Conference on FY2023
(April 1, 2023 to March 31, 2024)
Financial Results

Hiroshi Nomura, President and CEO

Sumitomo Pharma Co., Ltd.

May 14, 2024

Sumitomo Pharma
Innovation today, healthier tomorrows

Disclaimer Regarding Forward-looking Statements

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.

Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

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

Financial Results for FY2023

Financial Results for FY2023 (Core Basis)

Billions of yen

	FY2022 Results	FY2023 Results	Change			FY2023 Jan. 31 forecasts
			Value	FX impact	%	
Revenue	555.5	**314.6**	(241.0)	11.1	(43.4)	317.0
Cost of sales	176.7	**126.6**	(50.1)	(12.3)	(28.4)	125.0
Gross profit	378.8	**188.0**	(190.9)	23.4	(50.4)	192.0
SG&A expenses	305.6	**236.4**	(69.2)	11.3	(22.6)	240.0
R&D expenses	106.1	**90.9**	(15.2)	3.4	(14.3)	92.0
Other operating income/expenses	49.2	**6.4**	(42.8)	—		6.0
Core operating profit	16.4	**(133.0)**	(149.3)	8.3	—	(134.0)
Non-recurring items (negative number indicates net loss)	(93.3)	**(221.9)**	(128.5)			(22.0)
Operating profit	(77.0)	**(354.9)**	(277.9)		—	(156.0)
Finance income/costs	29.1	**31.7**	2.7			18.0
Profit before taxes	(47.9)	**(323.1)**	(275.2)		—	(138.0)
Income tax expenses	48.8	**(8.2)**	(57.0)			3.0
Net profit	(96.7)	**(314.9)**	(218.2)		—	(141.0)
Net profit attributable to owners of the parent	(74.5)	**(315.0)**	(240.5)		—	(141.0)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Other operating income/expenses:
  - FY2023: Share transfer of Sumitomo Pharma Animal Health Co., Ltd.
  - FY2022: Share transfer of Sumitomo Pharma Food & Chemical Co., Ltd.; Certain product transfers and Priority Review Voucher sale in the U.S.
- Non-recurring items:
  - FY2023: Impairment loss on intangible assets and goodwill; Business structure improvement expenses in North America
  - FY2022: Impairment loss on intangible assets; Business structure improvement expenses in North America

Average rates:
FY2022 Results : 1US$ = ¥135.51, 1RMB = ¥19.75
FY2023 Results : 1US$ = ¥144.59, 1RMB = ¥20.14
FY2023 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of March 2024 : 1US$ = ¥151.33, 1RMB = ¥20.84

Revenue of Major Products in North America

	FY2022 Results	FY2023 Results	Change	FY2022 Results	FY2023 Results	Change		
						Value	FX impact	%
North America	Million $			Billions of yen				
ORGOVYX®	182	**292**	110	24.7	**42.2**	17.5	2.7	70.8
MYFEMBREE®	33	**64**	30	4.5	**9.2**	4.7	0.6	104.7
GEMTESA®	182	**255**	73	24.7	**36.8**	12.1	2.3	49.2
APTIOM®	249	**235**	(14)	33.7	**34.0**	0.3	2.1	0.7
RETHYMIC®	33	**44**	11	4.4	**6.3**	1.9	0.4	42.3
LATUDA®	1,465	**47**	(1,418)	198.5	**6.7**	(191.8)	0.4	(96.6)
Others	76	**15**	(61)	10.3	**2.1**	(8.1)	0.1	(79.2)
Export products/ One-time revenue, etc. *	204	**150**	(54)	27.7	**21.7**	(6.0)	1.4	(21.7)
Total	2,424	**1,100**	(1,324)	328.5	**159.0**	(169.4)	10.0	(51.6)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S. despite the growth of three key products and RETHYMIC®
- Decrease in Others was due to the transfer of some products in FY2022
- Export products/One- time revenue, etc. in FY2022 included $50M for the licensing agreement for ORGOVYX® in the EU (See the breakdown below the table)

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

FY2022	Deferred revenue from the collaboration with Pfizer of $138M	FY2023	Deferred revenue from the collaboration with Pfizer of $117M
	Revenue from the license agreement for ORGOVYX® in EU of $50M		Milestone revenue from the approval of MYFEMBREE® for endometriosis in EU of $9M

Average rates:
FY2022 Results : 1US$ = ¥135.51
FY2023 Results : 1US$ = ¥144.59

Revenue of Major Products in Japan & Asia

Billions of yen

	FY2022 Results	FY2023 Results	Change	
			Value	%
Japan				
Equa®/EquMet®	33.6	**30.6**	(2.9)	(8.7)
TRERIEF®	16.7	**15.5**	(1.2)	(7.0)
LATUDA®	9.6	**11.7**	2.2	22.5
METGLUCO®	7.7	**7.3**	(0.4)	(5.3)
TWYMEEG®	2.2	**4.6**	2.3	105.6
LONASEN® Tape	2.9	**3.8**	0.9	29.9
AG products	9.2	**9.7**	0.5	5.8
Trulicity® *	24.8	**—**	(24.8)	—
Others	19.4	**22.1**	2.8	14.3
Export products/ One-time revenue, etc.	12.8	**8.0**	(4.8)	(37.7)
Non-pharmaceutical operations	44.8	**1.3**	(43.5)	(97.1)
Total	183.6	**114.7**	(69.0)	(37.6)
Asia				
MEROPEN® （China）	28.5	**21.3**	(7.3)	(25.5)
Others	14.9	**19.6**	4.7	31.4
Total	43.5	**40.9**	(2.6)	(6.0)

Japan

- Revenue decreased due to the termination of the sales collaboration for Trulicity® and the transfer of all shares of two domestic consolidated subsidiaries
- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Export products/One-time revenue, etc. in FY2022 includes one-time revenue ¥6.1B under the license agreement for DSP-0187
- Total impact of NHI drug price revision (¥4.2B)

Asia

- MEROPEN® (China) revenue decreased due to Volume-Based Procurement application

Note: Sales of each product in Japan are shown by invoice price (* Trulicity® is shown by NHI drug price)

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2023 Results	Revenue	114.7	159.0	40.9	314.6
	Cost of sales	54.2	62.0	10.4	126.6
	Gross profit	60.5	97.0	30.5	188.0
	SG&A expenses	47.1	177.2	12.1	236.4
	Core segment profit	13.4	(80.2)	18.4	(48.5)
	R&D expenses				90.9
	Core operating profit				(133.0)
FY2022 Results	Revenue	183.6	328.5	43.5	555.5
	Cost of sales	104.9	62.4	9.4	176.7
	Gross profit	78.7	266.0	34.1	378.8
	SG&A expenses	59.2	233.8	12.6	305.6
	Core segment profit	19.5	32.2	21.4	73.2
	R&D expenses				106.1
	Core operating profit				16.4
Change	Revenue	(69.0)	(169.4)	(2.6)	(241.0)
	SG&A expenses	(12.1)	(56.5)	(0.5)	(69.2)
	Core segment profit	(6.2)	(112.5)	(3.0)	(121.7)
	R&D expenses				(15.2)
	Core operating profit				(149.3)

