

Supplementary Financial Data (IFRS) for the Third Quarter of the Year Ending March 31, 2023

I.	Consolidated Financial Highlights	1
II.	Consolidated Statement of Profit or Loss	3
III.	Segment Information	4
IV.	Revenues Information	5
V.	Consolidated Statement of Financial Position	7
VI.	Changes in Quarterly Results	8
VII.	Major Consolidated Subsidiaries	8
VIII.	Development Pipeline	9
IX.	Profiles of Major Products under Development	12
X.	Development Status of Major Programs in Frontier Business	17

January 31, 2023

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 preparation 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. Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group beneficially owns approximately 52% of the outstanding shares of Myovant. ORGOVYX[®] (relugolix), MYFEMBREE[®]/RYEQO[®] (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com>.
- 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 yen)

	Q3 FY2021	Q3 FY2022	Change % YoY	FY2021	FY2022 (Forecast)	Change % YoY	
Revenue	432.1	460.3	6.5	560.0	[604.0]	563.0	0.5
Cost of sales *1	117.8	139.7	18.6	157.1	[182.0]	173.0	10.1
Gross profit	314.2	320.5	2.0	402.9	[422.0]	390.0	(3.2)
SG&A expenses *1	188.6	227.5	20.6	251.6	[312.0]	308.0	22.4
R&D expenses *1	67.8	74.9	10.4	94.0	[100.0]	98.0	4.3
Other operating income/expenses *2	1.1	24.8		1.2	[22.0]	50.0	
Core operating profit	59.0	42.9	(27.2)	58.5	[32.0]	34.0	(41.9)
Changes in fair value of contingent consideration (negative number indicates loss)	(0.2)	1.2		3.3		1.0	
Other non-recurring items *3 (negative number indicates loss)	(0.5)	(61.9)		(1.6)	[(63.0)]	(62.0)	
Operating profit (loss)	58.2	(17.8)	—	60.2	[(30.0)]	(27.0)	—
Net profit (loss)	35.2	(32.6)	—	40.6		N/A	
Net profit (loss) attributable to owners of the parent	46.4	(18.5)	—	56.4	[(15.0)]	(35.0)	—
Basic earnings per share (yen)	116.69	(46.57)		141.99		(88.10)	
Net profit/ Equity attributable to owners of the parent (ROE)	7.8%	(3.0%)		9.5%		(6.6%)	

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

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

(Billions of yen)

	Q3 FY2021	Q3 FY2022	Change % YoY
Revenue	432.1	460.3	6.5
Cost of sales	117.8	139.8	18.6
Gross profit	314.2	320.5	2.0
SG&A expenses	189.0	289.5	53.1
R&D expenses	67.8	76.0	12.1
Other operating income/expenses	0.8	27.2	
Operating profit (loss)	58.2	(17.8)	—
Finance income/costs	7.4	20.0	
Profit before taxes	65.6	2.2	(96.7)
Income tax expenses	30.4	34.8	
Net profit (loss)	35.2	(32.6)	—
Net profit (loss) attributable to owners of the parent	46.4	(18.5)	—

*1 Exclude non-recurring items (impairment losses, 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 losses, etc.)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q3 FY2021	Q3 FY2022
Net cash provided by (used in) operating activities	9.1	56.5
Net cash provided by (used in) investing activities	7.3	21.7
Net cash provided by (used in) financing activities	(20.4)	(33.0)
Cash and cash equivalents at the end of period	196.3	265.8

4. Foreign Exchange Rates

	FY2021 Apr.-Dec.		FY2022 Apr.-Dec.		FY2022 assumption	Forex sensitivity FY2022 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	Period end rate	Average rate	Average rate	Revenue	Core operating profit
Yen / USD	115.01	111.14	132.71	136.51	135.00	2.6	(0.5)
Yen / RMB	18.07	17.26	19.02	19.88	19.50	1.9	0.2

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q3 FY2021	Q3 FY2022	Change	FY2022 (Forecast)	Change	(Billions of yen)
Capital expenditures	9.2	6.9	(2.4)	[16.5]	16.2	3.5
Depreciation of Property, plant and equipment	8.5	9.4	0.9	[10.9]	12.0	0.5
Amortization of Intangible assets	19.6	22.7	3.0	[30.3]	29.5	2.6
Related to products (patent rights/ marketing rights) included in above	17.6	20.5	2.9	[27.1]	26.3	2.1

Notes: 1: The amount of capital expenditures are for tangible fixed assets and software.

