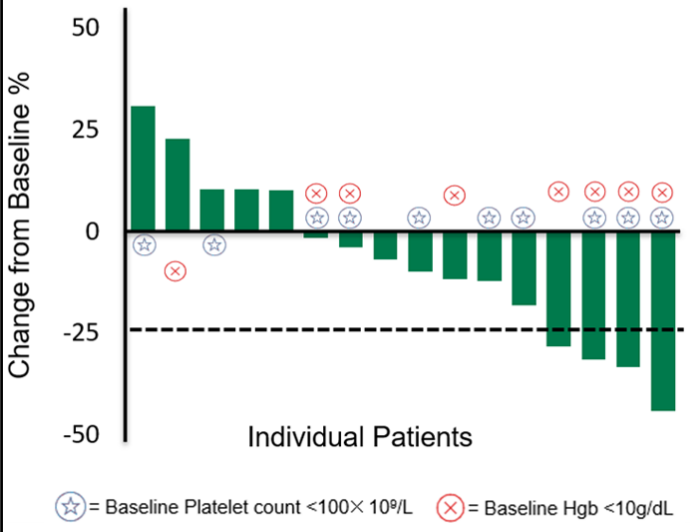
From data presented at ASH 2024

Oncology Area: Phase 1/2 Study of nuvisertib（TP-3654）for Myelofibrosis

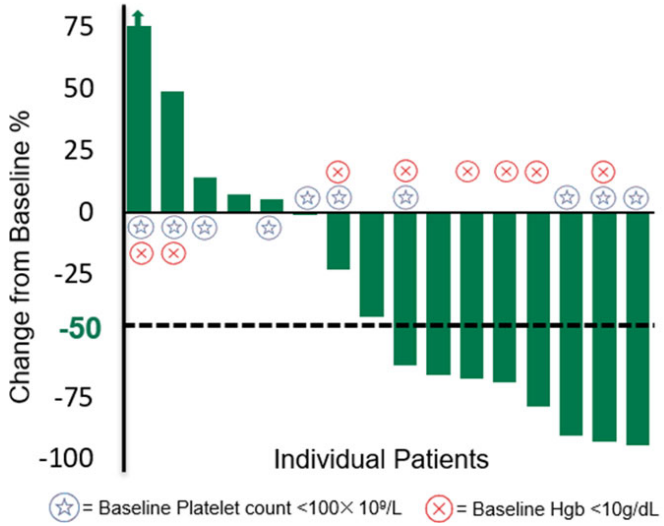
Data Cut-Off: October 1, 2024

- ✓ **Improvements in important efficacy measures were observed even in patients who did not respond to JAK inhibitor and in those with poor prognostic factors such as low hemoglobin and platelet counts**
- ✓ **No dose-limiting toxicities (DLTs) were reported. Among the 74 patients in the safety evaluation, Grade 1-2 gastrointestinal toxicities (diarrhea, nausea, etc.) were observed, but Grade 3 was rarely observed (diarrhea at 4.1%, nausea and vomiting at 0%)**

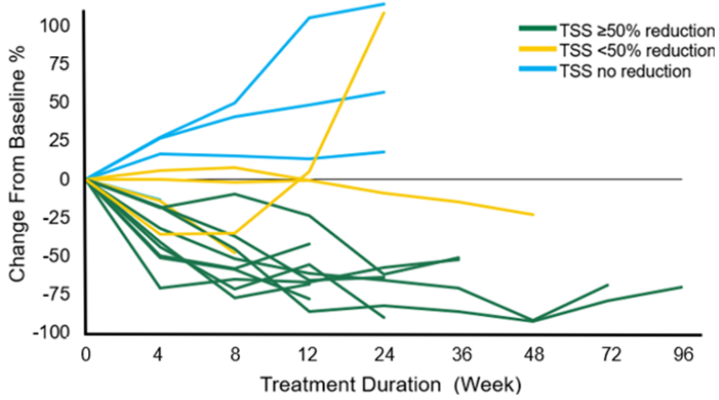
Spleen volume reduction of 25% or more(SVR25): 22.2% (4/18 patients)



Total symptom score improvement of 50% or more(TSS50): 44.4% (8/18 patients)



Patients with improved symptoms showed improvement from week 4 of treatment and maintained symptom improvement



* Evaluable patients = who completed ≥ 12 weeks of treatment or discontinued prior to week 12 for treatment-related AE or PD
Evaluable dose: 720 mg BID (projected RP2D)

Appendix

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Financial Results for Q3 FY2024 (Full Basis)

