Securities Code: 4506

Supplementary Financial Data (IFRS) for the First Quarter of the Year Ending March 31, 2021

July 30, 2020

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.
- 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 FY2019	**Q1 FY2020**	Change % YoY	FY2020 (Forecast)		Change % YoY
Revenue	117.5	**133.9**	13.9	[510.0]	495.0	2.5
Cost of sales *1	28.8	**36.0**	24.7	[145.0]	140.0	9.1
Gross profit	88.6	**97.9**	10.4	[365.0]	355.0	0.2
SG&A expenses *1	46.3	**47.8**	3.1	[229.0]	219.0	15.3
R&D expenses *1	20.0	**25.7**	28.4	[103.0]	103.0	11.2
Other operating income/expenses *2	0.0	**(0.0)**			-	
Core operating profit	22.3	**24.4**	9.4		33.0	(54.2)
Changes in fair value of contingent consideration (negative number indicates loss)	18.5	**(1.2)**			(24.0)	
Other non-recurring items *3 (negative number indicates loss)	(0.3)	**0.1**			15.0	
Operating profit	40.4	**23.3**	(42.4)		24.0	(71.2)
Net profit	6.7	**15.6**	132.2	[(14.0)]	(12.0)	-
Net profit attributable to owners of the parent	6.7	**18.3**	172.4	[7.0]	9.0	(77.9)
Basic earnings per share (yen)	16.87	**45.96**			22.65	
Net profit/ Equity attributable to owners of the parent (ROE)	1.4%	**3.4%**			1.7%	

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 "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 FY2019	**Q1 FY2020**	Change % YoY
Revenue	117.5	**133.9**	13.9
Cost of sales	29.0	**36.0**	24.2
Gross profit	88.5	**97.9**	10.6
SG&A expenses	27.9	**49.0**	75.8
R&D expenses	20.1	**25.7**	28.4
Other operating income/expenses	(0.2)	**0.1**	
Operating profit	40.4	**23.3**	(42.4)
Finance income/costs	(3.5)	**(1.3)**	
Profit before taxes	36.9	**22.0**	(40.4)
Income tax expenses	30.2	**6.4**	
Net profit	6.7	**15.6**	132.2
Net profit attributable to owners of the parent	6.7	**18.3**	172.4

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q1 FY2019	**Q1 FY2020**
Net cash provided by operating activities	8.2	**0.5**
Net cash provided by (used in) investing activities	16.7	**21.5**
Net cash used in financing activities	(9.3)	**(9.3)**
Cash and cash equivalents at the end of period	149.0	**113.4**

4. Foreign Exchange Rates

	FY2019 Apr.-Jun.		**FY2020 Apr.-Jun.**		FY2020 assumption	Forex sensitivity FY2020 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	**Period end rate**	**Average rate**	**Average rate**	Revenue	Core operating profit
Yen / USD	107.8	109.9	**107.7**	**107.6**	**108.0**	2.5	(0.6)
Yen / RMB	15.7	16.1	**15.2**	**15.2**	**15.5**	1.8	0.4

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q1 FY2019	**Q1 FY2020**	Change	FY2020 (Forecast)	Change
Capital expenditures	3.1	**2.1**	(1.0)	11.0	(1.0)
Depreciation of Property, plant and equipment	1.6	**2.6**	1.0	10.0	(0.5)
Amortization of Intangible assets	1.7	**1.8**	0.1	12.9	6.0
Related to products (patent rights/ marketing rights) included in above	1.1	**1.2**	0.0	9.8	5.4

(Billions of yen)

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

Major capital expenditure project in FY2020 (continued)