2: The forecasts have been revised. Figures in parentheses [] are previous forecasts. Change is calculated by using revised forecasts.

Major capital expenditure project in FY2022

(Continued) Reinforcement of production facilities, total budget ¥1.1billion, to be completed in FY2022

Relocation of Tokyo Head Office ¥1.6billion, to be completed in FY2022

Establishment of manufacturing facility for regenerative medicine and cell therapy (USA), total budget \$34million, to be completed in FY2023

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	Q3 FY2021	Q3 FY2022	Change	Change %	
Revenue	432.1	460.3	28.2	6.5	← Japan
Overseas revenue	284.6	324.7	40.2	14.1	North America
% of Revenue	65.9%	70.6%			China
Cost of sales	117.8	139.7	21.9	18.6	Other Regions
% of Revenue	27.3%	30.4%			
Gross profit	314.2	320.5	6.3	2.0	
SG&A expenses	188.6	227.5	38.9	20.6	← Include Sumitovant +32.0
Labor costs	84.1	92.5	8.4	10.0	
Advertising and promotion costs	13.4	15.9	2.5	18.4	
Sales promotion costs	15.3	31.9	16.6	108.3	
Amortization/Depreciation	23.1	26.4	3.3	14.5	
Others	52.7	60.8	8.1	15.3	
R&D expenses	67.8	74.9	7.1	10.4	
% of Revenue	15.7%	16.3%			
Other operating income/expenses	1.1	24.8	23.6		
Core operating profit	59.0	42.9	(16.0)	(27.2)	
Changes in fair value of contingent consideration *	(0.2)	1.2	1.5		
Other non-recurring items *	(0.5)	(61.9)	(61.4)		← Impairment losses (56.0)
Operating profit (loss)	58.2	(17.8)	(76.0)	—	
Finance income	9.6	22.6	13.0		
Finance costs	2.3	2.7	0.4		
Profit before taxes	65.6	2.2	(63.4)	(96.7)	
Income tax expenses	30.4	34.8	4.4		
Net profit (loss)	35.2	(32.6)	(67.8)	—	
Net profit (loss) attributable to owners of the parent	46.4	(18.5)	(64.9)	—	

* Negative number indicates loss.

2. Adjustments to Core Operating Profit

(Billions of yen)

Q3 FY2022 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	460.3	460.3	-	
Cost of sales	139.8	139.7	(0.0)	
Gross profit	320.5	320.5	0.0	
SG&A expenses	289.5	227.5	(62.0)	KYNMOBI® impairment losses (56.0)
R&D expenses	76.0	74.9	(1.1)	
Other operating income	28.3	24.8	(3.5)	
Other operating expenses	1.1	-	(1.1)	
Operating profit (loss)	(17.8)	42.9	60.7	

III. Segment Information (Core Basis)

(Billions of yen)

Q3 FY2022 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	102.2	279.4	31.2	13.5	426.3	34.0	460.3
Cost of sales	54.2	49.1	6.0	3.7	113.0	26.7	139.7
Gross profit	48.1	230.2	25.2	9.8	313.3	7.2	320.5
SG&A expenses	38.5	174.6	8.9	1.2	223.1	4.4	227.5
Core segment profit	9.6	55.7	16.3	8.6	90.2	2.9	93.0
R&D expenses *1					72.9	1.9	74.9
Other operating income/expenses (Core basis)*2					24.7	0.0	24.8
Core operating profit					42.0	1.0	42.9

(Billions of yen)

Q3 FY2021 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	117.2	250.7	27.0	7.3	402.2	29.9	432.1
Cost of sales	61.9	23.6	5.3	4.0	94.8	23.0	117.8
Gross profit	55.3	227.1	21.8	3.3	307.5	6.8	314.2
SG&A expenses	38.3	135.6	8.8	1.9	184.7	4.0	188.6
Core segment profit	17.0	91.5	12.9	1.4	122.8	2.8	125.6
R&D expenses *1					67.2	0.6	67.8
Other operating income/expenses (Core basis)*2					1.1	0.0	1.1
Core operating profit					56.7	2.2	59.0

(Billions of yen)

FY2022 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	126.1	340.6	37.6	17.0	521.3	41.7	563.0
Cost of sales	65.9	61.0	7.9	5.7	140.5	32.5	173.0
Gross profit	60.2	279.6	29.7	11.3	380.8	9.2	390.0
SG&A expenses	52.1	235.6	11.5	1.8	301.0	7.0	308.0
Core segment profit	8.1	44.0	18.2	9.5	79.8	2.2	82.0
R&D expenses *1					95.4	2.6	98.0
Other operating income/expenses (Core basis)*2					24.5	25.5	50.0
Core operating profit					8.9	25.1	34.0

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

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

Note: The forecasts have been revised.

