Securities Code: 4506

Supplementary Financial Data (IFRS) for the Year Ended March 31, 2023

May 15, 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.
- Information concerning pharmaceuticals and medical devices (including compounds 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 yen)

	FY2021	FY2022	Change % YoY	FY2023 (Forecast)	Change % YoY
Revenue	560.0	**555.5**	(0.8)	362.0	(34.8)
Cost of sales *1	157.1	**176.7**	12.5	132.0	(25.3)
Gross profit	402.9	**378.8**	(6.0)	230.0	(39.3)
SG&A expenses *1	251.6	**305.6**	21.5	220.0	(28.0)
R&D expenses *1	94.0	**106.1**	12.8	84.0	(20.8)
Other operating income/expenses *2	1.2	**49.2**	—	12.0	(75.6)
Core operating profit (loss)	58.5	**16.4**	(72.0)	(62.0)	—
Changes in fair value of contingent consideration (negative number indicates loss)	3.3	**3.4**		—	
Other non-recurring items *3 (negative number indicates loss)	(1.6)	**(96.7)**		(16.0)	
Operating profit (loss)	60.2	**(77.0)**	—	(78.0)	—
Net profit (loss)	40.6	**(96.7)**	—	(80.0)	
Net profit (loss) attributable to owners of the parent	56.4	**(74.5)**	—	(80.0)	—
Basic earnings per share (yen)	141.99	**(187.55)**		(201.36)	
Net profit/ Equity attributable to owners of the parent (ROE)	9.5%	**(14.7%)**		(21.9%)	
Return on invested capital (ROIC)	1.7%	**(3.9%)**		(8.5%)	
Payout ratio	19.7%	**—**		—	

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

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

(Billions of yen)

	FY2021	FY2022	Change % YoY
Revenue	560.0	**555.5**	(0.8)
Cost of sales	157.1	**178.9**	13.9
Gross profit	402.9	**376.6**	(6.5)
SG&A expenses	249.1	**373.3**	49.9
R&D expenses	94.9	**131.9**	38.9
Other operating income/expenses	1.3	**51.6**	
Operating profit (loss)	60.2	**(77.0)**	—
Finance income/costs	22.7	**29.1**	
Profit (loss) before taxes	83.0	**(47.9)**	—
Income tax expenses	42.4	**48.8**	
Net profit (loss)	40.6	**(96.7)**	—
Net profit (loss) attributable to owners of the parent	56.4	**(74.5)**	—

3. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2021	FY2022
Net cash provided by (used in) operating activities	31.2	**11.9**
Net cash provided by (used in) investing activities	(18.3)	**52.4**
Net cash provided by (used in) financing activities	(21.4)	**(146.8)**
Cash and cash equivalents at the end of period	203.0	**143.5**

4. Foreign Exchange Rates

	FY2021		FY2022		FY2023 assumption	Forex sensitivity FY2023 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	**Period end rate**	**Average rate**	**Average rate**	Revenue	Core operating profit
Yen / USD	122.41	112.40	**133.54**	**135.51**	**130.00**	1.7	(0.6)
Yen / RMB	19.26	17.52	**19.42**	**19.75**	**19.50**	1.7	0.7

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization

	FY2021	**FY2022**	Change	FY2023 (Forecast)	Change
Capital expenditures	12.6	**14.6**	1.9	17.4	2.8
Depreciation of Property, plant and equipment	11.5	**12.0**	0.5	10.5	(1.5)
Amortization of Intangible assets	26.9	**29.3**	2.4	25.8	(3.5)
Related to products (patent rights/ marketing rights) included in above	24.2	**26.5**	2.3	22.9	(3.6)

(Billions of yen)

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

Major capital expenditure completed in FY2022

Reinforcement of production facilities, ￥1.1billion

Relocation of Tokyo Head Office, ￥1.2billion

Major capital expenditure project in FY2023

(Continued) 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)

