Securities Code: 4506

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

July 29, 2022

Sumitomo Pharma Co., Ltd.

- This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
  Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group holds approximately 52% of the outstanding shares of Myovant. ORGOVYX® (relugolix), MYFEMBREE®/RYEQO® (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit https://www.myovant.com.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

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

(Billions of yen)

	Q1 FY2021	Q1 FY2022	Change % YoY	FY2021	FY2022 (Forecast)	Change % YoY
Revenue	131.2	**159.9**	21.9	560.0	550.0	(1.8)
Cost of sales *1	38.5	**46.1**	19.7	157.1	164.5	4.7
Gross profit	92.7	**113.8**	22.8	402.9	385.5	(4.3)
SG&A expenses *1	62.0	**76.0**	22.7	251.6	283.5	12.7
R&D expenses *1	22.4	**24.4**	8.9	94.0	93.0	(1.1)
Other operating income/expenses *2	0.2	**0.0**		1.2	21.0	
Core operating profit	8.5	**13.4**	57.2	58.5	30.0	(48.7)
Changes in fair value of contingent consideration (negative number indicates loss)	(0.1)	**(0.1)**		3.3	(0.5)	
Other non-recurring items *3 (negative number indicates loss)	(0.1)	**1.3**		(1.6)	(5.5)	
Operating profit	8.3	**14.6**	75.9	60.2	24.0	(60.2)
Net profit	0.8	**28.1**	—	40.6	N/A	
Net profit attributable to owners of the parent	4.8	**31.1**	547.8	56.4	22.0	(61.0)
Basic earnings per share (yen)	12.09	**78.30**		141.99	55.37	
Net profit/ Equity attributable to owners of the parent (ROE)	0.8%	**4.9%**		9.5%	3.6%	

*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)

	Q1 FY2021	Q1 FY2022	Change % YoY
Revenue	131.2	**159.9**	21.9
Cost of sales	38.5	**46.1**	19.7
Gross profit	92.7	**113.8**	22.8
SG&A expenses	62.1	**77.3**	24.5
R&D expenses	22.4	**24.4**	8.9
Other operating income/expenses	0.1	**2.5**	
Operating profit	8.3	**14.6**	75.9
Finance income/costs	(0.3)	**32.0**	
Profit before taxes	8.0	**46.6**	485.8
Income tax expenses	7.2	**18.5**	
Net profit	0.8	**28.1**	—
Net profit attributable to owners of the parent	4.8	**31.1**	547.8

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q1 FY2021	Q1 FY2022
Net cash provided by (used in) operating activities	(32.8)	**13.2**
Net cash provided by (used in) investing activities	17.7	**22.4**
Net cash provided by (used in) financing activities	(6.9)	**(6.6)**
Cash and cash equivalents at the end of period	170.9	**255.4**

4. Foreign Exchange Rates

	FY2021 Apr.-Jun.		FY2022 Apr.-Jun.		FY2022 assumption	Forex sensitivity FY2022 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	**Period end rate**	**Average rate**	**Average rate**	Revenue	Core operating profit
Yen / USD	110.6	109.5	**136.6**	**129.7**	**125.0**	2.8	(0.3)
Yen / RMB	17.1	17.0	**20.4**	**19.6**	**19.5**	1.4	0.5

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q1 FY2021	**Q1 FY2022**	Change	FY2022 (Forecast)	Change
Capital expenditures	2.4	**2.8**	0.4	15.9	3.3
Depreciation of Property, plant and equipment	2.7	**3.9**	1.2	10.7	(0.8)
Amortization of Intangible assets	5.5	**7.6**	2.1	29.3	2.4
Related to products (patent rights/ marketing rights) included in above	4.8	**6.9**	2.1	26.2	2.0

(Billions of yen)

