

Supplementary Financial Data (IFRS) for the Six Months Ended September 30, 2026

I.	Consolidated Financial Highlights	1
II.	Consolidated Statement of Profit or Loss	2
III.	Revenue Information	3
IV.	Gross Profit by Region	5
V.	Consolidated Statement of Financial Position	6
VI.	Changes in Quarterly Results	7
VII.	Major Group Companies	8
VIII.	Shareholder Positioning	9
IX.	Development Pipeline	10
X.	Profiles of Major Products under Development	11

October 30, 2026

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, due to various subsequent factors, 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 other products (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 FY2025	Q2 FY2026	Change %	FY2025	FY2026 (Forecasts)	Change % YoY	
Revenue	227.1	266.5	17.3	453.3	[540.0]	565.0	24.6
Cost of sales *1	89.7	123.5	37.7	196.4	[245.0]	246.0	25.3
Gross profit	137.4	143.0	4.0	256.9	[295.0]	319.0	24.2
SG&A expenses *1	74.0	78.3	5.9	159.3	[155.0]	164.0	2.9
R&D expenses *1	17.5	23.8	35.9	43.9	[51.0]	52.0	18.3
Others (core basis) *2	50.1	1.2		52.3	[2.0]	2.0	
Core operating profit	96.1	42.1	(56.2)	105.9	[91.0]	105.0	(0.9)
Adjustments *3 (negative number indicates net expense)	0.1	0.2		1.4	[(1.0)]	(1.0)	
Operating profit	96.2	42.3	(56.0)	107.3	[90.0]	104.0	(3.1)
Net profit attributable to owners of the parent	98.9	38.2	(61.3)	106.9	[77.0]	94.0	(12.0)
Basic earnings per share (JPY)	248.84	86.48		268.99	[172.89]	211.07	
Net profit/ Equity attributable to owners of the parent (ROE)				46.3%	[20.3%]	24.1%	
Return on invested capital (ROIC)				22.8%	[15.1%]	17.6%	
Note: The forecasts have been revised. Figures in brackets [] are previous forecasts. Change % is calculated by using revised forecasts.							

Note: The forecasts have been revised. Figures in brackets [] are previous forecasts. Change % is calculated by using revised forecasts.

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

(Billions of JPY)

	Q2 FY2025	Q2 FY2026	Change %
Revenue	227.1	266.5	17.3
Cost of sales	89.7	123.5	37.7
Gross profit	137.4	143.0	4.0
SG&A expenses	76.6	78.7	2.8
R&D expenses	17.5	23.8	35.6
Other operating income/expenses, etc.	52.8	1.8	
Operating profit	96.2	42.3	(56.0)
Finance income/costs	(3.4)	(2.9)	
Profit before taxes	92.8	39.4	(57.6)
Income tax expenses	(6.1)	1.1	
Net profit attributable to owners of the parent	98.9	38.2	(61.3)

- *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)

	Q2 FY2025	Q2 FY2026
Net cash provided by (used in) operating activities	18.0	16.7
Net cash provided by (used in) investing activities	27.6	0.5
Net cash provided by (used in) financing activities	(44.0)	17.6
Cash and cash equivalents at the end of period	38.5	77.8

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2026 assumption	Forex sensitivity FY2026 (Impact of JPY depreciation by ¥ 1)	
	Mar. 31 2026	Sep. 30 2026	FY2025 Apr.-Sep.	FY2026 Apr.-Sep.	Average rate	Revenue	Core operating profit
JPY / USD	159.90	157.31	146.03	159.49	157.00	2.9	0.7

(Billions of JPY)

II. Consolidated Statement of Profit or Loss

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

	Q2 FY2025	Q2 FY2026	Change	Change %	
Revenue	227.1	266.5	39.4	17.3	
Overseas revenue	184.8	221.8	37.1	20.1	
% of Revenue	81.3%	83.2%			
Cost of sales	89.7	123.5	33.8	37.7	
% of Revenue	39.5%	46.4%			
Gross profit	137.4	143.0	5.5	4.0	
SG&A expenses	74.0	78.3	4.4	5.9	
Labor costs	37.3	35.1	(2.2)	(5.9)	
Sales promotion/ Advertising costs	9.1	13.9	4.8	52.3	
Amortization/Depreciation	8.3	7.8	(0.5)	(6.3)	
Others	19.2	21.5	2.3	12.1	
R&D expenses	17.5	23.8	6.3	35.9	
% of Revenue	7.7%	8.9%			
Others (core basis)	50.1	1.2	(48.9)		
Core operating profit	96.1	42.1	(54.0)	(56.2)	
Adjustments (negative number indicates net expense)	0.1	0.2	0.1		
Operating profit	96.2	42.3	(53.9)	(56.0)	
Finance income	1.2	1.6	0.3		
Finance costs	4.6	4.5	(0.1)		
Profit before taxes	92.8	39.4	(53.4)	(57.6)	
Income tax expenses	(6.1)	1.1	7.2		
Net profit attributable to owners of the parent	98.9	38.2	(60.6)	(61.3)	

