Securities Code: 4506

Supplementary Financial Data (IFRS) for the Third Quarter of the Year Ending March 31, 2024

January 31, 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)

	Q3 FY2022	**Q3 FY2023**	Change %	FY2022	FY2023 (Forecasts)		Change %
Revenue	460.3	**235.0**	(48.9)	555.5	[362.0]	317.0	(42.9)
Cost of sales *1	139.7	**93.2**	(33.3)	176.7	[132.0]	125.0	(29.3)
Gross profit	320.5	**141.8**	(55.7)	378.8	[230.0]	192.0	(49.3)
SG&A expenses *1	227.5	**176.6**	(22.4)	305.6	[220.0]	240.0	(21.5)
R&D expenses *1	74.9	**68.0**	(9.2)	106.1	[84.0]	92.0	(13.3)
Other operating income/expenses *2	24.8	**6.4**		49.2	[12.0]	6.0	
Core operating profit (loss)	42.9	**(96.4)**	—	16.4	[(62.0)]	(134.0)	—
Non-recurring items *3 (negative number indicates net loss)	(60.7)	**(21.4)**		(93.3)	[(16.0)]	(22.0)	
Operating profit (loss)	(17.8)	**(117.7)**	—	(77.0)	[(78.0)]	(156.0)	—
Net profit (loss)	(32.6)	**(117.7)**	—	(96.7)	[(80.0)]	(141.0)	—
Net profit (loss) attributable to owners of the parent	(18.5)	**(117.7)**	—	(74.5)	[(80.0)]	(141.0)	—
Basic earnings per share (yen)	(46.57)	**(296.28)**		(187.55)	[(201.36)]	(354.90)	
Net profit/ Equity attributable to owners of the parent (ROE)				(14.7%)	[(21.9%)]	(38.8%)	
Return on invested capital (ROIC)				(3.9%)	[(8.5%)]	(18.6%)	

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

*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)

	Q3 FY2022	**Q3 FY2023**	Change %
Revenue	460.3	**235.0**	(48.9)
Cost of sales	139.8	**93.2**	(33.3)
Gross profit	320.5	**141.8**	(55.7)
SG&A expenses	289.5	**191.6**	(33.8)
R&D expenses	76.0	**73.6**	(3.1)
Other operating income/expenses	27.2	**5.6**	
Operating profit (loss)	(17.8)	**(117.7)**	—
Finance income/costs	20.0	**12.6**	
Profit (loss) before taxes	2.2	**(105.2)**	—
Income tax expenses	34.8	**12.5**	
Net profit (loss)	(32.6)	**(117.7)**	—
Net profit (loss) attributable to owners of the parent	(18.5)	**(117.7)**	—

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q3 FY2022	**Q3 FY2023**
Net cash provided by (used in) operating activities	56.5	**(230.7)**
Net cash provided by (used in) investing activities	21.7	**38.3**
Net cash provided by (used in) financing activities	(33.0)	**72.1**
Cash and cash equivalents at the end of period	265.8	**36.5**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2023 assumption	Forex sensitivity FY2023 (Impact of yen depreciation by ¥1)	
	Mar. 31 2023	**Dec. 31 2023**	FY2022 Apr.-Dec.	**FY2023 Apr.-Dec.**	**Average rate**	Revenue	Core operating profit
Yen / USD	133.54	**141.83**	136.51	**143.33**	**145.00**	1.2	(1.0)
Yen / RMB	19.42	**19.94**	19.88	**19.98**	**20.00**	1.7	0.6

(Billions of yen)

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q3 FY2022	**Q3 FY2023**	Change	FY2022	FY2023 (Forecasts)		Change
Capital expenditures	6.9	**8.5**	1.6	14.6	[17.4]	16.4	1.8
Depreciation of Property, plant and equipment	9.4	**7.3**	(2.1)	12.0	[10.5]	10.5	(1.5)
Amortization of Intangible assets	22.7	**20.9**	(1.7)	29.3	[25.8]	28.3	(1.0)
Related to products (patent rights/ marketing rights) included in above	20.5	**18.9**	(1.7)	26.5	[22.9]	25.4	(1.1)

Note1: The amount of capital expenditures are for tangible fixed assets and software.