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

Major capital expenditure project in FY2022

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

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

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

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	Q1 FY2021	Q1 FY2022	Change	Change %
Revenue	131.2	**159.9**	28.7	21.9
Overseas revenue	83.0	**115.4**	32.4	39.0
% of Revenue	63.2%	**72.2%**		
Cost of sales	38.5	**46.1**	7.6	19.7
% of Revenue	29.3%	**28.8%**		
Gross profit	92.7	**113.8**	21.1	22.8
SG&A expenses	62.0	**76.0**	14.1	22.7
Labor costs	27.7	**32.2**	4.4	16.0
Advertising and promotion costs	6.0	**7.3**	1.3	22.2
Sales promotion costs	4.3	**8.5**	4.3	99.8
Amortization/Depreciation	6.7	**9.2**	2.5	37.8
Others	17.2	**18.8**	1.5	8.8
R&D expenses	22.4	**24.4**	2.0	8.9
% of Revenue	17.1%	**15.3%**		
Other operating income/expenses	0.2	**0.0**	(0.2)	
Core operating profit	8.5	**13.4**	4.9	57.2
Changes in fair value of contingent consideration ＊	(0.1)	**(0.1)**	0.0	
Other non-recurring items ＊	(0.1)	**1.3**	1.4	
Operating profit	8.3	**14.6**	6.3	75.9
Finance income	0.6	**32.9**	32.3	
Finance costs	1.0	**0.9**	(0.1)	
Profit before taxes	8.0	**46.6**	38.7	485.8
Income tax expenses	7.2	**18.5**	11.4	
Net profit	0.8	**28.1**	27.3	—
Net profit attributable to owners of the parent	4.8	**31.1**	26.3	547.8

＊ Negative number indicates loss.

← Include Sumitovant +9.9

¥billion	Change	FX rate
Japan	(5.0)	
North America	23.8	14.8
China	3.1	1.6
Other Regions	5.6	

2. Adjustments to Core Operating Profit

(Billions of yen)

Q1 FY2021 Results	Full Basis	Core Basis	Adjustment
Revenue	159.9	**159.9**	-
Cost of sales	46.1	**46.1**	-
Gross profit	113.8	**113.8**	-
SG&A expenses	77.3	**76.0**	(1.3)
R&D expenses	24.4	**24.4**	-
Other operating income	2.8	**0.0**	(2.8)
Other operating expenses	0.3	**–**	(0.3)
Operating profit	14.6	**13.4**	(1.2)

III. Segment Information (Core Basis)

(Billions of yen)

Q1 FY2022 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	33.7	95.2	11.6	8.4	148.9	11.0	159.9
Cost of sales	19.1	13.5	3.7	1.2	37.5	8.5	46.1
Gross profit	14.6	81.7	7.9	7.2	111.4	2.5	113.8
SG&A expenses	13.0	58.6	2.6	0.4	74.6	1.4	76.0
Core segment profit	**1.6**	**23.1**	**5.3**	**6.8**	**36.8**	**1.0**	**37.8**
R&D expenses *1					23.8	0.6	24.4
Other operating income/expenses (Core basis)*2					(0.0)	0.0	0.0
Core operating profit					**13.0**	**0.4**	**13.4**

(Billions of yen)

Q1 FY2021 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	38.7	71.4	8.5	2.7	121.3	9.9	131.2
Cost of sales	20.0	8.0	1.6	1.3	30.9	7.6	38.5
Gross profit	18.7	63.4	6.9	1.4	90.5	2.3	92.7
SG&A expenses	11.9	45.3	2.7	0.8	60.7	1.3	62.0
Core segment profit	**6.7**	**18.1**	**4.3**	**0.6**	**29.8**	**1.0**	**30.8**
R&D expenses *1					22.3	0.2	22.4
Other operating income/expenses (Core basis)*2					0.2	0.0	0.2
Core operating profit					**7.7**	**0.9**	**8.5**

(Billions of yen)

FY2022 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	130.0	334.3	27.6	16.1	508.0	42.0	550.0
Cost of sales	67.6	53.6	5.6	5.2	132.0	32.5	164.5
Gross profit	62.4	280.7	22.0	10.9	376.0	9.5	385.5
SG&A expenses	53.0	211.0	11.6	1.6	277.2	6.3	283.5
Core segment profit	**9.4**	**69.7**	**10.4**	**9.3**	**98.8**	**3.2**	**102.0**
R&D expenses *1					90.5	2.5	93.0
Other operating income/expenses (Core basis)*2					21.0	-	21.0
Core operating profit					**29.3**	**0.7**	**30.0**

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

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

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	Q1 FY2021	**Q1 FY2022**	Change	Change %	FY2022 (Forecast)	Progress %
Japan	38.7	**33.7**	(5.0)	(12.9)	130.0	25.9
North America	71.4	**95.2**	23.8	33.3	334.3	28.5
China	8.5	**11.6**	3.1	36.4	27.6	42.1
Other Regions	2.7	**8.4**	5.6	206.0	16.1	52.1