	Change	FX impact
Japan	1.8	
U.S.	40.8	16.7
Other	(3.2)	1.1

2. Adjustments to Core Operating Profit

Q2 FY2026 Results	Full Basis	Adjustment items				Core Basis
		Impairment losses	Business structure improvement expenses	Change in fair value of contingent consideration	Other	
Revenue	266.5	—	—	—	—	266.5
Cost of sales	123.5	—	—	—	—	123.5
Gross profit	143.0	—	—	—	—	143.0
SG&A expenses	78.7	(0.0)	—	(0.0)	(0.4)	78.3
R&D expenses	23.8	—	—	—	—	23.8
Other operating income/expenses, etc.	1.8	—	—	(0.6)	0.1	1.2
Operating profit	42.3	0.0	—	(0.6)	0.4	42.1

Q2 FY2025 Results	Full Basis	Adjustment items				Core Basis
		Impairment losses	Business structure improvement expenses	Change in fair value of contingent consideration	Other	
Revenue	227.1	—	—	—	—	227.1
Cost of sales	89.7	—	—	—	—	89.7
Gross profit	137.4	—	—	—	—	137.4
SG&A expenses	76.6	(2.0)	(0.1)	(0.1)	(0.4)	74.0
R&D expenses	17.5	—	(0.0)	—	—	17.5
Other operating income/expenses, etc.	52.8	—	—	(1.6)	(1.2)	50.1
Operating profit	96.2	2.0	0.2	(1.5)	(0.7)	96.1

III. Revenue Information

1. Revenue by Region

(Billions of JPY)

Segment	Q2 FY2025	Q2 FY2026	Change	Change %	FY2026 (Forecasts)		Progress %
Japan	42.8	44.6	1.8	4.2	[87.6]	88.5	51.0
U.S.	157.0	197.8	40.8	26.0	[406.4]	425.1	48.7
Other	27.3	24.1	(3.2)	(11.8)	[46.0]	51.4	52.3
Total	227.1	266.5	39.4	17.3	[540.0]	565.0	49.4

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	Q2 FY2025	Q2 FY2026	Change	Change %	FY2026 (Forecasts)		Progress %
Japan							
XEPLION®/XEPLION TRI® Long-acting injectable antipsychotics (Jan. 2026～)	—	8.2	8.2	—		17.1	48.0
LATUDA® Atypical antipsychotic	6.9	7.3	0.4	5.2	[13.6]	13.9	53.3
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	5.0	6.6	1.6	31.4	[11.9]	13.2	55.1
METGLUCO® Therapeutic agent for type 2 diabetes	3.7	3.8	0.1	2.8		7.6	49.9
Equa®/EquMet® Therapeutic agent for type 2 diabetes	7.5	—	(7.5)	—		—	—
Authorized Generics	6.1	5.9	(0.1)	(1.9)	[11.2]	11.8	53.1

Note: The forecasts of some products have been revised. Figures in brackets [] are previous forecasts.

Progress rate is against previous forecast.

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	Q2 FY2025	Q2 FY2026	Change	Change %	FY2026 (Forecasts)		Progress %
U.S.							
ORGOVYX® Therapeutic agent for advanced prostate cancer	69.1	108.6	39.4	57.0	[209.9]	213.4	51.7
GEMTESA® Therapeutic agent for overactive bladder	43.4	64.9	21.5	49.6	[106.3]	118.0	61.0
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021 ~ / Aug. 2022 ~)	6.3	9.3	3.0	46.8	[15.4]	17.1	60.5
RETHYMIC® Cultured thymus tissue for pediatric congenital athymia (Mar. 2022 ~)	3.3	3.1	(0.2)	(5.5)	[5.4]	6.1	57.8
APTiom® Antiepileptic	10.7	2.5	(8.1)	(76.2)	[5.4]	5.2	47.1

(Ref.) Product sales in U.S. (based on local currency)

(Millions of USD)

Brand name	Q2 FY2025	Q2 FY2026	Change	Change %	FY2026 (Forecasts)		Progress %
ORGOVYX®	473	681	207	43.8	[1,354]	1,359	50.3
GEMTESA®	297	407	110	37.0	[686]	752	59.3
MYFEMBREE®	43	58	15	34.4	[100]	109	58.6
RETHYMIC®	22	20	(3)	(13.2)	[35]	38	55.7
APTiom®	73	16	(57)	(78.2)	[35]	33	45.5

Note: The forecasts have been revised. Figures in brackets [] are previous forecasts.