	FY2021	FY2022	Change	Change %
Revenue	560.0	**555.5**	(4.5)	(0.8)
Overseas revenue	370.8	**385.4**	14.6	3.9
% of Revenue	66.2%	**69.4%**		
Cost of sales	157.1	**176.7**	19.6	12.5
% of Revenue	28.1%	**31.8%**		
Gross profit	402.9	**378.8**	(24.1)	(6.0)
SG&A expenses	251.6	**305.6**	54.1	21.5
Labor costs	113.2	**126.7**	13.5	11.9
Advertising and promotion costs	16.1	**17.4**	1.3	8.1
Sales promotion costs	21.7	**42.4**	20.8	95.9
Amortization/Depreciation	31.5	**34.0**	2.5	7.8
Others	69.0	**85.0**	16.0	23.2
R&D expenses	94.0	**106.1**	12.1	12.8
% of Revenue	16.8%	**19.1%**		
Other operating income/expenses	1.2	**49.2**	48.0	
Core operating profit	58.5	**16.4**	(42.1)	(72.0)
Changes in fair value of contingent consideration *	3.3	**3.4**	0.1	
Other non-recurring items *	(1.6)	**(96.7)**	(95.2)	
Operating profit (loss)	60.2	**(77.0)**	(137.2)	—
Finance income	25.8	**32.2**	6.4	
Finance costs	3.1	**3.2**	0.1	
Profit (loss) before taxes	83.0	**(47.9)**	(130.9)	—
Income tax expenses	42.4	**48.8**	6.4	
Net profit (loss)	40.6	**(96.7)**	(137.3)	—
Net profit (loss) attributable to owners of the parent	56.4	**(74.5)**	(130.9)	—

¥billion	Change	FX rate
Japan	(23.8)	
North America	8.7	56.0
China	1.1	4.4
Other Regions	4.6	

← Include Sumitovant +49.2

← Impairment losses and restructuring expenses in North America

* Negative number indicates loss.

2. Adjustments to Core Operating Profit

(Billions of yen)

FY2022 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	555.5	**555.5**	-	
Cost of sales	178.9	**176.7**	(2.2)	
Gross profit	376.6	**378.8**	2.2	
SG&A expenses	373.3	**305.6**	(67.7)	Impairment loss on patent right of KYNMOBI® (55.4)
R&D expenses	131.9	**106.1**	(25.8)	Impairment loss on in-process R&D of TP-0903 (20.6)
Other operating income	53.3	**49.2**	(4.1)	
Other operating expenses	1.7	**–**	(1.7)	
Operating profit (loss)	(77.0)	**16.4**	93.3	

III. Segment Information (Core Basis)

(Billions of yen)

FY2022 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	126.1	328.5	39.4	16.8	510.7	44.8	555.5
Cost of sales	65.3	62.4	8.4	5.1	141.3	35.4	176.7
Gross profit	60.9	266.0	31.0	11.6	369.5	9.3	378.8
SG&A expenses	51.8	233.8	11.4	1.6	298.7	7.0	305.6
Core segment profit	**9.1**	**32.2**	**19.5**	**10.0**	**70.8**	**2.4**	**73.2**
R&D expenses *1					103.2	2.8	106.1
Other operating income/expenses (Core basis)*2					24.4	24.8	49.2
Core operating profit (loss)					**(8.0)**	**24.3**	**16.4**

(Billions of yen)

FY2023 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	105.0	208.8	33.0	13.7	360.5	1.5	362.0
Cost of sales	48.1	68.8	7.4	6.8	131.1	0.9	132.0
Gross profit	56.9	140.0	25.6	6.9	229.4	0.6	230.0
SG&A expenses	46.1	160.3	10.6	1.8	218.8	1.2	220.0
Core segment profit (loss)	**10.8**	**(20.3)**	**15.0**	**5.1**	**10.6**	**(0.6)**	**10.0**
R&D expenses *1					82.0	2.0	84.0
Other operating income/expenses (Core basis)*2					6.0	6.0	12.0
Core operating profit (loss)					**(65.4)**	**3.4**	**(62.0)**

(Billions of yen)

（Ref.）FY2021 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	149.9	319.8	38.3	12.2	520.2	39.9	560.0
Cost of sales	78.7	33.6	7.4	6.6	126.3	30.8	157.1
Gross profit	71.3	286.2	30.9	5.5	393.9	9.0	402.9
SG&A expenses	51.7	180.8	11.3	2.3	246.1	5.5	251.6
Core segment profit	**19.6**	**105.4**	**19.6**	**3.3**	**147.8**	**3.5**	**151.4**
R&D expenses *1					91.7	2.3	94.0
Other operating income/expenses (Core basis)*2					1.1	0.0	1.2
Core operating profit					**57.3**	**1.2**	**58.5**