Billions of JPY

	Q3YTD FY2023 Results	Q3YTD FY2024 Results	Change	
			Value	%
Revenue	235.0	293.2	58.2	24.7
Cost of sales	93.2	113.8	20.6	22.1
Gross profit	141.8	179.4	37.6	26.5
SG&A expenses	191.6	131.0	(60.5)	(31.6)
R&D expenses	73.6	36.7	(36.9)	(50.1)
Other operating income and expenses	5.6	1.6	(4.0)	
Operating profit	(117.7)	13.2	131.0	—
Finance income and costs	12.6	10.8	(1.8)	
Profit before taxes	(105.2)	24.0	129.2	—
Income tax expenses	12.5	2.8	(9.7)	
Net profit	(117.7)	21.2	138.9	—
Net profit attributable to owners of the parent	(117.7)	21.2	138.9	—

Financial Position and Cash Flow

Billions of JPY

B/S	As of March 2024	As of Dec. 2024	Change
Assets	907.5	852.1	(55.4)
Goodwill / Intangible assets	395.4	403.3	7.8
Other financial assets (Non-current)	161.7	38.2	(123.5)
Cash and deposit / Short-term loan receivable	29.0	85.4	56.3
Liabilities	751.4	686.0	(65.4)
Bonds and borrowings	418.9	374.4	(44.5)
Deferred tax liabilities	38.2	18.4	(19.8)
Income taxes payable	1.3	19.4	18.1
Equity	156.1	166.1	10.0
Attributable to owners of the parent	156.1	166.1	10.1
(Ratio of equity attributable to owners of the parent to total assets)	17.2%	19.5%	

C/F	Q3 FY2023	Q3 FY2024	Change
Operating CF	(230.7)	5.5	236.2
Investment CF	38.3	97.4	59.1
Financial CF	72.1	(45.3)	(117.4)
Cash and cash equivalents	36.5	85.4	48.9
(Operating funds)	36.5	85.4	48.9

Increase due to FX rate impact

Decrease due to sales of investment securities

Repayment of borrowings

Decrease due to sales of investment securities

Increase due to sales of investment securities

Q3 FY2023: In addition to net loss, decrease in provisions and increase in corporate income tax payments
Q3 FY2024: In addition to improvement in net profit, decrease in expenses due to business structure improvement and corporate income tax refunds

Q3 FY2023: Proceeds from sales of Sumitomo Pharma Animal Health Co., Ltd. shares
Q3 FY2024: Proceeds from sales of investment securities

Q3 FY2023: Increase in borrowings
Q3 FY2024: Repayment of borrowings

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Appendix (Financial Forecasts for FY2024)

Revenue of Major Products in Japan & Asia

Billions of JPY

	FY2024 May 14 Forecasts	FY2024 Revised Forecasts	Change	
			Value	%
Japan				
Equa®/EquMet®	26.3	**25.5**	(0.8)	(3.0)
LATUDA®	13.0	**13.2**	0.2	1.5
TWYMEEG®	11.3	**7.9**	(3.4)	(30.1)
METGLUCO®	7.4	**7.4**	0.0	0.0
LONASEN® Tape	4.4	**4.6**	0.2	4.5
TRERIEF®	2.1	**3.8**	1.7	81.0
AG products	11.1	**11.3**	0.2	1.8
Others Export products/ One-time revenue, etc.	24.7	**26.1**	1.4	5.7
Total	100.3	**99.8**	(0.5)	(0.5)
Asia				
MEROPEN® (China)	21.2	**25.5**	4.3	20.3
Others	17.8	**20.3**	2.5	14.0
Total	39.0	**45.8**	6.8	17.4

Japan

- Sales of TWYMEEG® revised down due to lower demand than expected by the impact of competitors
- Sales of TRERIEF® revised upward due to slower decline after loss of exclusivity

Asia

- Sales of MEROPEN® (China) revised up

Appendix (Research and Development)

Main Events / Targets for FY2024 (as of January 31, 2025)