Note2: The forecasts have been revised. Figures in parentheses [ ] are previous forecasts. Change is calculated by using revised forecasts.

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)

	Q3 FY2022	Q3 FY2023	Change	Change %
Revenue	460.3	**235.0**	(225.2)	(48.9)
Overseas revenue	324.7	**149.8**	(174.9)	(53.9)
% of Revenue	70.6%	**63.7%**		
Cost of sales	139.7	**93.2**	(46.5)	(33.3)
% of Revenue	30.4%	**39.7%**		
Gross profit	320.5	**141.8**	(178.7)	(55.7)
SG&A expenses	227.5	**176.6**	(50.9)	(22.4)
Labor costs	92.5	**76.0**	(16.5)	(17.8)
Sales promotion costs/ Advertising and promotion costs	47.8	**34.6**	(13.2)	(27.6)
Amortization/Depreciation	26.4	**23.8**	(2.6)	(9.8)
Others	60.8	**42.2**	(18.6)	(30.6)
R&D expenses	74.9	**68.0**	(6.9)	(9.2)
% of Revenue	16.3%	**28.9%**		
Other operating income/expenses	24.8	**6.4**	(18.4)	
Core operating profit (loss)	42.9	**(96.4)**	(139.3)	—
Non-recurring items (negative number indicates net loss)	(60.7)	**(21.4)**	39.3	
Operating profit (loss)	(17.8)	**(117.7)**	(100.0)	—
Finance income	22.6	**15.3**	(7.4)	
Finance costs	2.7	**2.7**	0.1	
Profit (loss) before taxes	2.2	**(105.2)**	(107.4)	—
Income tax expenses	34.8	**12.5**	(22.3)	
Net profit (loss)	(32.6)	**(117.7)**	(85.1)	—
Net profit (loss) attributable to owners of the parent	(18.5)	**(117.7)**	(99.2)	—

¥billion

	Change	FX impact
Japan	(57.5)	
North America	(164.0)	5.5
Asia	(3.7)	0.4

Change by segment

	Japan	North America	Asia
Labor costs	(4.5)	(11.2)	(0.7)
Sales promotion costs/ Advertising and promotion costs	(0.8)	(11.7)	(0.7)
Amortization/ Depreciation	(0.5)	(2.1)	(0.0)
Others	(1.7)	(17.4)	0.5

FY22: KYNMOBI® impairment losses (56.0)
FY23: Business structure improvement expenses in North America (20.5)

2. Adjustments to Core Operating Profit

(Billions of yen)

Q3 FY2023 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	235.0	**235.0**	—	
Cost of sales	93.2	**93.2**	—	
Gross profit	141.8	**141.8**	—	
SG&A expenses	191.6	**176.6**	(14.9)	Business structure improvement expenses in North America (14.8)
R&D expenses	73.6	**68.0**	(5.7)	Business structure improvement expenses in North America (5.7)
Other operating income	7.1	**6.4**	(0.8)	
Other operating expenses	1.5	**—**	(1.5)	
Operating profit (loss)	(117.7)	**(96.4)**	21.4	

III. Segment Information (Core Basis)

(Billions of yen)

Q3 FY2023 Results	Japan	North America	Asia	Total
Revenue	89.2	115.4	30.5	235.0
Cost of sales	42.1	43.4	7.7	93.2
Gross profit	47.0	72.0	22.8	141.8
SG&A expenses	35.7	132.1	8.8	176.6
Core segment profit (loss)	**11.3**	**(60.1)**	**14.0**	**(34.8)**
R&D expenses *1				68.0
Other operating income/expenses (Core basis) *2				6.4
Core operating profit (loss)				**(96.4)**

(Billions of yen)

