Securities Code: 4506

Supplementary Financial Data (IFRS) for the First Quarter of the Year Ended March 31, 2022

July 29, 2021

Sumitomo Dainippon Pharma Co., Ltd.

- This material contains forecasts, projections, targets, 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, 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 53% of the outstanding shares of 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 FY2020	Q1 FY2021	Change % YoY	FY2021 (Forecast)	Change % YoY
Revenue	133.9	**131.2**	(2.0)	578.0	12.0
Cost of sales *1	36.0	**38.5**	7.0	156.0	13.5
Gross profit	97.9	**92.7**	(5.3)	422.0	11.5
SG&A expenses *1	47.8	**62.0**	29.7	263.0	24.2
R&D expenses *1	25.7	**22.4**	(12.9)	95.0	(2.1)
Other operating income/expenses *2	(0.0)	**0.2**		-	
Core operating profit	24.4	**8.5**	(65.0)	64.0	(8.0)
Changes in fair value of contingent consideration (negative number indicates loss)	(1.2)	**(0.1)**		(1.0)	
Other non-recurring items *3 (negative number indicates loss)	0.1	**(0.1)**		(2.0)	
Operating profit	23.3	**8.3**	(64.3)	61.0	(14.4)
Net profit	15.6	**0.8**	(94.8)	N/A	
Net profit attributable to owners of the parent	18.3	**4.8**	(73.7)	41.0	(27.1)
Basic earnings per share (yen)	45.96	**12.09**		103.20	
Net profit/ Equity attributable to owners of the parent (ROE)	3.4%	**0.8%**		6.9%	

*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

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

(Billions of yen)

	Q1 FY2020	Q1 FY2021	Change % YoY
Revenue	133.9	**131.2**	(2.0)
Cost of sales	36.0	**38.5**	7.0
Gross profit	97.9	**92.7**	(5.3)
SG&A expenses	49.0	**62.1**	26.6
R&D expenses	25.7	**22.4**	(12.9)
Other operating income/expenses	0.1	**0.1**	
Operating profit	23.3	**8.3**	(64.3)
Finance income/costs	(1.3)	**(0.3)**	
Profit before taxes	22.0	**8.0**	(63.8)
Income tax expenses	6.4	**7.2**	
Net profit	15.6	**0.8**	(94.8)
Net profit attributable to owners of the parent	18.3	**4.8**	(73.7)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q1 FY2020	Q1 FY2021
Net cash provided by (used in) operating activities	0.5	**(32.8)**
Net cash provided by (used in) investing activities	21.5	**17.7**
Net cash provided by (used in) financing activities	(9.3)	**(6.9)**
Cash and cash equivalents at the end of period	113.4	**170.9**

4. Foreign Exchange Rates

	FY2020 Apr.-Jun.		FY2021 Apr.-Jun.		FY2021 assumption	Forex sensitivity FY2021 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	**Period end rate**	**Average rate**	**Average rate**	Revenue	Core operating profit
Yen / USD	107.7	107.6	**110.6**	**109.5**	**110.0**	3.2	(0.2)
Yen / RMB	15.2	15.2	**17.1**	**17.0**	**16.5**	1.8	0.5

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q1 FY2020	**Q1 FY2021**	Change	FY2021 (Forecast)	Change
Capital expenditures	2.1	**2.4**	0.4	12.0	(0.7)
Depreciation of Property, plant and equipment	2.6	**2.7**	0.2	10.1	(0.5)
Amortization of Intangible assets	1.8	**5.5**	3.7	26.4	14.4
Related to products (patent rights/ marketing rights) included in above	1.2	**4.8**	3.7	23.7	14.1

(Billions of yen)

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

Major capital expenditure project in FY2021

(Continued) Reinforcement of production facilities, total budget ￥2.0billion, to be completed in FY2022

Establishment of manufacturing facility for regenerative medicine and cell therapy, total budget ￥1.1billion, to be completed in FY2021