Japan

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

North America

- A decline in revenue resulted in significant gross profit and core segment profit decrease, despite a reduction in selling, general and administrative expenses

Asia

- A decline in revenue resulted in a decrease in gross profit and core segment profit

Financial Forecasts for FY2024

Structural Reform in Sumitomo Pharma America, Inc. (SMPA)

Established lean operational structure through rationalization of SMPA, resulting in approximately 1,200 employees

	Before Integration (As of Mar. 31, 2023)	After Integration (As of Dec. 31, 2023)	After Rationalization (As of Mar. 31, 2024)
SMPA headcount* R&D/Non R&D, （Unit: people）	**2,216** 805/1,411	**1,757** 451/1,306	**1,200**** 172/1,028

North America Segment	Financial Results for FY2022 (Million $)		Financial Results for FY2023 (Million $)		Financial Forecasts for FY2024 (Million $)
Revenue	2,424		1,100		1,370
Cost of sales	461		429		526
Gross Profit	1,963		671		844
SG&A expenses	1,725		1,226		758
Core segment profit	238		(555)		86

Seven U.S. subsidiaries were integrated as part of efforts to achieve sustained growth after the loss of exclusivity for LATUDA® in the U.S. (July 2023)

Rationalization of SMPA due to underperformance of revenue from the three key products (March 2024)

Include amortization expenses of patent rights and cost allocation, etc.

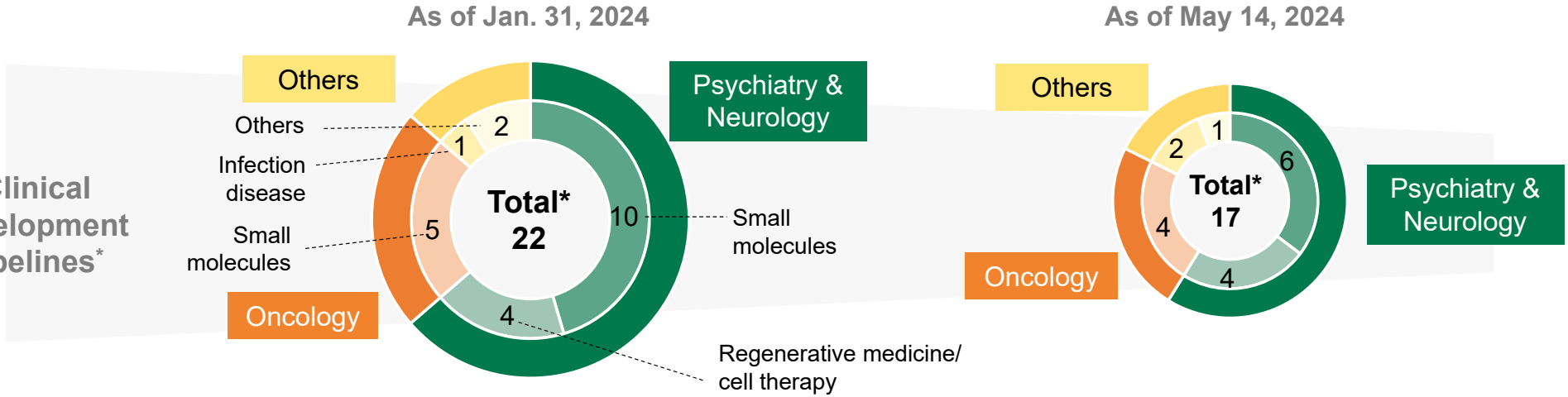
Average rates: FY2022 Results:1US$ = ¥135.51, FY2023 Results: 1US$ = ¥144.59, FY2024 forecasts:1US$ = ¥145.00

* Include Sumitomo Pharma Switzerland GmbH, ** Headcount reflects employees with known termination dates throughout FY2024

Review of Development Pipeline and Organizational Restructuring

Implementing a well balanced investment allocation in each area and establishing a new global operating model

- ✓ Focus on clinical development of two oncology compounds (TP-3654, DSP-5336) to accelerate value maximization
- ✓ Promote clinical development of regenerative medicine/cell therapy programs including CT1-DAP001/DSP-1083 for Parkinson's disease
- ✓ In the psychiatry & neurology area, revised the alliance with Otsuka Pharmaceutical and focus on identifying value inflection point of early stage pipelines
- ✓ Transform into a lean R&D organization by global integration of Japan and the U.S., through workforce optimization



*. Number of development assets in clinical study/clinical research phase. Psychiatry & Neurology area includes ophthalmology

Financial Forecasts for FY2024 (Core Basis)

Billions of yen

	FY2023 Results	FY2024 Forecasts	Change		
			Value	FX impact	%
Revenue	314.6	**338.0**	23.4	0.3	7.5
Cost of sales	126.6	**138.0**	11.4	0.1	9.0
Gross profit	188.0	**200.0**	12.0	0.3	6.4
SG&A expenses	236.4	**169.0**	(67.4)	0.2	(28.5)
R&D expenses	90.9	**50.0**	(40.9)	0.0	(45.0)
Other operating income and expenses (Core basis)	6.4	**20.0**	13.6		
Core operating profit	(133.0)	**1.0**	134.0	0.0	—
Non-recurring items (negative number indicates loss)	(221.9)	**(1.0)**	220.9		
Operating profit	(354.9)	**0.0**	354.9		—
Finance income/costs	31.7	**(18.0)**	(49.7)		
Income tax expenses	(8.2)	**(2.0)**	6.2		
Net profit	(314.9)	**(16.0)**	298.9		
Net profit attributable to owners of the parent	(315.0)	**(16.0)**	299.0		—
R O E	(111.9%)	**(10.8%)**			
R O I C	(19.0%)	**0.6%**			

Aiming to increase revenue and achieve a profitable core operating profit in FY2024

- **Revenue:**
  - Japan (¥14.4B) due to TRERIEF®'s loss of exclusivity
  - North America ¥39.7B due to the growth of three key products
  - Asia (¥1.9B) Meropenem sales decline in Southeast Asia
- **SG&A expenses, R&D expenses:**
  - Both SG&A and R&D expenses decreased due to the effects of the reorganization of the subsidiaries in North America in July 2023 and the reorganization of SMPA in March 2024
- **Other operating income and expenses (Core basis):**
  - Increase in anticipation of asset sales, etc.
- **Non-recurring items:**
  - No major expense is expected

FX rates:
FY2023 Results : 1US$ = ¥144.59, 1RMB = ¥20.14
FY2024 Forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Sumitomo Pharma

