Securities Code: 4506

Supplementary Financial Data (IFRS) for the Year Ended March 31, 2024

May 14, 2024

Sumitomo Pharma Co., Ltd.

- This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
- Information concerning pharmaceuticals and medical devices (including those under development) contained herein is not intended as advertising or as medical advice.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

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

(Billions of yen)

	FY2022	FY2023	Change %	FY2024 (Forecasts)	Change % YoY
Revenue	555.5	**314.6**	(43.4)	338.0	7.5
Cost of sales *1	176.7	**126.6**	(28.4)	138.0	9.0
Gross profit	378.8	**188.0**	(50.4)	200.0	6.4
SG&A expenses *1	305.6	**236.4**	(22.6)	169.0	(28.5)
R&D expenses *1	106.1	**90.9**	(14.3)	50.0	(45.0)
Other operating income/expenses *2	49.2	**6.4**		20.0	
Core operating profit (loss)	16.4	**(133.0)**	—	1.0	—
Non-recurring items *3 (negative number indicates net loss)	(93.3)	**(221.9)**		(1.0)	
Operating profit (loss)	(77.0)	**(354.9)**	—	0.0	—
Net profit (loss)	(96.7)	**(314.9)**	—	(16.0)	—
Net profit (loss) attributable to owners of the parent	(74.5)	**(315.0)**	—	(16.0)	—
Basic earnings per share (yen)	(187.55)	**(792.79)**		(40.27)	
Net profit/ Equity attributable to owners of the parent (ROE)	(14.7%)	**(111.9%)**		(10.8%)	
Return on invested capital (ROIC)	(3.9%)	**(19.0%)**		0.6%	
Payout ratio	—	**—**		—	

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

(Billions of yen)

	FY2022	FY2023	Change %
Revenue	555.5	**314.6**	(43.4)
Cost of sales	178.9	**126.6**	(29.3)
Gross profit	376.6	**188.0**	(50.1)
SG&A expenses	373.3	**429.5**	15.1
R&D expenses	131.9	**112.6**	(14.6)
Other operating income/expenses	51.6	**(0.7)**	
Operating profit (loss)	(77.0)	**(354.9)**	—
Finance income/costs	29.1	**31.7**	
Profit (loss) before taxes	(47.9)	**(323.1)**	—
Income tax expenses	48.8	**(8.2)**	
Net profit (loss)	(96.7)	**(314.9)**	—
Net profit (loss) attributable to owners of the parent	(74.5)	**(315.0)**	—

*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.)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2022	FY2023
Net cash provided by (used in) operating activities	11.9	**(241.9)**
Net cash provided by (used in) investing activities	52.4	**33.0**
Net cash provided by (used in) financing activities	(146.8)	**77.9**
Cash and cash equivalents at the end of period	143.5	**29.0**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2024 assumption	Forex sensitivity FY2024 (Impact of yen depreciation by ¥1)	
	Mar. 31 2023	**Mar. 31 2024**	FY2022	**FY2023**	**Average rate**	Revenue	Core operating profit
Yen / USD	133.54	**151.33**	135.51	**144.59**	**145.00**	1.4	(0.1)
Yen / RMB	19.42	**20.84**	19.75	**20.14**	**20.00**	1.7	0.8

(Billions of yen)

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	FY2022	**FY2023**	Change	FY2024 (Forecasts)	Change YoY
Capital expenditures	14.6	**14.1**	(0.4)	11.0	(3.1)
Depreciation of Property, plant and equipment	12.0	**9.7**	(2.3)	10.7	1.0
Amortization of Intangible assets	29.3	**28.1**	(1.2)	18.9	(9.2)
Related to products (patent rights/ marketing rights) included in above	26.5	**25.4**	(1.1)	15.5	(9.9)

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

Major capital expenditure completed in FY2023

Establishment of manufacturing facility for regenerative medicine and cell therapy (USA), $36million

