Securities Code: 4506

Supplementary Financial Data (IFRS) for the First Quarter of the Year Ending March 31, 2026

July 31, 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 (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)

	Q1 FY2024	Q1 FY2025	Change %	FY2024	FY2025 (Forecasts)	Change % YoY
Revenue	90.7	**108.0**	19.1	398.8	355.0	(11.0)
Cost of sales *1	34.9	**44.1**	26.2	153.2	146.0	(4.7)
Gross profit	55.7	**63.9**	14.7	245.6	209.0	(14.9)
SG&A expenses *1	43.8	**35.4**	(19.2)	167.7	153.5	(8.5)
R&D expenses *1	12.8	**8.1**	(36.9)	48.5	44.0	(9.3)
Others (core basis) *2	(0.0)	**(0.1)**		13.7	44.5	
Core operating profit (loss)	(0.9)	**20.4**	—	43.2	56.0	29.8
Adjustments *3 (negative number indicates net expense)	(2.2)	**0.0**		(14.3)	(2.0)	
Operating profit (loss)	(3.1)	**20.4**	—	28.8	54.0	87.5
Net profit attributable to owners of the parent	15.9	**11.2**	(29.7)	23.6	40.0	69.2
Basic earnings per share (JPY)	40.11	**28.21**		59.49	100.68	
Net profit/ Equity attributable to owners of the parent (ROE)				14.5%	21.1%	
Return on invested capital (ROIC)				9.4%	11.8%	

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

(Billions of JPY)

	Q1 FY2024	Q1 FY2025	Change %
Revenue	90.7	**108.0**	19.1
Cost of sales	34.9	**44.1**	26.2
Gross profit	55.7	**63.9**	14.7
SG&A expenses	45.4	**35.7**	(21.4)
R&D expenses	13.1	**8.2**	(37.7)
Other operating income/expenses, etc.	(0.3)	**0.3**	
Operating profit (loss)	(3.1)	**20.4**	—
Finance income/costs	20.3	**(8.5)**	
Profit before taxes	17.2	**11.9**	—
Income tax expenses	1.3	**0.7**	
Net profit attributable to owners of the parent	15.9	**11.2**	—

*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)

	Q1 FY2024	Q1 FY2025
Net cash provided by (used in) operating activities	(25.1)	**(0.2)**
Net cash provided by (used in) investing activities	102.1	**(4.3)**
Net cash provided by (used in) financing activities	(29.2)	**3.2**
Cash and cash equivalents at the end of period	78.4	**20.5**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2025 assumption	Forex sensitivity FY2025 (Impact of JPY depreciation by ¥1)	
	Mar. 31 2025	**June. 30 2025**	FY2024 Apr.-June	**FY2025 Apr.-June**	**Average rate**	Revenue	Core operating profit
JPY / USD	149.53	**144.81**	155.86	**144.60**	**145.00**	1.7	0.2
JPY / RMB	20.59	**20.20**	21.48	**19.99**	**20.00**	0.6	0.0

(Billions of JPY)

5. Financial Forecasts for First half of FY2025 (Core Basis)

(Billions of JPY)

	FY2025 (1H forecasts)	Q1 FY2025	Progress %
Revenue	**207.0**	108.0	52.2
Cost of sales	**81.5**	44.1	54.1
Gross profit	**125.5**	63.9	50.9
SG&A expenses	**78.0**	35.4	45.4
R&D expenses	**22.0**	8.1	36.8
Others (core basis)	**44.5**	(0.1)	
Core operating profit	**70.0**	20.4	29.1
Operating profit	**69.0**	20.4	29.6
Net profit attributable to owners of the parent	**56.0**	11.2	20.0

II. Consolidated Statement of Profit or Loss

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

(Billions of JPY)