Progress rate is against previous forecast.

IV. Gross Profit by Region (Core Basis)

(Billions of JPY)

Q2 FY2026 Results	Japan	U.S.	Other	Total
Revenue	44.6	197.8	24.1	266.5
Cost of sales	25.0	78.1	20.4	123.5
Gross profit	19.6	119.7	3.6	143.0

(Billions of JPY)

Q2 FY2025 Results	Japan	U.S.	Other	Total
Revenue	42.8	157.0	27.3	227.1
Cost of sales	21.9	56.9	10.9	89.7
Gross profit	21.0	100.1	16.3	137.4

(Billions of JPY)

FY2026 Forecasts	Japan	U.S.	Other	Total
Revenue	88.5	425.1	51.4	565.0
Cost of sales	50.7	152.3	43.0	246.0
Gross profit	37.8	272.8	8.4	319.0

Note: The forecasts have been revised. The above table shows the revised forecasts.

V. Consolidated Statement of Financial Position

(Billions of JPY)

	Mar. 31 2026	Sep. 30 2026	Change
Assets	804.6	851.1	46.5
Non-current assets	525.3	513.7	(11.6)
Property, plant and equipment	44.2	44.3	0.1
Goodwill	211.1	207.7	(3.4)
Intangible assets	160.5	154.0	(6.4)
Patent rights/Marketing rights	155.9	149.7	(6.1)
In-process R&D	0.7	0.7	—
Others	3.9	3.6	(0.3)
Other financial assets	44.7	58.6	13.9
Other non-current assets	64.4	48.4	(16.0)
Deferred tax assets	0.4	0.8	0.3
Current assets	279.3	337.4	58.1
Inventories	85.4	90.5	5.1
Trade and other receivables	131.4	152.0	20.6
Other financial assets	5.3	6.9	1.5
Other current assets	12.8	10.2	(2.6)
Cash and cash equivalents	44.3	77.8	33.4
Liabilities	512.1	419.9	(92.2)
Non-current liabilities	240.6	172.0	(68.6)
Bonds and borrowings	179.1	119.7	(59.4)
Other financial liabilities	16.6	16.6	—
Retirement benefit liabilities	5.7	5.6	(0.0)
Other non-current liabilities	23.5	15.2	(8.3)
Deferred tax liabilities	15.8	14.9	(0.9)
Current liabilities	271.5	247.9	(23.6)
Borrowings	38.1	20.0	(18.1)
Trade and other payables	56.7	61.8	5.1
Other financial liabilities	35.2	40.1	4.9
Income taxes payable	1.1	5.1	4.0
Provisions	89.6	88.4	(1.2)
Other current liabilities	50.8	32.6	(18.2)
Equity	292.5	431.1	138.6
Share capital	22.4	71.3	48.9
Capital surplus	—	48.3	48.3
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	159.0	200.3	41.3
Other components of equity	111.8	111.9	0.2
Equity attributable to owners of the parent	292.5	431.1	138.6

Major patent rights	26/3	26/9
ORGOVYX®	58.6	56.1
MYFEMBREE®	8.9	8.6
GEMTESA®	86.9	83.9

← Repayment of long-term Borrowings

← Increase due to share issuance

← Increase due to share issuance

VI. Changes in Quarterly Results

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

	FY2025				FY2026	
	Q1	Q2	Q3	Q4	Q1	Q2
Revenue	108.0	119.1	120.6	105.5	129.5	137.0
Cost of sales	44.1	45.6	55.4	51.3	61.4	62.1
Gross profit	63.9	73.5	65.2	54.3	68.1	74.9
SG&A expenses	35.4	38.6	42.5	42.9	39.0	39.4
R&D expenses	8.1	9.4	10.4	16.1	11.4	12.3
Others (core basis)	(0.1)	50.1	1.0	1.2	0.4	0.8
Core operating profit (loss)	20.4	75.7	13.4	(3.5)	18.1	24.0
Adjustments (negative number indicates net expense)	0.0	0.0	0.3	1.1	0.1	0.1
Operating profit (loss)	20.4	75.8	13.6	(2.4)	18.2	24.1
Net profit (loss) attributable to owners of the parent	11.2	87.7	8.8	(0.8)	17.0	21.2

