Securities Code: 4506

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

January 28, 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.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

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

(Billions of yen)

	Q3 YTD FY2019	Q3 YTD FY2020	Change % YoY	FY2019	Change % YoY	FY2020 (Forecast)	Change % YoY
Revenue	357.0	**394.8**	10.6	482.8	5.1	506.0	4.8
Cost of sales *1	93.1	**104.8**	12.6	128.3	13.5	141.0	9.9
Gross profit	264.0	**290.0**	9.9	354.4	2.4	365.0	3.0
SG&A expenses *1	138.6	**145.7**	5.1	190.0	2.1	215.0	13.2
R&D expenses *1	61.2	**71.7**	17.1	92.6	11.7	103.0	11.2
Other operating income/expenses *2	0.1	**(0.0)**		0.2		-	
Core operating profit	64.3	**72.6**	12.9	72.0	(6.9)	47.0	(34.7)
Changes in fair value of contingent consideration (negative number indicates loss)	40.8	**(0.4)**		48.5		(4.0)	
Other non-recurring items *3 (negative number indicates loss)	(23.6)	**15.4**		(37.2)		15.0	
Operating profit	81.5	**87.5**	7.5	83.2	43.8	58.0	(30.3)
Net profit	44.0	**57.9**	31.7	35.9	(26.1)	21.0	(41.5)
Net profit attributable to owners of the parent	44.0	**70.3**	59.8	40.8	(16.2)	42.0	3.1
Basic earnings per share (yen)	110.70	**176.84**		102.58		105.71	
Net profit/ Equity attributable to owners of the parent (ROE)	8.6%	**13.0%**		7.9%		7.7%	

*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)

	Q3 YTD FY2019	Q3 YTD FY2020	Change % YoY
Revenue	357.0	**394.8**	10.6
Cost of sales	93.3	**104.8**	12.3
Gross profit	263.7	**290.0**	10.0
SG&A expenses	97.8	**147.0**	50.3
R&D expenses	83.7	**71.7**	(14.4)
Other operating income/expenses	(0.7)	**16.3**	
Operating profit	81.5	**87.5**	7.5
Finance income/costs	3.0	**(7.8)**	
Profit before taxes	84.4	**79.7**	(5.6)
Income tax expenses	40.4	**21.8**	
Net profit	44.0	**57.9**	31.7
Net profit attributable to owners of the parent	44.0	**70.3**	59.8

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q3 YTD FY2019	Q3 YTD FY2020
Net cash provided by operating activities	36.8	**107.9**
Net cash provided by (used in) investing activities	(284.7)	**35.6**
Net cash provided by (used in) financing activities	240.5	**(18.4)**
Cash and cash equivalents at the end of period	129.3	**219.8**

4. Foreign Exchange Rates

	FY2019 Apr.-Dec.		FY2020 Apr.-Dec.		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	109.5	108.7	**103.5**	**106.1**	**108.0**	2.6	(0.5)
Yen / RMB	15.7	15.6	**15.9**	**15.5**	**15.5**	1.8	0.4

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization

(Billions of yen)

	Q3 YTD FY2019	**Q3 YTD FY2020**	Change	FY2020 (Forecast)	Change
Capital expenditures	7.7	**6.8**	(0.9)	11.0	(1.0)
Depreciation of Property, plant and equipment	7.7	**7.9**	0.2	10.0	(0.5)
Amortization of Intangible assets	5.2	**6.7**	1.5	11.7	4.8
Related to products (patent rights/ marketing rights) included in above	3.4	**4.8**	1.4	9.2	4.8