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	Q3 FY2021	Q3 FY2022	Change	Change %	FY2022 (Forecast)	Progress %
Japan	117.2	102.2	(15.0)	(12.8)	[125.8]	126.1 81.2
North America	250.7	279.4	28.7	11.4	[382.3]	340.6 73.1
China	27.0	31.2	4.2	15.6	[37.2]	37.6 83.9
Other Regions	7.3	13.5	6.2	84.2		17.0 79.4

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

Progress rate is against previous forecast.

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q3 FY2021	Q3 FY2022	Change	Change %	FY2022 (Forecast)	Progress %
Japan						
Promoted products						
Equa[®]/EquMet[®] Therapeutic agent for type 2 diabetes (Nov. 2019~)	29.4	27.3	(2.2)	(7.3)	[34.9]	34.1 78.1
Trulicity[®] * Therapeutic agent for type 2 diabetes	25.8	24.8	(1.0)	(3.7)	[23.8]	24.8 104.2
TRERIEF[®] Therapeutic agent for Parkinson's disease	12.9	13.1	0.2	1.5		17.0 77.0
LATUDA[®] Atypical antipsychotic (Jun. 2020~)	5.0	7.3	2.2	44.2	[9.9]	9.3 73.2
METGLUCO[®] Therapeutic agent for type 2 diabetes	6.3	6.0	(0.3)	(4.8)		7.8 76.8
LONASEN[®] Tape Atypical antipsychotic (Sep. 2019~)	1.5	2.2	0.7	45.2	[2.7]	2.8 82.9
TWYMEEG[®] Therapeutic agent for type 2 diabetes (Sep. 2021~)	0.1	1.3	1.2	—	[1.5]	1.8 84.9
Other products						
Authorized Generics	7.5	7.1	(0.4)	(5.1)	[9.7]	9.4 72.9

* Trulicity[®] revenue is shown by NHI price.

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

Progress rate is against previous forecast.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q3 FY2021	Q3 FY2022	Change	Change %	FY2022 (Forecast)	Progress %
North America						
LATUDA [®] Atypical antipsychotic	157.1	179.3	22.2	14.1	[241.6] 211.3	74.2
APTIOM [®] Antiepileptic	20.7	26.0	5.3	25.6	[35.7] 34.5	72.9
RETHYMIC [®] Pediatric congenital athymia	—	3.0	3.0	—	[6.4] 4.8	46.6
BROVANA [®] Therapeutic agent for COPD	11.5	2.8	(8.7)	(75.5)	[3.4] 2.8	82.6
KYNMOBI [®] OFF episodes associated with Parkinson's disease (Sep. 2020~)	0.4	0.3	(0.1)	(19.8)	0.4	80.3
ORGOVYX [®] Therapeutic agent for advanced prostate cancer (Jan. 2021~)	6.0	17.5	11.5	193.8	N/A	—
MYFEMBREE [®] Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021~ /Aug.2022~)	0.5	2.9	2.4	521.8	N/A	—
GEMTESA [®] Therapeutic agent for overactive bladder (Apr. 2021~)	4.2	17.0	12.8	303.6	N/A	—

China

MEROPEN [®] Carbapenem antibiotic	21.2	23.2	2.0	9.6	[25.8] 26.6	89.9
--	------	-------------	-----	-----	-------------	------

Other Regions

MEROPEN [®] Carbapenem antibiotic	4.6	4.6	0.0	0.7	[7.0] 6.9	66.2
--	-----	------------	-----	-----	-----------	------

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

(Millions of dollar)

Brand name	Q3 FY2021	Q3 FY2022	Change	Change %	FY2022 (Forecast)	Progress %
LATUDA [®]	1,413	1,313	(100)	(7.1)	[1,726] 1,565	76.1
APTIOM [®]	186	191	4	2.2	255	74.7
RETHYMIC [®]	—	22	22	—	[46] 35	47.5
BROVANA [®]	103	21	(83)	(80.1)	[24] 21	85.8
KYNMOBI [®]	4	2	(1)	(34.6)	3	78.4
ORGOVYX [®]	54	128	75	139.3	N/A	—
MYFEMBREE [®]	8	21	13	150.6	N/A	—
GEMTESA [®]	38	125	87	228.6	N/A	—

Note: The forecasts of some products have been revised. Figures in parentheses [] are previous forecasts.
Progress rate is against previous forecast.