2. Revenue of Major Products

	FY2025				FY2026	
	Q1	Q2	Q3	Q4	Q1	Q2
Japan	(Invoice price basis, Billions of JPY)					
XEPLION®/XEPLION TRI®	—	—	—	3.2	4.1	4.1
LATUDA®	3.5	3.4	3.8	3.0	3.7	3.6
TWYMEEG®	2.4	2.6	2.9	2.7	3.3	3.3
METGLUCO®	1.9	1.8	2.0	1.7	1.9	1.9
Equa®/EquMet®	4.2	3.3	1.2	—	—	—
Authorized Generics	3.1	3.0	3.3	2.8	3.0	2.9

U.S.	(Millions of USD)					
ORGOVYX®	226	247	304	252	323	357
GEMTESA®	147	150	189	151	189	217
MYFEMBREE®	20	24	30	22	30	28
RETHYMIC®	6	17	8	11	11	8
APTIOM®	49	24	11	15	8	8

VII. Major Group Companies (As of September 30, 2026)

Domestic	Establishment	Ownership	Number of employees	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	21	Manufacturing and sales of pharmaceuticals
Marubeni Pharmaceuticals Corporation *1	2025/ 5	40.0%	—	Manufacturing and sales of pharmaceuticals and others
RACTHERA Co., Ltd. *1	2024/11	33.4%	—	Research and development of regenerative medicine –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	Establishment	Ownership	Number of employees	Businesses
Sumitomo Pharma America, Inc.	1984/ 1	100%	1,234 *2	Manufacturing and sales of pharmaceuticals

*1 Associates

*2 Includes employees of consolidated subsidiaries

(Reference)

Number of employees	March 31, 2025		March 31, 2026		Sep. 30, 2026	
consolidated / non-consolidated	3,832	1,799	3,123	1,747	3,135	1,754
Number of MRs (approx., including contracted MRs)						
Japan Exclude managers/Total	390	450	460	510	470	530
U.S. Exclude managers/Total	380	430	390	440	370	430

VIII. Shareholder Positioning (As of September 30, 2026)

1. Total number of authorized shares: 1,500,000,000
2. Total number of shares outstanding: 449,204,554 (Including 611,469 shares of treasury stock)
3. Number of shareholders by category:

Shareholder category	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	31	78,570	17.49
Securities companies	58	5,753	1.28
Other Japanese corporations	916	216,845	48.28
Corporations outside Japan, etc.	1,294	72,814	16.21
Individuals and others (Including treasury stock)	106,253	75,222	16.74
Total	108,552	449,204	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	45.84
The Master Trust Bank of Japan, Ltd. (Trust account)	43,631	9.73
Custody Bank of Japan, Ltd. (Trust account)	13,643	3.04
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.56
Sumitomo Life Insurance Company	5,776	1.29
THE BANK OF NEW YORK, TREATY JASDEC ACCOUNT	4,519	1.01
Inabata & Co., Ltd.	4,400	0.98
Nippon Life Insurance Company	3,790	0.85
BROWN BROTHERS HARRIMAN (LUXEMBOURG) SCA CUSTODIAN FOR ARCUS FUND SICAV – ARCUS JAPAN FUND	3,746	0.84
GOVERNMENT OF NORWAY	3,647	0.81

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (611,469 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, 2026)

- This table shows key clinical studies for indications of products for which the Sumitomo Pharma Group aims to obtain regulatory approval.
- 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 updated based on the date when the relevant 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	Planned indication(s)	Development stage
Small molecule	LATUDA®/ Lurasidone hydrochloride	(New dosage and administration: pediatric) Schizophrenia	Submitted (March 2026)
	DSP-0038	Alzheimer's disease psychosis	Phase 1
	DSP-0187	Narcolepsy	Phase 1
	DSP-3456	Treatment-resistant depression	Phase 1
	DSP-0378	Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy	Phase 1
	DSP-2342	To be determined	Phase 1
	DSP-0551	Tremor associated with Parkinson's disease	Phase 1
Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.)	AMCHEPRY®/Raguneprocel /CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells) (Japan)	Parkinson's disease	Post-marketing clinical study
	Raguneprocel /CT1-DAP001/DSP-1083 (Allogeneic iPS cell-derived dopaminergic neural progenitor cells) (U.S.)	Parkinson's disease	Phase 1/2 (Investigator-initiated clinical study)
			Phase 1/2 (Company-sponsored clinical study)
	HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells) (Japan)	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077 (Allogeneic iPS cell-derived retinal sheet) (U.S.)	Retinitis pigmentosa	Phase 1/2