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

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

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	Q3 YTD FY2019	Q3 YTD FY2020	Change	Change %
Revenue	357.0	**394.8**	37.7	10.6
Overseas revenue	226.3	**249.1**	22.8	10.1
% of Revenue	63.4%	**63.1%**		
Cost of sales	93.1	**104.8**	11.7	12.6
% of Revenue	26.1%	**26.5%**		
Gross profit	264.0	**290.0**	26.0	9.9
SG&A expenses	138.6	**145.7**	7.1	5.1
Labor costs	59.4	**68.7**	9.4	15.8
Advertising and promotion costs	17.6	**14.9**	(2.7)	(15.3)
Sales promotion costs	11.1	**11.6**	0.4	3.7
Amortization/Depreciation	8.3	**10.1**	1.7	20.7
Others	42.1	**40.4**	(1.7)	(4.0)
R&D expenses	61.2	**71.7**	10.5	17.1
% of Revenue	17.1%	**18.2%**		
Other operating income/expenses	0.1	**(0.0)**	(0.1)	
Core operating profit	64.3	**72.6**	8.3	12.9
Changes in fair value of contingent consideration *	40.8	**(0.4)**	(41.2)	
Other non-recurring items *	(23.6)	**15.4**	39.0	
Operating profit	81.5	**87.5**	6.1	7.5
Finance income	3.3	**1.1**	(2.2)	
Finance costs	0.4	**8.9**	8.6	
Profit before taxes	84.4	**79.7**	(4.7)	(5.6)
Income tax expenses	40.4	**21.8**	(18.6)	
Net profit	44.0	**57.9**	13.9	31.7
Net profit attributable to owners of the parent	44.0	**70.3**	26.3	59.8

* Negative number indicates loss.

¥billion

	Change	FX rate
Japan	14.3	
North America	22.4	(5.2)
China	(1.1)	(0.2)
Other Regions	2.8	
Other	(0.6)	

・Include Sumitovant 26.6

・Include Sumitovant 18.8

Changes in fair value of contingent consideration

	Q3'19	Q3'20
LONHALA®MAGNAIR®	(0.7)	-
former BBI	*27.5	(0.5)
former Tolero	*14.0	*0.1

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

・FY19: Impairment loss of IPR&D
FY20: Gain on sale of fixed assets

・FY20: FX loss due to stronger yen

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

2. Adjustments to Core Operating Profit

(Billions of yen)

Q3YTD FY2020 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	394.8	**394.8**	-	
Cost of sales	104.8	**104.8**	-	
Gross profit	290.0	**290.0**	-	
SG&A expenses	147.0	**145.7**	(1.3)	Changes in fair value of contingent consideration (0.4) Business structure improvement expenses (0.9)
R&D expenses	71.7	**71.7**	-	
Other operating income	17.5	**(0.0)**	(17.5)	Gain on sale of former Ibaraki plant (16.7)
Other operating expenses	1.3	**-**	(1.3)	
Operating profit	87.5	**72.6**	(15.0)	

III. Segment Information (Core Basis)

(Billions of yen)

Q3 QTD FY2020 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	118.5	218.0	19.1	11.5	367.1	27.7	394.8
Cost of sales	59.5	16.3	3.9	4.2	83.8	21.0	104.8
Gross profit	59.1	201.7	15.2	7.3	283.3	6.6	290.0
SG&A expenses	36.1	97.2	6.7	2.0	142.0	3.8	145.7
Core segment profit	**23.0**	**104.5**	**8.5**	**5.3**	**141.4**	**2.9**	**144.2**
R&D expenses *1					71.1	0.6	71.7
Other operating income/expenses (Core basis)*2					(0.0)	-	(0.0)
Core operating profit					**70.3**	**2.2**	**72.6**

(Billions of yen)

Q3 QTD FY2019 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	104.3	195.7	20.2	8.7	328.8	28.2	357.0
Cost of sales	46.5	17.8	3.8	3.1	71.2	21.9	93.1
Gross profit	57.8	177.8	16.4	5.6	257.6	6.3	264.0
SG&A expenses	37.7	87.6	7.0	2.4	134.7	3.9	138.6
Core segment profit	**20.1**	**90.2**	**9.4**	**3.2**	**122.9**	**2.5**	**125.3**
R&D expenses *1					60.6	0.6	61.2
Other operating income/expenses (Core basis)*2					0.1	0.0	0.1
Core operating profit					**62.4**	**1.8**	**64.3**

(Billions of yen)

FY2020 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	153.3	272.1	27.7	16.9	470.0	36.0	506.0
Cost of sales	79.1	23.9	5.4	5.1	113.5	27.5	141.0
Gross profit	74.2	248.2	22.3	11.8	356.5	8.5	365.0
SG&A expenses	52.0	146.1	8.5	2.9	209.5	5.5	215.0
Core segment profit	**22.2**	**102.1**	**13.8**	**8.9**	**147.0**	**3.0**	**150.0**
R&D expenses *1					102.0	1.0	103.0
Other operating income/expenses (Core basis)*2					-	-	-
Core operating profit					**45.0**	**2.0**	**47.0**

