Securities Code: 4506

Supplementary Financial Data (IFRS) for the Second Quarter of the Year Ending March 31, 2025

October 30, 2024

Sumitomo Pharma Co., Ltd.

- 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.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of JPY)

	Q2 FY2023	**Q2 FY2024**	Change %	FY2023	FY2024 (Forecasts)	Change % YoY
Revenue	152.6	**180.7**	18.4	314.6	338.0	7.5
Cost of sales *1	60.3	**72.3**	19.8	126.6	138.0	9.0
Gross profit	92.3	**108.5**	17.5	188.0	200.0	6.4
SG&A expenses *1	118.8	**83.4**	(29.8)	236.4	169.0	(28.5)
R&D expenses *1	45.3	**25.1**	(44.6)	90.9	50.0	(45.0)
Other operating income/expenses *2	5.9	**(0.0)**		6.4	20.0	
Core operating profit (loss)	(65.8)	**(0.0)**	—	(133.0)	1.0	—
Non-recurring items *3 (negative number indicates net expense)	(20.6)	**(8.1)**		(221.9)	(1.0)	
Operating profit (loss)	(86.5)	**(8.2)**	—	(354.9)	0.0	—
Net profit (loss)	(67.7)	**(32.2)**	—	(314.9)	(16.0)	—
Net profit (loss) attributable to owners of the parent	(67.7)	**(32.2)**	—	(315.0)	(16.0)	—
Basic earnings per share (JPY)	(170.51)	**(81.12)**		(792.79)	(40.27)	
Net profit/ Equity attributable to owners of the parent (ROE)				(111.9%)	(10.8%)	
Return on invested capital (ROIC)				(19.0%)	0.6%	

*1 Exclude non-recurring items (impairment loss, changes in fair value of contingent consideration, etc.)
*2 Including P/L on business transfers, share of P/L of associates accounted for using equity method
*3 Non-recurring items ("other operating income and expenses" except for *2 items, impairment loss, etc.)

2. Consolidated Statement of Profit or Loss (Full Basis)

(Billions of JPY)

	Q2 FY2023	**Q2 FY2024**	Change %
Revenue	152.6	**180.7**	18.4
Cost of sales	60.3	**72.3**	19.9
Gross profit	92.3	**108.4**	17.4
SG&A expenses	134.0	**90.0**	(32.9)
R&D expenses	50.4	**26.3**	(47.8)
Other operating income/expenses	5.6	**(0.3)**	
Operating profit (loss)	(86.5)	**(8.2)**	—
Finance income/costs	30.4	**(24.2)**	
Profit (loss) before taxes	(56.1)	**(32.4)**	—
Income tax expenses	11.6	**(0.2)**	
Net profit (loss)	(67.7)	**(32.2)**	—
Net profit (loss) attributable to owners of the parent	(67.7)	**(32.2)**	—

3. Consolidated Statement of Cash Flows

(Billions of JPY)

	Q2 FY2023	**Q2 FY2024**
Net cash provided by (used in) operating activities	(174.5)	**4.6**
Net cash provided by (used in) investing activities	32.7	**97.5**
Net cash provided by (used in) financing activities	44.8	**(29.4)**
Cash and cash equivalents at the end of period	60.4	**99.1**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2024 assumption	Forex sensitivity FY2024 (Impact of JPY depreciation by ¥1)	
	Mar. 31 2024	**Sep. 30 2024**	FY2023 Apr.-Sep.	**FY2024 Apr.-Sep.**	**Average rate**	Revenue	Core operating profit
JPY / USD	151.33	**142.82**	141.07	**152.78**	**145.00**	1.4	(0.1)
JPY / RMB	20.84	**20.48**	19.75	**21.17**	**20.00**	1.7	0.8

(Billions of JPY)

(Billions of JPY)

5. Capital Expenditures/ Depreciation and Amortization	Q2 FY2023	**Q2 FY2024**	Change	FY2023	FY2024 (Forecasts)	Change YoY
Capital expenditures	6.2	**8.5**	2.3	14.1	11.0	(3.1)
Depreciation of Property, plant and equipment	4.9	**4.2**	(0.7)	9.7	10.7	1.0
Amortization of Intangible assets	13.8	**9.5**	(4.3)	28.1	18.9	(9.2)
Related to products (patent rights/ marketing rights) included in above	12.4	**8.2**	(4.2)	25.4	15.5	(9.9)

Note: The amount of capital expenditures are for tangible fixed assets and software.