2. Oncology

Brand name/ Generic name/ Product code	Planned indication(s)	Development stage
Enzomenib	Acute leukemia	Phase 2
Nuvisertib	Myelofibrosis	Phase 1/2
SMP-3124	Solid tumors	Phase 1/2
DSP-0390	Glioblastoma	Phase 1

3. Others

Brand name/ Generic name/ Product code	Planned indication(s)	Development stage
KSP-1007	Complicated urinary tract infections and complicated intra-abdominal infections, hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	Phase 1
fH1/DSP-0546LP	Influenza virus prophylaxis	Phase 1

X. Profiles of Major Products under Development (As of October 30, 2026)

1. Psychiatry & Neurology

(Small molecule)

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

- Planned indication: Alzheimer's disease psychosis
- DSP-0038 is a novel compound discovered at Sumitomo Pharma with the assistance of Recursion's AI technologies. DSP-0038 is a serotonin 5-HT_{2A} receptor antagonist and a serotonin 5-HT_{1A} receptor agonist. DSP-0038 may demonstrate a large antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have broad efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) including Alzheimer's disease, such as agitation, aggression, anxiety, and depression symptoms. Furthermore, DSP-0038 has no dopamine D₂ receptor antagonistic activity, and therefore may show improved safety and tolerability compared to existing antipsychotics.

DSP-0187

Origin: in-house, Formulation: oral

- Planned indication: Narcolepsy
- DSP-0187 is a selective orexin 2 receptor agonist. It may improve excessive daytime sleepiness (EDS) and cataplexy of narcolepsy caused by orexin deficiency. DSP-0187 also may have potential in hypersomnia disorders other than narcolepsy.

DSP-3456

Origin: in-house, Formulation: oral

- Planned indication: Treatment-resistant depression
- DSP-3456 is a metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM). DSP-3456 may exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex via enhanced glutamate release, while avoiding ketamine-associated side effects (psychotic symptoms, cognitive dysfunction).

DSP-0378

Origin: in-house, Formulation: oral

- Planned indications: Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy
- DSP-0378 is a gamma-aminobutyric acid (GABA)_A receptor positive allosteric modulator. DSP-0378 acts on various subtypes of GABA_A receptors expressed in synaptic and extra synaptic regions in a

manner different from common GABA_A receptor potentiators such as benzodiazepines and neurosteroids. DSP-0378 may exhibit an antiepileptic effect against a broad range of epilepsies including Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy.

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

- Planned indication: TBD
- DSP-2342 is a novel compound discovered at Sumitomo Pharma with the assistance of Recursion's AI technologies. DSP-2342 is a serotonin 5-HT_{2A} and 5-HT₇ receptor antagonist. DSP-2342 may demonstrate a broad antipsychotic effect in psychosis, anxiety, and depression, based on the dual antagonism of 5-HT_{2A} and 5-HT₇ receptors. Furthermore, DSP-2342 has high selectivity for 5-HT_{2A} and 5-HT₇ receptors and may exhibit a high level of safety and tolerability.

DSP-0551 Origin: in-house, Formulation: oral

- Planned indication: Tremor associated with Parkinson's disease
- DSP-0551 is a multi-ion channel modulator identified through phenotype-based drug discovery. It exhibits inhibitory activity against multiple calcium and sodium ion channels that have been implicated in tremor. Through these mechanisms, DSP-0551 may modulate abnormal neuronal firing and excessive synchronization in neural circuits associated with tremor, thereby improving tremor associated with Parkinson's disease.

(Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.))

In collaboration with RACTHERA Co., Ltd., and our partners in industry-academia collaborations, we are advancing the research and development of regenerative medicine / cell therapy using iPS cells 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 cell-derived dopaminergic neural progenitor cells)

- Partnering: Kyoto University, UC San Diego, and others
- Planned indication: Parkinson's disease
- In Japan, CT1-DAP001/DSP-1083 obtained manufacturing and marketing approval under the conditional and time-limited approval framework in March 2026 for the indication of the improvement of motor symptoms in patients with Parkinson's disease who have an inadequate response to existing pharmacological therapies, including levodopa-containing products. The product name is AMCHEPRY® (INN: raguneprocel).
- In the U.S., an investigator-initiated clinical study is being conducted at UC San Diego and other institutions, while a company-sponsored study is also being pursued in parallel.