*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

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	FY2021	FY2022	Change	Change %	FY2023 (Forecast)
Japan	149.9	**126.1**	(23.8)	(15.9)	105.0
North America	319.8	**328.5**	8.7	2.7	208.8
China	38.3	**39.4**	1.1	2.9	33.0
Other Regions	12.2	**16.8**	4.6	37.6	13.7

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2021	FY2022	Change	Change %	FY2023 (Forecast)
Japan					
Promoted products					
Equa®/EquMet® Therapeutic agent for type 2 diabetes (Nov. 2019～)	37.5	**33.6**	(4.0)	(10.5)	32.4
Trulicity® * Therapeutic agent for type 2 diabetes	33.6	**24.8**	(8.8)	(26.2)	—
TRERIEF® Therapeutic agent for Parkinson's disease	16.4	**16.7**	0.3	1.8	15.0
LATUDA® Atypical antipsychotic (Jun. 2020～)	6.9	**9.6**	2.7	39.3	12.5
METGLUCO® Therapeutic agent for type 2 diabetes	8.1	**7.7**	(0.4)	(5.5)	7.5
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	2.1	**2.9**	0.9	42.8	3.3
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	0.2	**2.2**	2.0	—	4.2
Other products					
Authorized Generics	9.7	**9.2**	(0.5)	(5.2)	8.6

* Trulicity® revenue is shown by NHI price.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	FY2021	**FY2022**	Change	Change %	FY2023 (Forecast)
North America					
LATUDA® Atypical antipsychotic	204.1	**198.5**	(5.6)	(2.8)	20.9
APTIOM® Antiepileptic	27.1	**33.7**	6.6	24.4	35.5
RETHYMIC® Pediatric congenital athymia	0.3	**4.4**	4.1	—	7.0
BROVANA® Therapeutic agent for COPD	14.5	**2.8**	(11.7)	(80.7)	—
KYNMOBI® OFF episodes associated with Parkinson's disease (Sep. 2020～)	0.6	**0.4**	(0.2)	(29.1)	—
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	9.3	**24.7**	15.4	164.9	51.5
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug.2022～)	0.7	**4.5**	3.8	528.8	24.9
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	7.1	**24.7**	17.5	246.0	47.0
China					
MEROPEN® Carbapenem antibiotic	29.9	**28.5**	(1.4)	(4.6)	18.7
Other Regions					
MEROPEN® Carbapenem antibiotic	7.2	**6.5**	(0.7)	(9.3)	9.1

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

(Millions of dollar)

Brand name	FY2021	**FY2022**	Change	Change %	FY2023 (Forecast)
LATUDA®	1,816	**1,465**	(351)	(19.3)	161
APTIOM®	241	**249**	8	3.1	273
RETHYMIC®	3	**33**	30	—	54
BROVANA®	129	**21**	(108)	(84.0)	—
KYNMOBI®	5	**3**	(2)	(41.1)	—
ORGOVYX®	83	**182**	99	119.7	396
MYFEMBREE®	6	**33**	27	421.8	192
GEMTESA®	63	**182**	119	187.0	362