Financial Forecasts for FY2024

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2024 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
FY2023 Results	Revenue	114.7	159.0	40.9	314.6
	Cost of sales	54.2	62.0	10.4	126.6
	Gross profit	60.5	97.0	30.5	188.0
	SG&A expenses	47.1	177.2	12.1	236.4
	Core segment profit	13.4	(80.2)	18.4	(48.5)
	R&D expenses				90.9
	Core operating profit				(133.0)
Change	Revenue	(14.4)	39.7	(1.9)	23.4
	SG&A expenses	(0.5)	(67.3)	0.4	(67.4)
	Core segment profit	(12.4)	92.7	(0.9)	79.5
	R&D expenses				(40.9)
	Core operating profit				134.0

Japan

- Gross profit is expected to fall sharply due to the decline in sales, resulting in a decline in profits

North America

- In addition to increased sales, cost reductions through rationalization are expected to contribute to increased profits

Asia

- Profits are expected to decrease due to the impact of decreased revenue

Financial Forecasts for FY2024

Revenue of Major Products in North America

	FY2023 Results	FY2024 Forecasts	Change	FY2023 Results	FY2024 Forecasts	Change		
						Value	FX impact	%
North America	Million $			Billions of yen				
ORGOVYX®	292	**400**	108	42.2	**57.9**	15.7	0.2	37.2
MYFEMBREE®	64	**124**	60	9.2	**17.9**	8.7	0.1	94.6
GEMTESA®	255	**380**	125	36.8	**55.0**	18.2	0.2	49.4
APTIOM®	235	**201**	(34)	34.0	**29.1**	(4.9)	0.1	(14.3)
RETHYMIC®	44	**49**	5	6.3	**7.2**	0.9	0.0	14.0
LATUDA®	47	**37**	(10)	6.7	**5.4**	(1.3)	0.0	(19.7)
Others	15	**179**	14	2.1	**26.2**	2.4	0.1	111.7
Export products/ One-time revenue, etc. *	150			21.7				
Total	1,100	**1,370**	270	159.0	**198.7**	39.7	0.6	24.9

- ORGOVYX®, MYFEMBREE® and GEMTESA® expecting continued growth
- APTIOM® decline due to an increasingly competitive environment
- Bulk shipment to Europe and royalties expected to increase

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

FY2023	Deferred revenue from the collaboration with Pfizer of $117M	FY2024	Deferred revenue from the collaboration with Pfizer of $117M
	Milestone revenue from the approval of MYFEMBREE® for endometriosis in EU of $9M		

FX rates:
FY2023 Results : 1US$ = ¥144.59
FY2024 Forecasts : 1US$ = ¥145.00

Financial Forecasts for FY2024

ORGOVYX®

ORGOVYX® (relugolix) 120 mg tablets

FY2023 Results

Forecasts	Results	YoY comparison	Volume and price influence against results	
$290M	**$292M (101% to forecasts)**	**Approx. 60% increase**	Volume	$1.2M
			Price	$0.7M

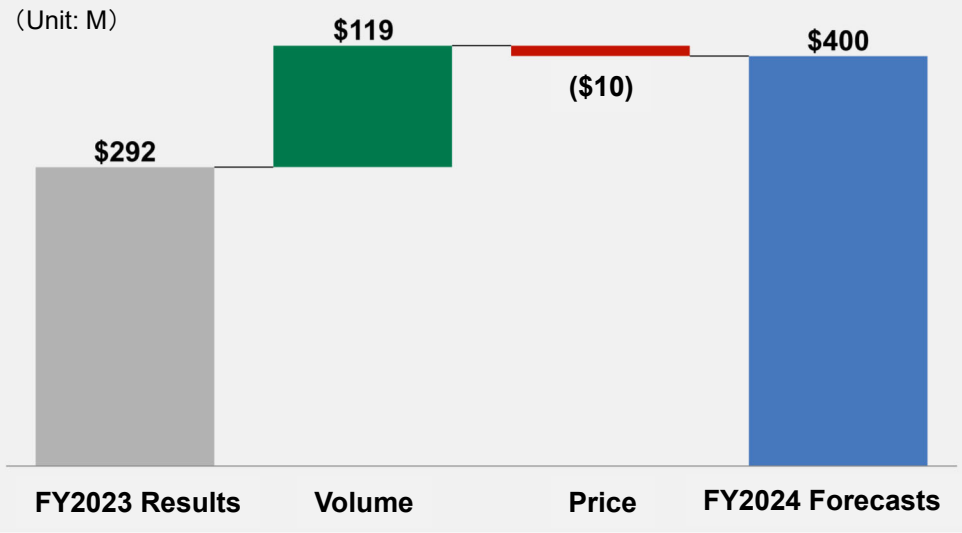
Share in ADT Market* March 2024

✓ Products Share 6.0%

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

FY2024 Plans

Breakdown of the sales growth in FY2024 VS FY2023



Breakdown of the volume growth in FY2024 VS FY2023

$119M of volume increase is expected to be driven by the linear growth in demand of $99M and incremental demand through the sales and marketing plan, etc. of $20M

Topic for Sales and Marketing Plan

- Educating patients and HCPs on the ORGOVYX® as a result of changes to the Medicare Part D benefit design

(From January 2024, the Medicare Part D benefit design was changed, including eliminating of out of pocket following catastrophic coverage and relaxing the low-income subsidy threshold)

- Engaging mainly Oncologists to drive awareness of favorable clinical data and recently updated NCCN guidelines in February 2024 regarding combination use of ORGOVYX®
- Activating and preparing patients to have productive discussions with their doctors about medication options

NCCN (National Comprehensive Cancer Network) Guidelines Update

ORGOVYX® (relugolix) 120 mg tablets

NCCN Guidelines

- Standardized clinical practice guidelines for the diagnosis, treatment, and management of cancer, and highly valued by oncologists
- Language on combination use may impact prescriptions since combined treatments are common in advanced prostate cancer

Guidelines Revision

- Under previous guidelines, ORGOVYX® (generic name: relugolix) in combination therapy in some conditions were not recommended in the guidelines
- In Feb. 2024, however, guidelines included ORGOVYX® as a recommended option for some combination therapies*
- We anticipate increasing utilization, particularly in Academic Centers & Integrated Delivery Networks

Change in combination therapy

Before February 27, 2024	→	After February 27, 2024
Degarelix + Combinational Drugs**		LHRH antagonist (Degarelix & Relugolix) + Combinational Drugs**

*Regional (N1,M0) disease, Metastatic Castration-sensitive disease, and Secondary hormone therapy for M0/M1 Castration-resistant prostate cancer
**abiraterone acetate, apalutamide, darolutamide, enzalutamide, docetaxel, cabazitaxel