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	FY2022	FY2023	Change	Change %
Revenue	555.5	**314.6**	(241.0)	(43.4)
Overseas revenue	385.4	**207.9**	(177.5)	(46.1)
% of Revenue	69.4%	**66.1%**		
Cost of sales	176.7	**126.6**	(50.1)	(28.4)
% of Revenue	31.8%	**40.2%**		
Gross profit	378.8	**188.0**	(190.9)	(50.4)
SG&A expenses	305.6	**236.4**	(69.2)	(22.6)
Labor costs	137.9	**100.6**	(37.3)	(27.0)
Sales promotion costs/ Advertising and promotion costs	59.9	**42.4**	(17.5)	(29.2)
Amortization/Depreciation	34.0	**31.8**	(2.2)	(6.4)
Others	73.8	**61.6**	(12.2)	(16.6)
R&D expenses	106.1	**90.9**	(15.2)	(14.3)
% of Revenue	19.1%	**28.9%**		
Other operating income/expenses	49.2	**6.4**	(42.8)	
Core operating profit (loss)	16.4	**(133.0)**	(149.3)	—
Non-recurring items (negative number indicates net loss)	(93.3)	**(221.9)**	(128.5)	
Operating profit (loss)	(77.0)	**(354.9)**	(277.9)	—
Finance income	32.2	**36.0**	3.8	
Finance costs	3.2	**4.3**	1.1	
Profit (loss) before taxes	(47.9)	**(323.1)**	(275.2)	—
Income tax expenses	48.8	**(8.2)**	(57.0)	
Net profit (loss)	(96.7)	**(314.9)**	(218.2)	—
Net profit (loss) attributable to owners of the parent	(74.5)	**(315.0)**	(240.5)	—

Change FX impact

Japan (69.0)

North America (169.4) 10.0

Asia (2.6) 1.1

Change by segment

	Japan	North America	Asia
Labor costs	(6.4)	(30.4)	(0.4)
Sales promotion costs/ Advertising and promotion costs	(0.8)	(15.8)	(0.8)
Amortization/ Depreciation	(0.5)	(1.7)	0.0
Others	(4.4)	(8.6)	0.7

FY22: Impairment loss (88.2)
Business structure improvement expenses (13.0)

FY23: Impairment loss (180.9)
Business structure improvement expenses in North America (30.1)

2. Adjustments to Core Operating Profit

(Billions of yen)

FY2023 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	314.6	**314.6**	—	
Cost of sales	126.6	**126.6**	—	
Gross profit	188.0	**188.0**	—	
SG&A expenses	429.5	**236.4**	(193.1)	Impairment loss on goodwill (35.9) Impairment loss on patent right (133.5) Business structure improvement expenses in North America (19.0)
R&D expenses	112.6	**90.9**	(21.7)	Impairment loss on in-process R&D (10.6) Business structure improvement expenses in North America (11.2)
Other operating income	7.5	**6.4**	(1.1)	
Other operating expenses	8.1	**—**	(8.1)	
Operating profit (loss)	(354.9)	**(133.0)**	221.9	

III. Segment Information (Core Basis)

(Billions of yen)

FY2023 Results	Japan	North America	Asia	Total
Revenue	114.7	159.0	40.9	314.6
Cost of sales	54.2	62.0	10.4	126.6
Gross profit	60.5	97.0	30.5	188.0
SG&A expenses	47.1	177.2	12.1	236.4
Core segment profit (loss)	**13.4**	**(80.2)**	**18.4**	**(48.5)**
R&D expenses *1				90.9
Other operating income/expenses (Core basis) *2				6.4
Core operating profit (loss)				**(133.0)**

(Billions of yen)

FY2024 Forecasts	Japan	North America	Asia	Total
Revenue	100.3	198.7	39.0	338.0
Cost of sales	52.7	76.3	9.0	138.0
Gross profit	47.6	122.4	30.0	200.0
SG&A expenses	46.6	109.9	12.5	169.0
Core segment profit	**1.0**	**12.5**	**17.5**	**31.0**
R&D expenses *1				50.0
Other operating income/expenses (Core basis) *2				20.0
Core operating profit				**1.0**

(Billions of yen)

（Ref.）FY2022 Results	Japan	North America	Asia	Total
Revenue	183.6	328.5	43.5	555.5
Cost of sales	104.9	62.4	9.4	176.7
Gross profit	78.7	266.0	34.1	378.8
SG&A expenses	59.2	233.8	12.6	305.6
Core segment profit	**19.5**	**32.2**	**21.4**	**73.2**
R&D expenses *1				106.1
Other operating income/expenses (Core basis) *2				49.2
Core operating profit				**16.4**

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

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

Note: From FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia).
FY2022 results has been prepared based on the current classification.