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar. 31 2022	Mar. 31 2023	Change
Assets	**1,308.0**	**1,134.7**	**(173.3)**
Non-current assets	**808.5**	**752.9**	**(55.6)**
Property, plant and equipment	64.1	58.9	(5.2)
Goodwill	195.1	209.4	14.3
Intangible assets	398.7	329.3	(69.4)
Patent rights/Marketing rights	361.6	310.9	(50.7)
In-process R&D	29.8	11.7	(18.1)
Others	7.3	6.7	(0.6)
Other financial assets	115.8	134.0	18.2
Other non-current assets	12.1	10.4	(1.7)
Deferred tax assets	22.7	10.8	(11.8)
Current assets	**499.5**	**381.9**	**(117.7)**
Inventories	99.0	94.4	(4.6)
Trade and other receivables	151.4	95.9	(55.5)
Other financial assets	35.6	20.2	(15.4)
Other current assets	10.5	20.4	9.9
Cash and cash equivalents	203.0	143.5	(59.5)
Subtotal	499.5	374.4	(125.2)
Assets held for sale	—	7.5	7.5
Liabilities	**634.4**	**728.0**	**93.5**
Non-current liabilities	**356.1**	**355.3**	**(0.8)**
Bonds and borrowings	244.0	244.1	0.2
Other financial liabilities	16.5	11.9	(4.6)
Retirement benefit liabilities	11.5	5.0	(6.5)
Other non-current liabilities	57.6	57.8	0.1
Deferred tax liabilities	26.6	36.5	10.0
Current liabilities	**278.4**	**372.7**	**94.3**
Borrowings	25.1	90.6	65.5
Trade and other payables	46.2	52.1	6.0
Other financial liabilities	13.3	7.0	(6.3)
Income taxes payable	7.6	24.1	16.5
Provisions	119.1	119.1	(0.1)
Other current liabilities	67.1	78.0	10.9
Liabilities directly associated with assets held for sale	—	1.8	1.8
Equity	**673.6**	**406.8**	**(266.8)**
Share capital	22.4	22.4	—
Capital surplus	16.7	—	(16.7)
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	514.2	281.0	(233.2)
Other components of equity	55.2	103.4	48.1
Other comprehensive income associated with assets held for sale	—	0.7	0.7
Equity attributable to owners of the parent	**607.9**	**406.7**	**(201.1)**
Non-controlling interests	65.7	0.0	(65.6)

Goodwill	22/3	23/3
Other than oncology(SMPO)	168.3	183.7
Oncology(SMPO)	26.8	25.8

Major patent rights	22/3	23/3
KYNMOBI® (apomorphine)	51.5	-
ORGOVYX® (relugolix)	64.7	66.1
MYFEMBREE® (relugolix)	139.6	142.5
GEMTESA® (vibegron)	93.9	94.7

Major IPR&D	22/3	23/3
TP-0903	18.6	-

Increase by change in value of securities

Total bonds and borrowings
269.0 → 334.7

Contingent consideration liabilities included in "Other financial liabilities (Non-current/Current)"
4.4 → 1.5

VI. Changes in Quarterly Results

(Billions of yen)

Core Basis	FY2021				FY2022			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	131.2	162.5	138.3	128.0	159.9	159.4	141.0	95.3
Cost of sales	38.5	38.4	41.0	39.3	46.1	46.8	46.9	37.0
Gross profit	92.7	124.2	97.4	88.7	113.8	112.6	94.1	58.3
SG&A expenses	62.0	62.5	64.2	62.9	76.0	76.2	75.3	78.1
R&D expenses	22.4	23.3	22.1	26.2	24.4	25.0	25.5	31.2
Other operating income/expenses	0.2	1.0	(0.0)	0.0	0.0	(0.0)	24.7	24.4
Core operating profit (loss)	8.5	39.4	11.0	(0.4)	13.4	11.5	18.1	(26.6)
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)	2.2
Other non-recurring items (negative number indicates loss)	(0.1)	(0.1)	(0.3)	(1.1)	1.3	(56.3)	(6.9)	(34.8)
Operating profit (loss)	8.3	39.3	10.7	2.0	14.6	(43.5)	11.1	(59.2)
Net profit (loss)	0.8	29.2	5.2	5.4	28.1	(43.3)	(17.4)	(64.1)
Net profit (loss) attributable to owners of the parent	4.8	31.6	9.9	10.1	31.1	(38.4)	(11.2)	(56.0)