Reinforcement of production facilities, total budget ￥2.0billion, 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 FY2019	Q1 FY2020	Change	Change %
Revenue	117.5	**133.9**	16.4	13.9
Overseas revenue	75.5	**85.2**	9.7	12.8
% of Revenue	64.2%	**63.6%**		
Cost of sales	28.8	**36.0**	7.1	24.7
% of Revenue	24.5%	**26.9%**		
Gross profit	88.6	**97.9**	9.2	10.4
SG&A expenses	46.3	**47.8**	1.4	3.1
Labor costs	20.4	**23.1**	2.7	13.4
Advertising and promotion costs	6.7	**6.6**	(0.1)	(1.2)
Sales promotion costs	3.4	**2.4**	(1.0)	(29.2)
Amortization/Depreciation	2.7	**3.0**	0.2	7.8
Others	13.2	**12.7**	(0.4)	(3.4)
R&D expenses	20.0	**25.7**	5.7	28.4
% of Revenue	17.1%	**19.2%**		
Other operating income/expenses	0.0	**(0.0)**	(0.0)	
Core operating profit	22.3	**24.4**	2.1	9.4
Changes in fair value of contingent consideration *	18.5	**(1.2)**	(19.7)	
Other non-recurring items *	(0.3)	**0.1**	0.5	
Operating profit	40.4	**23.3**	(17.2)	(42.4)
Finance income	1.4	**0.6**	(0.8)	
Finance costs	4.9	**1.9**	(3.0)	
Profit before taxes	36.9	**22.0**	(14.9)	(40.4)
Income tax expenses	30.2	**6.4**	(23.8)	
Net profit	6.7	**15.6**	8.9	132.2
Net profit attributable to owners of the parent	6.7	**18.3**	11.6	172.4

* Negative number indicates loss.

Revenue

¥billion	Change	FX rate
Japan	7.1	
North America	8.1	(1.6)
China	(1.7)	(0.3)
Other Regions	3.0	
Other	(0.2)	

SG&A expenses

・Include Sumitovant 6.4

R&D expenses

・Include Sumitovant 7.3

Changes in fair value of contingent consideration	Q1'19	Q1'20
LONHALA®MAGNAIR®	(0.3)	-
BBI	*19.1	(0.6)
Tolero	(0.4)	(0.6)

* Decrease in fair value of contingent consideration by review of business plan

Income tax expenses

・FY19: Reversal of deferred tax assets in U.S.

2. Adjustments to Core Operating Profit

(Billions of yen)

Q1FY2020 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	133.9	**133.9**	-	
Cost of sales	36.0	**36.0**	-	
Gross profit	97.9	**97.9**	-	
SG&A expenses	49.0	**47.8**	(1.2)	Changes in fair value of contingent consideration (1.2)
R&D expenses	25.7	**25.7**	-	
Other operating income	0.3	**(0.0)**	(0.3)	
Other operating expenses	0.2	**—**	(0.2)	
Operating profit	23.3	**24.4**	1.1	

III. Segment Information (Core Basis)

(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)

Q1 FY2019 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	32.6	66.0	6.8	2.5	107.9	9.6	117.5
Cost of sales	13.4	6.3	1.0	0.8	21.4	7.4	28.8
Gross profit	19.3	59.7	5.8	1.7	86.5	2.1	88.6
SG&A expenses	12.0	30.2	2.0	0.8	45.1	1.3	46.3
Core segment profit	**7.3**	**29.5**	**3.8**	**0.9**	**41.5**	**0.8**	**42.3**
R&D expenses *1					19.8	0.2	20.0
Other operating income/expenses (Core basis)*2					0.0	(0.0)	0.0
Core operating profit					**21.7**	**0.6**	**22.3**

(Billions of yen)

FY2020 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	153.1	258.5	28.5	16.9	457.0	38.0	495.0
Cost of sales	77.9	22.5	5.3	5.0	110.7	29.3	140.0
Gross profit	75.2	236.0	23.2	11.9	346.3	8.7	355.0
SG&A expenses	52.5	148.2	9.4	3.2	213.3	5.7	219.0
Core segment profit	**22.7**	**87.8**	**13.8**	**8.7**	**133.0**	**3.0**	**136.0**
R&D expenses *1					102.0	1.0	103.0
Other operating income/expenses (Core basis)*2					-	-	-
Core operating profit					**31.0**	**2.0**	**33.0**

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

*2 P/L of associates accounted for using equity method

Note: The forecasts have been revised.