Q3 FY2022 Results	Japan	North America	Asia	Total
Revenue	146.7	279.4	34.2	460.3
Cost of sales	83.9	49.1	6.8	139.7
Gross profit	62.8	230.2	27.5	320.5
SG&A expenses	43.1	174.6	9.8	227.5
Core segment profit	**19.7**	**55.7**	**17.7**	**93.0**
R&D expenses *1				74.9
Other operating income/expenses (Core basis) *2				24.8
Core operating profit				**42.9**

(Billions of yen)

FY2023 Forecasts	Japan	North America	Asia	Total
Revenue	115.8	161.1	40.1	317.0
Cost of sales	55.2	59.4	10.4	125.0
Gross profit	60.6	101.7	29.7	192.0
SG&A expenses	47.4	180.6	12.0	240.0
Core segment profit (loss)	**13.2**	**(78.9)**	**17.7**	**(48.0)**
R&D expenses *1				92.0
Other operating income/expenses (Core basis) *2				6.0
Core operating profit (loss)				**(134.0)**

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

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

Note1: The forecasts have been revised. The above table shows the revised forecasts.

Note2: From Q1 FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia).
Q3 FY2022 results has been prepared based on the current classification.

IV. Revenue Information

1. Revenue by segment

(Billions of yen)

Segment	Q3 FY2022	**Q3 FY2023**	Change	Change %	FY2023 (Forecasts)		Progress %
Japan	146.7	**89.2**	(57.5)	(39.2)	[114.1]	115.8	78.1
North America	279.4	**115.4**	(164.0)	(58.7)	[208.8]	161.1	55.3
Asia	34.2	**30.5**	(3.7)	(10.9)	[39.1]	40.1	78.0

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

2. Revenue of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q3 FY2022	**Q3 FY2023**	Change	Change %	FY2023 (Forecasts)		Progress %
Japan							
Promoted products							
Equa®/EquMet® Therapeutic agent for type 2 diabetes (Nov. 2019～)	27.3	**24.6**	(2.7)	(9.8)	[32.4]	31.1	76.0
TRERIEF® Therapeutic agent for Parkinson's disease	13.1	**13.1**	0.0	0.2	[15.0]	15.5	87.4
LATUDA® Atypical antipsychotic (Jun. 2020～)	7.3	**9.0**	1.7	24.1	[12.5]	12.0	72.0
METGLUCO® Therapeutic agent for type 2 diabetes	6.0	**5.7**	(0.3)	(5.2)		7.5	75.7
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	1.3	**3.5**	2.2	174.2		4.2	83.1
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	2.2	**2.9**	0.7	31.3	[3.3]	3.8	89.0
Trulicity® * Therapeutic agent for type 2 diabetes	24.8	**—**	(24.8)	—		—	—
Other products							
Authorized Generics	7.1	**7.1**	0.0	0.0	[8.6]	9.4	82.2
Export products, Lump-sum revenue, Others	57.7	**23.3**	(34.4)	(59.7)	[30.6]	32.3	76.0

* Trulicity® revenue is shown by NHI drug price.

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

2. Revenue of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q3 FY2022	**Q3 FY2023**	Change	Change %	FY2023 (Forecasts)		Progress %
North America							
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	17.5	**30.9**	13.4	76.6	[51.5]	42.1	60.0
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug.2022～)	2.9	**7.1**	4.2	148.2	[24.9]	10.1	28.5
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	17.0	**24.9**	7.9	46.5	[47.0]	37.7	53.0
APTIOM® Antiepileptic	26.0	**25.2**	(0.9)	(3.3)	[35.5]	34.2	70.9
RETHYMIC® Pediatric congenital athymia (Mar. 2022~)	3.0	**4.3**	1.3	44.3	[7.0]	7.0	61.5
LATUDA® Atypical antipsychotic	179.3	**5.1**	(174.2)	(97.2)	[20.9]	6.9	24.4
Export products, Lump-sum revenue, Others	33.7	**17.9**	(15.8)	(46.8)	[22.0]	23.1	81.5
Asia							
MEROPEN® (China) Carbapenem antibiotic	23.8	**15.3**	(8.5)	(35.8)	[18.7]	20.5	81.8
MEROPEN® (Southeast Asia) Carbapenem antibiotic	2.3	**4.8**	2.5	110.6	[4.9]	5.5	98.3