IV. Revenue Information

1. Revenue by segment

(Billions of yen)

Segment	FY2022	**FY2023**	Change	Change %	FY2024 (Forecasts)
Japan	183.6	**114.7**	(69.0)	(37.6)	100.3
North America	328.5	**159.0**	(169.4)	(51.6)	198.7
Asia	43.5	**40.9**	(2.6)	(6.0)	39.0

2. Revenue of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2022	**FY2023**	Change	Change %	FY2024 (Forecasts)
Japan					
Promoted products					
Equa®/EquMet® Therapeutic agent for type 2 diabetes (Nov. 2019～)	33.6	**30.6**	(2.9)	(8.7)	26.3
TRERIEF® Therapeutic agent for Parkinson's disease	16.7	**15.5**	(1.2)	(7.0)	2.1
LATUDA® Atypical antipsychotic (Jun. 2020～)	9.6	**11.7**	2.2	22.5	13.0
METGLUCO® Therapeutic agent for type 2 diabetes	7.7	**7.3**	(0.4)	(5.3)	7.4
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	2.2	**4.6**	2.3	105.6	11.3
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	2.9	**3.8**	0.9	29.9	4.4
Trulicity® * Therapeutic agent for type 2 diabetes	24.8	**—**	(24.8)	—	—
Other products					
Authorized Generics	9.2	**9.7**	0.5	5.8	11.1
Export products, One-time revenue, Others	77.0	**31.4**	(45.6)	(59.2)	24.7

* Trulicity® revenue is shown by NHI drug price.

2. Revenue of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	FY2022	**FY2023**	Change	Change %	FY2024 (Forecasts)
North America					
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	24.7	**42.2**	17.5	70.8	57.9
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug.2022～)	4.5	**9.2**	4.7	104.7	17.9
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	24.7	**36.8**	12.1	49.2	55.0
APTIOM® Antiepileptic	33.7	**34.0**	0.3	0.7	29.1
RETHYMIC® Pediatric congenital athymia (Mar. 2022~)	4.4	**6.3**	1.9	42.3	7.2
LATUDA® Atypical antipsychotic	198.5	**6.7**	(191.8)	(96.6)	5.4
Export products, One-time revenue, Others	38.0	**23.8**	(14.1)	(37.3)	26.2
Asia					
MEROPEN® (China) Carbapenem antibiotic	28.5	**21.3**	(7.3)	(25.5)	21.2
MEROPEN® (Southeast Asia) Carbapenem antibiotic	3.1	**5.7**	2.7	87.0	3.6

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

Brand name	FY2022	**FY2023**	Change	Change %	FY2024 (Forecasts)
ORGOVYX®	182	**292**	110	60.1	400
MYFEMBREE®	33	**64**	30	91.8	124
GEMTESA®	182	**255**	73	39.9	380
APTIOM®	249	**235**	(14)	(5.6)	201
RETHYMIC®	33	**44**	11	33.3	49
LATUDA®	1,465	**47**	(1,418)	(96.8)	37