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	1Q FY2019	1Q FY2020	Change	Change %	FY2020 (Forecast)		Progress %
Japan	32.6	**39.7**	7.1	21.8	[154.4]	153.1	25.7
North America	66.0	**74.1**	8.1	12.3	[268.0]	258.5	27.7
China	6.8	**5.1**	(1.7)	(25.0)	[30.8]	28.5	16.6
Other Regions	2.5	**5.5**	3.0	123.0	[18.8]	16.9	29.3

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	1Q FY2019	1Q FY2020	Change	Change %	FY2020 (Forecast)		Progress %
Japan							
Promoted products							
Equa®/EquMet® *1 Therapeutic agent for type 2 diabetes (Nov. 2019～)	–	**10.3**	10.3	–		40.5	25.4
Trulicity® *2 Therapeutic agent for type 2 diabetes (Sep. 2015～)	7.2	**8.4**	1.2	16.0		36.6	22.9
TRERIEF® Therapeutic agent for Parkinson's disease	4.2	**4.3**	0.0	0.2		17.0	25.0
REPLAGAL® Therapeutic agent for Anderson-Fabry disease	3.4	**3.5**	0.1	2.3		13.3	26.0
METGLUCO® Therapeutic agent for type 2 diabetes	2.5	**2.5**	(0.0)	(0.4)	[7.8]	8.8	31.6
AmBisome® Therapeutic agent for systemic fungal infection	1.0	**0.9**	(0.1)	(11.2)		4.0	22.0
LATUDA® Atypical antipsychotic (June 2020～)	–	**0.5**	0.5	–		2.2	23.6
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	–	**0.3**	0.3	–	[5.3]	2.5	4.9
Other products							
AMLODIN® Therapeutic agent for hypertension and angina pectoris	2.1	**1.7**	(0.4)	(19.9)		6.1	28.1
SUREPOST® Therapeutic agent for type 2 diabetes	1.8	**1.8**	0.1	4.3	[3.0]	3.5	61.4
Authorized Generics	2.0	**1.9**	(0.1)	(5.0)	[9.4]	7.2	20.2

*1 Excluding promotion fee revenue

*2 Trulicity® revenue is shown by NHI price.

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

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q1 FY2019	**Q1 FY2020**	Change	Change %	FY2020 (Forecast)		Progress %
North America							
LATUDA® Atypical antipsychotic	49.0	**53.0**	4.1	8.3	[194.2]	187.9	27.3
BROVANA® Therapeutic agent for COPD	8.1	**7.8**	(0.3)	(4.2)	[31.1]	29.7	25.0
APTIOM® Antiepileptic	5.3	**6.8**	1.5	27.8		23.3	29.1
LONHALA® MAGNAIR® Therapeutic agent for COPD (Apr. 2018～)	0.7	**0.5**	(0.1)	(20.1)	[3.8]	3.0	13.9
XOPENEX® Therapeutic agent for asthma	0.8	**1.3**	0.5	61.9	[4.1]	4.6	32.9
KYNMOBI™ OFF episodes associated with Parkinson's disease (To be launched in Sep. 2020)	—	—	—	—		1.1	—
China							
MEROPEN® Carbapenem antibiotic	5.9	**3.9**	(1.9)	(32.7)	[25.3]	23.0	15.6
Other Regions							
MEROPEN® Carbapenem antibiotic	1.6	**2.5**	0.9	56.1	[8.0]	5.7	30.6

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

(Millions of dollar)

Brand name	Q1 FY2019	**Q1 FY2020**	Change	Change %	FY2020 (Forecast)		Progress %
LATUDA®	445	**493**	47	10.6	[1,798]	1,740	27.4
BROVANA®	74	**72**	(2)	(2.2)	[288]	275	25.1
APTIOM®	48	**63**	15	30.5		216	29.2
LONHALA® MAGNAIR®	6	**5**	(1)	(18.5)	[35]	28	14.0
XOPENEX®	8	**13**	5	65.3	[38]	43	33.0
KYNMOBI™	—	—	—	—		10	—