Financial Forecasts for FY2024

MYFEMBREE®

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

FY2023 Results

Forecasts	Results	YoY comparison	Volume and price influence against results	
$70M	**$64M (91% to forecasts)**	**Approx. 94% increase**	Volume	**($3.8M)**
			Price	**($2.1M)**

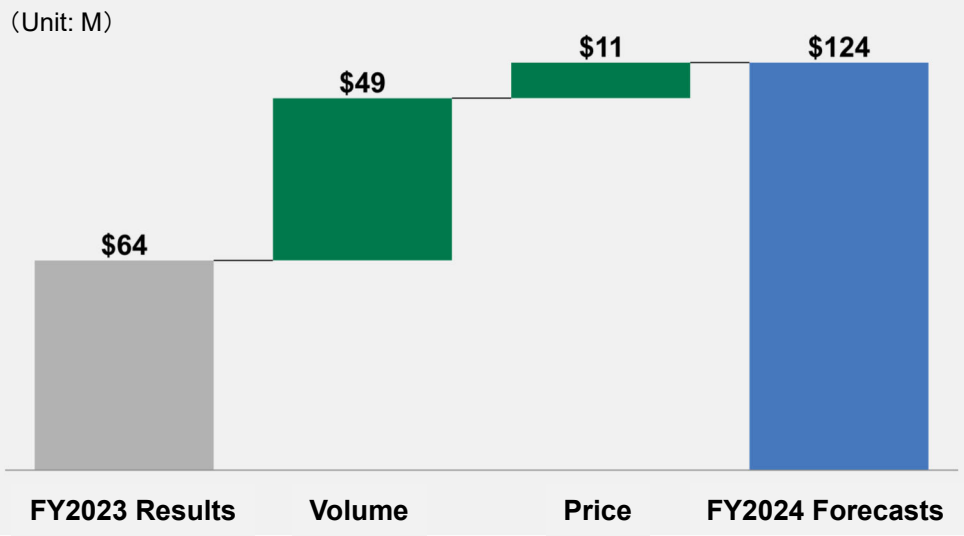
Rx Share in Oral GnRH antagonists Market* March 2024

- ✓ TRx 44% (UF: 84% EM: 20%)
- ✓ NBRx 47% (UF: 90% EM: 21%)

*Symphony Health, an ICON plc Company, Metys®, March 1, 2024, to March 31, 2024.

FY2024 Plans

Breakdown of the sales growth in FY2024 VS FY2023



Breakdown of the volume growth in FY2024 VS FY2023

$49M of volume increase is expected to be driven by the linear growth in demand of $30M and incremental demand through the sales and marketing plan, etc. of $19M

Topic for Sales and Marketing Plan

- Optimized sales force focusing on OBGYN targets with high prescription volumes of oral GnRH antagonists
- Launch of new more impactful messaging to engage HCPs on MYFEMBREE® as the GnRH of choice after OC failure for both UF and EM
- Help patients start and stay on MYFEMBREE® with introduction of a 5$/3-month Co-pay card

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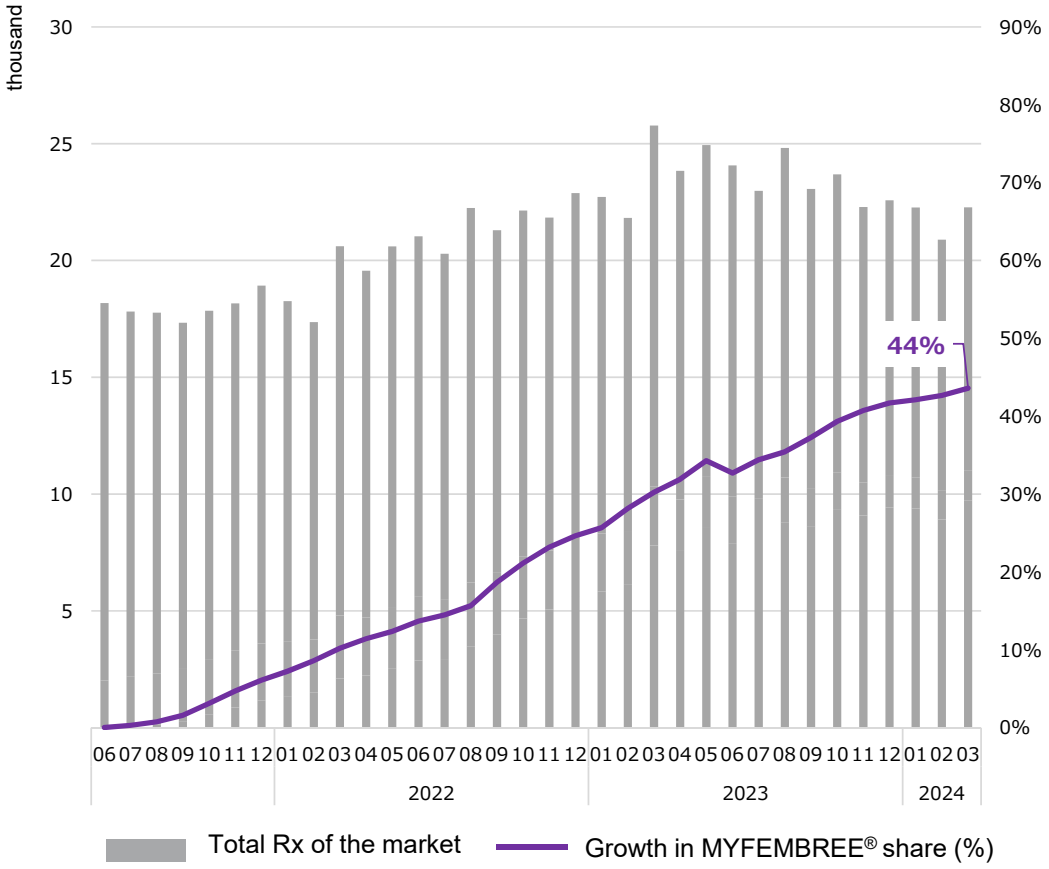
Trends in Prescriptions for MYFEMBREE® (TRx and Share)

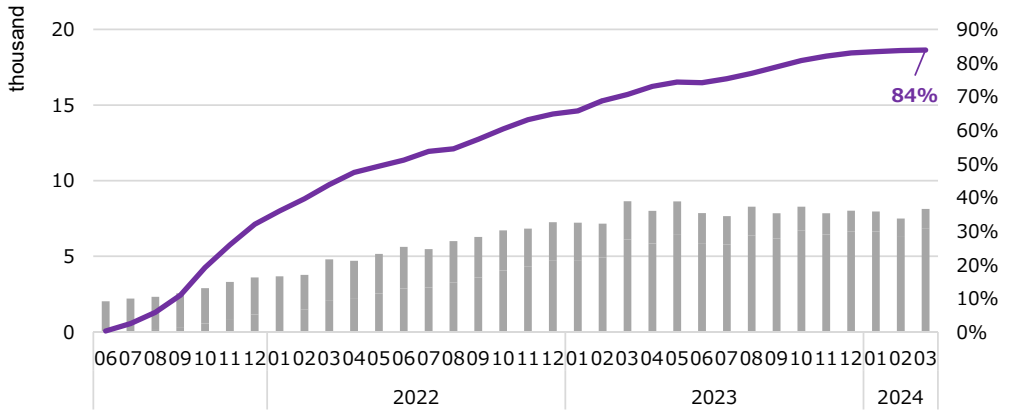
Myfembree®
(relugolix, estradiol, and norethindrone acetate) tablets
40 mg, 1 mg, 0.5 mg

