

**Supplementary Financial Data (IFRS) for
the Second Quarter of the Year Ending March 31, 2020**

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October 28, 2019

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)

	Q2 FY2018	Q2 FY2019	Change % YoY	FY2018	Change % YoY	FY2019 (Forecast)	Change % YoY
Revenue	226.2	230.6	2.0	459.3	(1.6)	475.0	3.4
Cost of sales *1	55.6	56.1	0.9	113.1	0.7	[126.0]	10.5
Gross profit	170.6	174.5	2.3	346.2	(2.4)	[349.0]	1.1
SG&A expenses *1	92.2	88.8	(3.7)	186.1	(0.0)	[186.0]	0.5
R&D expenses *1	41.3	41.0	(0.7)	82.9	(4.6)	86.0	3.8
Other operating income/expenses (Core Basis)*2	0.1	0.1		0.2		0.0	
Core operating profit	37.2	44.8	20.5	77.3	(14.7)	77.0	(0.4)
Changes in fair value of contingent consideration (negative number indicates loss)	(6.9)	41.8		9.1		[12.0]	35.0
Other non-recurring items *3 (negative number indicates loss)	(0.7)	(19.7)		(28.5)		[(1.0)]	(24.0)
Operating profit	29.6	66.8	125.7	57.9	(34.4)	88.0	52.0
Net profit attributable to owners of the parent	27.9	30.3	8.8	48.6	(9.0)	36.0	(26.0)
Basic earnings per share (yen)	70.15	76.34		122.39		90.61	
Net profit/ Equity attributable to owners of the parent (ROE)	5.9%	6.0%		10.2%		7.1%	

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

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

(Billions of yen)

	Q2 FY2018	Q2 FY2019	Change % YoY
Revenue	226.2	230.6	2.0
Cost of sales	55.6	56.3	1.2
Gross profit	170.6	174.3	2.2
SG&A expenses	99.0	47.0	(52.5)
R&D expenses	41.3	60.2	45.6
Other operating income/expenses	(0.6)	(0.3)	
Operating profit	29.6	66.8	125.7
Finance income/costs	8.0	(2.7)	
Profit before taxes	37.6	64.1	70.6
Net profit attributable to owners of the parent	27.9	30.3	8.8

*1 Exclude non-recurring items (impairment loss, changes in fair value of contingent consideration, etc.)

*2 "P/L on business transfer" and "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.)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q2 FY2018	Q2 FY2019
Net cash provided by operating activities	7.0	31.8
Net cash provided by (used in) investing activities	(0.6)	10.8
Net cash used in financing activities	(23.1)	(11.2)
Cash and cash equivalents at the end of period	137.6	164.7

4. Foreign Exchange Rates

	FY2018 Apr.-Sep.		FY2019 Apr.-Sep.		FY2019 assumption Average rate	Forex sensitivity FY2019 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	Period end rate	Average rate		Revenue	Core operating profit
Yen / USD	113.6	110.3	107.9	108.6	110.0	2.4	0.1
Yen / RMB	16.5	16.7	15.1	15.7	15.5	1.8	0.3

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization	Q2 FY2018	Q2 FY2019	Change	FY2019 (Forecast)	Change
Capital expenditures	7.2	5.4	(1.8)	9.0	(4.2)
Property, plant and equipment	3.7	5.1	1.4	9.5	2.2
Intangible assets	3.3	3.5	0.1	6.7	0.1

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

Major capital expenditure project in FY2019

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)