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar. 31 2023	Mar. 31 2024	Change
Assets	**1,134.7**	**907.5**	**(227.2)**
Non-current assets	**752.9**	**637.9**	**(114.9)**
Property, plant and equipment	58.9	57.9	(1.0)
Goodwill	209.4	199.8	(9.6)
Intangible assets	329.3	195.7	(133.7)
Patent rights/Marketing rights	310.9	186.4	(124.4)
In-process R&D	11.7	3.2	(8.5)
Others	6.7	6.0	(0.7)
Other financial assets	134.0	161.7	27.7
Other non-current assets	10.4	20.7	10.3
Deferred tax assets	10.8	2.2	(8.6)
Current assets	**381.9**	**269.6**	**(112.3)**
Inventories	94.4	115.4	20.9
Trade and other receivables	95.9	81.0	(14.9)
Other financial assets	20.2	7.1	(13.1)
Other current assets	20.4	35.2	14.8
Cash and cash equivalents	143.5	29.0	(114.4)
Assets held for sale	7.5	1.9	(5.6)
Liabilities	**728.0**	**751.4**	**23.4**
Non-current liabilities	**355.3**	**235.9**	**(119.4)**
Bonds and borrowings	244.1	133.4	(110.8)
Other financial liabilities	11.9	12.7	0.9
Retirement benefit liabilities	5.0	11.2	6.1
Other non-current liabilities	57.8	40.4	(17.3)
Deferred tax liabilities	36.5	38.2	1.7
Current liabilities	**372.7**	**515.5**	**142.8**
Borrowings	90.6	285.5	194.9
Trade and other payables	52.1	67.7	15.6
Other financial liabilities	7.0	14.1	7.1
Income taxes payable	24.1	1.3	(22.7)
Provisions	119.1	79.5	(39.5)
Other current liabilities	78.0	67.2	(10.8)
Liabilities directly associated with assets held for sale	1.8	—	(1.8)
Equity	**406.8**	**156.1**	**(250.6)**
Share capital	22.4	22.4	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	281.0	(22.7)	(303.7)
Other components of equity	103.4	157.0	53.7
Other comprehensive income associated with assets held for sale	0.7	—	(0.7)
Equity attributable to owners of the parent	**406.7**	**156.1**	**(250.7)**
Non-controlling interests	0.0	0.1	0.0

Impairment loss (35.9)

Major patent rights	23/3	24/3
ORGOVYX® (relugolix)	66.1	69.7
MYFEMBREE® (relugolix)	142.5	10.6
GEMTESA® (vibegron)	94.7	98.5

Impairment loss (133.5)

Impairment loss (10.6)

Increase by change in fair value of securities

Transfer of long-term borrowings to current liabilities (110.9)

Transfer of long-term borrowings from non-current liabilities 110.9
New borrowings 84.0

Decrease in reserve for sales rebates of LATUDA® due to payment

・Increase in valuation reserve for securities due to change in fair value of securities
・Increase in exchange difference on translation of foreign operations due to yen depreciation

VI. Changes in Quarterly Results

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

(Billions of yen)

	FY2022				FY2023			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	159.9	159.4	141.0	95.3	75.7	77.0	82.4	79.5
Cost of sales	46.1	46.8	46.9	37.0	30.4	29.9	32.9	33.4
Gross profit	113.8	112.6	94.1	58.3	45.3	47.1	49.5	46.1
SG&A expenses	76.0	76.2	75.3	78.1	61.8	56.9	57.9	59.8
R&D expenses	24.4	25.0	25.5	31.2	22.8	22.5	22.7	22.9
Other operating income/expenses	0.0	(0.0)	24.7	24.4	5.9	(0.0)	0.5	0.0
Core operating profit (loss)	13.4	11.5	18.1	(26.6)	(33.5)	(32.3)	(30.5)	(36.6)
Non-recurring items (negative number indicates net loss)	1.2	(55.0)	(6.9)	(32.6)	(18.1)	(2.6)	(0.7)	(200.5)
Operating profit (loss)	14.6	(43.5)	11.1	(59.2)	(51.6)	(34.9)	(31.2)	(237.1)
Net profit (loss)	28.1	(43.3)	(17.4)	(64.1)	(38.9)	(28.9)	(50.0)	(197.2)
Net profit (loss) attributable to owners of the parent	31.1	(38.4)	(11.2)	(56.0)	(38.9)	(28.9)	(50.0)	(197.3)

2. Revenue of Major Products

	FY2022				FY2023			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Japan					(Invoice price basis, Billions of yen)			
Equa®/EquMet®	8.8	8.5	10.0	6.3	8.2	7.6	8.8	6.0
TRERIEF®	4.4	4.2	4.5	3.6	4.4	4.1	4.6	2.4
LATUDA®	2.3	2.4	2.6	2.3	2.8	2.9	3.3	2.7
METGLUCO®	2.0	2.0	2.0	1.7	1.9	1.8	2.0	1.6
TWYMEEG®	0.1	0.4	0.8	0.9	1.2	1.5	0.9	1.1
LONASEN® Tape	0.7	0.7	0.8	0.7	0.9	0.9	1.1	0.9
Trulicity® *	8.6	8.0	8.1	(0.0)	—	—	—	—
Authorized Generics	2.3	2.3	2.4	2.1	2.3	2.3	2.5	2.6
Export products, One-time revenue, Others	23.9	18.5	18.2	19.3	8.6	7.1	7.6	8.2

* Trulicity® revenue is shown by NHI drug price.