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

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	Q1 FY2020	Q1 FY2021	Change	Change %
Revenue	133.9	**131.2**	(2.7)	(2.0)
Overseas revenue	85.2	**83.0**	(2.2)	(2.6)
% of Revenue	63.6%	**63.2%**		
Cost of sales	36.0	**38.5**	2.5	7.0
% of Revenue	26.9%	**29.3%**		
Gross profit	97.9	**92.7**	(5.2)	(5.3)
SG&A expenses	47.8	**62.0**	14.2	29.7
Labor costs	23.1	**27.7**	4.6	20.0
Advertising and promotion costs	6.6	**6.0**	(0.6)	(9.0)
Sales promotion costs	2.4	**4.3**	1.9	78.5
Amortization/Depreciation	3.0	**6.7**	3.8	127.1
Others	12.7	**17.2**	4.5	35.5
R&D expenses	25.7	**22.4**	(3.3)	(12.9)
% of Revenue	19.2%	**17.1%**		
Other operating income/expenses	(0.0)	**0.2**	0.2	
Core operating profit	24.4	**8.5**	(15.8)	(65.0)
Changes in fair value of contingent consideration ＊	(1.2)	**(0.1)**	1.2	
Other non-recurring items ＊	0.1	**(0.1)**	(0.3)	
Operating profit	23.3	**8.3**	(15.0)	(64.3)
Finance income	0.6	**0.6**	(0.0)	
Finance costs	1.9	**1.0**	(1.0)	
Profit before taxes	22.0	**8.0**	(14.0)	(63.8)
Income tax expenses	6.4	**7.2**	0.7	
Net profit	15.6	**0.8**	(14.8)	(94.8)
Net profit attributable to owners of the parent	18.3	**4.8**	(13.5)	(73.7)

＊ Negative number indicates loss.

¥billion

	Change	FX rate
Japan	(1.1)	
North America	(2.7)	1.2
China	3.4	0.7
Other Regions	(2.8)	

・Include Sumitovant +12.3

Changes in fair value of contingent consideration

	Q1 '20	Q1' 21
former BBI	(0.6)	-
former Tolero	(0.6)	(0.1)

2. Adjustments to Core Operating Profit

(Billions of yen)

Q1 FY2021 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	131.2	**131.2**	-	
Cost of sales	38.5	**38.5**	-	
Gross profit	92.7	**92.7**	-	
SG&A expenses	62.1	**62.0**	(0.1)	Changes in fair value of contingent consideration (0.1)
R&D expenses	22.4	**22.4**	-	
Other operating income	0.4	**0.2**	(0.2)	
Other operating expenses	0.3	**-**	(0.3)	
Operating profit	8.3	**8.5**	0.2	

III. Segment Information (Core Basis)

(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)

Q1 FY2020 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	39.7	74.1	5.1	5.5	124.5	9.3	133.9
Cost of sales	20.4	5.4	0.8	2.4	29.0	7.0	36.0
Gross profit	19.4	68.8	4.3	3.1	95.6	2.3	97.9
SG&A expenses	11.4	32.9	1.6	0.7	46.5	1.2	47.8
Core segment profit	**8.0**	**35.9**	**2.7**	**2.4**	**49.0**	**1.1**	**50.1**
R&D expenses *1					25.6	0.2	25.7
Other operating income/expenses (Core basis)*2					(0.0)	0.0	(0.0)
Core operating profit					**23.4**	**0.9**	**24.4**

(Billions of yen)

FY2021 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	150.0	349.7	29.8	10.3	539.8	38.2	578.0
Cost of sales	78.1	38.5	5.5	4.6	126.7	29.3	156.0
Gross profit	71.9	311.2	24.3	5.7	413.1	8.9	422.0
SG&A expenses	52.9	191.9	10.9	1.6	257.3	5.7	263.0
Core segment profit	**19.0**	**119.3**	**13.4**	**4.1**	**155.8**	**3.2**	**159.0**
R&D expenses *1					94.0	1.0	95.0
Other operating income/expenses (Core basis)*2					-	-	-
Core operating profit					**61.8**	**2.2**	**64.0**

*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 FY2020	**Q1 FY2021**	Change	Change %	FY2021 (Forecast)	Progress %
Japan	39.7	**38.7**	(1.1)	(2.8)	150.0	25.8
North America	74.1	**71.4**	(2.7)	(3.7)	349.7	20.4
China	5.1	**8.5**	3.4	66.3	29.8	28.6
Other Regions	5.5	**2.7**	(2.8)	(50.3)	10.3	26.6