Note: The forecasts of some products 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 2020	Jun. 30 2020	Change
Assets	**1,252.9**	**1,236.2**	**(16.7)**
Non-current assets	**888.8**	**882.7**	**(6.1)**
Property, plant and equipment	65.7	64.5	(1.2)
Goodwill	169.0	167.3	(1.7)
Intangible assets	421.8	416.3	(5.5)
Patent rights/Marketing rights	8.5	60.8	52.3
In-process R&D	406.3	348.7	(57.5)
Others	7.0	6.8	(0.2)
Other financial assets	200.9	201.4	0.5
Other non-current assets	4.2	4.1	(0.1)
Deferred tax assets	27.1	29.0	1.9
Current assets	**364.1**	**353.5**	**(10.6)**
Inventories	79.4	79.0	(0.4)
Trade and other receivables	134.5	137.4	2.9
Other financial assets	28.7	3.8	(24.9)
Other current assets	15.5	15.7	0.2
Cash and cash equivalents	101.7	113.4	11.7
Subtotal	359.8	349.2	(10.6)
Assets held for sale	4.3	4.3	—
Liabilities	**620.8**	**599.4**	**(21.4)**
Non-current liabilities	**124.3**	**122.4**	**(1.9)**
Bonds and borrowings	25.0	24.3	(0.7)
Other financial liabilities	41.3	42.1	0.8
Retirement benefit liabilities	23.9	24.0	0.1
Other non-current liabilities	7.2	5.5	(1.7)
Deferred tax liabilities	26.9	26.6	(0.2)
Current liabilities	**496.5**	**477.0**	**(19.5)**
Bonds and borrowings	273.0	273.0	—
Trade and other payables	62.3	54.0	(8.2)
Other financial liabilities	13.9	13.7	(0.2)
Income taxes payable	22.6	9.5	(13.1)
Provisions	84.6	90.4	5.7
Other current liabilities	40.1	36.4	(3.7)
Equity	**632.1**	**636.8**	**4.7**
Share capital	22.4	22.4	—
Capital surplus	14.7	17.5	2.9
Treasury shares	(0.7)	(0.7)	0.0
Retained earnings	457.3	470.0	12.7
Other components of equity	35.8	31.8	(4.0)
Equity attributable to owners of the parent	**529.5**	**541.0**	**11.6**
Non-controlling interests	102.6	95.8	(6.9)

Goodwill	20/3	20/6
Other than oncology	145.2	143.8
Oncology	23.8	23.6

IPR&D of KYNMOBI™ transferred to Patent right

IPR&D	20/3	20/6
Apomorphine	54.1	* -
BBI products	27.6	27.4
Tolero products	26.1	25.9
Relugolix	175.1	173.3
Vibegron	109.0	107.9
Others	14.3	14.3

*Transferred to Patent Right

← Decrease in short-term loan receivable

Total bonds and borrowings
298.0 → 297.3

Contingent consideration liabilities	20/3	20/6	Total probable payment (Max)
LONHALA®MAGNAIR®	-	-	$210M
BBI	17.4	17.9	$1,390M
Tolero	13.8	14.3	$580M
Total	31.2	32.2	

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

FX rate	20/3		20/6
USD	¥108.8	⇒	¥107.7
RMB	¥ 15.3	⇒	¥ 15.2

VI. Changes in Quarterly Results

(Billions of yen)

	FY2019				FY2020
	1Q	2Q	3Q	4Q	1Q
Revenue	117.5	113.1	126.4	125.7	133.9
Cost of sales	28.8	27.3	37.0	35.3	36.0
Gross profit	88.6	85.9	89.4	90.5	97.9
SG&A expenses	46.3	42.4	49.8	51.4	47.8
R&D expenses	20.0	21.0	20.2	31.4	25.7
Other operating income/expenses	0.0	0.0	0.1	0.0	(0.0)
Core operating profit	22.3	22.5	19.5	7.7	24.4
Changes in fair value of contingent consideration (negative number indicates loss)	18.5	23.3	(0.9)	7.7	(1.2)
Other non-recurring items (negative number indicates loss)	(0.3)	(19.4)	(3.9)	(13.6)	0.1
Operating profit	40.4	26.4	14.6	1.8	23.3
Net profit	6.7	23.6	13.6	(8.1)	15.6
Net profit attributable to owners of the parent	6.7	23.6	13.6	(3.2)	18.3