*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

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	Q3 QTD FY2019	**Q3 QTD FY2020**	Change	Change %	FY2020 (Forecast)	Progress %
Japan	104.3	**118.5**	14.3	13.7	153.3	77.3
North America	195.7	**218.0**	22.4	11.4	272.1	80.1
China	20.2	**19.1**	(1.1)	(5.4)	27.7	68.8
Other Regions	8.7	**11.5**	2.8	31.9	16.9	67.8

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q3 QTD FY2019	**Q3 QTD FY2020**	Change	Change %	FY2020 (Forecast)	Progress %
Japan						
Promoted products						
Equa®/EquMet® *1 Therapeutic agent for type 2 diabetes (Nov. 2019～)	7.8	**31.3**	23.5	301.2	40.5	77.3
Trulicity® *2 Therapeutic agent for type 2 diabetes (Sep. 2015～)	22.9	**25.9**	3.0	13.2	36.6	70.7
TRERIEF® Therapeutic agent for Parkinson's disease	12.6	**12.7**	0.1	0.5	17.0	74.5
REPLAGAL® Therapeutic agent for Fabry disease	10.3	**10.6**	0.2	2.4	13.7	77.0
METGLUCO® Therapeutic agent for type 2 diabetes	7.4	**7.2**	(0.2)	(3.1)	8.8	81.8
AmBisome® Therapeutic agent for systemic fungal infection	3.3	**2.8**	(0.5)	(14.8)	4.0	70.1
LATUDA® Atypical antipsychotic (Jun. 2020～)	—	**1.6**	1.6	—	2.2	73.0
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	0.3	**0.9**	0.6	211.3	2.5	37.5
Other products						
AMLODIN® Therapeutic agent for hypertension and angina pectoris	6.0	**5.1**	(0.9)	(14.8)	6.1	83.9
SUREPOST® Therapeutic agent for type 2 diabetes	5.2	**3.5**	(1.8)	(33.9)	3.5	99.1
Authorized Generics	5.8	**5.9**	0.1	1.7	7.2	81.3

*1 Excluding promotion fee revenue

*2 Trulicity® revenue is shown by NHI price.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q3 YTD FY2019	**Q3 YTD FY2020**	Change	Change %	FY2020 (Forecast)	Progress %
North America						
LATUDA® Atypical antipsychotic	142.1	**160.5**	18.4	12.9	199.0	80.7
BROVANA® Therapeutic agent for COPD	26.0	**22.5**	(3.5)	(13.4)	29.7	75.7
APTIOM® Antiepileptic	17.0	**19.8**	2.8	16.7	24.6	80.6
LONHALA® MAGNAIR® Therapeutic agent for COPD (Apr. 2018～)	2.3	**1.7**	(0.6)	(26.0)	3.0	55.5
XOPENEX® Therapeutic agent for asthma	2.8	**3.6**	0.8	30.2	4.6	78.2
KYNMOBI™ OFF episodes associated with Parkinson's disease (Sep. 2020～)	—	**0.2**	0.2	—	1.1	14.4
China						
MEROPEN® Carbapenem antibiotic	16.9	**15.3**	(1.6)	(9.3)	22.5	68.1
Other Regions						
MEROPEN® Carbapenem antibiotic	5.1	**4.4**	(0.7)	(13.6)	5.7	77.6

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

(Millions of dollar)

Brand name	Q3 YTD FY2019	**Q3 YTD FY2020**	Change	Change %	FY2020 (Forecast)	Progress %
LATUDA®	1,308	**1,513**	205	15.6	1,843	82.1
BROVANA®	239	**212**	(27)	(11.3)	275	77.0
APTIOM®	156	**187**	31	19.5	228	82.0
LONHALA® MAGNAIR®	21	**16**	(5)	(24.2)	28	56.1
XOPENEX®	25	**34**	8	33.3	43	78.8
KYNMOBI™	—	**1**	1	—	10	14.9