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q1 FY2020	**Q1 FY2021**	Change	Change %	FY2021 (Forecast)	Progress %
Japan						
Promoted products						
Equa®/EquMet® Therapeutic agent for type 2 diabetes (Nov. 2019～)	10.3	**9.8**	(0.5)	(4.7)	37.4	26.3
Trulicity® * Therapeutic agent for type 2 diabetes	8.4	**8.8**	0.4	5.3	38.2	23.1
TRERIEF® Therapeutic agent for Parkinson's disease	4.3	**4.3**	0.1	1.4	17.9	24.1
REPLAGAL® Therapeutic agent for Fabry disease	3.5	**3.5**	0.0	1.0	13.8	25.3
METGLUCO® Therapeutic agent for type 2 diabetes	2.5	**2.1**	(0.4)	(14.7)	6.9	30.4
LATUDA® Atypical antipsychotic (Jun. 2020～)	0.5	**1.4**	0.9	167.1	6.7	20.7
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	0.3	**0.5**	0.2	78.5	2.5	18.6
Other products						
AMLODIN® Therapeutic agent for hypertension and angina pectoris	1.7	**1.5**	(0.2)	(13.1)	5.0	29.8
Authorized Generics	1.9	**2.4**	0.5	27.6	10.1	24.0

* Trulicity® revenue is shown by NHI price.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q1 FY2020	**Q1 FY2021**	Change	Change %	FY2021 (Forecast)	Progress %
North America						
LATUDA® Atypical antipsychotic	53.0	**51.4**	(1.7)	(3.1)	220.4	23.3
APTIOM® Antiepileptic	6.8	**6.9**	0.1	1.9	27.4	25.2
BROVANA® Therapeutic agent for COPD	7.8	**5.6**	(2.2)	(28.3)	11.7	47.6
KYNMOBI™ OFF episodes associated with Parkinson's disease (Sep. 2020～)	—	**0.2**	0.2	—	3.1	7.4
ORGOVYX™ Therapeutic agent for advanced prostate cancer (Jan. 2021～)	—	**1.2**	1.2	—	N/A	—
MYFEMBREE® Therapeutic agent for uterine fibroids (Jun. 2021～)	—	**0.1**	0.1	—	N/A	—
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021～)	—	**0.8**	0.8	—	N/A	—
China						
MEROPEN® Carbapenem antibiotic	3.9	**6.6**	2.7	67.6	22.5	29.4
Other Regions						
MEROPEN® Carbapenem antibiotic	2.5	**1.8**	(0.7)	(27.9)	5.7	31.0

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

(Millions of dollar)

Brand name	Q1 FY2020	**Q1 FY2021**	Change	Change %	FY2021 (Forecast)	Progress %
LATUDA®	493	**469**	(24)	(4.8)	2,004	23.4
APTIOM®	63	**63**	0	0.2	249	25.4
BROVANA®	72	**51**	(21)	(29.5)	106	48.0
KYNMOBI™	—	**2**	2	—	28	7.5
ORGOVYX™	—	**11**	11	—	N/A	—
MYFEMBREE®	—	**1**	1	—	N/A	—
GEMTESA®	—	**7**	7	—	N/A	—

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar.31 2021	Jun. 30 2021	Change
Assets	**1,308.1**	**1,276.7**	**(31.4)**
Non-current assets	**848.3**	**834.1**	**(14.3)**
Property, plant and equipment	65.0	64.1	(0.9)
Goodwill	176.5	176.3	(0.2)
Intangible assets	383.4	380.6	(2.8)
Patent rights/Marketing rights	210.7	345.6	134.9
In-process R&D	165.9	28.1	(137.8)
Others	6.8	6.9	0.1
Other financial assets	193.0	180.9	(12.2)
Other non-current assets	10.2	10.5	0.2
Deferred tax assets	20.2	21.7	1.6
Current assets	**459.8**	**442.6**	**(17.2)**
Inventories	92.2	95.2	3.0
Trade and other receivables	135.9	155.2	19.3
Other financial assets	29.5	11.3	(18.2)
Other current assets	8.5	10.0	1.5
Cash and cash equivalents	193.7	170.9	(22.8)
Liabilities	**659.9**	**638.0**	**(21.9)**
Non-current liabilities	**381.8**	**381.2**	**(0.6)**
Bonds and borrowings	263.9	263.2	(0.7)
Other financial liabilities	21.4	19.4	(2.0)
Retirement benefit liabilities	15.1	15.2	0.1
Other non-current liabilities	53.0	57.1	4.1
Deferred tax liabilities	28.4	26.4	(2.1)
Current liabilities	**278.1**	**256.8**	**(21.3)**
Borrowings	10.0	10.0	0.0
Trade and other payables	64.6	65.7	1.1
Other financial liabilities	23.3	22.0	(1.4)
Income taxes payable	24.5	7.8	(16.7)
Provisions	99.9	97.8	(2.1)
Other current liabilities	55.8	53.5	(2.3)
Equity	**648.2**	**638.7**	**(9.5)**
Share capital	22.4	22.4	—
Capital surplus	15.9	17.6	1.7
Treasury shares	(0.7)	(0.7)	—
Retained earnings	508.7	510.0	1.3
Other components of equity	34.3	24.8	(9.5)
Equity attributable to owners of the parent	**580.6**	**574.0**	**(6.5)**
Non-controlling interests	67.6	64.7	(3.0)