Major capital expenditure project in FY2024

(New) Establishment of manufacturing facility for regenerative medicine and cell therapy (S-RACMO, Osaka), total budget ￥3.1billion, to be completed in FY2025

S-RACMO Co., Ltd. was a consolidated subsidiary as of September 30, 2024, but has been excluded from the scope of consolidation and has become an equity method affiliate as of the date of disclosure of this supplementary financial data.

II. Consolidated Statement of Profit or Loss

1. Consolidated Statement of Profit or Loss (Core Basis) (Billions of JPY)

	Q2 FY2023	Q2 FY2024	Change	Change %
Revenue	152.6	**180.7**	28.1	18.4
Overseas revenue	98.7	**131.9**	33.2	33.6
% of Revenue	64.7%	**73.0%**		
Cost of sales	60.3	**72.3**	11.9	19.8
% of Revenue	39.5%	**40.0%**		
Gross profit	92.3	**108.5**	16.2	17.5
SG&A expenses	118.8	**83.4**	(35.3)	(29.8)
Labor costs	49.6	**38.2**	(11.4)	(22.9)
Sales promotion costs/ Advertising and promotion costs	24.3	**13.9**	(10.3)	(42.6)
Amortization/Depreciation	15.7	**10.9**	(4.8)	(30.4)
Others	29.2	**20.3**	(8.9)	(30.4)
R&D expenses	45.3	**25.1**	(20.2)	(44.6)
% of Revenue	29.7%	**13.9%**		
Other operating income/expenses	5.9	**(0.0)**	(5.9)	
Core operating profit (loss)	(65.8)	**(0.0)**	65.8	—
Non-recurring items (negative number indicates net expense)	(20.6)	**(8.1)**	12.5	
Operating profit (loss)	(86.5)	**(8.2)**	78.3	—
Finance income	32.0	**1.2**	(30.8)	
Finance costs	1.7	**25.4**	23.8	
Profit (loss) before taxes	(56.1)	**(32.4)**	23.7	—
Income tax expenses	11.6	**(0.2)**	(11.8)	
Net profit (loss)	(67.7)	**(32.2)**	35.5	—
Net profit (loss) attributable to owners of the parent	(67.7)	**(32.2)**	35.5	—

	Change	FX impact
Japan	(5.7)	
North America	30.9	8.0
Asia	2.9	1.6

Change by segment

	Japan	North America	Asia
Labor costs	(3.2)	(8.6)	0.4
Sales promotion costs/ Advertising and promotion costs	(0.5)	(9.8)	(0.1)
Amortization/ Depreciation	(0.1)	(4.7)	0.0
Others	(1.3)	(8.0)	0.4

FY23: Business structure improvement expenses in North America (20.3)
FY24: Business structure improvement expenses in Japan (4.2)
Business structure improvement expenses in North America (2.8)

2. Adjustments to Core Operating Profit

(Billions of JPY)

Q2 FY2024 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	180.7	**180.7**	—	
Cost of sales	72.3	**72.3**	(0.1)	
Gross profit	108.4	**108.5**	0.1	
SG&A expenses	90.0	**83.4**	(6.6)	Business structure improvement expenses in Japan (3.5) Business structure improvement expenses in North America (2.3)
R&D expenses	26.3	**25.1**	(1.2)	Business structure improvement expenses in Japan (0.7) Business structure improvement expenses in North America (0.5)
Other operating income	0.5	**(0.0)**	(0.5)	
Other operating expenses	0.8	**—**	(0.8)	
Operating profit (loss)	(8.2)	**(0.0)**	8.1	

III. Segment Information (Core Basis)

(Billions of JPY)