UF＋EM

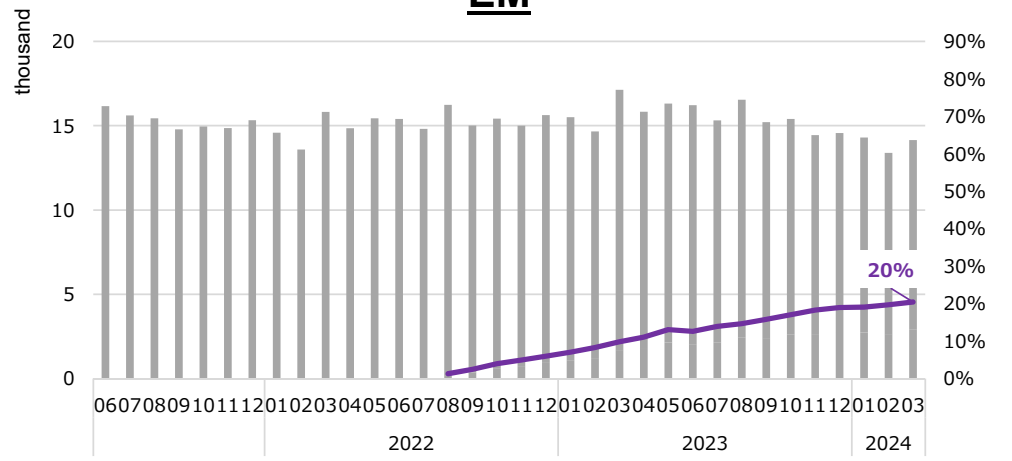


Symphony Health, an ICON plc Company, Metys®, January 1, 2021, to March 31, 2024

UF



EM



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Financial Forecasts for FY2024

GEMTESA®

GEMTESA® (vibegron) 75 mg tablets

FY2023 Results

Forecasts	Results	YoY comparison	Volume and price influence against results	
$260M	**$255M (98% to forecasts)**	**Approx. 40% increase**	Volume	($10.9M)
			Price	$5.9M

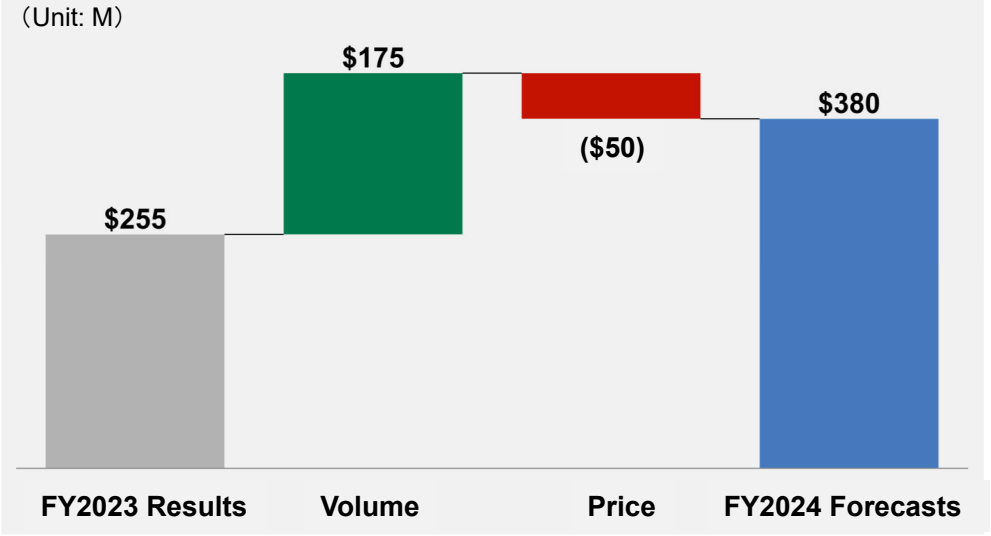
Rx Share in β3 Market* March 2024

- ✓ TRx 25%
- ✓ NBRx 35%

*This is based on information licensed from IQVIA: NPA for the period 3/1, 2024 to 3/31, 2024 reflecting estimates of real-world activity. All rights reserved.

FY2024 Plans

Breakdown of the sales growth in FY2024 VS FY2023



Breakdown of the volume growth in FY2024 VS FY2023

$175M of volume increase is expected to be driven by the linear growth in demand of $150M and incremental demand through the sales and marketing plan, etc. of $25M

Topic for Sales and Marketing Plan

- An expanded sales team focused on increasing GEMTESA® market share in Primary Care
- Preparing for the potential launch of OAB+BPH indication
- Negotiating Medicare Part D contracts to improve GTN

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Financial Forecasts for FY2024

Revenue of Major Products in Japan & Asia

Billions of yen

	FY2023 Results	FY2024 Forecasts	Change	
			Value	%
Japan				
Equa®/EquMet®	30.6	**26.3**	(4.3)	(14.1)
LATUDA®	11.7	**13.0**	1.3	10.8
TWYMEEG®	4.6	**11.3**	6.7	147.7
METGLUCO®	7.3	**7.4**	0.1	1.4
LONASEN® Tape	3.8	**4.4**	0.6	15.2
TRERIEF®	15.5	**2.1**	(13.4)	(86.4)
AG products	9.7	**11.1**	1.4	14.6
Others	22.1	**24.7**	(6.7)	(30.5)
Export products/ One-time revenue, etc.	8.0			
Non-pharmaceutical operations	1.3			
Total	114.7	**100.3**	(14.4)	(12.5)
Asia				
MEROPEN® (China)	21.3	**21.2**	(0.1)	(0.3)
Others	19.6	**17.8**	(1.8)	(9.2)
Total	40.9	**39.0**	(1.9)	(4.6)

Japan

- Continue to focus on increasing revenue of LATUDA® and TWYMEEG®
- TRERIEF®'s sales are expected to decline significantly due to loss of exclusivity
- NHI drug price revision effect in FY2024 : (¥5.2B)

Asia

- In China, sales are expected to remain at the same level as FY2023, despite the impact of Volume-Based Procurement application
- The temporary expansion of MEROPEN® (Southeast Asia) shipments that occurred in FY2023 is expected to subside