VII. Major Consolidated Subsidiaries (As of June 30, 2020)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
DSP Gokyo Food & Chemical Co., Ltd.	1947/10	100%	202	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
DS Pharma Animal Health Co., Ltd.	2010/ 7	100%	92	Manufacturing, and sales of veterinary medicines, etc.
DS Pharma Promo Co., Ltd.	1998/ 6	100%	47	Manufacturing and sales of pharmaceuticals, etc.
Overseas	**Establish-ment**	**Ownership**	**Number of employees**	**Businesses**
Sumitomo Dainippon Pharma America, Inc.	2009/7	100%	59	Holding company of Sunovion Pharmaceuticals Inc., Boston Biomedical, Inc., and Tolero Pharmaceuticals, Inc. and providing general and administrative service with these subsidiaries
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,494	Manufacturing and sales of pharmaceuticals
Boston Biomedical, Inc.†	2006/11	100%	149	R&D in the oncology area
Tolero Pharmaceuticals, Inc.†	2011/ 6	100%	53	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	51	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	54%	*240	R&D in the women's health, prostate cancer area
Urovant Sciences Ltd.	2016/ 1	74%	*90	R&D in the urology area
Enzyvant Therapeutics Ltd.	2016/ 1	100%	*20	R&D in the pediatric rare diseases area
Altavant Sciences Ltd.	2017/ 9	100%	*12	R&D in the respiratory rare diseases area
Spirovant Sciences Ltd.	2019/ 2	100%	*15	R&D in the cystic fibrosis gene therapy area
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	2003/12	100%	764	Manufacturing and sales of pharmaceuticals

† On July 1, 2020, these two companies merged and changed name to Sumitomo Dainippon Pharma Oncology, Inc.

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2019		March 31, 2020		June 30, 2020	
consolidated / non-consolidated	6,140	3,067	6,457	3,072	**6,548**	**3,072**
MRs (include number of contracted MRs)						
Japan Exclude managers/Total	1,120	1,240	1,220	1,340	**1,210**	**1,330**
U.S. Exclude managers/Total	720	820	650	740	**580**	**670**
China Exclude managers/Total	340	400	330	400	**340**	**420**

VIII. Development Pipeline (As of July 30, 2020)

- This table shows clinical studies on indications for which the Sumitomo Dainippon Pharma Group aims to obtain approval in Japan, U.S. or China, and does not cover all clinical studies.
- For 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/approved by the authority.

1. Psychiatry & Neurology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
LONASEN® (blonanserin)	(New usage: pediatric) Schizophrenia	Japan	NDA submitted in May 2020
SEP-363856	Schizophrenia	U.S.	Phase 3
		Japan	Phase 1
	Parkinson's disease psychosis	U.S.	Phase 2
EPI-743 (vatiquinone)	Leigh syndrome	Japan	Phase 2/3
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	Agitation in Alzheimer's disease	U.S.	Phase 1
DSP-1181	Obsessive compulsive disorder	Japan	Phase 1

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
relugolix	Prostate cancer (Monotherapy)	U.S.	NDA submitted in April 2020
BBI608 (napabucasin)	Colorectal cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
	Gastrointestinal cancer (Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Combination therapy)	U.S.	Phase 1/2
DSP-2033 (alvocidib)	Acute myeloid leukemia (AML) (Monotherapy / Combination therapy) (Refractory or relapsed patients)	U.S.	Phase 2
	Myelodysplastic syndromes (MDS) (Combination therapy)	U.S.	Phase 1/2
DSP-7888 (adegramotide/ nelatimotide)	Glioblastoma (Combination therapy)	U.S., Japan	Phase 2 (Global clinical study)
	Solid tumors (Combination therapy)	U.S.	Phase 1/2
TP-0903 (dubermatinib)	Solid tumors (Monotherapy / Combination therapy)	U.S., Japan	Phase 1
DSP-0509	Solid tumors (Monotherapy / Combination therapy)	U.S.	Phase 1/2
TP-0184	Anemia associated with myelodysplastic syndromes (Monotherapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy)	U.S.	Phase 1
DSP-0337	Solid tumors (Monotherapy)	U.S.	Phase 1
TP-1287	Solid tumors (Monotherapy)	U.S.	Phase 1
TP-3654	Solid tumors (Monotherapy)	U.S.	Phase 1
	Myelofibrosis (Monotherapy / Combination therapy)	U.S.	Phase 1
TP-1454	Solid tumors (Monotherapy / Combination therapy)	U.S.	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
Allo iPS 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
vibegron	Overactive bladder (OAB)	U.S.	NDA submitted in December 2019
	Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	Phase 3
	IBS-associated pain	U.S.	Phase 2
relugolix	Uterine fibroids	Europe	MAA submitted in March 2020
		U.S.	NDA submitted in May 2020
	Endometriosis	U.S.	Phase 3 (Global clinical study)
PXL008 (imeglimin)	Type 2 diabetes	Japan	NDA submitted in July 2020
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

【Main revisions since the announcement of May 2020】

Changes	Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
Approval	APL-130277 (apomorphine hydrochloride)	OFF episodes associated with Parkinson's disease	U.S.	Approved in May 2020
Submitted	LONASEN® (blonanserin)	(New usage: pediatric) Schizophrenia	Japan	NDA submitted in May 2020
	relugolix	Uterine fibroids	U.S.	NDA submitted in May 2020
	PXL008 (imeglimin)	Type 2 diabetes	Japan	NDA submitted in July 2020
Deleted from the table due to the study completed	DSP-2033 (alvocidib)	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed patients)	U.S.	Phase 1
	DSP-7888 (adegramotide/ nelatimotide)	Pediatric malignant gliomas (Monotherapy)	Japan	Phase 1/2

IX. Profiles of Major Products under Development (As of July 30, 2020)

1. Psychiatry & Neurology

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

- SEP-363856 is an antipsychotic agent with a novel mechanism of action, a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity and doesn't bind to dopamine D_2 or serotonin 5-HT_{2A} receptors. Sunovion discovered SEP-363856 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 SEP-363856 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 1 in Japan

vatiquinone (EPI-743) In-licensed from PTC Therapeutics, Inc. (Acquired from BioElectron Technology Corporation), Formulation: oral

- EPI-743 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be the world's first treatment for mitochondrial diseases, beginning with Leigh syndrome, for which there is no effective therapy.
- Development stage:
  A Phase 2 / 3 study for Leigh syndrome in Japan completed, development strategy under consideration

EPI-589 In-licensed from 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 Developed 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 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 Developed 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 Developed 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 Developed 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 Developed 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 Developed 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: Agitation in Alzheimer's disease: Phase 1 in the U.S.

DSP-1181 Developed in-house, 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.

2. Oncology

napabucasin (BBI608) Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI608 is an orally administered small molecule agent with a novel mechanism of action that is bioactivated by the enzyme NQO1 in cancer cells, which generates reactive oxygen species (ROS) to inhibit cancer stemness and tumor progression-related pathways including STAT3, which is expected to result in cancer cell death.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 3	Colorectal cancer (combination therapy)	U.S., Japan	FOLFIRI*3, FOLFIRI*3 + bevacizumab	CanStem303C
Phase 1 / 2	Solid tumors*1 (combination therapy)	U.S.	paclitaxel	201
	Hepatocellular carcinoma*2 (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S.	ipilimumab, pembrolizumab, nivolumab	201CIT
	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX*3, FOLFOX*3 + bevacizumab, CAPOX*3, FOLFIRI*3, FOLFIRI*3 + bevacizumab, regorafenib, irinotecan	246
Phase 1	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel, FOLFIRINOX*3, FOLFIRI*3, irinotecan liposome injection + fluorouracil + leucovorin	118

*1 Phase 2 stage: Ovarian cancer, Breast cancer, Melanoma, etc.

*2 Phase 2 stage

*3 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
CAPOX: Combination therapy with capecitabine, oxaliplatin
FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan
FOLFIRINOX: Combination therapy with fluorouracil, leucovorin, irinotecan, oxaliplatin

alvocidib (DSP-2033) In-licensed from Sanofi S.A., Formulation: injection

- Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Acute myeloid leukemia (monotherapy/combination therapy) (refractory or relapsed patients following treatment with venetoclax combination therapy)	U.S.	cytarabine	TPI-ALV-202
Phase 1/2	Myelodysplastic syndromes (combination therapy)	U.S.	decitabine, azacitidine	TPI-ALV-102 (Zella 102)
Phase 1	Acute myeloid leukemia (combination therapy) (refractory or relapsed patients)	U.S.	venetoclax	M16-186*

* Co-development with AbbVie

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

- DSP-7888 is a therapeutic cancer peptide vaccine derived from 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:

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

dubermatinib (TP-0903) In-licensed from University of Utah, Formulation: oral

- 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. TP-0903 may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL. TP-0903 has been shown to inhibit AXL signaling and reverse the mesenchymal to epithelial phenotype in pre-clinical studies.
- Development stage:
  Solid tumors (monotherapy / combination therapy): Phase 1 in the U.S. and Japan

DSP-0509 Developed in-house, Formulation: injection

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

TP-0184 Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- 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. TP-0184 is expected to show anti-cancer activities through the kinase inhibitory effect.
- Development stage:
  Anemia associated with myelodysplastic syndromes (monotherapy): Phase 1/2 in the U.S.
  Solid tumors (monotherapy): Phase 1 in the U.S.

DSP-0337 Developed in-house, Formulation: oral

- DSP-0337 is a small molecule oral prodrug of napabucasin. DSP-0337 is expected to be stable and dispersed in the stomach, and converted to napabucasin in the intestine, which may be absorbed and exert its pharmacologic activities.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

TP-1287 Developed in-house (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 preclinical 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 (monotherapy): Phase 1 in the U.S.

TP-3654 Developed in-house (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:
  Solid tumors (monotherapy): Phase 1 in the U.S.
  Myelofibrosis (monotherapy / combination therapy): Phase 1 in the U.S.

TP-1454 Developed in-house (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 (monotherapy / combination therapy): Phase 1 in the U.S.

3. Regenerative medicine / cell therapy

RVT-802 In-licensed from 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 can 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

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 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

vibegron In-licensed from 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, relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in overactive bladder.
- Development stage:
  Overactive bladder: NDA submitted in the U.S. in December 2019
  Overactive bladder in men with BPH: Phase 3 in the U.S.
  IBS-associated pain: Phase 2 in the U.S.

relugolix In-licensed from 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 is developing a relugolix monotherapy tablet (120 mg) for men with advanced prostate cancer. Myovant is developing a distinct product, relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for uterine fibroids and endometriosis.
- Development stage:
  Uterine fibroids: MAA submitted in Europe in March 2020, NDA submitted in the U.S. in May 2020
  Prostate cancer: NDA submitted in the U.S. in April 2020
  Endometriosis: Phase 3 in the U.S.

imeglimin (PXL008) In-licensed from Poxel SA, Formulation: oral

- Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the pancreas, muscles, and the liver, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.
- Development stage: Type 2 diabetes: NDA submitted in Japan in July 2020 (Co-development with Poxel)

rodatristat ethyl In-licensed from 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 In-licensed from 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. 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 that acts as a trigger for egg maturation prior to oocyte collection.
- Development stage: Female infertility: Phase 2 in Germany

URO-902 In-licensed from 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 symptoms of overactive bladder.
- Development stage: Overactive bladder: Phase 2 in the U.S.