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar. 31 2022	Dec. 31 2022	Change
Assets	1,308.0	1,371.5	63.5
Non-current assets	808.5	793.0	(15.5)
Property, plant and equipment	64.1	59.5	(4.6)
Goodwill	195.1	211.6	16.4
Intangible assets	398.7	357.4	(41.3)
Patent rights/Marketing rights	361.6	318.4	(43.2)
In-process R&D	29.8	32.3	2.5
Others	7.3	6.7	(0.6)
Other financial assets	115.8	141.5	25.7
Other non-current assets	12.1	10.5	(1.6)
Deferred tax assets	22.7	12.5	(10.1)
Current assets	499.5	578.5	79.0
Inventories	99.0	90.5	(8.6)
Trade and other receivables	151.4	149.4	(2.0)
Other financial assets	35.6	22.5	(13.1)
Other current assets	10.5	16.7	6.1
Cash and cash equivalents	203.0	265.8	62.8
Subtotal	499.5	544.8	45.2
Assets held for sale	—	33.7	33.7
Liabilities	634.4	673.5	39.1
Non-current liabilities	356.1	363.9	7.9
Bonds and borrowings	244.0	244.1	0.1
Other financial liabilities	16.5	14.0	(2.4)
Retirement benefit liabilities	11.5	10.5	(0.9)
Other non-current liabilities	57.6	59.5	1.9
Deferred tax liabilities	26.6	35.8	9.2
Current liabilities	278.4	309.5	31.2
Borrowings	25.1	5.6	(19.5)
Trade and other payables	46.2	52.7	6.5
Other financial liabilities	13.3	10.5	(2.8)
Income taxes payable	7.6	12.2	4.6
Provisions	119.1	149.1	30.0
Other current liabilities	67.1	69.1	2.0
Subtotal	278.4	299.2	20.8
Liabilities directly associated with assets held for sale	—	10.4	10.4
Equity	673.6	698.0	24.5
Share capital	22.4	22.4	—
Capital surplus	16.7	18.1	1.3
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	514.2	486.2	(28.0)
Other components of equity	55.2	107.6	52.3
Other comprehensive income associated with assets held for sale	—	1.6	1.6
Equity attributable to owners of the parent	607.9	635.1	27.3
Non-controlling interests	65.7	62.9	(2.8)

Goodwill	22/3	22/12
Other than oncology(SMPO)	168.3	182.5
Oncology(SMPO)	26.8	29.1

Major patent rights	22/3	22/12
KYNMOBI® (apomorphine)	51.5	—
ORGOVYX® (relugolix)	64.7	66.9
MYFEMBREE® (relugolix)	139.6	144.0
GEMTESA® (vibegron)	93.9	96.0

Major IPR&D	22/3	22/12
former Tolero products	18.6	20.2

Increase by change in value of securities

Total bonds and borrowings
269.0 → 249.7

Contingent consideration liabilities	22/3	22/12
former Tolero	4.4	3.6

Included in "Other financial liabilities (Non-current/Current)"

Increase in reserve for sales returns in advance of LATUDA® LOE and reserve for sales rebates of Sumitovant products

VI. Changes in Quarterly Results

(Billions of yen)

Core Basis	FY2021				FY2022		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Revenue	131.2	162.5	138.3	128.0	159.9	159.4	141.0
Cost of sales	38.5	38.4	41.0	39.3	46.1	46.8	46.9
Gross profit	92.7	124.2	97.4	88.7	113.8	112.6	94.1
SG&A expenses	62.0	62.5	64.2	62.9	76.0	76.2	75.3
R&D expenses	22.4	23.3	22.1	26.2	24.4	25.0	25.5
Other operating income/expenses (Core basis) *	0.2	1.0	(0.0)	0.0	0.0	(0.0)	24.7
Core operating profit	8.5	39.4	11.0	(0.4)	13.4	11.5	18.1
Changes in fair value of contingent consideration (negative number indicates loss)	(0.1)	(0.1)	(0.1)	3.5	(0.1)	1.4	(0.1)
Other non-recurring items (negative number indicates loss)	(0.1)	(0.1)	(0.3)	(1.1)	1.3	(56.3)	(6.9)
Operating profit (loss)	8.3	39.3	10.7	2.0	14.6	(43.5)	11.1
Net profit (loss)	0.8	29.2	5.2	5.4	28.1	(43.3)	(17.4)
Net profit (loss) attributable to owners of the parent	4.8	31.6	9.9	10.1	31.1	(38.4)	(11.2)