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

(Millions of dollar)

Brand name	Q3 FY2022	**Q3 FY2023**	Change	Change %	FY2023 (Forecasts)		Progress %
ORGOVYX®	128	**215**	87	68.2	[396]	290	54.4
MYFEMBREE®	21	**49**	29	136.4	[192]	70	25.8
GEMTESA®	125	**174**	49	39.5	[362]	260	48.1
APTIOM®	191	**175**	(15)	(7.9)	[273]	236	64.3
RETHYMIC®	22	**30**	8	37.5	[54]	48	55.6
LATUDA®	1,313	**36**	(1,278)	(97.3)	[161]	47	22.1

Note: The forecasts 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 2023	Dec. 31 2023	Change
Assets	**1,134.7**	**1,060.0**	**(74.8)**
Non-current assets	**752.9**	**795.8**	**42.9**
Property, plant and equipment	58.9	59.0	0.1
Goodwill	209.4	222.4	13.0
Intangible assets	329.3	332.4	3.1
Patent rights/Marketing rights	310.9	312.3	1.4
In-process R&D	11.7	13.9	2.2
Others	6.7	6.1	(0.6)
Other financial assets	134.0	161.0	27.0
Other non-current assets	10.4	12.2	1.8
Deferred tax assets	10.8	8.8	(2.0)
Current assets	**381.9**	**264.2**	**(117.7)**
Inventories	94.4	104.8	10.4
Trade and other receivables	95.9	94.5	(1.4)
Other financial assets	20.2	6.3	(13.8)
Other current assets	20.4	22.1	1.7
Cash and cash equivalents	143.5	36.5	(107.0)
Assets held for sale	7.5	—	(7.5)
Liabilities	**728.0**	**716.4**	**(11.6)**
Non-current liabilities	**355.3**	**295.2**	**(60.0)**
Bonds and borrowings	244.1	184.3	(59.9)
Other financial liabilities	11.9	12.7	0.8
Retirement benefit liabilities	5.0	4.6	(0.4)
Other non-current liabilities	57.8	44.8	(12.9)
Deferred tax liabilities	36.5	48.8	12.3
Current liabilities	**372.7**	**421.2**	**48.5**
Borrowings	90.6	227.6	137.0
Trade and other payables	52.1	50.4	(1.8)
Other financial liabilities	7.0	13.9	6.9
Income taxes payable	24.1	1.8	(22.3)
Provisions	119.1	77.4	(41.7)
Other current liabilities	78.0	50.1	(27.9)
Liabilities directly associated with assets held for sale	1.8	—	(1.8)
Equity	**406.8**	**343.6**	**(63.2)**
Share capital	22.4	22.4	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	281.0	171.7	(109.3)
Other components of equity	103.4	150.1	46.8
Other comprehensive income associated with assets held for sale	0.7	—	(0.7)
Equity attributable to owners of the parent	**406.7**	**343.6**	**(63.2)**
Non-controlling interests	0.0	0.0	0.0

Major patent rights	23/3	23/12
ORGOVYX® (relugolix)	66.1	66.5
MYFEMBREE® (relugolix)	142.5	143.5
GEMTESA® (vibegron)	94.7	94.4

Increase by change in value of securities

Transfer of current portion of long-term borrowings to current liabilities (60.0)

Increase in short-term borrowings 77.0
Transfer of current portion of long-term borrowings from non-current liabilities 60.0

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

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

2. Revenue of Major Products

	FY2022				FY2023		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Japan					(Invoice price basis, Billions of yen)		
Equa®/EquMet®	8.8	8.5	10.0	6.3	8.2	7.6	8.8
TRERIEF®	4.4	4.2	4.5	3.6	4.4	4.1	4.6
LATUDA®	2.3	2.4	2.6	2.3	2.8	2.9	3.3
METGLUCO®	2.0	2.0	2.0	1.7	1.9	1.8	2.0
TWYMEEG®	0.1	0.4	0.8	0.9	1.2	1.5	0.9
LONASEN® Tape	0.7	0.7	0.8	0.7	0.9	0.9	1.1
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
Export products, Lump-sum revenue, Others	23.9	18.5	18.2	19.3	8.6	7.1	7.6

* Trulicity® revenue is shown by NHI drug price.