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q1 FY2021	**Q1 FY2022**	Change	Change %	FY2022 (Forecast)	Progress %
Japan						
Promoted products						
Equa®/EquMet® Therapeutic agent for type 2 diabetes (Nov. 2019～)	9.8	**8.8**	(1.0)	(10.4)	34.9	25.2
Trulicity® * Therapeutic agent for type 2 diabetes	8.8	**8.6**	(0.2)	(2.2)	31.0	27.8
TRERIEF® Therapeutic agent for Parkinson's disease	4.3	**4.4**	0.1	2.7	17.3	25.6
LATUDA® Atypical antipsychotic (Jun. 2020～)	1.4	**2.3**	0.9	65.5	9.9	23.2
METGLUCO® Therapeutic agent for type 2 diabetes	2.1	**2.0**	(0.1)	(5.2)	7.8	25.5
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	0.5	**0.7**	0.2	41.6	2.7	24.4
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	—	**0.1**	0.1	—	1.5	6.9
Other products						
Authorized Generics	2.4	**2.3**	(0.1)	(4.4)	9.7	23.9

* Trulicity® revenue is shown by NHI price.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q1 FY2021	**Q1 FY2022**	Change	Change %	FY2022 (Forecast)	Progress %
North America						
LATUDA® Atypical antipsychotic	51.4	**62.5**	11.1	21.7	215.8	29.0
APTIOM® Antiepileptic	6.9	**8.4**	1.5	21.3	31.8	26.4
RETHYMIC® Pediatric congenital athymia	—	**0.7**	0.7	—	6.0	11.8
BROVANA® Therapeutic agent for COPD	5.6	**1.8**	(3.8)	(68.6)	3.2	54.7
KYNMOBI® OFF episodes associated with Parkinson's disease (Sep. 2020～)	0.2	**(0.0)**	(0.3)	(110.9)	2.3	(1.1)
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021～)	1.2	**4.7**	3.5	293.5	N/A	—
MYFEMBREE® Therapeutic agent for uterine fibroids (Jun. 2021～)	0.1	**0.5**	0.4	339.8	N/A	—
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	0.8	**4.4**	3.6	454.4	N/A	—
China						
MEROPEN® Carbapenem antibiotic	6.6	**9.1**	2.5	37.7	16.8	54.1
Other Regions						
MEROPEN® Carbapenem antibiotic	1.8	**1.8**	0.0	2.5	6.1	29.7

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

(Millions of dollar)

Brand name	Q1 FY2021	**Q1 FY2022**	Change	Change %	FY2021 (Forecast)	Progress %
LATUDA®	469	**482**	13	2.7	1,726	27.9
APTIOM®	63	**65**	2	2.4	255	25.4
RETHYMIC®	—	**5**	5	—	48	11.4
BROVANA®	51	**14**	(37)	(73.5)	26	51.9
KYNMOBI®	2	**(0)**	(2)	(109.3)	18	(1.1)
ORGOVYX®	11	**36**	25	232.3	N/A	—
MYFEMBREE®	1	**4**	3	271.8	N/A	—
GEMTESA®	7	**34**	27	367.8	N/A	—

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar. 31 2022	Jun. 30 2022	Change
Assets	**1,308.0**	**1,422.9**	**114.9**
Non-current assets	**808.5**	**865.8**	**57.4**
Property, plant and equipment	64.1	61.9	(2.2)
Goodwill	195.1	217.8	22.7
Intangible assets	398.7	436.6	37.9
Patent rights/Marketing rights	361.6	396.5	34.9
In-process R&D	29.8	32.7	2.9
Others	7.3	7.3	0.0
Other financial assets	115.8	114.4	(1.5)
Other non-current assets	12.1	12.6	0.5
Deferred tax assets	22.7	22.6	(0.0)
Current assets	**499.5**	**557.1**	**57.6**
Inventories	99.0	110.1	11.1
Trade and other receivables	151.4	168.7	17.3
Other financial assets	35.6	10.1	(25.4)
Other current assets	10.5	12.7	2.2
Cash and cash equivalents	203.0	255.4	52.5
Liabilities	**634.4**	**678.5**	**44.1**
Non-current liabilities	**356.1**	**357.8**	**1.7**
Bonds and borrowings	244.0	244.0	0.0
Other financial liabilities	16.5	16.2	(0.3)
Retirement benefit liabilities	11.5	11.5	0.1
Other non-current liabilities	57.6	56.3	(1.3)
Deferred tax liabilities	26.6	29.7	3.2
Current liabilities	**278.4**	**320.7**	**42.3**
Borrowings	25.1	24.9	(0.2)
Trade and other payables	46.2	58.7	12.5
Other financial liabilities	13.3	9.7	(3.6)
Income taxes payable	7.6	17.3	9.7
Provisions	119.1	142.9	23.7
Other current liabilities	67.1	67.2	0.1
Equity	**673.6**	**744.4**	**70.8**
Share capital	22.4	22.4	—
Capital surplus	16.7	17.1	0.4
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	514.2	539.1	24.9
Other components of equity	55.2	95.1	39.9
Equity attributable to owners of the parent	**607.9**	**673.0**	**65.1**
Non-controlling interests	65.7	71.4	5.7