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar.31 2020	Dec. 31 2020	Change
Assets	**1,256.5**	**1,308.8**	**52.3**
Non-current assets	**892.4**	**844.1**	**(48.3)**
Property, plant and equipment	65.7	62.8	(3.0)
Goodwill	173.5	165.0	(8.5)
Intangible assets	421.0	398.5	(22.5)
Patent rights/Marketing rights	8.5	201.8	193.2
In-process R&D	405.5	190.3	(215.2)
Others	7.0	6.4	(0.6)
Other financial assets	200.9	167.5	(33.5)
Other non-current assets	4.2	10.4	6.3
Deferred tax assets	27.1	40.0	12.9
Current assets	**364.1**	**464.7**	**100.6**
Inventories	79.4	82.9	3.5
Trade and other receivables	134.5	148.7	14.2
Other financial assets	28.7	5.3	(23.5)
Other current assets	15.5	8.0	(7.5)
Cash and cash equivalents	101.7	219.8	118.1
Subtotal	359.8	464.7	104.9
Assets held for sale	4.3	—	(4.3)
Liabilities	**620.7**	**670.3**	**49.6**
Non-current liabilities	**124.2**	**407.1**	**282.9**
Bonds and borrowings	25.0	264.6	239.5
Other financial liabilities	41.3	41.8	0.4
Retirement benefit liabilities	23.9	24.5	0.7
Other non-current liabilities	7.2	49.5	42.3
Deferred tax liabilities	26.8	26.8	0.0
Current liabilities	**496.5**	**263.2**	**(233.3)**
Borrowings	273.0	30.0	(243.0)
Trade and other payables	62.3	54.8	(7.4)
Other financial liabilities	13.9	24.3	10.4
Income taxes payable	22.6	14.5	(8.1)
Provisions	84.6	95.1	10.4
Other current liabilities	40.1	44.5	4.4
Equity	**635.9**	**638.6**	**2.7**
Share capital	22.4	22.4	—
Capital surplus	17.8	16.4	(1.4)
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	457.3	516.2	58.9
Other components of equity	35.8	(7.2)	(43.0)
Equity attributable to owners of the parent	**532.7**	**547.2**	**14.5**
Non-controlling interests	103.2	91.4	(11.8)

The related items as of Mar. 31 2020 have been retrospectively adjusted due to the finalization in this Q3 of the purchase price allocation of Sumitovant, which was acquired in Dec. 2019.

Goodwill	20/3	20/12
Other than oncology(SDPO)	**149.6	142.3
Oncology(SDPO)	23.8	22.7

**Retroactively adjusted

Major patent rights	20/3	20/12
KYNMOBI™ (apomorphine)	-	*49.1
ORGOVYX™ (relugolix)	-	*59.2
GEMTESA® (vibegron)	-	*86.9

*Transferred from IPR&D

Major IPR&D	20/3	20/12
KYNMOBI™ (apomorphine)	54.1	* -
former BBI products	27.6	26.3
former Tolero products	26.1	24.8
relugolix	**193.2	*124.5
vibegron	**90.0	* -

*Transferred to Patent rights
**Retroactively adjusted

← Decrease in short-term loan receivable

← Completed selling procedure of the former Ibaraki plant

Total bonds and borrowings
298.0 → 294.5
Shifted to long-term funding from bridge loans through issuance of subordinated bonds and refinancing to long-term borrowings

← Deferred revenue increased due to upfront of the collaborative agreement

Contingent consideration liabilities	20/3	20/12	Total probable payment (Max)
former BBI	17.4	17.1	$1,390M
former Tolero	13.8	13.0	$580M
Total	31.2	30.1	

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

← FX rate

FX rate	20/3		20/12
USD	108.8	⇒	103.5
RMB	15.3	⇒	15.9

VI. Changes in Quarterly Results

(Billions of yen)