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

VII. Major Consolidated Subsidiaries (As of December 31, 2022)

Domestic	Establishment	Ownership	Number of employees	Businesses
Sumitomo Pharma Food & Chemical Co., Ltd.	1947/10	100%	205	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
Sumitomo Pharma Animal Health Co., Ltd.	2010/ 7	100%	100	Manufacturing and sales of veterinary medicines, etc.
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	33	Manufacturing and sales of pharmaceuticals, etc.
Overseas	Establishment	Ownership	Number of employees	Businesses
Sumitomo Pharma America Holdings, Inc.	2009/ 7	100%	238	Holding company, shared services for general management operations
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,005	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Oncology, Inc.	2006/11	100%	153	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	123	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	52%	*608	Manufacturing and sales of pharmaceuticals in the women's health, prostate cancer area
Urovant Sciences, Inc.	2016/11	100%	*321	Manufacturing and sales of pharmaceuticals in the urology area
Enzyvant Therapeutics, Inc.	2015/ 3	100%	*68	R&D, manufacturing and sales of pharmaceuticals in the pediatric and Respiratory rare diseases area
Spirovant Sciences, Inc.	2019/ 2	100%	*42	R&D in the cystic fibrosis gene therapy area
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	632	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2021	March 31, 2022	Dec. 31, 2022	
consolidated / non-consolidated	6,822	3,067	6,987	3,040
MRs (include number of contracted MRs)				
Japan Exclude managers/Total	1,150	1,270	1,110	1,220
U.S. Exclude managers/Total	720	840	820	950
China Exclude managers/Total	340	410	340	420

VIII. Development Pipeline (As of January 31, 2023)

- 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/ Product code (Generic name)	Proposed indication	Region	Development stage
SEP-363856 (ulotaront)	Schizophrenia	U.S.	Phase 3
		Japan, China	Phase 2/3
	Adjunctive major depressive disorder (aMDD)	U.S.	Phase 2/3
	Generalized anxiety disorder (GAD)	U.S., Japan	Phase 2/3
	Parkinson's disease psychosis	U.S.	Phase 2
SEP-4199	Bipolar I depression	U.S., Japan	Phase 3
LATUDA® (lurasidone hydrochloride)	(New usage: pediatric) Schizophrenia	Japan	Phase 3
EPI-589	Parkinson's disease	U.S.	Phase 2
	Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2
		Japan	Phase 2 (Investigator-initiated study)
SEP-378608	Bipolar disorder	U.S.	Phase 1
DSP-3905	Neuropathic pain	U.S.	Phase 1
SEP-378614	To be determined	U.S.	Phase 1
SEP-380135	To be determined	U.S.	Phase 1
DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1
DSP-9632P	Levodopa-induced dyskinesia in Parkinson's disease	Japan	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

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
DSP-5336	Acute leukemia	U.S., Japan	Phase 1/2
DSP-0390	Glioblastoma	U.S., Japan	Phase 1
TP-1287	Solid tumors	U.S.	Phase 1
TP-1454	Solid tumors	U.S.	Phase 1

3. Regenerative medicine / cell therapy

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
CT1-DAP001/ DSP-1083 (Allo iPS (induced pluripotent stem) cell-derived dopamine neural progenitor cells)	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated study)
		U.S.	Preparing the start of clinical study
HLCR011 (Allo iPS cell-derived retinal pigment epithelium cells)	Age-related macular degeneration (AMD)	Japan	Preparing the start of clinical study

4. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
lefamulin	Bacterial community-acquired pneumonia	China	NDA submitted in October 2021
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	Phase 3
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	U.S.	Phase 2
MVT-602	Female infertility	Germany	Phase 2
URO-902	Overactive bladder (OAB)	U.S.	Phase 2
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections	U.S.	Phase 1