Goodwill	22/3	22/6
Other than oncology(SMPO)	168.3	187.9
Oncology(SMPO)	26.8	29.9

Major patent rights	22/3	22/6
KYNMOBI® (apomorphine)	51.5	56.4
ORGOVYX® (relugolix)	64.7	71.1
MYFEMBREE® (relugolix)	139.6	153.3
GEMTESA® (vibegron)	93.9	102.9

Major IPR&D	22/3	22/6
former Tolero products	18.6	20.8

← Mainly due to decrease in Short-term loan receivable

Total bonds and borrowings
269.0 → 268.9

Contingent consideration liabilities	22/3	22/6
former Tolero	4.4	5.0

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

VI. Changes in Quarterly Results

(Billions of yen)

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

VII. Major Consolidated Subsidiaries (As of June 30, 2022)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
Sumitomo Pharma Food & Chemical Co., Ltd.	1947/10	100%	206	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
Sumitomo Pharma Animal Health Co., Ltd.	2010/ 7	100%	102	Manufacturing and sales of veterinary medicines, etc.
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	35	Manufacturing and sales of pharmaceuticals, etc.
Overseas	**Establish-ment**	**Ownership**	**Number of employees**	**Businesses**
Sumitomo Pharma America Holdings, Inc.	2009/7	100%	238	Holding company, shared services for general management operations
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,071	Manufacturing and sales of pharmaceuticals
Sumitomo Pharma Oncology, Inc.	2006/11	100%	187	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	116	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	52%	*590	Manufacturing and sales of pharmaceuticals in the women's health, prostate cancer area
Urovant Sciences Ltd.	2016/ 1	100%	*312	Manufacturing and sales of pharmaceuticals in the urology area
Enzyvant Therapeutics Ltd.	2016/ 1	100%	*29	Manufacturing and sales of pharmaceuticals in the pediatric rare diseases area
Altavant Sciences Ltd.	2017/ 9	100%	*25	R&D in the 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%	738	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2021		March 31, 2022		June 30, 2022	
consolidated / non-consolidated	6,822	3,067	6,987	3,040	**7,026**	**3,102**
MRs (include number of contracted MRs)						
Japan Exclude managers/Total	1,150	1,270	1,110	1,220	**1,050**	**1,150**
U.S. Exclude managers/Total	720	840	820	950	**800**	**920**
China Exclude managers/Total	340	410	340	420	**330**	**410**

VIII. Development Pipeline (As of July 29, 2022)

- This table shows clinical studies on indications for which the Sumitomo Pharma Group aims to obtain approval in Japan, U.S., China, or Europe and does not cover all clinical studies.
- The study for the most advanced development stage is listed if there are multiple studies with the same region and indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed and/or approved by the applicable authority.

1. Psychiatry & Neurology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
SEP-363856 (ulotaront)	Schizophrenia	U.S.	Phase 3
		Japan, China	Phase 2/3 (Global study)
	Parkinson's disease psychosis	U.S.	Phase 2
SEP-4199	Bipolar I depression	U.S., Japan	Phase 3 (Global study)
LATUDA® (lurasidone hydrochloride)	(New indication) Bipolar I depression	China	Phase 3
	(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-6745	Parkinson's disease psychosis	U.S.	Phase 1
SEP-378608	Bipolar disorder	U.S.	Phase 1
DSP-3905	Neuropathic pain	U.S.	Phase 1
SEP-378614	To be determined	U.S.	Phase 1
SEP-380135	To be determined	U.S.	Phase 1
DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1
DSP-9632P	Levodopa-induced dyskinesia in Parkinson's disease	Japan	Phase 1
DSP-0187	Narcolepsy	Japan	Phase 1
DSP-3456	Treatment resistant depression	U.S.	Phase 1