North America								(Millions of dollar)
ORGOVYX®	36	43	49	54	68	70	78	76
MYFEMBREE®	4	6	11	12	13	16	20	14
GEMTESA®	34	37	54	57	63	49	62	81
APTIOM®	65	65	61	58	58	57	61	59
RETHYMIC®	5	14	3	11	11	11	8	14
LATUDA®	482	470	362	151	8	20	7	11
Export products, One-time revenue, Others	108	98	41	33	37	39	50	40

Asia								(Billions of yen)
MEROPEN® (China)	9.1	9.6	5.1	4.7	4.4	5.8	5.1	6.0
MEROPEN® (Southeast Asia)	0.8	0.5	0.9	0.8	2.3	1.8	0.8	0.9

VII. Major Consolidated Subsidiaries (As of March 31, 2024)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	30	Manufacturing and sales of pharmaceuticals, etc.

Overseas	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma UK Holdings, Ltd.	2019/10	100%	0	Holding company, management of the group companies, and formulation and promotion of business strategies, etc.
Sumitomo Pharma America, Inc.	1984/ 1	100%	*1,174	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Switzerland GmbH	2016/ 8	100%	26	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma (China) Co., Ltd.	2022/ 6	100%	55	Holding company, management of the Company's China business, etc.
Sumitomo Pharma (Suzhou) Co., Ltd.	2003/12	100%	557	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference)

Number of employees	March 31, 2022		March 31, 2023		**March 31, 2024**	
consolidated / non-consolidated	6,987	3,040	6,250	3,026	**4,980**	**2,908**
Number of MRs （approx., include contracted MRs）						
Japan Exclude managers/Total	1,110	1,220	1,040	1,140	**910**	**1,000**
U.S. Exclude managers/Total	820	950	500	580	**430**	**490**
China Exclude managers/Total	340	420	270	340	**270**	**340**

VIII. Shareholder Positioning (As of March 31, 2024)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 609,393)

3. Number of shareholders by category:

Shareholder category	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	28	64,192	16.13
Securities companies	52	4,418	1.11
Other Japanese corporations	422	223,892	56.27
Corporations outside Japan, etc.	582	37,291	9.37
Individuals and others (Including treasury stock)	48,713	68,104	17.12
Total	49,797	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)	22,995	5.79
Custody Bank of Japan, Ltd. (Trust account)	11,100	2.79
Inabata & Co., Ltd.	8,782	2.21
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	3,627	0.91
Custody Bank of Japan, Ltd. (Trust account 4)	3,352	0.84
NORTHERN TRUST GLOBAL SERVICES SE, LUXEMBOURG RE LUDU RE: UCITS CLIENTS 15.315 PCT NON TREATY ACCOUNT	2,835	0.71

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (609,393 shares*).
*Exclude 1,000 shares under name of the Company which are not owned by the Company substantially
2: The numbers of shares held are rounded down to the nearest thousand shares.

IX. Development Pipeline (As of May 14, 2024)

- 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	LATUDA® (lurasidone hydrochloride)	(New usage: pediatric) Schizophrenia	Japan	Phase 3
	DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Narcolepsy	Japan	Phase 1
	DSP-3456	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	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 dopaminergic neural progenitor cells)	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated study)
			U.S.	Phase 1/2 (Investigator-initiated study)
				Phase 1/2 （Company-sponsored clinical study）
	HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)	Retinal pigment epithelium tear	Japan	Phase 1/2

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
SMP-3124	Solid tumors	U.S.	Phase 1/2

3. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	sNDA submitted in February 2024
vibegron	Overactive bladder (OAB)	China	Phase 3
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	U.S., Japan	Phase 1
fH1/DSP-0546LP	Influenza	Europe	Phase 1