【Main revisions since the announcement of October 2022】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
SEP-363856 (ulotaront)	Generalized anxiety disorder (GAD)	U.S.	Phase 2/3	Newly added
LATUDA® (lurasidone hydrochloride)	(New indication) Bipolar I depression	China	Phase 3	Deleted from the table due to discontinuation

DSP-0509 (guretolimod)	Solid tumors	U.S., Japan	Phase 1/2	Deleted from the table due to discontinuation of the study, development strategy under consideration
---------------------------	--------------	-------------	-----------	--

IX. Profiles of Major Products under Development (As of January 31, 2023)

1. Psychiatry & Neurology

ulotaront (SEP-363856) Origin: in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- Ulotaront (SEP-363856) is a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity. Ulotaront does not bind to dopamine D₂ or serotonin 5-HT_{2A} receptors. Sunovion discovered ulotaront in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Phase 2 results in patients with an acute exacerbation of schizophrenia support the efficacy of ulotaront in treating both positive and negative symptoms of schizophrenia, with a side effect profile similar to placebo. Notably, ulotaront was not associated with extrapyramidal symptoms, weight gain, changes in lipids or glucose, prolactin elevation.
- Development stage: (Co-development with Otsuka Pharmaceutical Co., Ltd.)
Schizophrenia: Phase 3 in the U.S.
Schizophrenia: Phase 2/3 in Japan and China
Adjunctive major depressive disorder (aMDD): Phase 2/3 in the U.S.
Generalized anxiety disorder (GAD): Phase 2/3 in the U.S. and Japan
Parkinson's disease psychosis: Phase 2 in the U.S.

SEP-4199 Origin: in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-4199 is a non-racemic ratio of amisulpride enantiomers. Sunovion discovered that the pharmacology of amisulpride is enantiomer-specific, and that increasing the ratio of R-amisulpride to S-amisulpride increases the potency for serotonin 5-HT₇ receptors relative to dopamine D₂ receptors. SEP-4199 was discovered with an 85:15 ratio of R-amisulpride to S-amisulpride to increase levels of serotonin 5-HT₇ activity intended to enhance antidepressant efficacy and produce reduced levels of D₂ receptor occupancy appropriate for the treatment of bipolar depression.
- Development stage: (Co-development with Otsuka Pharmaceutical Co., Ltd.)
Bipolar I depression: Phase 3 in the U.S. and Japan

EPI-589 Origin: PTC Therapeutics, Inc. (Acquired from BioElectron Technology Corporation), Formulation: oral

- EPI-589 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be developed for neurodegenerative indications arising through redox stress.
- Development stage:
Parkinson's disease: Phase 2 in the U.S.
Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S.
Amyotrophic lateral sclerosis (ALS): Phase 2 (Investigator-initiated study*) in Japan
* Sponsor: Tokushima University

SEP-378608 Origin: in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378608 is a novel CNS-active molecule. Sunovion discovered SEP-378608 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of the brain associated with the regulation of mood.
- Development stage: Bipolar disorder: Phase 1 in the U.S.

DSP-3905 Origin: in-house, Formulation: oral

- DSP-3905 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7. Based on its

inhibitory mode of action, the agent is expected to show a potent analgesic effect on the pain occurring when neurons get excessively excited. In addition, DSP-3905 has a high selectivity for Nav1.7 expressed in peripheral neuron and may not produce central nervous system or cardiovascular system side effects, which are present with the current drugs for neuropathic pain.

- Development stage: Neuropathic pain: Phase 1 in the U.S.

SEP-378614 Origin: in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378614 is a novel CNS-active molecule. Sunovion discovered SEP-378614 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies suggest that it may have rapid onset antidepressant-like activity.
- Development stage: Phase 1 in the U.S. (Co-development with Otsuka Pharmaceutical Co., Ltd.)

SEP-380135 Origin: in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-380135 is a novel CNS-active molecule. Sunovion discovered SEP-380135 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies showed a broad range of in vivo activities suggesting efficacy against a number of behavioral and psychological symptoms in dementia, including agitation/aggression, psychomotor hyperactivity and depression.
- Development stage: Phase 1 in the U.S. (Co-development with Otsuka Pharmaceutical Co., Ltd.)