	Q1 FY2024	Q1 FY2025	Change	Change %
Revenue	90.7	**108.0**	17.3	19.1
Overseas revenue	65.7	**86.9**	21.2	32.2
% of Revenue	72.5%	**80.5%**		
Cost of sales	34.9	**44.1**	9.2	26.2
% of Revenue	38.5%	**40.8%**		
Gross profit	55.7	**63.9**	8.2	14.7
SG&A expenses	43.8	**35.4**	(8.4)	(19.2)
Labor costs	19.2	**17.1**	(2.1)	(10.8)
Sales promotion/ Advertising costs	7.2	**4.5**	(2.7)	(37.2)
Amortization/Depreciation	5.5	**4.1**	(1.4)	(25.1)
Others	11.9	**9.6**	(2.3)	(19.2)
R&D expenses	12.8	**8.1**	(4.7)	(36.9)
% of Revenue	14.1%	**7.5%**		
Others (core basis)	(0.0)	**(0.1)**	(0.0)	
Core operating profit (loss)	(0.9)	**20.4**	21.3	—
Adjustments (negative number indicates net expense)	(2.2)	**0.0**	2.2	
Operating profit (loss)	(3.1)	**20.4**	23.5	—
Finance income	22.3	**0.6**	(21.7)	
Finance costs	2.0	**9.1**	7.0	
Profit (loss) before taxes	17.2	**11.9**	(5.3)	—
Income tax expenses	1.3	**0.7**	(0.5)	
Net profit (loss) attributable to owners of the parent	15.9	**11.2**	(4.7)	—

	Change	FX impact
Japan	(3.8)	
North America	20.7	(5.6)
Asia	0.4	(0.9)

Change by segment

	Japan	North America	Asia
Labor costs	(0.5)	(1.5)	(0.0)
Sales promotion/ Advertising costs	(0.7)	(2.0)	0.0
Amortization/ Depreciation	(0.3)	(1.0)	(0.1)
Others	(0.9)	(1.3)	(0.1)

FY24: Business structure improvement expenses in North America (1.7)

2. Adjustments to Core Operating Profit

(Billions of JPY)

Q1 FY2025 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	108.0	**108.0**	—	
Cost of sales	44.1	**44.1**	—	
Gross profit	63.9	**63.9**	—	
SG&A expenses	35.7	**35.4**	(0.3)	Facility closure costs in North America (0.1) Business structure improvement expenses in North America (0.1)
R&D expenses	8.2	**8.1**	(0.1)	Business structure improvement expenses in North America (0.1)
Other operating income/expenses, etc.	0.3	**(0.0)**	(0.4)	Gain on sale of assets 0.6 Share of loss of investments accounted for using the equity method (0.6)
Operating profit	20.4	**20.4**	(0.0)	

III. Segment Information (Core Basis)

(Billions of JPY)

Q1 FY2025 Results	Japan	North America	Asia	Total
Revenue	23.2	72.6	12.3	108.0
Cost of sales	12.0	29.8	2.3	44.1
Gross profit	11.2	42.7	10.0	63.9
SG&A expenses	7.3	25.3	2.8	35.4
Core segment profit	**3.8**	**17.5**	**7.2**	**28.5**
R&D expenses *1				8.1
Others (core basis) *2				(0.1)
Core operating profit				**20.4**

(Billions of JPY)

Q1 FY2024 Results	Japan	North America	Asia	Total
Revenue	27.0	51.8	11.9	90.7
Cost of sales	13.2	18.5	3.2	34.9
Gross profit	13.8	33.3	8.7	55.7
SG&A expenses	9.7	31.1	3.0	43.8
Core segment profit (loss)	**4.0**	**2.1**	**5.7**	**11.9**
R&D expenses *1				12.8
Others (core basis) *2				(0.0)
Core operating profit (loss)				**(0.9)**

(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**

*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	Q1 FY2024	**Q1 FY2025**	Change	Change %	FY2025 (Forecasts)	Progress %
Japan	27.0	**23.2**	(3.8)	(14.1)	85.7	27.0
North America	51.8	**72.6**	20.7	40.0	248.2	29.2
Asia	11.9	**12.3**	0.4	3.4	21.1	58.2