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
DSP-7888 (adegramotide/ nelatimotide)	Solid tumors	U.S.	Phase 1/2
TP-0903 (dubermatinib)	Acute myeloid leukemia (AML)	U.S.	Phase 1/2 (Research group-initiated study)
DSP-0509 (guretolimod)	Solid tumors	U.S., Japan	Phase 1/2
DSP-5336	Hematologic malignancies	U.S., Japan	Phase 1/2

TP-1287	Solid tumors	U.S.	Phase 1
TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
TP-1454	Solid tumors	U.S.	Phase 1
DSP-0390	Solid tumors	U.S., Japan	Phase 1

3. Regenerative medicine / cell therapy

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

4. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
MYFEMBREE® (relugolix)	(New indication) Endometriosis	U.S.	sNDA submitted in July 2021
METGLUCO® (metformin hydrochloride)	(New indication) "ovulation induction for patients with polycystic ovary syndrome" and "controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome"	Japan	sNDA submitted in March 2022
lefamulin	Bacterial community-acquired pneumonia	China	NDA submitted in October 2021
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	Phase 3
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	U.S.	Phase 2
MVT-602	Female infertility	Germany	Phase 2
URO-902	Overactive bladder (OAB)	U.S.	Phase 2
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections	U.S.	Phase 1

【Main revisions since the announcement of May 2022】

None

IX. Profiles of Major Products under Development (As of July 29, 2022)

1. Psychiatry & Neurology

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

- Ulotaront (SEP-363856) is a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity. Ulotaront does not bind to dopamine 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.
- Development stage: (Co-development with Otsuka Pharmaceutical Co., Ltd.)
  Schizophrenia: Phase 3 in the U.S.
  Schizophrenia: Phase 2/3 in Japan and China
  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-6745 Origin: in-house, Formulation: oral

- DSP-6745 is a serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors dual antagonist, which is expected to be effective for Parkinson's disease psychosis and one or more Parkinson's disease non-motor symptoms (depression, anxiety, or cognitive impairment). In addition, DSP-6745 has negligible affinity for dopamine D_2 receptors.
- Development stage: Parkinson's disease psychosis: Phase 1 in the U.S.

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

- SEP-378608 is a novel CNS-active molecule. Sunovion discovered SEP-378608 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of the brain

associated with the regulation of mood.

- Development stage: Bipolar disorder: Phase 1 in the U.S.

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

- DSP-3905 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7. Based on its inhibitory mode of action, the agent is expected to show a potent analgesic effect on the pain occurring when neurons get excessively excited. In addition, DSP-3905 has a high selectivity for Nav1.7 expressed in peripheral neuron and may not produce central nervous system or cardiovascular system side effects, which are present with the current drugs for neuropathic pain.
- Development stage: Neuropathic pain: Phase 1 in the U.S.

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

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

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

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

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

- DSP-0038 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies. DSP-0038 is a serotonin 5-HT_{2A} receptor antagonist and a serotonin 5-HT_{1A} receptor agonist. DSP-0038 is expected to demonstrate a greater antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have a broader efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) which include agitation, aggression, anxiety, and depression. Furthermore, DSP-0038 has negligible affinity for dopamine 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-9632P Origin: in-house, Formulation: patch

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

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

- DSP-0187 is an orexin 2 receptor agonist. It is expected to improve excessive daytime sleepiness (EDS) and cataplexy of narcolepsy caused by orexin deficiency. DSP-0187 is also expected to

demonstrate an efficacy for EDS other than narcolepsy. Sumitomo Pharma granted Jazz Pharmaceuticals plc the exclusive development and commercialization rights in the territories, except for Japan, China, and certain other Asia/Pacific markets in April 2022.