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

- 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 D₂ receptors, and therefore it can be expected to show improved safety and tolerability compared to existing antipsychotic.
- Development stage: Alzheimer's disease psychosis: Phase 1 in the U.S.

DSP-9632P Origin: in-house, Formulation: patch

- DSP-9632P is a serotonin 5-HT_{1A} receptor partial agonist. It is expected to exert an effect on dyskinesia expressed after administration of levodopa by suppressing the excessive release of levodopa-derived dopamine. Pre-clinical studies suggest DSP-9632P suppresses the dyskinesia symptom induced by levodopa. The transdermal patch formulation of DSP-9632P could potentially have an effective treatment option for levodopa-induced dyskinesia in Parkinson's disease by showing stable blood concentration, and may also lead to improved convenience for patients in terms of drug administration.
- Development stage: Levodopa-induced dyskinesia in Parkinson's disease: Phase 1 in Japan

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

- 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.
- Development stage: Narcolepsy: Phase 1 in Japan

DSP-3456

Origin: in-house, Formulation: oral

- 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).
- Development stage: Treatment resistant depression: Phase 1 in the U.S.

DSP-0378

Origin: in-house, Formulation: oral

- 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.
- Development stage: Dravet syndrome and Lennox-Gastaut syndrome: Phase 1 in Japan

2. Oncology**TP-3654**

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

- TP-3654 inhibits the inflammatory signaling pathways through inhibition of PIM (proviral integration site for Moloney murine leukemia virus) kinases. PIM kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth.
- Development stage: Myelofibrosis: Phase 1/2 in the U.S. and Japan

DSP-5336

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

- DSP-5336 is a small molecule inhibitor against the binding of menin and mixed-lineage leukemia (MLL) protein. Acute leukemia with MLL rearrangements or nucleophosmin 1 (NPM1) mutations rely on the menin-MLL interaction for upregulation of genes instrumental to leukemogenesis. DSP-5336 has been shown to have anti-cancer activity through downregulation of the genes by inhibition of menin-MLL interaction in pre-clinical studies.
- Development stage: Acute leukemia: Phase 1/2 in the U.S. and Japan

DSP-0390

Origin: in-house, Formulation: oral

- DSP-0390 is an inhibitor of Emopamil Binding Protein (EBP), which is one of cholesterol biosynthetic enzymes. EBP is an endoplasmic 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.
- Development stage: Glioblastoma: Phase 1 in the U.S. and Japan

TP-1287

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

- TP-1287 is a small molecule oral agent that inhibits cyclin-dependent kinase 9 (CDK9). TP-1287 has shown favorable oral bioavailability in pre-clinical studies. It is enzymatically cleaved, yielding alvocidib, a potent inhibitor of CDK9. The oral administration of TP-1287 may allow for administration for a prolonged period, which may lead to a continuous inhibition of CDK9.
- Development stage: Solid tumors: Phase 1 in the U.S.

TP-1454

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

- TP-1454 inhibits tumor growth through activation of PKM2 (pyruvate kinase M2) which leads to the inhibition of tumor cell proliferation and enhances antitumor immune response in tumor microenvironment. TP-1454 induces the activity of PKM2 through tetramerization of the enzyme which mainly exists in enzymatically less active dimer state in cancer cells. Tetramerization of PKM2 leads to the reduction of aerobic glycolysis in cancer cells and reverts the immunosuppressive

microenvironment. TP-1454 is expected to show synergistic effect with immune checkpoint inhibitor.

- Development stage: Solid tumors: Phase 1 in the U.S.

3. Regenerative medicine / cell therapy

Allo iPS cell-derived products

- In cooperation with the partners in the industry-academia collaboration, we are promoting toward the commercialization of regenerative medicine / cell therapy using allo iPS (induced pluripotent stem) cell (healthy patients) for AMD (age-related macular degeneration), Parkinson's disease, retinitis pigmentosa, and spinal cord injury.
- Development stage:

Development code	Partnering	Proposed indication	Area	Development stage
CT1-DAP001/ DSP-1083	Kyoto University CiRA	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated study, Sponsor: Kyoto University Hospital)
			U.S.	Preparing to start of clinical study
HLCR011	RIKEN, Healios	Age-related macular degeneration (AMD)	Japan	Preparing to start of clinical study

4. Others

GEMTESA® (vibegron)