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	Q1 FY2024	**Q1 FY2025**	Change	Change %	FY2025 (Forecasts)	Progress %
Japan						
Promoted products						
LATUDA® Atypical antipsychotic	3.4	**3.5**	0.1	3.1	13.5	25.7
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	1.7	**2.4**	0.7	40.6	11.2	21.8
METGLUCO® Therapeutic agent for type 2 diabetes	1.9	**1.9**	(0.1)	(3.0)	7.6	24.4
Equa®/EquMet® Therapeutic agent for type 2 diabetes	7.4	**4.2**	(3.2)	(42.9)	7.0	60.1
LONASEN® Tape Atypical antipsychotic	1.1	**1.2**	0.1	10.4	5.2	23.9
Other products						
Authorized Generics	2.8	**3.1**	0.3	9.2	11.6	26.5
Export products, One-time revenue, Others	8.7	**6.9**	(1.8)	(20.5)	29.6	23.3

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	Q1 FY2024	**Q1 FY2025**	Change	Change %	FY2025 (Forecasts)	Progress %
North America						
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	16.8	**32.7**	16.0	95.3	103.0	31.8
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug. 2022～)	3.0	**2.9**	(0.2)	(5.2)	12.3	23.2
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	12.1	**21.3**	9.1	75.3	82.9	25.7
RETHYMIC® Cultured thymus tissue for pediatric congenital athymia (Mar. 2022～)	1.7	**0.8**	(0.9)	(52.2)	6.5	12.5
APTIOM® Antiepileptic	10.2	**7.1**	(3.1)	(30.2)	4.8	147.7
Export products, One-time revenue, Others	8.0	**7.8**	(0.3)	(3.4)	38.7	20.1

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

(Millions of USD)

Brand name	Q1 FY2024	**Q1 FY2025**	Change	Change %	FY2025 (Forecasts)	Progress %
ORGOVYX®	108	**226**	119	110.5	710	31.9
MYFEMBREE®	19	**20**	0	2.2	85	23.2
GEMTESA®	78	**147**	69	89.0	572	25.7
RETHYMIC®	11	**6**	(5)	(48.5)	45	12.5
APTIOM®	65	**49**	(16)	(24.8)	33	148.6

V. Consolidated Statement of Financial Position

(Billions of JPY)

	Mar. 31 2025	June 30 2025	Change
Assets	**742.6**	**733.3**	**(9.3)**
Non-current assets	**489.4**	**476.6**	**(12.8)**
Property, plant and equipment	46.6	46.1	(0.5)
Goodwill	197.4	191.2	(6.2)
Intangible assets	172.5	164.7	(7.8)
Patent rights/Marketing rights	167.7	160.1	(7.6)
In-process R&D	0.5	0.5	—
Others	4.4	4.2	(0.2)
Other financial assets	44.1	44.4	0.2
Other non-current assets	28.2	29.7	1.5
Deferred tax assets	0.5	0.5	(0.0)
Current assets	**253.2**	**256.7**	**3.5**
Inventories	94.2	89.8	(4.5)
Trade and other receivables	74.8	83.4	8.5
Other financial assets	16.8	15.9	(1.0)
Other current assets	13.8	14.3	0.5
Cash and cash equivalents	23.1	20.5	(2.7)
Assets held for sale	30.4	33.0	2.6
Liabilities	**573.1**	**557.1**	**(16.0)**
Non-current liabilities	**332.5**	**325.4**	**(7.1)**
Bonds and borrowings	259.0	259.1	0.1
Other financial liabilities	15.8	16.2	0.4
Retirement benefit liabilities	6.5	6.5	(0.1)
Other non-current liabilities	24.6	17.8	(6.9)
Deferred tax liabilities	26.6	25.9	(0.7)
Current liabilities	**240.6**	**231.7**	**(8.9)**
Borrowings	46.4	50.2	3.7
Trade and other payables	38.5	39.3	0.8
Other financial liabilities	32.9	30.8	(2.1)
Income taxes payable	1.6	1.0	(0.6)
Provisions	72.0	71.8	(0.2)
Other current liabilities	45.7	35.5	(10.1)
Liabilities directly associated with assets held for sale	3.5	3.0	(0.5)
Equity	**169.5**	**176.2**	**6.8**
Share capital	22.4	22.4	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	46.8	57.9	11.1
Other components of equity	97.5	93.9	(3.6)
Other comprehensive income associated with assets held for sale	3.5	2.7	(0.7)
Equity attributable to owners of the parent	**169.5**	**176.2**	**6.8**