- Development stage: Narcolepsy: Phase 1 in Japan

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

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

2. Oncology

adegramotide/nelatimotide (DSP-7888) Origin: in-house, Formulation: injection

- DSP-7888 is an immunotherapeutic cancer peptide vaccine targeting Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1 by inducing WT1-specific CTLs that attack WT1-expressing cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage: Solid tumors: Phase 1/2 in the U.S.

dubermatinib (TP-0903) Origin: University of Utah, Formulation: oral

- Dubermatinib (TP-0903) is an inhibitor of multikinase including AXL receptor tyrosine kinase inhibitor, which is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. Dubermatinib may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL. Dubermatinib has been shown to inhibit AXL signaling and reverse the mesenchymal to epithelial phenotype in pre-clinical studies.
- Development stage: Acute Myeloid Leukemia: Phase 1/2 (Research group-initiated study*) in the U.S.
  * One arm in the Beat AML study led by the U.S. non-profit organization LLS (The Leukemia & Lymphoma Society)

guretolimod (DSP-0509) Origin: in-house, Formulation: injection

- Guretolimod (DSP-0509) is a novel Toll-like receptor (TLR) 7 agonist. Guretolimod may promote the cytokine induction and cytotoxic T lymphocyte (CTL) activation mediated by agonistic effect of TLR 7 expressing in plasmacytoid dendritic cell. Furthermore, guretolimod is expected to sustain the immune-mediated anti-cancer activity by induction of immune system memory T cells.
- Development stage: Solid tumors: Phase 1/2 in the U.S. and Japan

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

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

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

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

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

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

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.

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 reticulam membrane protein involved in cholesterol biosynthesis. When functional, EBP mediates de novo cholesterol synthesis for cell membrane structure and signaling, enabling aberrant growth of tumors. Inhibition of EBP causes an efficient cellular cholesterol depletion and it is expected to show anti-cancer activities.
- Development stage: Solid tumors: Phase 1 in the U.S. and Japan

3. Regenerative medicine / cell therapy

Allo iPS cell-derived products

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

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

4. Others

relugolix Origin: Takeda Pharmaceutical Company Ltd., Formulation: oral

- Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone production, the hormone primarily responsible for stimulating prostate cancer, and ovarian estradiol production, hormones known to stimulate the growth of uterine fibroids and endometriosis. Myovant received approval in the U.S. in December 2020 for a relugolix single agent tablet (120 mg) for men with advanced prostate cancer and in May 2021 for a distinct product, a relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for uterine fibroids.
- Development stage:
  (New indication) Endometriosis: sNDA submitted in the U.S. in July 2021

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.

lefamulin Origin: Nabriva Therapeutics plc, Formulation: oral, injection

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

rodatristat ethyl Origin: Karos Pharmaceuticals, Inc., Formulation: oral

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

MVT-602 Origin: Takeda Pharmaceutical Company Ltd., Formulation: oral

- MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Activation of kisspeptin in upstream hypothalamic neurons is hypothesized to lead to the transmission of a signal that stimulates downstream neurons to increase the secretion of GnRH. However continued stimulation of kisspeptin is thought to result in the desensitization of receptor transduction, which is anticipated to result in a complete cessation of the signaling pathway. Myovant is developing MVT-602 as part of the hormonal preparation for women with infertility undergoing in vitro fertilization. MVT-602 is believed to stimulate GnRH which in turn increases secretion of luteinizing hormone (LH) that acts as a trigger for egg maturation prior to oocyte collection.
- Development stage: Female infertility: Phase 2 in Germany

URO-902 Origin: Ion Channel Innovations, LLC., Formulation: injection

- URO-902 is a novel gene therapy for patients with overactive bladder symptoms who have failed oral pharmacologic therapy. URO-902 is a plasmid vector containing a human cDNA encoding the pore-

forming component of the Maxi-K ion channel. Expression of the Maxi-K protein in muscle cells is hypothesized to increase potassium ion flow across the cell membrane, reducing excitability of smooth muscle cells. This mechanism could potentially normalize the heightened detrusor smooth muscle tone in overactive bladder, thereby reducing the related symptoms.

- Development stage: Overactive bladder: Phase 2 in the U.S.

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

- KSP-1007 can broadly and strongly inhibit β-lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. KSP-1007 is expected to become an effective treatment option against carbapenem-resistant bacterial infections in a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Pharma's product for the domestic market: MEROPEN®).
- Development stage: Complicated urinary tract infections and Complicated intra-abdominal infections: Phase 1 in the U.S.

X. Development Status of Major Programs in Frontier Business (As of July 29, 2022)

- Through collaborations with academia and startup companies, we work for the research and development of new non-pharmaceutical healthcare solutions by utilizing digital technologies focusing on “mental resilience” (detect signs of mental disease and prevent deterioration) and “active aging” (improve, maintain, and enhance the health of the elderly by enhancing their awareness). Development status of major programs is as follows.

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