Financial and Dividend Policy, Schedule to Revise the Mid-term Business Plan 2027 (MTBP 2027)

Financial Policy:

- The repayment deadline for the bridge loan of approximately 145.0 billion yen (balance as of the end of March 2024) has been extended to the end of September 2024
- Cash from the sale of shares of Roivant Sciences Ltd. in April 2024 is planned to be allocated to repaying borrowings

Dividend Policy:

Dividends will be suspended for FY2024 because 1.0 billion yen of core operating profit for FY2024 is forecasted, which is significantly below the assumption stated in the MTBP 2027

Schedule to Revise the MTBP 2027:

In light of the business environment facing Sumitomo Pharma Group, the Company believes that it is necessary to review the MTBP 2027, and will strive to disclose a new MTBP as soon as possible

Research and Development

Research and Development

Development Pipeline (as of May 14, 2024)

: Psychiatry & Neurology : Oncology : Others

Revisions since the announcement of January 2024 are shown in red

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

Major Progress in Clinical Development

- **Allo iPS cell-derived products (dopaminergic neural progenitor cells)**
  U.S.: Started Phase 1/2 study (Company-sponsored clinical study) for Parkinson's disease
- **ulotaront, SEP-380135**
  Granted Otsuka the exclusive worldwide rights to develop, manufacture, and commercialize ulotaront all indications and out-licensing
- **SMP-3124**
  U.S. : Started Phase 1/2 study for solid tumors
- **GEMTESA® (vibegron)**
  U.S.: Submitted sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in February 2024
- **fH1/DSP-0546LP (universal influenza vaccine)**
  Europe: Started Phase 1 study for influenza in Belgium

【Discontinuation of the development and the study】

- EPI-589　U.S.: Parkinson's disease (Phase 2), U.S. and Japan: Amyotrophic lateral sclerosis (ALS) (Phase 2)
- SEP-378614　U.S.: Indication undetermined (Phase 1)
- TP-1287 and TP-1454 U.S.: Solid tumors (Phase 1)

＊Decided to discontinue development of SEP-4199 and rodatristat ethyl, which were under consideration for development strategy

＊Deleted SP-101 from the table due to spin-out (U.S.: Phase 1/2 for cystic fibrosis)

Allogeneic iPS cell-derived Dopaminergic Neural Progenitor Cells Started Company-Sponsored Clinical Study in the U.S.

Overview of this clinical study

Test cells	DSP-1083 Allogeneic iPS cell-derived dopaminergic neural progenitor cells (cryopreserved cells)
Development stage	Phase 1/2
Proposed indication	Parkinson's disease
Study design (Target number of subjects)	Multicenter, double-blind (active and sham), randomized study (dozens of subjects)
Primary endpoint	Safety: Frequency and severity of adverse events
Secondary endpoint (Efficacy)	Motor symptoms and others
Company conducting study	Sumitomo Pharma America, Inc.

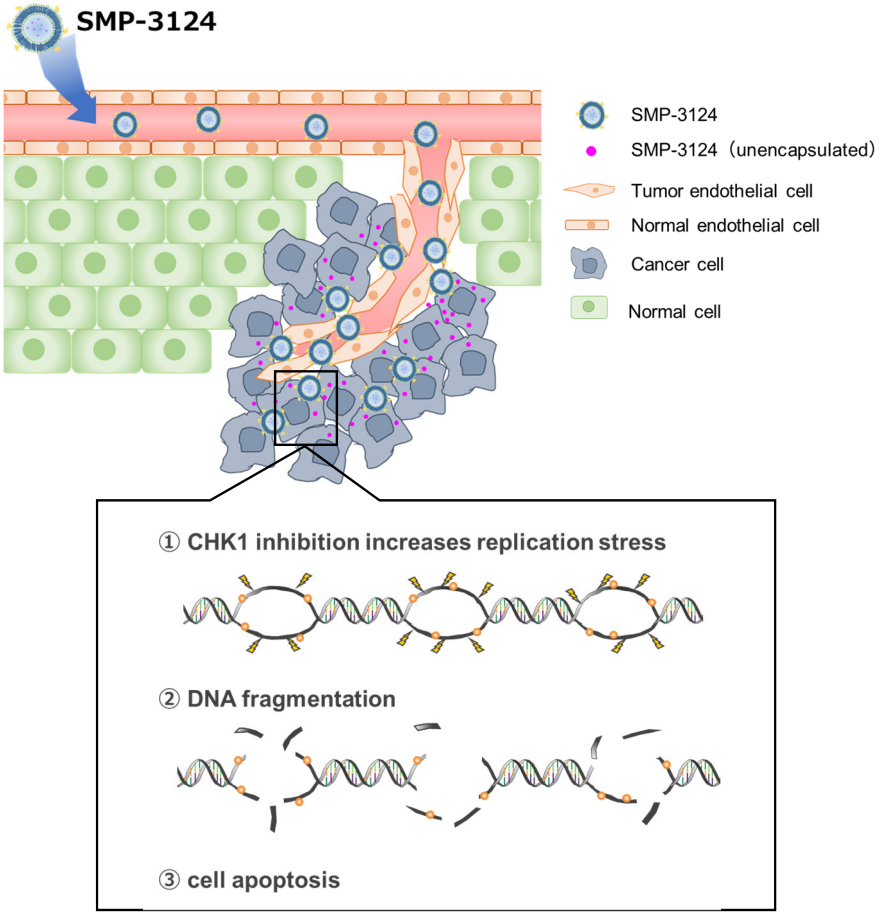
Overview of the developments for Parkinson's disease in the U.S.

- ✓ In addition to the investigator-initiated study (University of California San Diego School of Medicine) started in November 2023, started the company-sponsored clinical study in February 2024
- ✓ Allogeneic iPS cell-derived dopaminergic neural progenitor cells for the company-sponsored clinical study are cryopreserved cells produced at SMaRT in Japan and transported and provided to U.S.
- ✓ In U.S., we expect to launch the cell product during the next Mid-term Business Plan period (by the end of FY2032), and aim to grow into a blockbuster in the 2030s

New Chemical Entity: SMP-3124 (CHK1 inhibitor, Liposomal nanomedicine)

- ✓ Target indication: Solid tumors
- ✓ Origin: In-house
- ✓ Mechanism of action: Induce cell apoptosis by CHK1 (Checkpoint kinase 1) inhibition
- ✓ Stage: Phase 1/2 in the U.S.
- ✓ Expected profile:
  - ➢ CHK1 is activated by DNA damage response, then arrests the cell cycle, and induces DNA repair that is a serine-threonine kinase. CHK1 inhibition leads cancer cell with high replication stressed to apoptosis by inducing further DNA damages
  - ➢ SMP-3124 is expected to accomplish strengthen the anti-tumor activity and weaken side effects by changing pharmacokinetics of the compound with liposomal nanomedicinal encapsulation
- ✓ Japan will join the same Phase 1/2 study
- ✓ Pre-clinical study data was presented in a poster at AACR2024