	Q2 FY2018	Q2 FY2019	Change	Change %
Revenue	226.2	230.6	4.4	2.0
Overseas revenue	141.3	149.4	8.1	5.7
% of Revenue	62.5%	64.8%		
Cost of sales	55.6	56.1	0.5	0.9
% of Revenue	24.6%	24.3%		
Gross profit	170.6	174.5	3.9	2.3
SG&A expenses	92.2	88.8	(3.4)	(3.7)
Labor costs	37.8	39.9	2.1	5.5
Advertising and promotion costs	11.8	10.4	(1.4)	(11.9)
Sales promotion costs	7.8	7.0	(0.7)	(9.3)
Amortization/Depreciation	3.9	5.5	1.6	41.5
Others	30.9	25.9	(5.0)	(16.1)
R&D expenses	41.3	41.0	(0.3)	(0.7)
% of Revenue	18.3%	17.8%		
Other operating income/expenses (Core Basis)	0.1	0.1	(0.0)	(33.8)
Core operating profit	37.2	44.8	7.6	20.5
Changes in fair value of contingent consideration *	(6.9)	41.8	48.6	
Other non-recurring items *	(0.7)	(19.7)	(19.0)	
Operating profit	29.6	66.8	37.2	125.7
Finance income	8.1	2.3	(5.8)	
Finance costs	0.1	5.0	4.9	
Profit before taxes	37.6	64.1	26.5	70.6
Income tax expenses	9.7	33.8	24.1	
Net profit	27.9	30.3	2.5	8.8
Net profit attributable to owners of the parent	27.9	30.3	2.5	8.8

	¥billion	Change	FX rate
Japan		(2.2)	
North America		6.8	(2.0)
China		2.6	(0.9)
Other Regions		(2.7)	
Other		(0.2)	

Changes in fair value of contingent consideration	Q2FY18	Q2FY19
LONHALA®MAGNAIR®	(0.9)	(0.5)
BBI	(2.5)	*28.1
Tolero	(3.5)	*14.1

* Decrease in fair value by revising business plans

• FY19: Impairment of intangible assets in North America (19.1)
• Foreign exchange gain /loss on financial assets denominated in USD
FY18: gain (Finance income)
FY19: loss (Finance costs)

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

* Negative number indicates loss.

2. Adjustments to Core Operating Profit

(Billions of yen)

Q2 FY2019 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	230.6	230.6	—	
Cost of sales	56.3	56.1	(0.2)	
Gross profit	174.3	174.5	0.2	
SG&A expenses	47.0	88.8	41.8	Changes in fair value of contingent consideration 41.8
R&D expenses	60.2	41.0	(19.1)	Impairment loss (19.1)
Other operating income	0.5	0.1	(0.5)	
Other operating expenses	0.8	—	(0.8)	
Operating profit	66.8	44.8	(22.1)	

III. Segment Information (Core Basis)

(Billions of yen)

Q2 FY2019 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	64.2	129.3	14.0	4.3	211.9	18.7	230.6
Cost of sales	26.3	11.4	2.3	1.5	41.6	14.5	56.1
Gross profit	37.9	117.9	11.7	2.8	170.3	4.2	174.5
SG&A expenses	24.6	55.9	4.2	1.6	86.2	2.6	88.8
Core segment profit	13.3	62.1	7.5	1.2	84.2	1.6	85.7
R&D expenses *1					40.6	0.4	41.0
Other operating income/expenses (Core basis)*2					0.1	(0.0)	0.1
Core operating profit					43.6	1.1	44.8

(Billions of yen)

Q2 FY2018 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	66.4	122.5	11.4	7.0	207.3	18.8	226.2
Cost of sales	25.9	9.7	1.9	3.5	41.0	14.6	55.6
Gross profit	40.5	112.8	9.5	3.6	166.4	4.2	170.6
SG&A expenses	25.1	58.1	4.4	1.9	89.4	2.7	92.2
Core segment profit	15.4	54.8	5.1	1.7	76.9	1.5	78.4
R&D expenses *1					40.8	0.5	41.3
Other operating income/expenses (Core basis)*2					0.1	0.0	0.1
Core operating profit					36.2	1.0	37.2

(Billions of yen)

FY2019 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	136.0	260.0	27.3	13.7	437.0	38.0	475.0
Cost of sales	63.0	22.7	5.0	4.9	95.6	29.4	125.0
Gross profit	73.0	237.3	22.3	8.8	341.4	8.6	350.0
SG&A expenses	53.3	116.0	9.0	3.2	181.5	5.5	187.0
Core segment profit	19.7	121.3	13.3	5.6	159.9	3.1	163.0
R&D expenses *1					85.0	1.0	86.0
Other operating income/expenses (Core basis)*2					0.0	0.0	0.0
Core operating profit					74.9	2.1	77.0

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

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

Note: FY2019 forecasts have been revised.