← Milestone lump sum by MYFEMBREE approval 11.1

← Mainly due to decrease in Short-term loan receivable

Goodwill	21/3	21/6
Other than oncology(SDPO)	152.3	152.1
Oncology(SDPO)	24.2	24.2

Major patent rights	21/3	21/6
KYNMOBI™ (apomorphine)	51.3	50.1
ORGOVYX™ (relugolix)	62.3	61.3
MYFEMBREE® (relugolix)	-	*132.2
GEMTESA® (vibegron)	91.3	89.7

*Transferred from IPR&D

Major IPR&D	21/3	21/6
former Tolero products	17.7	17.7
relugolix	133.2	* -

*Transferred to Patent rights

Total bonds and borrowings
273.8 → 273.1

Contingent consideration liabilities	21/3	21/6	Total probable payment (Max)
former Tolero	8.3	7.3	$360M

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

VI. Changes in Quarterly Results

(Billions of yen)

Core basis	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2021 Q1
Revenue	133.9	127.6	133.3	121.2	131.2
Cost of sales	36.0	34.7	34.1	32.7	38.5
Gross profit	97.9	92.9	99.2	88.5	92.7
SG&A expenses	47.8	45.8	52.1	66.0	62.0
R&D expenses	25.7	23.5	22.5	25.4	22.4
Other operating income/expenses	(0.0)	(0.0)	0.0	(0.0)	0.2
Core operating profit	24.4	23.6	24.6	(3.0)	8.5
Changes in fair value of contingent consideration (negative number indicates loss)	(1.2)	1.3	(0.4)	22.8	(0.1)
Other non-recurring items (negative number indicates loss)	0.1	(0.6)	15.9	(36.2)	(0.1)
Operating profit	23.3	24.3	40.0	(16.3)	8.3
Net profit	15.6	14.8	27.6	(21.1)	0.8
Net profit attributable to owners of the parent	18.3	19.0	33.0	(14.0)	4.8

VII. Major Consolidated Subsidiaries (As of June 30, 2021)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
DSP GOKYO FOOD & CHEMICAL Co., Ltd.	1947/10	100%	208	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
DS Pharma Animal Health Co., Ltd.	2010/ 7	100%	98	Manufacturing, and sales of veterinary medicines, etc.
DS Pharma Promo Co., Ltd.	1998/ 6	100%	42	Manufacturing and sales of pharmaceuticals, etc.
Overseas	**Establish-ment**	**Ownership**	**Number of employees**	**Businesses**
Sumitomo Dainippon Pharma America, Inc.	2009/7	100%	166	Holding company, shared service for general management operations
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,251	Manufacturing and sales of pharmaceuticals
Sumitomo Dainippon Pharma Oncology, Inc.	2006/11	100%	193	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	79	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	53%	*538	R&D, manufacturing and sales of pharmaceuticals in the women's health, prostate cancer area
Urovant Sciences Ltd.	2016/ 1	100%	*290	R&D, manufacturing and sales of pharmaceuticals in the urology area
Enzyvant Therapeutics Ltd.	2016/ 1	100%	*26	R&D in the pediatric rare diseases area
Altavant Sciences Ltd.	2017/ 9	100%	*21	R&D in the respiratory rare diseases area
Spirovant Sciences Ltd.	2019/ 2	100%	*25	R&D in the cystic fibrosis gene therapy area
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	2003/12	100%	764	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2020		March 31, 2021		June 30, 2021	
consolidated / non-consolidated	6,457	3,023	6,822	3,067	**7,032**	**3,109**
MRs (include number of contracted MRs)						
Japan Exclude managers/Total	1,220	1,340	1,150	1,270	**1,130**	**1,230**
U.S. Exclude managers/Total	650	740	* 720	* 840	*** 830**	*** 960**
China Exclude managers/Total	330	400	340	410	**330**	**410**