VII. Major Consolidated Subsidiaries (As of March 31, 2023)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma Animal Health Co., Ltd.	2010/ 7	100%	99	Manufacturing and sales of veterinary medicines, etc.
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	33	Manufacturing and sales of pharmaceuticals, etc.
Overseas	**Establish-ment**	**Ownership**	**Number of employees**	**Businesses**
Sumitomo Pharma America Holdings, Inc.	2009/ 7	100%	225	Holding company, shared services for general management operations
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*654	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Oncology, Inc.	2006/11	100%	150	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	121	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	100%	*622	Manufacturing and sales of pharmaceuticals in the women's health, prostate cancer area
Urovant Sciences, Inc.	2016/11	100%	*325	Manufacturing and sales of pharmaceuticals in the urology area
Enzyvant Therapeutics, Inc.	2015/ 3	100%	*76	R&D, manufacturing and sales of pharmaceuticals in the pediatric and Respiratory rare diseases area
Spirovant Sciences, Inc.	2019/ 2	100%	*43	R&D in the cystic fibrosis gene therapy area
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	638	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2021		March 31, 2022		March. 31, 2023	
consolidated / non-consolidated	6,822	3,067	6,987	3,040	**6,250**	**3,026**
MRs (include number of contracted MRs)						
Japan Exclude managers/Total	1,150	1,270	1,110	1,220	**1,040**	**1,140**
U.S. Exclude managers/Total	720	840	820	950	**420**	**490**
China Exclude managers/Total	340	410	340	420	**270**	**340**

VIII. Shareholder Positioning (As of March 31, 2023)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 608,365)

3. Number of shareholders by category:

Shareholder category	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	32	87,431	21.97
Securities companies	50	8,461	2.13
Other Japanese corporations	344	223,039	56.05
Corporations outside Japan, etc.	515	43,752	11.00
Individuals and others (Including treasury stock)	35,454	35,215	8.85
Total	36,395	397,900	100.00

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

4. Major shareholders:

Shareholders	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	205,634	51.76
The Master Trust Bank of Japan, Ltd. (Trust account)	39,494	9.94
Custody Bank of Japan, Ltd. (Trust account)	15,797	3.98
Inabata & Co., Ltd.	9,782	2.46
Nippon Life Insurance Company	7,581	1.91
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Sumitomo Pharma Employee shareholders' association	3,136	0.79
BNYM AS AGT/CLTS NON TREATY JASDEC	3,098	0.78
Aioi Nissay Dowa Insurance Co.,Ltd.	2,661	0.67

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (608,365 shares *).
*Exclude 1,000 shares under name of the Company which are not owned by the Company substancially
2: The numbers of shares held are rounded down to the nearest thousand shares.

IX. Development Pipeline (As of May 15, 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
Small molecule	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)
	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
	DSP-2342	To be determined	U.S.	Phase 1
Regenerative medicine / cell therapy	CT1-DAP001/ DSP-1083 (Allogeneic 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 (Allogeneic iPS cell-derived retinal pigment epithelial cells)	Retinal pigment epithelium tear	Japan	Preparing the start of clinical study

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. 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
vibegron	Overactive bladder (OAB)	China	Phase 3
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	U.S.	Phase 2
MVT-602	Female infertility	Germany	Phase 2
SP-101	Cystic fibrosis	U.S.	Phase 1/2
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections	U.S.	Phase 1

【Main revisions since the announcement of January 2023】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
vibegron	Overactive bladder (OAB)	China	Phase 3	Newly added
DSP-2342	To be determined	U.S.	Phase 1	Newly added
SP-101	Cystic fibrosis	U.S.	Phase 1/2	Newly added
URO-902	Overactive bladder (OAB)	U.S.	Phase 2	Deleted from the table due to discontinuation of in-house development, out-licensing under consideration
SEP-378608	Bipolar disorder	U.S.	Phase 1	Deleted from the table due to discontinuation

X. Profiles of Major Products under Development (As of May 15, 2023)

1. Psychiatry & Neurology

(Small molecule)

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 D_2 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. The Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for ulotaront for the indication of schizophrenia in May 2019.
- 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-HT_7 receptors relative to dopamine D_2 receptors. SEP-4199 was discovered with an 85:15 ratio of R-amisulpride to S-amisulpride to increase levels of serotonin 5-HT_7 activity intended to enhance antidepressant efficacy and produce reduced levels of D_2 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

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 D_2 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-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

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

- 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 include 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.
- Development stage: Phase 1 in the U.S.