【Main revisions since the announcement of January 2024】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	sNDA submitted in February 2024	sNDA submitted
CT1-DAP001/DSP-1083 (Allogeneic iPS cell-derived dopaminergic neural progenitor cells)	Parkinson's disease	U.S.	Phase 1/2 (Company - sponsored clinical study)	Newly added
SMP-3124	Solid tumors	U.S.	Phase 1/2	Newly added
fH1/DSP-0546LP	Influenza	Europe	Phase 1	Newly added
SEP-363856 (ulotaront hydrochloride)	Schizophrenia	U.S.	Phase 3	Deleted from the table due to out-licensing
		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	

EPI-589	Parkinson’s disease	U.S.	Phase 2	Deleted from the table due to discontinuation of the development
	Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2	
		Japan	Phase 2 (Investigator-initiated study)	
SP-101	Cystic fibrosis	U.S.	Phase 1/2	Deleted from the table due to spin-out
SEP-378614	To be determined	U.S.	Phase 1	Deleted from the table due to discontinuation of the development
SEP-380135	To be determined	U.S.	Phase 1	Deleted from the table due to out-licensing
TP-1287	Solid tumors	U.S.	Phase 1	Deleted from the table due to discontinuation of the study
TP-1454	Solid tumors	U.S.	Phase 1	Deleted from the table due to discontinuation of the development

X. Profiles of Major Products under Development (As of May 14, 2024)

1. Psychiatry & Neurology

(Small molecule)

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

- Development stage: Alzheimer's disease psychosis: Phase 1 in the U.S.
- DSP-0038 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies. DSP-0038 is a serotonin 5-HT_{2A} receptor antagonist and a serotonin 5-HT_{1A} receptor agonist. DSP-0038 is expected to demonstrate a greater antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have a broader efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) which include agitation, aggression, anxiety, and depression. Furthermore, DSP-0038 has negligible affinity for dopamine D_2 receptors, and therefore it can be expected to show improved safety and tolerability compared to existing antipsychotic.

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

- Development stage: Narcolepsy: Phase 1 in Japan
- DSP-0187 is an orexin 2 receptor agonist. It is expected to improve excessive daytime sleepiness (EDS) and cataplexy of narcolepsy caused by orexin deficiency. DSP-0187 is also expected to demonstrate an efficacy for EDS other than narcolepsy. Sumitomo Pharma granted Jazz Pharmaceuticals plc the exclusive development and commercialization rights in the territories, except for Japan, China, and certain other Asia/Pacific markets in April 2022.

DSP-3456 Origin: in-house, Formulation: oral

- Development stage: Treatment resistant depression: Phase 1 in the U.S.
- DSP-3456 is a metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM). DSP-3456 is expected to exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex by enhancing the glutamate release, while avoiding side effects (psychotic symptoms, cognitive dysfunction).

DSP-0378 Origin: in-house, Formulation: oral

- Development stage: Dravet syndrome and Lennox-Gastaut syndrome: Phase 1 in Japan
- DSP-0378 is a gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator. It acts on various subtypes of $GABA_A$ receptors expressed in synaptic and extrasynaptic regions in a manner different from common $GABA_A$ receptor potentiators such as benzodiazepines and neurosteroids. It is expected to exhibit an antiepileptic effect against broad epilepsies including intractable rare diseases like Dravet syndrome and Lennox-Gastaut syndrome.

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

- Development stage: Phase 1 in the U.S.
- DSP-2342 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies. DSP-2342 is a serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist. DSP-2342 is expected to demonstrate a broader antipsychotic effect which includes psychosis, anxiety, and depression, based on the additive effect of 5-HT_{2A} and 5-HT_7 receptor antagonist. Furthermore, DSP-2342 has high selectivity for 5-HT_{2A} and 5-HT_7 receptors, which can be expected to show a high level of safety and tolerability.

(Regenerative medicine / cell therapy)

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

pigmentosa, and spinal cord injury.

CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells)

- Partnering: Kyoto University CiRA, University of California San Diego School of Medicine
- Development stage:
  Parkinson's disease: Phase 1/2 (Investigator-initiated study, Sponsor: Kyoto University Hospital) in Japan
  Parkinson's disease: Phase 1/2 (Investigator-initiated study, Sponsor: University of California San Diego School of Medicine) in the U.S.
  Parkinson's disease: Phase 1/2 (Company-sponsored clinical study) in the U.S.
- The Ministry of Health, Labour and Welfare (MHLW) designated "Sakigake Designation System" product for regenerative medicine & cell therapy for the indication of Parkinson's disease in February 2017.