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

- Partnering: HEALIOS K.K., Kyushu University, and others
- Planned indication: Retinal pigment epithelium tear

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

- Partnering: Massachusetts Eye and Ear in Boston, Massachusetts (Teaching hospital of Harvard Medical School) and the University of Minnesota, and others
- Planned indication: Retinitis pigmentosa
- The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for the indication of retinitis pigmentosa in March 2026.

2. Oncology

Enzomenib Origin: in-house (Joint research with Kyoto University), Formulation: oral

- Planned indication: Acute leukemia
- Enzomenib (DSP-5336) is an oral small molecule inhibitor of the menin and lysine methyltransferase 2A (KMT2A) protein interaction. Acute myeloid leukemia with KMT2A rearrangement or nucleophosmin 1 (NPM1) mutation relies on the menin-KMT2A interaction for upregulation of genes instrumental to leukemogenesis. Enzomenib has been shown to have anti-cancer activity through downregulation of these genes by inhibition of menin-KMT2A interaction in

preclinical studies. The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and for acute lymphoblastic leukemia in July 2026, and granted Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in June 2024. In October 2026, the FDA also granted Breakthrough Therapy Designation for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement. Furthermore, the MHLW granted Orphan Drug Designation for enzomenib in September 2024 for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation. In August 2026, the MHLW granted Orphan Drug Designation for acute myeloid leukemia in an expanded patient population, including newly diagnosed patients with KMT2A rearrangement or NPM1 mutation, and for the treatment of relapsed or refractory acute lymphoblastic leukemia with KMT2A rearrangement.

Nuvisertib Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

- Planned indication: Myelofibrosis
- Nuvisertib (TP-3654) inhibits the inflammatory signaling pathways through inhibition of PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinase. PIM1 kinase is frequently overexpressed in various hematologic malignancies and solid tumors, which could cause evasion of cancer cells' apoptosis and promotion of tumor growth. The FDA, the MHLW, and the European Medicines Agency (EMA) granted Orphan Drug Designation for nuvisertib for the indication of myelofibrosis in May 2022, November 2024, and July 2025, respectively. Additionally, the FDA granted nuvisertib Fast Track Designation in June 2025, also for the indication of myelofibrosis.

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

- Planned indication: Solid tumors
- SMP-3124 is an injectable formulation of a CHK1 inhibitor encapsulated in PEGylated liposomes. CHK1 is a serine/threonine kinase activated by the DNA damage response, leading to cell-cycle arrest and DNA repair. CHK1 inhibition leads cancer cells with high replication stress to apoptosis by inducing further DNA damage. SMP-3124 may enhance the anti-tumor activity and reduce side effects of the CHK1 inhibitor through optimized pharmacokinetics of the compound by liposomal nanoparticle formulation.

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

- Planned indication: Glioblastoma
- DSP-0390 is an inhibitor of Emopamil Binding Protein (EBP), an endoplasmic reticulum membrane protein involved in cholesterol biosynthesis. EBP mediates de novo cholesterol synthesis for cell membrane structure and signaling, enabling aberrant growth of tumors. Inhibition of EBP causes depletion of cellular cholesterol, which may lead to anti-cancer activity. The FDA granted Orphan Drug Designation for DSP-0390 for the indication of brain tumor in May 2022.

3. Others

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

- Planned indications: Complicated urinary tract infections and complicated intra-abdominal infections, hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia
- KSP-1007 broadly and strongly inhibits β -lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. KSP-1007 may become an effective treatment option against carbapenem-resistant bacterial infections as a component of a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Pharma's product for the Japanese 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

- Planned indication: Influenza virus prophylaxis

- fH1/DSP-0546LP is a next-generation candidate vaccine formulation composed of the post-fusion hemagglutinin antigen (fH1) that may be effective against a broad range of influenza viruses, and TLR7 adjuvant “DSP-0546LP” that enhances the quantity, quality, and durability of immune responses. 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 preclinical study of fH1/DSP-0546LP demonstrated broad cross-protection against influenza viruses antigenically different from those used in vaccine formulations, and the significance of the TLR7 adjuvant, DSP-0546LP. fH1/DSP-0546LP may improve the breadth and durability of protection against seasonal influenza viruses and be effective against novel and potentially pandemic strains.