← Exchange rate fluctuations

← Exchange rate fluctuations

Major patent rights	25/3	25/6
ORGOVYX® (relugolix)	63.8	60.5
MYFEMBREE® (relugolix)	9.7	9.2
GEMTESA® (vibegron)	92.2	88.6

VI. Changes in Quarterly Results

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

(Billions of JPY)

	FY2024				FY2025
	Q1	Q2	Q3	Q4	Q1
Revenue	90.7	90.1	112.4	105.6	108.0
Cost of sales	34.9	37.3	41.3	39.7	44.1
Gross profit	55.7	52.8	71.2	66.0	63.9
SG&A expenses	43.8	39.6	41.0	43.3	35.4
R&D expenses	12.8	12.3	10.2	13.1	8.1
Others (core basis)	(0.0)	(0.0)	1.7	12.1	(0.1)
Core operating profit (loss)	(0.9)	0.9	21.6	21.6	20.4
Adjustments (negative number indicates net expense)	(2.2)	(5.9)	(0.2)	(6.1)	0.0
Operating profit (loss)	(3.1)	(5.1)	21.4	15.6	20.4
Net profit (loss) attributable to owners of the parent	15.9	(48.2)	53.4	2.4	11.2

2. Revenue of Major Products

	FY2024				FY2025
	Q1	Q2	Q3	Q4	Q1
Japan					(Invoice price basis, Billions of JPY)
LATUDA®	3.4	3.3	3.6	2.9	3.5
TWYMEEG®	1.7	1.8	2.1	1.9	2.4
METGLUCO®	1.9	1.9	1.9	1.7	1.9
Equa®/EquMet®	7.4	6.8	6.8	4.0	4.2
LONASEN® Tape	1.1	1.2	1.3	1.0	1.2
Authorized Generics	2.8	2.7	3.2	2.7	3.1
Export products, One-time revenue, Others	8.7	8.2	6.7	7.2	6.9
North America					(Millions of USD)
ORGOVYX®	108	125	146	166	226
MYFEMBREE®	19	20	26	18	20
GEMTESA®	78	87	118	148	147
RETHYMIC®	11	8	14	11	6
APTIOM®	65	65	69	59	49
Export products, One-time revenue, Others	52	43	120	73	54

VII. Major Group Companies (As of June 30, 2025)

Domestic	Establish-ment	Ownership	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	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	Businesses
Sumitomo Pharma America, Inc.	1984/ 1	100%	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Switzerland GmbH	2016/ 8	100%	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma (China) Co., Ltd.	2022/ 6	100%	Holding company, management of the Company's China business, etc.
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	Manufacturing and sales of pharmaceuticals

*1 Associates

Ⅷ. Development Pipeline (As of July 31, 2025)

- This table shows the main clinical studies related to indications for which the Sumitomo Pharma Group aims to obtain approval in Japan, U.S., China, or Europe.
- The study at the most advanced development stage is listed if multiple studies are being conducted for 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 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, China	Phase 1
fH1/DSP-0546LP	Influenza	Europe	Phase 1

【Main revisions since the announcement of May 2025】

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage	Changes
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	U.S., Japan, China	Phase 1	Added region (China)

IX. Profiles of Major Products under Development (As of July 31, 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 lysine methyltransferase 2A (KMT2A) protein. Acute myeloid leukemia with KMT2A rearrangements or nucleophosmin 1 (NPM1) mutations rely on the menin-KMT2A 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-KMT2A interaction in pre-clinical studies. The U.S. Food and Drug Administration (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 KMT2A 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 KMT2A 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. Nuvisertib was granted Orphan Drug Designation by the FDA for the indication of myelofibrosis in May 2022, and received Fast Track Designation for the same indication in June 2025. 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. Furthermore, in July 2025, nuvisertib was granted Orphan Drug Designation by the European Medicines Agency (EMA) for the indication of myelofibrosis

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), 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., Japan and China
- 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.