Revision since the announcement in October 2024 are shown in red

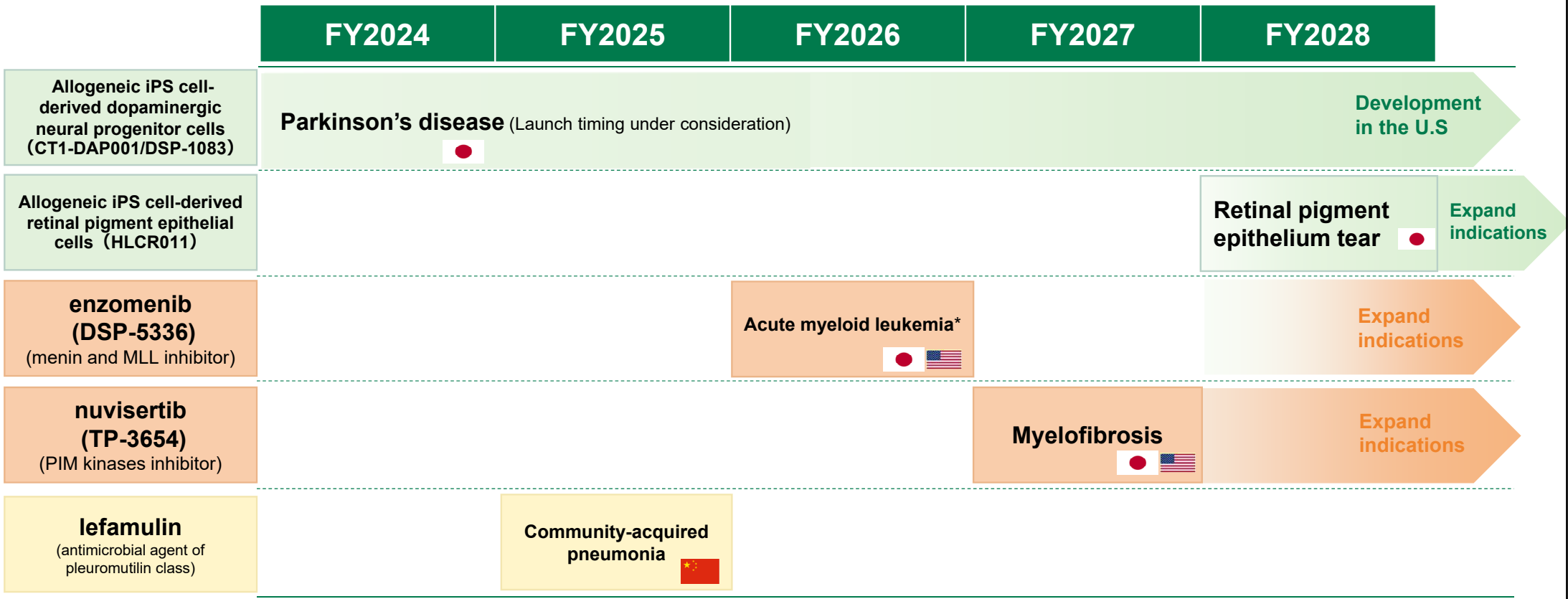
Psychiatry & Neurology	☐ Allogeneic iPS cell-derived products (Parkinson's disease): Submit NDA in Japan → Target submission date under consideration ☐ Allogeneic iPS cell-derived products (Parkinson's disease): Obtain approval in Japan → Target approval date under consideration ☐ Allogeneic iPS cell-derived products (Parkinson's disease): First patient implantation in the U.S. ☐ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear): Start a randomized part of Phase 1/2 study in Japan ☐ Advance early Phase studies
Oncology	☐ nuvisertib (TP-3654) (☐ Advance Phase 1/2 study ☑ Start the combination part of the study with a JAK inhibitor) ☐ enzomenib (DSP-5336) (☐ Advance Phase 1/2 study ☐ Start the Phase 2 part) ☐ SMP-3124 (☐ Advance Phase 1/2 study in the U.S. ☑ Start the same Phase 1/2 study in Japan)
Others	☐ vibegron: Obtain approval for overactive bladder (OAB) on pharmacological therapy for benign prostatic hyperplasia in the U.S. ☐ Advance early Phase studies of universal influenza vaccine and others
Frontier	☐ Promote the current themes and generate evidence data for maximizing the value of the launched products

Appendix (Research and Development)

Product Launch Target (as of January 31, 2025)

Psychiatry & Neurology | Oncology | Others

No revision since the announcement in October 2024



* Relapsed or refractory acute myeloid leukemia with MLL rearrangement or NPM1 mutation

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Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of January 31, 2025)

Revision since the announcement in October 2024 are shown in red

Brand name/Cell type Product code	Indications	JP/ US	Pre-clinical	Clinical research	Phase 1/2	Phase 3	Approval application	Approval→ Launch
RETHYMIC®	Congenital athymia	US						●
Dopaminergic neural progenitor cells (Allo iPS cell-derived) CT1-DAP001/DSP-1083	Parkinson's disease	JP US			●1 ●4 ●5			Launch timing under consideration
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP			●5			
Retinal sheet (3D retinal tissue) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US		●2	●5			
Neural progenitor cells (Allo iPS cell-derived)	Spinal cord injury	JP US		●3				
Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced)	Kidney failure	JP/ US	●					

1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego School of Medicine
5. Company-sponsored clinical study

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Product Launch Target (FrontAct) (as of January 31, 2025)

Revisions since the announcement in October 2024 are shown in red

: Non-medical device
: Medical device

	Launched	FY2024	FY2025	FY2026	FY2027	FY2028
MELTz®	"MELTz® " (Neurorehabilitation device for hand/fingers paralysis) ●		"MELTz® Portable" (finger exercise training system) ●			
Wearable EEG meter (NeuroSky Co., Ltd.)			Depression ●		Depression ●	
Violet Light (Tsubota Laboratory Incorporated)			Depression / Dementia ●		Dementia ●	

Due to changes in BehaVR's focus disease area strategy, discontinued VR contents development and removed

Based on the results of clinical studies, discontinued Violet light for depression development as a medical device and removed

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