Q2 FY2024 Results	Japan	North America	Asia	Total
Revenue	52.8	104.2	23.7	180.7
Cost of sales	27.0	39.4	5.9	72.3
Gross profit	25.9	64.8	17.8	108.5
SG&A expenses	19.6	57.4	6.4	83.4
Core segment profit	**6.3**	**7.4**	**11.4**	**25.1**
R&D expenses *1				25.1
Other operating income/expenses (Core basis) *2				(0.0)
Core operating profit (loss)				**(0.0)**

(Billions of JPY)

Q2 FY2023 Results	Japan	North America	Asia	Total
Revenue	58.5	73.3	20.8	152.6
Cost of sales	28.0	27.0	5.3	60.3
Gross profit	30.6	46.3	15.5	92.3
SG&A expenses	24.7	88.4	5.6	118.8
Core segment profit (loss)	**5.9**	**(42.2)**	**9.9**	**(26.4)**
R&D expenses *1				45.3
Other operating income/expenses (Core basis) *2				5.9
Core operating profit (loss)				**(65.8)**

(Billions of JPY)

FY2024 Forecasts	Japan	North America	Asia	Total
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 *1				50.0
Other operating income/expenses (Core basis) *2				20.0
Core operating profit				**1.0**

*1 R&D expenses are controlled globally and not allocated to each segment.

*2 Including P/L on business transfers and share of P/L of associates accounted for using equity method

IV. Revenue Information

1. Revenue by segment

(Billions of JPY)

Segment	Q2 FY2023	**Q2 FY2024**	Change	Change %	FY2024 (Forecasts)	Progress %
Japan	58.5	**52.8**	(5.7)	(9.8)	100.3	52.7
North America	73.3	**104.2**	30.9	42.2	198.7	52.4
Asia	20.8	**23.7**	2.9	14.0	39.0	60.9

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	Q2 FY2023	**Q2 FY2024**	Change	Change %	FY2024 (Forecasts)	Progress %
Japan						
Promoted products						
Equa®/EquMet® Therapeutic agent for type 2 diabetes	15.8	**14.2**	(1.6)	(10.4)	26.3	53.8
LATUDA® Atypical antipsychotic (Jun. 2020～)	5.7	**6.7**	0.9	16.2	13.0	51.2
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	2.6	**3.6**	0.9	34.7	11.3	31.5
METGLUCO® Therapeutic agent for type 2 diabetes	3.7	**3.8**	0.0	1.2	7.4	50.9
LONASEN® Tape Atypical antipsychotic	1.8	**2.3**	0.4	24.1	4.4	51.7
TRERIEF® Therapeutic agent for Parkinson's disease	8.5	**2.4**	(6.2)	(72.1)	2.1	113.7
Other products						
Authorized Generics	4.6	**5.6**	1.0	20.9	11.1	50.1
Export products, One-time revenue, Others	15.7	**14.5**	(1.2)	(7.7)	24.7	58.6

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	Q2 FY2023	**Q2 FY2024**	Change	Change %	FY2024 (Forecasts)	Progress %
North America						
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	19.4	**35.5**	16.1	83.0	57.9	61.3
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug. 2022～)	4.2	**6.0**	1.9	45.4	17.9	33.8
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	15.8	**25.2**	9.4	59.6	55.0	45.9
APTIOM® Antiepileptic	16.1	**19.9**	3.8	23.6	29.1	68.6
RETHYMIC® Pediatric congenital athymia (Mar. 2022～)	3.1	**2.9**	(0.1)	(4.4)	7.2	40.9
Export products, One-time revenue, Others	14.7	**14.5**	(0.2)	(1.2)	31.6	45.9
Asia						
MEROPEN® (China) Carbapenem antibiotic	10.2	**13.5**	3.2	31.4	21.2	63.5
MEROPEN® (Southeast Asia) Carbapenem antibiotic	4.0	**1.8**	(2.3)	(55.9)	3.6	49.6

(Ref.) Products sales in North America (based on local currency)

(Millions of USD)

Brand name	Q2 FY2023	**Q2 FY2024**	Change	Change %	FY2024 (Forecasts)	Progress %
ORGOVYX®	138	**232**	95	68.9	400	58.1
MYFEMBREE®	29	**40**	10	34.2	124	31.9
GEMTESA®	112	**165**	53	47.4	380	43.5
APTIOM®	114	**131**	16	14.1	201	65.0
RETHYMIC®	22	**19**	(3)	(11.8)	49	39.3

V. Consolidated Statement of Financial Position

(Billions of JPY)

	Mar. 31 2024	Sep. 30 2024	Change	
Assets	**907.5**	**799.8**	**(107.7)**	
Non-current assets	**637.9**	**487.8**	**(150.1)**	
Property, plant and equipment	57.9	57.4	(0.5)	
Goodwill	199.8	188.5	(11.2)	
Intangible assets	195.7	180.0	(15.7)	
Patent rights/Marketing rights	186.4	171.4	(15.1)	
In-process R&D	3.2	3.2	(0.0)	
Others	6.0	5.4	(0.6)	
Other financial assets	161.7	39.4	(122.3)	← Decrease by sales of investment securities
Other non-current assets	20.7	19.9	(0.7)	
Deferred tax assets	2.2	2.6	0.3	
Current assets	**269.6**	**311.9**	**42.4**	
Inventories	115.4	105.6	(9.7)	
Trade and other receivables	81.0	66.1	(15.0)	
Other financial assets	7.1	16.8	9.7	
Other current assets	35.2	20.6	(14.6)	
Cash and cash equivalents	29.0	99.1	70.0	
Assets held for sale	1.9	3.8	1.9	
Liabilities	**751.4**	**685.5**	**(65.8)**	
Non-current liabilities	**235.9**	**199.0**	**(36.9)**	
Bonds and borrowings	133.4	133.4	0.1	
Other financial liabilities	12.7	13.5	0.7	
Retirement benefit liabilities	11.2	11.1	(0.1)	
Other non-current liabilities	40.4	27.0	(13.5)	
Deferred tax liabilities	38.2	14.1	(24.1)	← Decrease due to sales of investment securities
Current liabilities	**515.5**	**486.5**	**(29.0)**	
Borrowings	285.5	256.0	(29.6)	← Repayment of short-term borrowings
Trade and other payables	67.7	58.6	(9.1)	
Other financial liabilities	14.1	23.4	9.3	
Income taxes payable	1.3	18.6	17.3	← Increase due to sales of investment securities
Provisions	79.5	79.3	(0.3)	
Other current liabilities	67.2	48.4	(18.8)	
Liabilities directly associated with assets held for sale	—	2.3	2.3	
Equity	**156.1**	**114.2**	**(41.9)**	
Share capital	22.4	22.4	—	
Treasury shares	(0.7)	(0.7)	(0.0)	
Retained earnings	(22.7)	(13.3)	9.4	← Transfer from valuation difference on investment securities
Other components of equity	157.0	105.7	(51.3)	← Decrease in valuation difference due to sales of investment securities
Equity attributable to owners of the parent	**156.1**	**114.2**	**(41.9)**	
Non-controlling interests	0.1	0.1	0.0	

Major patent rights	24/3	24/9
ORGOVYX® (relugolix)	69.7	63.4
MYFEMBREE® (relugolix)	10.6	9.7
GEMTESA® (vibegron)	98.5	90.9

VI. Changes in Quarterly Results

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of JPY)

	FY2023				FY2024	
	Q1	Q2	Q3	Q4	Q1	Q2
Revenue	75.7	77.0	82.4	79.5	90.7	90.1
Cost of sales	30.4	29.9	32.9	33.4	34.9	37.3
Gross profit	45.3	47.1	49.5	46.1	55.7	52.8
SG&A expenses	61.8	56.9	57.9	59.8	43.8	39.6
R&D expenses	22.8	22.5	22.7	22.9	12.8	12.3
Other operating income/expenses	5.9	(0.0)	0.5	0.0	(0.0)	(0.0)
Core operating profit (loss)	(33.5)	(32.3)	(30.5)	(36.6)	(0.9)	0.9
Non-recurring items (negative number indicates net expense)	(18.1)	(2.6)	(0.7)	(200.5)	(2.2)	(5.9)
Operating profit (loss)	(51.6)	(34.9)	(31.2)	(237.1)	(3.1)	(5.1)
Net profit (loss)	(38.9)	(28.9)	(50.0)	(197.2)	15.9	(48.2)
Net profit (loss) attributable to owners of the parent	(38.9)	(28.9)	(50.0)	(197.3)	15.9	(48.2)

2. Revenue of Major Products

	FY2023				FY2024	
	Q1	Q2	Q3	Q4	Q1	Q2
Japan					(Invoice price basis, Billions of JPY)	
Equa®/EquMet®	8.2	7.6	8.8	6.0	7.4	6.8
LATUDA®	2.8	2.9	3.3	2.7	3.4	3.3
TWYMEEG®	1.2	1.5	0.9	1.1	1.7	1.8
METGLUCO®	1.9	1.8	2.0	1.6	1.9	1.9
LONASEN® Tape	0.9	0.9	1.1	0.9	1.1	1.2
TRERIEF®	4.4	4.1	4.6	2.4	1.5	0.9
Authorized Generics	2.3	2.3	2.5	2.6	2.8	2.7
Export products, One-time revenue, Others	8.6	7.1	7.6	8.2	7.2	7.3
North America					(Millions of USD)	
ORGOVYX®	68	70	78	76	108	125
MYFEMBREE®	13	16	20	14	19	20
GEMTESA®	63	49	62	81	78	87
APTIOM®	58	57	61	59	65	65
RETHYMIC®	11	11	8	14	11	8
Export products, One-time revenue, Others	45	59	57	50	52	43
Asia					(Billions of JPY)	
MEROPEN® (China)	4.4	5.8	5.1	6.0	6.4	7.1
MEROPEN® (Southeast Asia)	2.3	1.8	0.8	0.9	1.0	0.8

VII. Major Consolidated Subsidiaries (As of September 30, 2024)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	29	Manufacturing and sales of pharmaceuticals, etc.

Overseas	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma UK Holdings, Ltd.	2019/10	100%	0	Holding company, management of the group companies, and formulation and promotion of business strategies, etc.
Sumitomo Pharma America, Inc.	1984/ 1	100%	*1,130	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Switzerland GmbH	2016/ 8	100%	23	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma (China) Co., Ltd.	2022/ 6	100%	53	Holding company, management of the Company's China business, etc.
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	560	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference)

Number of employees	March 31, 2023		March 31, 2024		**Sep. 30, 2024**	
consolidated / non-consolidated	6,250	3,026	4,980	2,908	**4,767**	**2,709**
Number of MRs （approx., include contracted MRs）						
Japan Exclude managers/Total	1,040	1,140	910	1,000	**800**	**900**
U.S. Exclude managers/Total	500	580	430	490	**370**	**410**
China Exclude managers/Total	270	340	270	340	**270**	**340**

VIII. Shareholder Positioning (As of September 30, 2024)

1. Total number of authorized shares: 1,500,000,000

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 609,806)

3. Number of shareholders by category:

Shareholder category	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	24	63,698	16.01
Securities companies	48	4,796	1.21
Other Japanese corporations	389	222,027	55.80
Corporations outside Japan, etc.	574	43,841	11.02
Individuals and others (Including treasury stock)	50,245	63,536	15.96
Total	51,280	397,900	100.00

Note: The numbers of shares are rounded down to the nearest thousand shares.

4. Major shareholders:

Shareholders	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	205,634	51.76
The Master Trust Bank of Japan, Ltd. (Trust account)	26,635	6.70
Custody Bank of Japan, Ltd. (Trust account)	11,401	2.87
Nippon Life Insurance Company	7,581	1.91
Inabata & Co., Ltd.	7,543	1.90
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Sumitomo Pharma Employee shareholders' association	3,830	0.96
JP JPMSE LUX RE J.P. MORGAN SEC PLC EQ CO	3,793	0.95
STATE STREET BANK AND TRUST COMPANY 505001	2,865	0.72

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (609,806 shares*).
*Exclude 1,000 shares under name of the Company which are not owned by the Company substantially
2: The numbers of shares held are rounded down to the nearest thousand shares.

IX. Development Pipeline (As of October 30, 2024)

- This table shows clinical studies on indications for which the Sumitomo Pharma Group aims to obtain approval in Japan, U.S., China, or Europe and does not cover all clinical studies.
- The study for the most advanced development stage is listed if there are multiple studies with the same region and indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed and/or approved by the applicable authority.

1. Psychiatry & Neurology

Brand name/Generic name/Product code		Proposed indication	Region	Development stage
Small molecule	LATUDA®/ lurasidone hydrochloride	(New usage: pediatric) Schizophrenia	Japan	Phase 3
	DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Narcolepsy	Japan	Phase 1
	DSP-3456	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	Dravet syndrome, Lennox-Gastaut syndrome	Japan	Phase 1
	DSP-2342	To be determined	U.S.	Phase 1
Regenerative medicine / cell therapy	CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells)	Parkinson's disease	Japan	Under preparation for the NDA
			U.S.	Phase 1/2 (Investigator-initiated study)
				Phase 1/2 （Company-sponsored clinical study）
	HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)	Retinal pigment epithelium tear	Japan	Phase 1/2

2. Oncology

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage
nuvisertib/ TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
enzomenib/ DSP-5336	Acute myeloid leukemia	U.S., Japan	Phase 1/2
DSP-0390	Glioblastoma	U.S., Japan	Phase 1
SMP-3124	Solid tumors	U.S., Japan	Phase 1/2

3. Others

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage
GEMTESA®/ vibegron	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	sNDA submitted in February 2024
vibegron	Overactive bladder (OAB)	China	Phase 3
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	U.S., Japan	Phase 1
fH1/DSP-0546LP	Influenza	Europe	Phase 1

【Main revisions since the announcement of July 2024】

None

X. Profiles of Major Products under Development (As of October 30, 2024)

1. Psychiatry & Neurology

(Small molecule)

DSP-0038 Origin: in-house (Joint research with Exscientia Ltd.), Formulation: oral

- Development stage: Alzheimer's disease psychosis: Phase 1 in the U.S.
- DSP-0038 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies. DSP-0038 is a serotonin 5-HT_{2A} receptor antagonist and a serotonin 5-HT_{1A} receptor agonist. DSP-0038 is expected to demonstrate a greater antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have a broader efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) which include agitation, aggression, anxiety, and depression. Furthermore, DSP-0038 has negligible affinity for dopamine D_2 receptors, and therefore it can be expected to show improved safety and tolerability compared to existing antipsychotics.

DSP-0187 Origin: in-house, Formulation: oral

- Development stage: Narcolepsy: Phase 1 in Japan
- DSP-0187 is an orexin 2 receptor agonist. It is expected to improve excessive daytime sleepiness (EDS) and cataplexy of narcolepsy caused by orexin deficiency. DSP-0187 is also expected to demonstrate an efficacy for EDS other than narcolepsy. Sumitomo Pharma granted Jazz Pharmaceuticals plc the exclusive development and commercialization rights in the territories, except for Japan, China, and certain other Asia/Pacific markets in April 2022.

DSP-3456 Origin: in-house, Formulation: oral

- Development stage: Treatment resistant depression: Phase 1 in the U.S.
- DSP-3456 is a metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM). DSP-3456 is expected to exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex by enhancing the glutamate release, while avoiding side effects (psychotic symptoms, cognitive dysfunction).

DSP-0378 Origin: in-house, Formulation: oral

- Development stage: Dravet syndrome and Lennox-Gastaut syndrome: Phase 1 in Japan
- DSP-0378 is a gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator. It acts on various subtypes of $GABA_A$ receptors expressed in synaptic and extrasynaptic regions in a manner different from common $GABA_A$ receptor potentiators such as benzodiazepines and neurosteroids. It is expected to exhibit an antiepileptic effect against broad epilepsies including intractable rare diseases like Dravet syndrome and Lennox-Gastaut syndrome.

DSP-2342 Origin: in-house (Joint research with Exscientia Ltd.), Formulation: oral

- Development stage: Phase 1 in the U.S.
- DSP-2342 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies. DSP-2342 is a serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist. DSP-2342 is expected to demonstrate a broader antipsychotic effect which includes psychosis, anxiety, and depression, based on the additive effect of 5-HT_{2A} and 5-HT_7 receptor antagonist. Furthermore, DSP-2342 has high selectivity for 5-HT_{2A} and 5-HT_7 receptors, which can be expected to show a high level of safety and tolerability.

(Regenerative medicine / cell therapy)

In cooperation with the partners in the industry-academia collaboration, we are developing Parkinson's disease, regenerative medicine / cell therapy using allogeneic iPS (induced pluripotent stem) cell (healthy patients) for RPE (retinal pigment epithelium) tear, AMD (age-related macular degeneration), retinitis pigmentosa, and spinal cord injury.

CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells)

- Partnering: Kyoto University CiRA, University of California San Diego School of Medicine
- Development stage:
  Parkinson's disease: Under preparation for the NDA in Japan
  Parkinson's disease: Phase 1/2 (Investigator-initiated study, Sponsor: University of California San Diego School of Medicine) in the U.S.
  Parkinson's disease: Phase 1/2 (Company-sponsored clinical study) in the U.S.
- The Ministry of Health, Labour and Welfare (MHLW) designated "Sakigake Designation System" product for regenerative medicine & cell therapy for the indication of Parkinson's disease in February 2017.

HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)

- Partnering: RIKEN, Healios
- Development stage: Retinal pigment epithelium tear: Phase 1/2 in Japan

2. Oncology

nuvisertib/TP-3654 Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

- Development stage: Myelofibrosis: Phase 1/2 in the U.S. and Japan
- Nuvisertib (TP-3654) inhibits the inflammatory signaling pathways through inhibition of PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinases. PIM1 kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth. The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for nuvisertib for the indication of myelofibrosis in May 2022.

enzomenib/DSP-5336 Origin: in-house (Joint research with Kyoto University), Formulation: oral

- Development stage: Acute leukemia: Phase 1/2 in the U.S. and Japan
- Enzomenib (DSP-5336) is a small molecule inhibitor against the binding of menin and mixed-lineage leukemia (MLL) protein. Acute myeloid leukemia with MLL rearrangements or nucleophosmin 1 (NPM1) mutations rely on the menin-MLL interaction for upregulation of genes instrumental to leukemogenesis. Enzomenib has been shown to have anti-cancer activity through downregulation of the genes by inhibition of menin-MLL interaction in pre-clinical studies. The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and granted Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with MLL rearrangement or NPM1 mutation in June 2024. Furthermore, the Ministry of Health, Labour and Welfare in Japan granted Orphan Drug Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with MLL rearrangement or NPM1 mutation in September 2024.

DSP-0390 Origin: in-house, Formulation: oral

- Development stage: Glioblastoma: Phase 1 in the U.S. and Japan
- DSP-0390 is an inhibitor of Emopamil Binding Protein (EBP), which is one of cholesterol biosynthetic enzymes. EBP is an endoplastic reticulum membrane protein involved in cholesterol biosynthesis. When functional, EBP mediates de novo cholesterol synthesis for cell membrane structure and signaling, enabling aberrant growth of tumors. Inhibition of EBP causes an efficient cellular cholesterol depletion and it is expected to show anti-cancer activities. The FDA granted Orphan Drug Designation for DSP-0390 for the indication of brain cancer in May 2022.

SMP-3124 Origin: in-house, Formulation: injection (Liposomal Nanomedicine)

- Development stage: Solid tumors: Phase 1/2 in the U.S. and Japan
- SMP-3124 is an injection, a liposomally encapsulated CHK1 (checkpoint kinase 1) inhibitor. CHK1 is activated by DNA damage response, then arrests the cell cycle, and induces DNA repair via serine-

threonine kinase. CHK1 inhibition leads cancer cell with high replication stress to apoptosis by inducing further DNA damages. SMP-3124 is expected to strengthen the anti-tumor activity and weaken side effects by changing pharmacokinetics of the compound with liposomal nanomedicinal encapsulation.

3. Others

GEMTESA®/vibegron Origin: Merck Sharp & Dohme Corp., Formulation: oral

- Development stage:
  (New indication) Overactive bladder in men with BPH: sNDA submitted in the U.S. in February 2024
  Overactive bladder: Phase 3 in China
- Vibegron is an oral, once-daily, small molecule β3 adrenergic receptor agonist. Vibegron selectively acts on the β3 adrenergic receptor in the bladder that relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in patients with overactive bladder. Former Urovant received approval for overactive bladder in the U.S. in December 2020.