*Include sales reps of Sumitovant's subsidiaries

VIII. Development Pipeline (As of July 29, 2021)

- This table shows clinical studies on indications for which the Sumitomo Dainippon Pharma Group aims to obtain approval in Japan, U.S., China, or Europe and does not cover all clinical studies.
- For the oncology area, the study for the most advanced development stage is listed if there are multiple studies with the same 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 clinical study)
	Parkinson's disease psychosis	U.S.	Phase 2
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 1
SEP-4199	Bipolar I depression	U.S., Japan	Phase 2 (Global clinical 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	Treatment resistant depression	U.S.	Phase 1
SEP-380135	Alzheimer's disease agitation	U.S.	Phase 1
DSP-1181	Obsessive compulsive disorder	Japan	Phase 1
DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
relugolix	Prostate cancer	Europe	MAA submitted in March 2021
DSP-7888 (adegramotide/ nelatimotide)	Glioblastoma	U.S., Japan	Phase 3 (Global clinical study)
	Solid tumors	U.S.	Phase 1/2
TP-0903 (dubermatinib)	Acute myeloid leukemia (AML)	U.S.	Phase 1/2 (Research group-initiated clinical study)

DSP-0509 (guretolimod)	Solid tumors	U.S.	Phase 1/2
TP-0184 （itacnosertib）	Anemia associated with myelodysplastic syndromes	U.S.	Phase 1/2
DSP-5336	Hematologic malignancies	U.S.	Phase 1/2
TP-1287	Solid tumors	U.S.	Phase 1
TP-3654	Myelofibrosis	U.S.	Phase 1
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
RVT-802	Pediatric congenital athymia	U.S.	BLA submitted in April 2019 Received Complete Response Letter in December 2019 BLA resubmitted in April 2021
Allo iPS (induced pluripotent stem) cell-derived dopamine neural progenitor	Parkinson’s disease	Japan	Phase 1/2 (Investigator-initiated clinical 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
lefamulin	Bacterial community-acquired pneumonia	China	Phase 3
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

5. Frontier business

Brand name/ Product code	Proposed indication	Region	Development stage
SMC-01 (mobile app for management of type 2 diabetic patients)	Type 2 diabetes	Japan	Phase 3 (Co-development with Save Medical)

【Main revisions since the announcement of May 2021】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
MYFEMBREE® (relugolix)	Uterine fibroids	U.S.	Approved in May 2021	Deleted from the table due to approval
RYEQO® (relugolix)	Uterine fibroids	Europe	Approved in July 2021	
TWYMEEG® (imeglimin)	Type 2 diabetes	Japan	Approved in June 2021	
MYFEMBREE® (relugolix)	(New indication) Endometriosis	U.S.	sNDA submitted in July 2021	Submitted
DSP-7888 (adegramotide/ nelatimotide)	Glioblastoma	U.S., Japan	Phase 3	Development stage changed in Japan
DSP-5336	Hematologic malignancies	U.S.	Phase 1/2	Newly added
lefamulin	Bacterial community-acquired pneumonia	China	Phase 3	
DSP-0390	Solid tumors	U.S., Japan	Phase 1	Added Japan

IX. Profiles of Major Products under Development (As of July 29, 2021)

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 schizophrenia support the efficacy of ulotaront in treating both positive and negative symptoms of schizophrenia, while demonstrating a side effect of profile with notable similarities to placebo: extrapyramidal symptoms, weight gain, lipid and glucose derangements or prolactin elevation.
- Development stage:
  Schizophrenia: Phase 3 in the U.S.
  Parkinson's disease psychosis: Phase 2 in the U.S.
  Schizophrenia: Phase 2/3 in Japan and China

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 1 in Japan

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 designed 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: Bipolar I depression: Phase 2 in the U.S. and Japan

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 and long lasting antidepressant-like activity and enhance neuroplasticity.
- Development stage: Treatment resistant depression: Phase 1 in the U.S.