Mode of action



Research and Development

Main Events / Targets for FY2024 (as of May 14, 2024)

Psychiatry & Neurology	☐ Allogeneic iPS cell-derived products (Parkinson's disease): Submit NDA in Japan ☐ Allogeneic iPS cell-derived products (Parkinson's disease): Obtain approval in Japan ☐ 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	☐ Advance Phase 1/2 study of TP-3654, start the combination part of the study with a JAK inhibitor ☐ Advance Phase 1/2 study of DSP-5336, start the pivotal part of the monotherapy study ☐ Advance Phase 1/2 study of SMP-3124 in the U.S., start the same Phase 1/2 study of SMP-3124 in Japan
Others	☐ vibegron: Obtain approval for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S. ☐ Advance early Phase studies of universal influenza vaccine and others
Frontier	☐ Promoting the current themes and generating evidence data for maximizing the value of the launched products

Appendix

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Appendix (Financial Results for FY2023)

Financial Results for FY2023 (Full Basis)

Billions of yen

	FY2022 Results	FY2023 Results	Change	
			Value	%
Revenue	555.5	314.6	(241.0)	(43.4)
Cost of sales	178.9	126.6	(52.3)	(29.3)
Gross profit	376.6	188.0	(188.6)	(50.1)
SG&A expenses	373.3	429.5	56.2	15.1
R&D expenses	131.9	112.6	(19.2)	(14.6)
Other operating income and expenses	51.6	(0.7)	(52.2)	
Operating profit	(77.0)	(354.9)	(277.9)	—
Finance income and costs	29.1	31.7	2.7	
Profit before taxes	(47.9)	(323.1)	(275.2)	—
Income tax expenses	48.8	(8.2)	(57.0)	
Net profit	(96.7)	(314.9)	(218.2)	—
Net profit attributable to owners of the parent	(74.5)	(315.0)	(240.5)	—

Financial Position and Cash Flow

Billions of yen

B / S	As of March 2023	As of March 2024	Change
Assets	1,134.7	907.5	(227.2)
Goodwill / Intangible assets	538.7	395.4	(143.3)
Other financial assets (Non-current)	134.0	161.7	27.7
Cash and deposit / Short-term loan receivable	143.5	29.0	(114.4)
Liabilities	728.0	751.4	23.4
Bonds and borrowings	334.7	418.9	84.2
Income taxes payable	24.1	1.3	(22.7)
Provisions	119.1	79.5	(39.5)
Equity	406.8	156.1	(250.6)
Attributable to owners of the parent	406.7	156.1	(250.7)
(Ratio of equity attributable to owners of the parent to total assets)	35.8%	17.2%	

C / F	FY2022	FY2023	Change
Operating CF	11.9	(241.9)	(253.8)
Investment CF	52.4	33.0	(19.4)
Financial CF	(146.8)	77.9	224.7
Cash and cash equivalents	143.5	29.0	(114.4)
(Operating funds)	158.0	29.0	(128.9)

Impairment losses

Increase due to changes in valuation of securities

Increase in short-term borrowings

Impact of net loss

Decrease in sales rebate reserves due to LATUDA®'s rebate payments, etc.

Increase in net loss

FY2022：Proceeds from sales of Sumitomo Pharma Food & Chemical Co., Ltd. shares and intangible assets, etc.
FY2023：Proceeds from sales of Sumitomo Pharma Animal Health Co., Ltd. shares and securities, etc.

FY2022：Decrease in payment for making Myovant a wholly owned subsidiary
FY2023：Increase in short-term borrowings

Sumitomo Pharma

Appendix (Research and Development)

Main Events / Targets for FY2023 (as of May 14, 2024)

Revisions since the announcement of January 2024 are shown in red

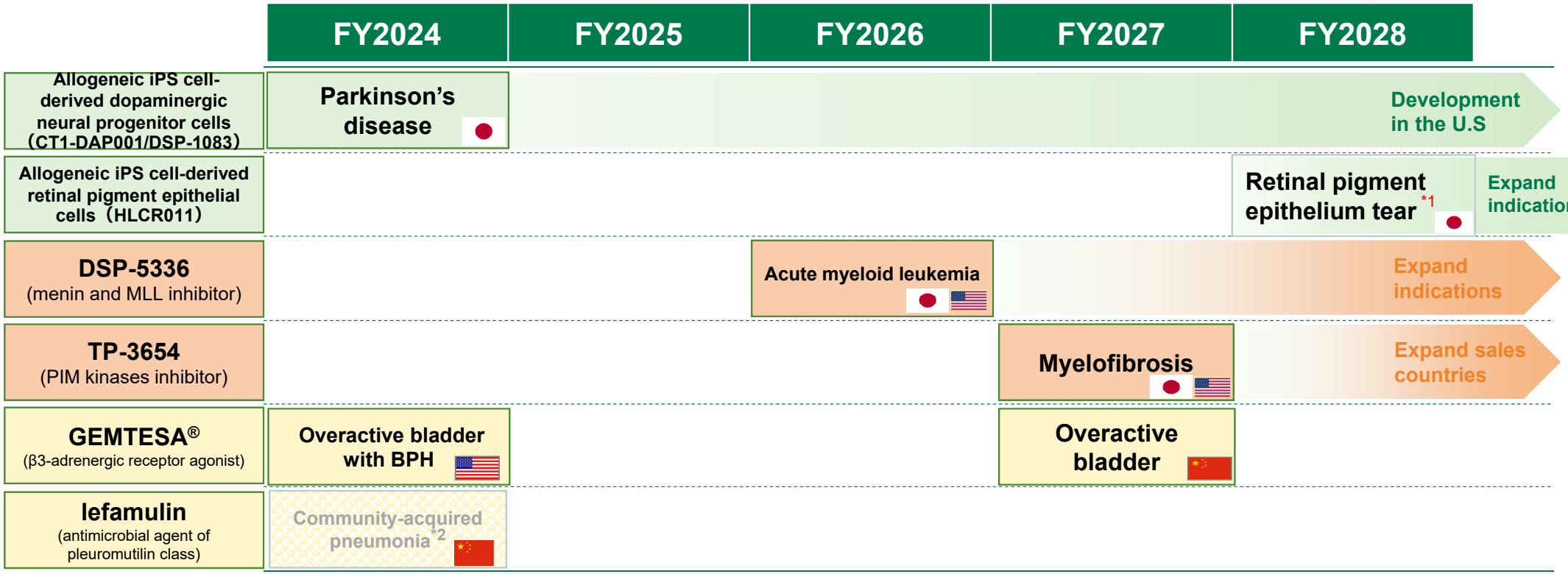
Psychiatry & Neurology	☐ ulotaront: ☑ Obtain results from two Phase 3 studies for schizophrenia (☑ DIAMOND 1 ☑ DIAMOND 2) ~~☐ Submit NDA for schizophrenia in the U.S.~~ ~~☐ Advance Phase 2/3 study in Japan and China for schizophrenia~~ ~~☐ Advance Phase 2/3 studies for two additional indications (aMDD, GAD)~~ ~~☐ SEP-4199: Advance Phase 3 studies for Bipolar I depression~~ ☑ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear): Start clinical study in Japan ☑ Allogeneic iPS cell-derived products (Parkinson's disease): Start clinical study in the U.S. ☑ Complete manufacturing plant in the U.S. (for RETHYMIC® and allogeneic iPS cell-derived products)
Oncology	☐ Advance early Phase studies
Others	☑ relugolix: Obtain approval for endometriosis in Europe ☐ vibegron: Obtain results from Phase 3 study and submit sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S. ☑ rodatristat ethyl: Obtain results from Phase 2 study for pulmonary arterial hypertension (PAH) ☐ universal influenza vaccine, malaria vaccines : Promote joint research and development projects
Frontier	~~☐ Launch product: (Japan) Automated blood collection/stabilization device~~ ☑ Promoting the current themes and generating evidence data for maximizing the value of the launched products