Origin: Merck Sharp & Dohme Corp., Formulation: oral

- Vibegron is an oral, once-daily, small molecule $\beta 3$ adrenergic receptor agonist. Vibegron selectively acts on the $\beta 3$ 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. Urovant has received approval for overactive bladder in the U.S. in December 2020.
- Development stage: (New indication) Overactive bladder in men with BPH: Phase 3 in the U.S.

lefamulin

Origin: Nabriva Therapeutics plc, Formulation: oral, injection

- Lefamulin is an antimicrobial agent of pleuromutilin class and a novel treatment for infectious diseases with a mechanism of action that differs from existing antibiotics. Lefamulin is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. Lefamulin's binding occurs with high affinity, high specificity and at molecular sites that are distinct from other antibiotic classes. Lefamulin has been marketed by Nabriva Therapeutics in the U.S. since 2019.
- Development stage: Bacterial community-acquired pneumonia: NDA submitted in China in October 2021

rodatristat ethyl

Origin: Karos Pharmaceuticals, Inc., Formulation: oral

- Rodatristat ethyl is a prodrug of tryptophan hydroxylase (TPH) inhibitor designed to reduce peripheral production of serotonin without entering the brain. It is believed that rodatristat ethyl may halt or reverse the pathology of diseases that are driven by excessive serotonin production, such as PAH, idiopathic pulmonary fibrosis (IPF) and sarcoidosis.
- Development stage: Pulmonary arterial hypertension (PAH): Phase 2 in the U.S.

MVT-602

Origin: Takeda Pharmaceutical Company Ltd., Formulation: oral

- MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Activation of kisspeptin in upstream hypothalamic neurons is hypothesized to lead to the transmission of a signal that stimulates downstream neurons to increase the secretion of GnRH. However continued stimulation of kisspeptin

is thought to result in the desensitization of receptor transduction, which is anticipated to result in a complete cessation of the signaling pathway. Myovant is developing MVT-602 as part of the hormonal preparation for women with infertility undergoing in vitro fertilization. MVT-602 is believed to stimulate GnRH which in turn increases secretion of luteinizing hormone (LH) that acts as a trigger for egg maturation prior to oocyte collection.

- Development stage: Female infertility: Phase 2 in Germany

URO-902

Origin: Ion Channel Innovations, LLC., Formulation: injection

- URO-902 is a novel gene therapy for patients with overactive bladder symptoms who have failed oral pharmacologic therapy. URO-902 is a plasmid vector containing a human cDNA encoding the pore-forming component of the Maxi-K ion channel. Expression of the Maxi-K protein in muscle cells is hypothesized to increase potassium ion flow across the cell membrane, reducing excitability of smooth muscle cells. This mechanism could potentially normalize the heightened detrusor smooth muscle tone in overactive bladder, thereby reducing the related symptoms.
- Development stage: Overactive bladder: Phase 2 in the U.S.

KSP-1007

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

- 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[®]).
- Development stage: Complicated urinary tract infections and Complicated intra-abdominal infections: Phase 1 in the U.S.

X. Development Status of Major Programs in Frontier Business (As of January 31, 2023)

- Through collaborations with academia and startup companies, we work 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). Development status of major programs is as follows.

Area	Program	Summary	Development status	Partnering
Psychiatry Neurology	Digital devices for relieving BPSD	Tailor-made contents for stimulating five senses that digitally realize non-pharmacotherapy	Japan In trial sale (non-medical device)	Aikomi Ltd., Sompo Japan Insurance Inc.
	VR contents for mental health wellness	VR program for the self-management of mental health issues related to stress, worry and low mood. Users will set goals and objectives meaningful to them while they learn how to cope with negative situations encountered in their daily lives	U.S. In trial sale (non-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	Japan Product development (medical device)	NeuroSky Co., Ltd.
	Smart device for hard of hearing people	Develop smart devices that display multiple utterances as subtitles as a new communication support tool for hard of hearing people	Japan Product development (non-medical device)	Pixie Dust Technologies, Inc.
Motor dysfunction	Neurorehabilitation device for hand/fingers	Robotic neurorehabilitation device utilizing motion intention of patients with hand/fingers paralysis from electromyogram for the patients (Aiming for the NHI reimbursement as an approved device)	Japan Product development (medical device)	MELTIN
Metabolic disease	Automated blood collection/stabilization device	Blood collection device designed for low pain, long-term storage, and simple transportation for the self-management tool such as diabetes	Japan Product development (medical device)	Drawbridge Health, Inc.