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

- Partnering: RIKEN, Healios
- Development stage: Retinal pigment epithelium tear: Phase 1/2 in Japan

2. Oncology

TP-3654 Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

- Development stage: Myelofibrosis: Phase 1/2 in the U.S. and Japan
- TP-3654 inhibits the inflammatory signaling pathways through inhibition of PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinases. PIM1 kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth. The FDA granted Orphan Drug Designation for TP-3654 for the indication of myelofibrosis in May 2022.

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

- Development stage: Acute leukemia: Phase 1/2 in the U.S. and Japan
- 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.

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

- Development stage: Glioblastoma: Phase 1 in the U.S. and Japan
- DSP-0390 is an inhibitor of Emopamil Binding Protein (EBP), which is one of cholesterol biosynthetic enzymes. EBP is an endoplastic reticulum membrane protein involved in cholesterol biosynthesis. When functional, EBP mediates de novo cholesterol synthesis for cell membrane structure and signaling, enabling aberrant growth of tumors. Inhibition of EBP causes an efficient cellular cholesterol depletion and it is expected to show anti-cancer activities. The FDA granted Orphan Drug Designation for DSP-0390 for the indication of brain cancer in May 2022.

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

- Development stage: Solid tumors: Phase 1/2 in the U.S.
- SMP-3124 is an injection, a CHK1 (checkpoint kinase 1) inhibitor encapsulated within liposome. CHK1 is activated by DNA damage response, then arrests the cell cycle, and induces DNA repair that is a serine-threonine kinase. CHK1 inhibition leads cancer cell with high replication stressed to apoptosis

by inducing further DNA damages. SMP-3124 is expected to accomplish strengthen the anti-tumor activity and weaken side effects by changing pharmacokinetics of the compound with liposomal nanomedicinal encapsulation.

3. Others

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

- Development stage:
  (New indication) Overactive bladder in men with BPH: sNDA submitted in the U.S. in February 2024
  Overactive bladder: Phase 3 in China
- 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. Former Urovant has received approval for overactive bladder in the U.S. in December 2020.

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

- Development stage: Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia: Phase 1 in the U.S. and Japan
- KSP-1007 can broadly and strongly inhibit β-lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. KSP-1007 is expected to become an effective treatment option against carbapenem-resistant bacterial infections in a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Pharma's product for the domestic market: MEROPEN®). The FDA granted Qualified Infectious Disease Product (QIDP) status and Fast Track Designation for KSP-1007 for the indication of complicated urinary tract infections, complicated intra-abdominal infections, hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia in August 2022.

fH1/DSP-0546LP Origin: in-house (Joint research with the National Institutes of Biomedical Innovation, Health and Nutrition), Formulation: injection

- Development stage: Influenza: Phase 1 in Europe
- fH1/DSP-0546LP is the next-generation candidate vaccine formulation composed of the post-fusion hemagglutinin antigen (fH1) that is expected to be effective against a broad range of influenza viruses, and TLR7 adjuvant "DSP-0546LP" that enhances the quantity, quality, and durability of immune response. Conventional influenza vaccines lose effectiveness due to viral mutations, making it necessary to select, produce, and inoculate a vaccine to immunize against strains predicted to circulate each year. They may also not respond well to emerging strains of influenza. The pre-clinical study of fH1/DSP-0546LP demonstrated the broad cross protection against influenza viruses antigenically different from those used in vaccine formulations, and indicated the significance of the TLR7 adjuvant, DSP-0546LP. It is expected that fH1/DSP-0546LP improves the breadth and durability of protection against seasonal influenza viruses and is effective against novel and potentially pandemic strains.

XI. Development Status of Major Programs in Frontier Business (As of May 14, 2024)

- 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®” and “Aikomi DS.” 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
	Violet light	We aim to develop neuromodulation technology via vision with violet lights flashing at 40 Hz to treat and prevent mental illness.	Japan Product development (medical device)	Tsubota Laboratory, Inc.
Motor dysfunction	Neurorehabilitation device for hand/fingers paralysis	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® Portable". 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