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	Q2 FY2018	Q2 FY2019	Change	Change %	FY2018 2nd Half	FY2018 FY2018	FY2019 2nd Half	FY2019 (Forecast)
Japan	66.4	64.2	(2.2)	(3.3)	62.9	129.3	71.8	[135.0] 136.0
North America	122.5	129.3	6.8	5.6	130.0	252.5	130.7	260.0
China	11.4	14.0	2.6	23.2	13.3	24.7	13.3	[28.3] 27.3
Other Regions	7.0	4.3	(2.7)	(38.0)	7.3	14.3	9.4	13.7

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q2 FY2018	Q2 FY2019	Change	Change %	FY2018 2nd Half	FY2018 FY2018	FY2019 2nd Half	FY2019 (Forecast)
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Japan

Promoted products

Trulicity® *1 Therapeutic agent for type 2 diabetes (Launch:Sep. 2015)	10.7	14.5	3.7	34.8	12.4	23.1	13.7	28.2
TRERIEF® Therapeutic agent for Parkinson's disease	7.9	8.3	0.4	4.6	7.7	15.7	8.8	17.1
REPLAGAL® Therapeutic agent for Anderson-Fabry disease	6.3	7.0	0.7	11.1	6.2	12.5	5.6	[11.8] 12.6
METGLUCO® Therapeutic agent for type 2 diabetes	5.1	4.9	(0.2)	(3.8)	4.9	10.1	4.4	9.3
SUREPOST® Therapeutic agent for type 2 diabetes	3.0	3.4	0.5	15.8	3.1	6.1	2.8	6.2
AmBisome® Therapeutic agent for systemic fungal infection	2.0	2.1	0.1	3.9	2.1	4.0	1.8	3.9
LONASEN® Tape Atypical antipsychotic (Launch:Sep. 2019)	—	0.1	0.1	—	—	—	1.7	1.8
Euqa®/EquMet® *2 Therapeutic agent for type 2 diabetes	—	—	—	—	—	—	16.0	16.0

Other products

AMLODIN® Therapeutic agent for hypertension and angina pectoris	4.7	4.0	(0.7)	(15.1)	4.4	9.1	3.5	7.5
LONASEN® tablet/powder Atypical antipsychotic	6.3	3.9	(2.4)	(38.4)	5.9	12.2	1.3	5.2
AIMIX® Therapeutic agent for hypertension	5.8	2.1	(3.7)	(63.3)	2.4	8.2	1.6	3.7
PRORENAL® Vasodilator	2.1	1.7	(0.4)	(19.3)	1.9	4.0	1.6	3.3
GASMOTIN® Gastroprokinetic	2.0	1.6	(0.4)	(18.8)	1.8	3.8	1.5	3.1
Authorized Generics	2.3	3.8	1.4	61.3	3.2	5.5	3.1	6.9

*1 Revenue of Trulicity® is shown by NHI price.

*2 Not including promotion fee revenue

Note: The forecasts of some products have been revised. Figures in parentheses [] are previous forecasts.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q2 FY2018	Q2 FY2019	Change	Change %	FY2018 2nd Half	FY2018	FY2019 2nd Half (Forecast)	FY2019 (Forecast)
North America								
LATUDA [®] Atypical antipsychotic	89.7	94.8	5.1	5.7	94.8	184.5	94.5	189.3
BROVANA [®] Therapeutic agent for COPD	16.7	16.5	(0.3)	(1.5)	17.0	33.7	16.5	33.0
APTIOM [®] Antiepileptic	9.7	10.9	1.2	12.0	10.8	20.5	11.6	22.5
LONHALA [®] MAGNAIR [®] Therapeutic agent for COPD (Launch: Apr. 2018)	0.4	1.4	1.0	241.9	1.0	1.4	2.8	4.2
XOPENEX [®] