Securities Code: 4506

Supplementary Financial Data (IFRS) for the Year Ended March 31, 2025

May 13, 2025

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)

	FY2023	FY2024	Change %	FY2025 (Forecasts)	Change % YoY
Revenue	314.6	**398.8**	26.8	355.0	(11.0)
Cost of sales *1	126.6	**153.2**	21.0	146.0	(4.7)
Gross profit	188.0	**245.6**	30.7	209.0	(14.9)
SG&A expenses *1	236.4	**167.7**	(29.1)	153.5	(8.5)
R&D expenses *1	90.9	**48.5**	(46.7)	44.0	(9.3)
Others (core basis) *2	6.4	**13.7**		44.5	
Core operating profit (loss)	(133.0)	**43.2**	—	56.0	29.8
Adjustments *3 (negative number indicates net expense)	(221.9)	**(14.3)**		(2.0)	
Operating profit (loss)	(354.9)	**28.8**	—	54.0	87.5
Net profit (loss)	(314.9)	**23.6**	—	40.0	69.2
Net profit (loss) attributable to owners of the parent	(315.0)	**23.6**	—	40.0	69.2
Basic earnings per share (JPY)	(792.79)	**59.49**		100.68	
Net profit/ Equity attributable to owners of the parent (ROE)	(111.9%)	**14.5%**		21.1%	
Return on invested capital (ROIC)	(19.0%)	**9.4%**		11.8%	
Payout ratio	—	**0.0%**		0.0%	

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

(Billions of JPY)

	FY2023	FY2024	Change %
Revenue	314.6	**398.8**	26.8
Cost of sales	126.6	**153.4**	21.2
Gross profit	188.0	**245.4**	30.5
SG&A expenses	429.5	**180.6**	(58.0)
R&D expenses	112.6	**49.9**	(55.7)
Other operating income/expenses, etc.	(0.7)	**13.9**	
Operating profit (loss)	(354.9)	**28.8**	—
Finance income/costs	31.7	**(11.2)**	
Profit (loss) before taxes	(323.1)	**17.6**	—
Income tax expenses	(8.2)	**(6.0)**	
Net profit (loss)	(314.9)	**23.6**	—
Net profit (loss) attributable to owners of the parent	(315.0)	**23.6**	—

*1 Exclude adjustments
*2 Including P/L on business transfers, share of P/L of associates accounted for using equity method
*3 Impairment loss, business structure improvement expenses, and changes in fair value of contingent consideration, etc.

3. Consolidated Statement of Cash Flows

(Billions of JPY)

	FY2023	FY2024
Net cash provided by (used in) operating activities	(241.9)	**16.5**
Net cash provided by (used in) investing activities	33.0	**99.8**
Net cash provided by (used in) financing activities	77.9	**(108.8)**
Cash and cash equivalents at the end of period	29.0	**23.1**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2025 assumption	Forex sensitivity FY2025 (Impact of JPY depreciation by ¥1)	
	Mar. 31 2024	**Mar. 31 2025**	FY2023 Apr.-Mar.	**FY2024 Apr.-Mar.**	**Average rate**	Revenue	Core operating profit
JPY / USD	151.33	**149.53**	144.59	**152.62**	**145.00**	1.7	0.2
JPY / RMB	20.84	**20.59**	20.14	**21.11**	**20.00**	0.6	0.0

(Billions of JPY)

(Billions of JPY)

5. Capital Expenditures/ Depreciation and Amortization	FY2023	**FY2024**	Change	FY2025 (Forecasts)	Change YoY
Capital expenditures	14.1	**12.1**	(2.0)	7.0	(5.1)
Depreciation of Property, plant and equipment	9.7	**8.3**	(1.4)	6.7	(1.6)
Amortization of Intangible assets	28.1	**17.3**	(10.8)	14.4	(2.9)
Related to products (patent rights/ marketing rights) included in above	25.4	**15.0**	(10.4)	12.0	(3.0)

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

II. Consolidated Statement of Profit or Loss

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

	FY2023	FY2024	Change	Change %
Revenue	314.6	**398.8**	84.3	26.8
Overseas revenue	207.9	**306.9**	99.0	47.6
% of Revenue	66.1%	**76.9%**		
Cost of sales	126.6	**153.2**	26.6	21.0
% of Revenue	40.2%	**38.4%**		
Gross profit	188.0	**245.6**	57.7	30.7
SG&A expenses	236.4	**167.7**	(68.7)	(29.1)
Labor costs	100.6	**78.9**	(21.7)	(21.6)
Sales promotion/ Advertising costs	42.4	**25.0**	(17.4)	(41.0)
Amortization/Depreciation	31.8	**20.1**	(11.7)	(36.8)
Others	61.6	**43.7**	(17.9)	(29.1)
R&D expenses	90.9	**48.5**	(42.4)	(46.7)
% of Revenue	28.9%	**12.2%**		
Others (core basis)	6.4	**13.7**	7.3	
Core operating profit (loss)	(133.0)	**43.2**	176.1	—
Adjustments (negative number indicates net expense)	(221.9)	**(14.3)**	207.5	
Operating profit (loss)	(354.9)	**28.8**	383.7	—
Finance income	36.0	**2.3**	(33.7)	
Finance costs	4.3	**13.5**	9.2	
Profit (loss) before taxes	(323.1)	**17.6**	340.7	—
Income tax expenses	(8.2)	**(6.0)**	2.2	
Net profit (loss)	(314.9)	**23.6**	338.6	—
Net profit (loss) attributable to owners of the parent	(315.0)	**23.6**	338.6	—

	Change	FX impact
Japan	(14.8)	
North America	92.8	13.2
Asia	6.3	2.2

Change by segment

	Japan	North America	Asia
Labor costs	(6.6)	(15.6)	0.5
Sales promotion/ Advertising costs	(2.3)	(15.0)	(0.1)
Amortization/ Depreciation	(0.3)	(11.5)	0.0
Others	(1.3)	(16.8)	0.2

FY23: Impairment loss (180.9)
Business structure improvement expenses in North America (30.1)
FY24: Impairment loss (5.5)
Business structure improvement expenses in Japan (5.9)
Business structure improvement expenses in North America (2.9)

2. Adjustments to Core Operating Profit

(Billions of JPY)

FY2024 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	398.8	**398.8**	—	
Cost of sales	153.4	**153.2**	(0.3)	
Gross profit	245.4	**245.6**	0.3	
SG&A expenses	180.6	**167.7**	(12.9)	Business structure improvement expenses in Japan (4.8) Impairment loss (4.5) Business structure improvement expenses in North America (2.5)
R&D expenses	49.9	**48.5**	(1.4)	Business structure improvement expenses in Japan (1.0) Business structure improvement expenses in North America (0.4)
Other operating income/expenses, etc.	13.9	**13.7**	(0.2)	
Operating profit	28.8	**43.2**	14.3	

III. Segment Information (Core Basis)

(Billions of JPY)

FY2024 Results	Japan	North America	Asia	Total
Revenue	99.8	251.8	47.2	398.8
Cost of sales	51.8	90.8	10.6	153.2
Gross profit	48.0	161.0	36.6	245.6
SG&A expenses	36.6	118.4	12.7	167.7
Core segment profit	**11.4**	**42.6**	**23.9**	**77.9**
R&D expenses *1				48.5
Others (core basis) *2				13.7
Core operating profit				**43.2**

(Billions of JPY)

FY2025 Forecasts	Japan	North America	Asia	Total
Revenue	85.7	248.2	21.1	355.0
Cost of sales	46.0	92.1	7.9	146.0
Gross profit	39.7	156.1	13.2	209.0
SG&A expenses	32.2	115.8	5.5	153.5
Core segment profit	**7.5**	**40.3**	**7.7**	**55.5**
R&D expenses *1				44.0
Others (core basis) *2				44.5
Core operating profit				**56.0**

(Billions of JPY)

FY2023 Results	Japan	North America	Asia	Total
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 (loss)	**13.4**	**(80.2)**	**18.4**	**(48.5)**
R&D expenses *1				90.9
Others (core basis) *2				6.4
Core operating profit (loss)				**(133.0)**

*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	FY2023	**FY2024**	Change	Change %	FY2025 (Forecasts)
Japan	114.7	**99.8**	(14.8)	(12.9)	85.7
North America	159.0	**251.8**	92.8	58.3	248.2
Asia	40.9	**47.2**	6.3	15.5	21.1

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	FY2023	**FY2024**	Change	Change %	FY2025 (Forecasts)
Japan					
Promoted products					
LATUDA® Atypical antipsychotic (Jun. 2020～)	11.7	**13.2**	1.4	12.1	13.5
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	4.6	**7.6**	3.1	66.9	11.2
METGLUCO® Therapeutic agent for type 2 diabetes	7.3	**7.3**	0.0	0.6	7.6
Equa®/EquMet® Therapeutic agent for type 2 diabetes	30.6	**24.9**	(5.7)	(18.7)	7.0
LONASEN® Tape Atypical antipsychotic	3.8	**4.6**	0.8	20.2	5.2
Other products					
Authorized Generics	9.7	**11.4**	1.8	18.2	11.6
Export products, One-time revenue, Others	46.9	**30.8**	(16.2)	(34.4)	29.6

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	FY2023	**FY2024**	Change	Change %	FY2025 (Forecasts)
North America					
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	42.2	**83.1**	40.9	96.9	103.0
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug. 2022～)	9.2	**12.8**	3.6	39.0	12.3
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	36.8	**65.8**	28.9	78.6	82.9
RETHYMIC® Cultured thymus tissue for pediatric congenital athymia (Mar. 2022～)	6.3	**6.8**	0.5	7.7	6.5
APTIOM® Antiepileptic	34.0	**39.4**	5.5	16.1	4.8
Export products, One-time revenue, Others	30.5	**44.0**	13.4	43.9	38.7
Asia					
MEROPEN® (China) Carbapenem antibiotic	21.3	**26.3**	5.1	23.9	21.1
Others	19.6	**20.8**	1.2	6.3	

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

(Millions of USD)

Brand name	FY2023	**FY2024**	Change	Change %	FY2025 (Forecasts)
ORGOVYX®	292	**544**	253	86.5	710
MYFEMBREE®	64	**84**	20	31.7	85
GEMTESA®	255	**431**	176	69.2	572
RETHYMIC®	44	**45**	1	2.1	45
APTIOM®	235	**258**	23	9.9	33

V. Consolidated Statement of Financial Position

(Billions of JPY)

	Mar. 31 2024	Mar. 31 2025	Change
Assets	**907.5**	**742.6**	**(164.9)**
Non-current assets	**637.9**	**489.4**	**(148.5)**
Property, plant and equipment	57.9	46.6	(11.2)
Goodwill	199.8	197.4	(2.4)
Intangible assets	195.7	172.5	(23.1)
Patent rights/Marketing rights	186.4	167.7	(18.8)
In-process R&D	3.2	0.5	(2.8)
Others	6.0	4.4	(1.6)
Other financial assets	161.7	44.1	(117.6)
Other non-current assets	20.7	28.2	7.5
Deferred tax assets	2.2	0.5	(1.7)
Current assets	**269.6**	**253.2**	**(16.4)**
Inventories	115.4	94.2	(21.1)
Trade and other receivables	81.0	74.8	(6.2)
Other financial assets	7.1	16.8	9.8
Other current assets	35.2	13.8	(21.4)
Cash and cash equivalents	29.0	23.1	(5.9)
Assets held for sale	1.9	30.4	28.5
Liabilities	**751.4**	**573.1**	**(178.2)**
Non-current liabilities	**235.9**	**332.5**	**96.6**
Bonds and borrowings	133.4	259.0	125.6
Other financial liabilities	12.7	15.8	3.1
Retirement benefit liabilities	11.2	6.5	(4.6)
Other non-current liabilities	40.4	24.6	(15.8)
Deferred tax liabilities	38.2	26.6	(11.7)
Current liabilities	**515.5**	**240.6**	**(274.9)**
Borrowings	285.5	46.4	(239.1)
Trade and other payables	67.7	38.5	(29.2)
Other financial liabilities	14.1	32.9	18.8
Income taxes payable	1.3	1.6	0.2
Provisions	79.5	72.0	(7.5)
Other current liabilities	67.2	45.7	(21.6)
Liabilities directly associated with assets held for sale	—	3.5	3.5
Equity	**156.1**	**169.5**	**13.3**
Share capital	22.4	22.4	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	(22.7)	46.8	69.4
Other components of equity	157.0	97.5	(59.5)
Other comprehensive income associated with assets held for sale	—	3.5	3.5
Equity attributable to owners of the parent	**156.1**	**169.5**	**13.4**
Non-controlling interests	0.1	—	(0.1)

Major patent rights	24/3	25/3
ORGOVYX® (relugolix)	69.7	63.8
MYFEMBREE® (relugolix)	10.6	9.7
GEMTESA® (vibegron)	98.5	92.2

Decrease due to sale of investment securities

Repayment of borrowings and refinancing

Decrease in accounts payable

Increase in net income, and transfer from valuation difference on investment securities

Decrease in valuation difference on investment securities

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	Q3	Q4
Revenue	75.7	77.0	82.4	79.5	90.7	90.1	112.4	105.6
Cost of sales	30.4	29.9	32.9	33.4	34.9	37.3	41.3	39.7
Gross profit	45.3	47.1	49.5	46.1	55.7	52.8	71.2	66.0
SG&A expenses	61.8	56.9	57.9	59.8	43.8	39.6	41.0	43.3
R&D expenses	22.8	22.5	22.7	22.9	12.8	12.3	10.2	13.1
Others (core basis)	5.9	(0.0)	0.5	0.0	(0.0)	(0.0)	1.7	12.1
Core operating profit (loss)	(33.5)	(32.3)	(30.5)	(36.6)	(0.9)	0.9	21.6	21.6
Adjustments (negative number indicates net expense)	(18.1)	(2.6)	(0.7)	(200.5)	(2.2)	(5.9)	(0.2)	(6.1)
Operating profit (loss)	(51.6)	(34.9)	(31.2)	(237.1)	(3.1)	(5.1)	21.4	15.6
Net profit (loss)	(38.9)	(28.9)	(50.0)	(197.2)	15.9	(48.2)	53.4	2.4
Net profit (loss) attributable to owners of the parent	(38.9)	(28.9)	(50.0)	(197.3)	15.9	(48.2)	53.4	2.4

2. Revenue of Major Products

	FY2023				FY2024			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Japan					(Invoice price basis, Billions of JPY)			
LATUDA®	2.8	2.9	3.3	2.7	3.4	3.3	3.6	2.9
TWYMEEG®	1.2	1.5	0.9	1.1	1.7	1.8	2.1	1.9
METGLUCO®	1.9	1.8	2.0	1.6	1.9	1.9	1.9	1.7
Equa®/EquMet®	8.2	7.6	8.8	6.0	7.4	6.8	6.8	4.0
LONASEN® Tape	0.9	0.9	1.1	0.9	1.1	1.2	1.3	1.0
Authorized Generics	2.3	2.3	2.5	2.6	2.8	2.7	3.2	2.7
Export products, One-time revenue, Others	13.1	11.2	12.1	10.6	8.7	8.2	6.7	7.2
North America					(Millions of USD)			
ORGOVYX®	68	70	78	76	108	125	146	166
MYFEMBREE®	13	16	20	14	19	20	26	18
GEMTESA®	63	49	62	81	78	87	118	148
RETHYMIC®	11	11	8	14	11	8	14	11
APTIOM®	58	57	61	59	65	65	69	59
Export products, One-time revenue, Others	45	59	57	50	52	43	120	73
Asia					(Billions of JPY)			
MEROPEN® (China)	4.4	5.8	5.1	6.0	6.4	7.1	6.3	6.6
MEROPEN® (Southeast Asia)	2.3	1.8	0.8	0.9	1.0	0.8	1.2	1.0

VII. Major Group Companies (As of March 31, 2025)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	31	Manufacturing and sales of pharmaceuticals, etc.
RACTHERA Co., Ltd. *1	2024/11	33.4%	—	Research, development, manufacture, sales, and import and export of regenerative medicine and cell therapy products, cell processing products, and regenerative medicine and cell therapy-related products
S-RACMO Co., Ltd. *1	2020/9	33.4%	—	Contract development and manufacturing services in the field of regenerative and cellular medicine

Overseas	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma America, Inc.	1984/ 1	100%	1,157 *2	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%	48	Holding company, management of the Company's China business, etc.
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	569	Manufacturing and sales of pharmaceuticals

*1 Associate companies

*2 Include employees of consolidated subsidiaries

(Reference)

Number of employees	March 31, 2023		March 31, 2024		**March 31, 2025**	
consolidated / non-consolidated	6,250	3,026	4,980	2,908	**3,832**	**1,799**
Number of MRs （approx., include contracted MRs）						
Japan Exclude managers/Total	1,040	1,140	910	1,000	**390**	**450**
U.S. Exclude managers/Total	500	580	430	490	**380**	**430**
China Exclude managers/Total	270	340	270	340	**280**	**350**

VIII. Shareholder Positioning (As of March 31, 2025)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 610,242)

3. Number of shareholders by category:

Shareholder category	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	23	70,228	17.65
Securities companies	34	3,925	0.99
Other Japanese corporations	362	217,716	54.71
Corporations outside Japan, etc.	511	54,136	13.61
Individuals and others (Including treasury stock)	43,941	51,892	13.04
Total	44,871	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)	33,887	8.53
Custody Bank of Japan, Ltd. (Trust account)	12,534	3.15
Nippon Life Insurance Company	7,581	1.91
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Inabata & Co., Ltd.	5,800	1.46
Sumitomo Life Insurance Company	5,776	1.45
UBS AG LONDON A/C IPB SEGREGATED CLIENT ACCOUNT	3,136	0.79
STATE STREET BANK AND TRUST COMPANY 505001	2,987	0.75
MORGANSTANLEY & CO. LLC	2,906	0.73

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (610,242 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 May 13, 2025)

- 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	Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy	Japan	Phase 1
	DSP-2342	To be determined	U.S.	Phase 1
Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.)	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
	DSP-3077 （Allogeneic iPS cell-derived retinal sheet）	Retinitis pigmentosa	U.S.	Phase 1/2

2. Oncology

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage
enzomenib／DSP-5336	Acute myeloid leukemia	U.S., Japan	Phase 2
nuvisertib／TP-3654	Myelofibrosis	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
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 January 2025】

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage	Changes
enzomenib／DSP-5336	Acute myeloid leukemia	U.S., Japan	Phase 2	Development stage changed

X. Profiles of Major Products under Development (As of May 13, 2025)

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: Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy: 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 Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy.

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 (Collaboration with RACTHERA Co., Ltd.))

In collaboration with RACTHERA Co., Ltd. and our partners in the industry-academia collaboration, we are developing allogeneic iPS cell-derived products using iPS cells from healthy donors for the treatment of Parkinson's disease, 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: Healios
- Development stage: Retinal pigment epithelium tear: Phase 1/2 in Japan

DSP-3077 (Allogeneic iPS cell-derived retinal sheet)

- Partnering: Massachusetts Eye and Ear in Boston, Massachusetts (Teaching hospital of Harvard Medical School), USA
- Development stage: Retinitis pigmentosa: Phase 1/2 in the U.S.

2. Oncology

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

- Development stage: Acute leukemia: Phase 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.

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. In addition, the Ministry of Health, Labour and Welfare in Japan granted Orphan Drug Designation for nuvisertib for the indication of myelofibrosis in November 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

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.