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, depression and deficits in social interaction.
- Development stage: Alzheimer's disease agitation: Phase 1 in the U.S.

DSP-1181 Origin: in-house (Joint research with Exscientia), Formulation: oral

- DSP-1181 is a novel compound created by Sumitomo Dainippon Pharma using Exscientia's AI technologies. In contrast to conventional serotonin 5-HT_{1A} receptor partial agonists (non-benzodiazepine anxiolytics), DSP-1181 has a potent full agonistic activity for serotonin 5-HT_{1A} receptors and is expected to have a long half-life, and therefore it is suggested that DSP-1181 has strong efficacy over a long period of time. In obsessive compulsive disorder (OCD) model mice manipulated OCD-related neural circuit, DSP-1181 is expected to have an earlier onset of efficacy than a standard medication, a selective serotonin reuptake inhibitor (SSRI).
- Development stage: Obsessive compulsive disorder: Phase 1 in Japan.

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

- DSP-0038 is a novel compound discovered at Sumitomo Dainippon 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.

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:

Proposed indication	Combination products	Country/ Area	Stage	Study number
Glioblastoma	bevacizumab	U.S., Japan	Phase 3	BBI-DSP7888-201G
Solid tumors	nivolumab, pembrolizumab	U.S.	Phase 1/2	BBI-DSP7888-102CI

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 clinical 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.

itacnosertib (TP-0184) Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

- Itacnosertib (TP-0184) has an inhibitory effect against kinase such as ALK2 and ALK5, part of the transforming growth factor beta (TGFβ) receptor superfamily. In myelodysplastic syndromes, the ALK5 pathway is activated and caused abnormal erythroid differentiation. Itacnosertib is expected to show anti-cancer activities through the kinase inhibitory effect decrease hepcidin expression, increase bioavailable iron, and restore normal levels of hemoglobin.
- Development stage:

  Anemia associated with myelodysplastic syndromes : Phase 1/2 in the U.S.

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.

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 in the U.S.

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

- TP-1454 inhibits tumor growth through activation of PKM2 (pyruvate kinase M2) which lead 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 lead to the reduction of aerobic glycolysis in cancer cells and revert 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

RVT-802 Origin: Duke University

- RVT-802, a one-time regenerative therapy, is cultured human thymus tissue engineered to generate a functioning immune response when implanted in pediatric patients with congenital athymia. The key source material for RVT-802 is human thymus tissue that has been removed during pediatric cardiac surgery for unrelated conditions. Patients receive RVT-802 in the quadricep muscle during a single surgical procedure. The patient's own bone marrow stem cells migrate to RVT-802, where they develop into mature T-cells that will be able to fight infection. For patients who respond to RVT-802, a diverse T-cell population is established and thymic function sufficient to protect from infection usually develops between 6 and 12 months post treatment.
- Development stage: Pediatric congenital athymia: BLA submitted in the U.S. in April 2019, Complete Response Letter received in December 2019, BLA resubmitted in the U.S. in April 2021

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 clinical study)
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. Myovant submitted sNDA for the relugolix combination tablet in the U.S. for endometriosis.
- Development stage:
  Prostate cancer: MAA submitted in Europe in March 2021
  (New indication) Endometriosis: sNDA submitted in July 2021in the U.S.

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 relax the bladder, enhance urinary storage, and improve 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, Formulation: oral, injection

- Lefamulin is a 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: Phase 3 in China

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, 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.

5. Frontier business

SMC-01 (mobile app for management of type 2 diabetic patients)(medical device) Origin: Save Medical

- The purpose of the App is to promote behavioral change in patients and improve clinical parameters by managing their daily activities related to type 2 diabetes care (meals, exercise, body weight, medication, blood pressure, and glucose level). Unlike other apps, the App is intended to be used under the guidance and endorsement of a physician, which will motivate patients to continue with their treatment and support their efforts to change their behavior.
- Development stage: Type 2 diabetes: Phase 3 in Japan (Co-development with Save Medical)