KSP-1007 Origin: in-house (Joint research with The Kitasato Institute), Formulation: injection

- Development stage: Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia: Phase 1 in the U.S. and Japan
- KSP-1007 can broadly and strongly inhibit β-lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. KSP-1007 is expected to become an effective treatment option against carbapenem-resistant bacterial infections in a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Pharma's product for the domestic market: MEROPEN®). The FDA granted Qualified Infectious Disease Product (QIDP) status and Fast Track Designation for KSP-1007 for the indications of complicated urinary tract infections, complicated intra-abdominal infections, and hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia in August 2022.

fH1/DSP-0546LP Origin: in-house (Joint research with the National Institutes of Biomedical Innovation, Health and Nutrition), Formulation: injection

- Development stage: Influenza: Phase 1 in Europe
- fH1/DSP-0546LP is the next-generation candidate vaccine formulation composed of the post-fusion hemagglutinin antigen (fH1) that is expected to be effective against a broad range of influenza viruses, and TLR7 adjuvant "DSP-0546LP" that enhances the quantity, quality, and durability of immune response. 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. The pre-clinical study of fH1/DSP-0546LP demonstrated the broad cross protection against influenza viruses antigenically different from those used in vaccine formulations, and indicated the significance of the TLR7 adjuvant, DSP-0546LP. It is expected that fH1/DSP-0546LP improves the breadth and durability of protection against seasonal influenza viruses and is effective against novel and potentially pandemic strains.

XI. Development Status of Major Programs in Frontier Business (As of October 30, 2024)

- Through collaborations with academia and startup companies, the Company's consolidated subsidiary FrontAct Co., Ltd. works for the research and development of new non-pharmaceutical healthcare solutions by utilizing digital technologies focusing on “mental resilience” (detect signs of mental disease and prevent deterioration) and “active aging” (improve, maintain, and enhance the health of the elderly by enhancing their awareness). The development status of major programs is as follows.

Area	Program	Summary	Development status	Partnering
Psychiatry Neurology	Digital devices for relieving BPSD	Under trial sale as a general wellness product, “Aikomi Care®” and “Aikomi DS.” We are researching and developing a DTx product that enables non-pharmacotherapy, incorporating individually optimized five sensory stimulation contents, and aiming for NHI reimbursement as an approved device.	Japan Preparing for clinical research (medical device)	Aikomi Ltd.
	VR contents for social anxiety disorder (BVR-100)	We are researching and developing a DTx product that converts modules, etc. based on cognitive behavioral therapy (CBT) such as exposure therapy and cognitive restructuring training into VR content. Launched mental health VR contents “First Resort™” as a general wellness product.	U.S. Preparing for clinical study (medical device)	BehaVR, Inc.
	Wearable EEG meter	Service for early detection of mental diseases by daily capture of the EEG profile with simple wearable EEG meter. We aim to develop a service that enables early detection of mental illness by grasping brain wave trends.	Japan Product development (medical device)	NeuroSky Co., Ltd.
	Support Program for Screening of Depression/ Rating of Severity	This product is designed to detect depressive episodes caused by depression or bipolar disorder and help rate the severity of the disease by analyzing patients’ vital signs and activity data collected from wearable devices. We aim to develop a medical device.	Japan Product development (medical device)	Keio University, i2medical LLC
	Violet light	We aim to develop neuromodulation technology via vision with violet lights flashing at 40 Hz to treat and prevent mental illness.	Japan Product development (medical device)	Tsubota Laboratory, Inc.
Motor dysfunction	Neurorehabilitation device for hand/fingers paralysis	Launched “MELTz®” as a medical device. We are developing Robotic neurorehabilitation device utilizing motion intention of patients with hand/fingers paralysis from electromyogram for the patients, and aim for the NHI reimbursement as an approved device.	Japan Product development (medical device)	—
	Training device for hand/fingers paralysis	Under development as "MELTz® Portable". We aim to develop a small and simple device that trains patients with hand/fingers paralysis using a robot that uses myoelectric signals.	Japan Product development (non-medical device)	—