(Regenerative medicine / cell therapy)

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

CT1-DAP001/ DSP-1083 (Allogeneic iPS cell-derived products)

- Partnering: Kyoto University CiRA
- Development stage:
  Parkinson's disease: Phase 1/2 (Investigator-initiated study, Sponsor: Kyoto University Hospital) in Japan
  Parkinson's disease: Preparing the start of clinical study in the U.S.
- The Ministry of Health, Labor 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 products)

- Partnering: RIKEN, Healios
- Development stage: Retinal pigment epithelium tear: Preparing the start of clinical study 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. The FDA granted Orphan Drug Designation for TP-3654 for the indication of myelofibrosis in May 2022.
- 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. The FDA granted Orphan Drug Designation for DSP-5336 for the indication of acute myeloid leukemia in June 2022.
- 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 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.

- 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. The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation for TP-1287 for the indication of ewing sarcoma in February and March 2023, respectively.
- 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. Others

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

- Vibegron is an oral, once-daily, small molecule β3 adrenergic receptor agonist. Vibegron selectively acts on the β3 adrenergic receptor in the bladder that relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in patients with overactive bladder. 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.
  Overactive bladder: Phase 3 in China

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

SP-101 Origin: in-house (Spirovant Sciences, Inc.), Formulation: Inhalation Suspension

- SP-101 is a novel adeno-associated viral (AAV) vector engineered to efficiently transduce human airway epithelia from the apical (lumen) surface. It is designed to deliver a shortened but fully functional cystic fibrosis transmembrane conductance regulator (CFTR) gene to the airways of people living with Cystic Fibrosis (CF). Based on preclinical data, the addition of doxorubicin substantially improves SP-101 transduction and subsequent expression of the CFTR gene. SP-101 followed by doxorubicin administered via a nebulizer is being developed as a combination product for the treatment of CF. SP-101 is expected to restore CFTR function and halting disease progression in the lungs of people living with CF.
- Development stage: Cystic Fibrosis: Phase 1/2 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®). The FDA granted Qualified Infectious Disease Product (QIDP) status and Fast Track Designation for KSP-1007 for the indication of complicated urinary tract infections, complicated intra-abdominal infections, hospital-acquired bacterial pneumonia, and ventilator-associated bacterial pneumonia In August 2022.
- Development stage: Complicated urinary tract infections and Complicated intra-abdominal infections: Phase 1 in the U.S.

XI. Development Status of Major Programs in Frontier Business (As of May 15, 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	Under trial sale as a general wellness product, “Aikomi Care®.” We are researching and developing a DTx product for tailor-made contents for stimulating five senses that digitally realize non-pharmacotherapy, and aim for the NHI reimbursement as an approved device.	Japan Preparing for clinical research (medical device)	Aikomi Ltd.
	VR contents for social anxiety disorder (BVR-100)	We are researching and developing a DTx product that converts modules, etc. based on cognitive behavioral therapy (CBT) such as exposure therapy and cognitive restructuring training into VR content. Launched mental health VR contents “First Resort™” as a general wellness product.	U.S. Preparing for clinical study (medical device)	BehaVR, Inc.
	Wearable EEG meter	Service for early detection of mental diseases by daily capture of the EEG profile with simple wearable EEG meter. We aim to develop a service that enables early detection of mental illness by grasping brain wave trends.	Japan Product development (medical device)	NeuroSky Co., Ltd.
	Support Program for Screening of Depression/ Rating of Severity	This product is designed to detect depressive episodes caused by depression or bipolar disorder and help rate the severity of the disease by analyzing patients’ vital signs and activity data collected from wearable devices. We aim to develop a medical device.	Japan Product development (medical device)	Keio University, i2medical LLC
Motor dysfunction	Neurorehabilitation device for hand/fingers	Launched “MELTz®” as a medical device. We are developing Robotic neurorehabilitation device utilizing motion intention of patients with hand/fingers paralysis from electromyogram for the patients, and aim for the NHI reimbursement as an approved device.	Japan Product development (medical device)	MELTIN
	Training device for hand/fingers paralysis	Under development as "MELTz® Potarble". We aim to develop a small and simple device that trains patients with hand/fingers paralysis using a robot that uses myoelectric signals.	Japan Product development (non-medical device)	MELTIN
Metabolic disease	Automated blood collection/stabilization device	We aim to develop blood collection device designed for low pain, long-term storage, and simple transportation for the self-management tool such as metabolic disease.	Japan Product development (medical device)	Drawbridge Health, Inc.