North America							(Millions of dollar)
ORGOVYX®	36	43	49	54	68	70	78
MYFEMBREE®	4	6	11	12	13	16	20
GEMTESA®	34	37	54	57	63	49	62
APTIOM®	65	65	61	58	58	57	61
RETHYMIC®	5	14	3	11	11	11	8
LATUDA®	482	470	362	151	8	20	7
Export products, Lump-sum revenue, Others	108	98	41	33	37	39	50
Asia							(Billions of yen)
MEROPEN® (China)	9.1	9.6	5.1	4.7	4.4	5.8	5.1
MEROPEN® (Southeast Asia)	0.8	0.5	0.9	0.8	2.3	1.8	0.8

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

Domestic	Establish-ment	Ownership	Number of employees	Businesses
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 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%	*1,732	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Switzerland GmbH	2016/ 8	100%	25	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%	572	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference)

Number of employees	March 31, 2022		March 31, 2023		**Dec. 31, 2023**	
consolidated / non-consolidated	6,987	3,040	6,250	3,026	**5,610**	**2,957**
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	**410**	**490**
China Exclude managers/Total	340	420	270	340	**260**	**330**

VIII. Development Pipeline (As of January 31, 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	SEP-363856 (ulotaront hydrochloride)	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
	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-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-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)
	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
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
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
SP-101	Cystic fibrosis	U.S.	Phase 1/2
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

【Main revisions since the announcement of October 2023】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
XENLETA® (lefamulin)	Community-acquired pneumonia	China	Approved in November 2023	Deleted from the table due to approval
CT1-DAP001/ DSP-1083 (Allogeneic iPS cell-derived dopaminergic neural progenitor cells)	Parkinson’s disease	U.S.	Phase 1/2 (Investigator-initiated study)	Development stage changed
KSP-1007	Complicated urinary tract infections, Complicated intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	U.S., Japan	Phase 1	Added a part of proposed indication and region (Japan)
DSP-9632P	Levodopa-induced dyskinesia in Parkinson's disease	Japan	Phase 1	Deleted from the table due to discontinuation of the development

IX. Profiles of Major Products under Development (As of January 31, 2024)

1. Psychiatry & Neurology

(Small molecule)

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

- 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.
- 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. Former Sunovion discovered ulotaront in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. The Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for ulotaront for the indication of schizophrenia in May 2019.
- 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. Although Phase 3 (DIAMOND 1 and 2) did not achieve their primary endpoint, significant improvements were observed in the placebo group in both studies, which may have masked the efficacy of the drug. Regarding safety, ulotaront was generally safe and well-tolerated throughout both studies. Future development strategy for schizophrenia is currently being discussed with Otsuka Pharmaceutical.

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

- 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
- 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.

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

- Development stage: Phase 1 in the U.S. (Co-development with Otsuka Pharmaceutical Co., Ltd.)
- SEP-378614 is a novel CNS-active molecule. Former 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.

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

- Development stage: Phase 1 in the U.S. (Co-development with Otsuka Pharmaceutical Co., Ltd.)
- SEP-380135 is a novel CNS-active molecule. Former 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.

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 cell-derived products)

- 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.
- 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 products)

- 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.

TP-1287 Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

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

TP-1454 Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

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

3. Others

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

- Development stage:
  (New indication) Overactive bladder in men with BPH: Phase 3 in the U.S.
  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.

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

- Development stage: Cystic Fibrosis: Phase 1/2 in the U.S.
- 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.

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.

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