Appendix (Research and Development)

Product Launch Target (as of May 14, 2024)

Psychiatry & Neurology | Oncology | Others

Revisions since the announcement of January 2024 are shown in red



*1 Revised from under review for launch target to FY2028

*2 Under review for launch target

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Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of May 14, 2024)

Revisions since the announcement of January 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 Target* (FY2024)
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP			●5			
Photoreceptor (3D) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US	●	●2				
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	●					

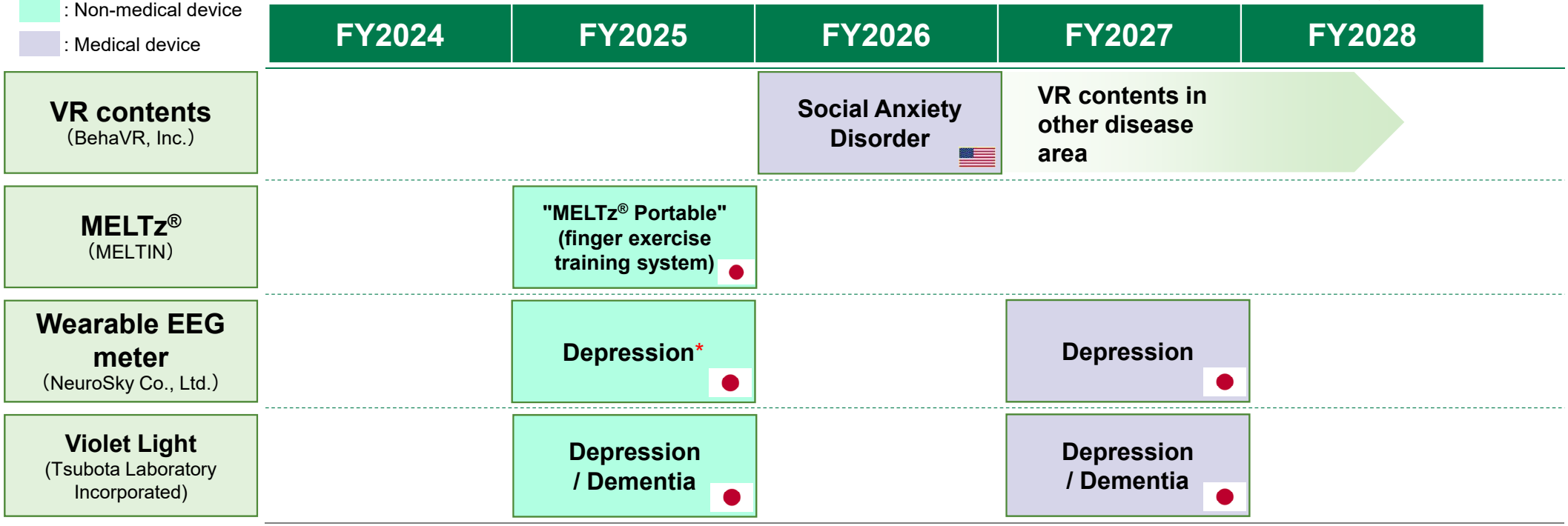
1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego School of Medicine
5. Company-sponsored clinical study * Subject to conditional and time-limited approval

Appendix (Research and Development)

Frontier Business Product Launch Target (as of May 14, 2024)

Revisions since the announcement of January 2024 are shown in red

: Non-medical device
: Medical device



* Revised from FY2024 to FY2025

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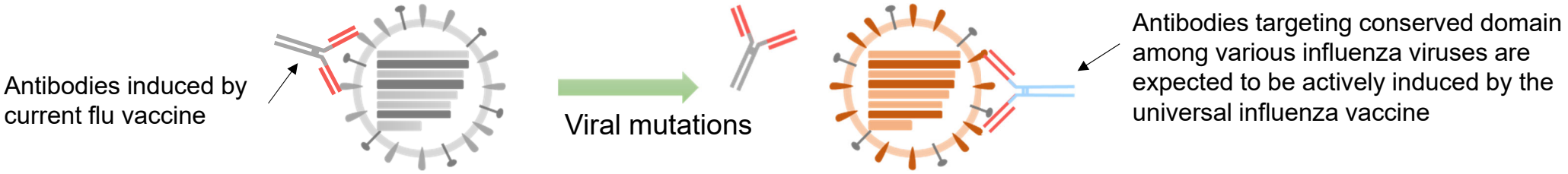
New Vaccine: fH1/DSP-0546LP

- ✓ Target indication: Influenza
- ✓ Origin: In-house (Joint research with the National Institutes of Biomedical Innovation, Health and Nutrition)
- ✓ Mode of action: Cross-protection by enhancing ADCC activity through the elicitation of Th1-mediated immune responses
- ✓ Stage: Phase 1 in Belgium
- ✓ Expected profile:
  - ➢ The next-generation candidate vaccine formulation composed of the post-fusion hemagglutinin antigen (fH1) that is effective against a broad range of influenza viruses, and TLR7 adjuvant “DSP-0546LP” that enhances the quantity, quality, and durability of immune response
  - ➢ Improving the breadth and durability of protection against seasonal influenza viruses and being effective against novel and potentially pandemic strains

    * Conventional influenza vaccines lose effectiveness due to viral mutations, making it necessary to select, produce, and inoculate a vaccine to immunize against strains predicted to circulate each year. They may also not respond well to emerging strains of influenza



Ref. SUMITOMO KAGAKU, 2022, 29 (2022) (modified)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