Core basis	FY2019				FY2020		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Revenue	117.5	113.1	126.4	125.7	133.9	127.6	133.3
Cost of sales	28.8	27.3	37.0	35.3	36.0	34.7	34.1
Gross profit	88.6	85.9	89.4	90.5	97.9	92.9	99.2
SG&A expenses	46.3	42.4	49.8	51.4	47.8	45.8	52.1
R&D expenses	20.0	21.0	20.2	31.4	25.7	23.5	22.5
Other operating income/expenses	0.0	0.0	0.1	0.0	(0.0)	(0.0)	0.0
Core operating profit	22.3	22.5	19.5	7.7	24.4	23.6	24.6
Changes in fair value of contingent consideration (negative number indicates loss)	18.5	23.3	(0.9)	7.7	(1.2)	1.3	(0.4)
Other non-recurring items (negative number indicates loss)	(0.3)	(19.4)	(3.9)	(13.6)	0.1	(0.6)	15.9
Operating profit	40.4	26.4	14.6	1.8	23.3	24.3	40.0
Net profit	6.7	23.6	13.6	(8.1)	15.6	14.8	27.6
Net profit attributable to owners of the parent	6.7	23.6	13.6	(3.2)	18.3	19.0	33.0

VII. Major Consolidated Subsidiaries (As of Dec. 31, 2020)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
DSP GOKYO FOOD & CHEMICAL Co., Ltd.	1947/10	100%	205	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
DS Pharma Animal Health Co., Ltd.	2010/ 7	100%	91	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%	149	Holding company of Sunovion Pharmaceuticals Inc. and Sumitomo Dainippon Pharma Oncology, Inc. and providing general and administrative service with these subsidiaries
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,260	Manufacturing and sales of pharmaceuticals
Sumitomo Dainippon Pharma Oncology, Inc.	2006/11	100%	209	R&D in the oncology area
Sumitovant Biopharma, Inc.	2019/10	100%	68	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc.
Myovant Sciences Ltd.	2016/ 2	54%	*387	R&D in the women's health, prostate cancer area
Urovant Sciences Ltd.	2016/ 1	71%	*134	R&D in the urology area
Enzyvant Therapeutics Ltd.	2016/ 1	100%	*22	R&D in the pediatric rare diseases area
Altavant Sciences Ltd.	2017/ 9	100%	*14	R&D in the respiratory rare diseases area
Spirovant Sciences Ltd.	2019/ 2	100%	*19	R&D in the cystic fibrosis gene therapy area
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	2003/12	100%	763	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	March 31, 2019		March 31, 2020		Dec. 31, 2020	
consolidated / non-consolidated	6,140	3,067	6,457	3,023	**6,646**	**3,074**
MRs (include number of contracted MRs)						
Japan Exclude managers/Total	1,120	1,240	1,220	1,340	**1,150**	**1,270**
U.S. Exclude managers/Total	720	820	650	740	*** 720**	*** 830**
China Exclude managers/Total	340	400	330	400	**340**	**410**

*Include sales reps of Sumitovant's subsidiaries

VIII. Development Pipeline (As of January 28, 2021)

- 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
LATUDA® (lurasidone hydrochloride)	(New indication) Bipolar I depression	China	Phase 3
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
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
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
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 October 2020】

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage	Changes
LATUDA® (lurasidone hydrochloride)	(New indication) Bipolar I depression	China	Phase 3	Newly added
ORGOVYX™ (relugolix)	Prostate cancer (Monotherapy)	U.S.	Approved in December 2020	Deleted from the table due to approval
GEMTESA® (vibegron)	Overactive bladder (OAB)	U.S.	Approved in December 2020	Deleted from the table due to approval
	IBS-associated pain	U.S.	Phase 2	Deleted from the table due to discontinuation

IX. Profiles of Major Products under Development (As of January 28, 2021)

1. Psychiatry & Neurology

SEP-363856 Origin: 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) Origin: 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 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: Agitation in Alzheimer's disease: Phase 1 in the U.S.

DSP-1181 Origin: 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) Origin: in-house (former 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

*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

alvocidib (DSP-2033) Origin: 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)

adegramotide/nelatimotide (DSP-7888) Origin: 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) Origin: 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 Origin: 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 Origin: in-house (former 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 Origin: 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 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 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 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:
  Solid tumors (monotherapy): Phase 1 in the U.S.
  Myelofibrosis (monotherapy / combination therapy): 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 (monotherapy / combination therapy): Phase 1 in the U.S.

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 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 the U.S. 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

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 has received approval in the U.S. in December 2020 for 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

Endometriosis: Phase 3 in the U.S.

imeglimin (PXL008) Origin: 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)

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, relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in 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.

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. 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 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 symptoms of overactive bladder.
- 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)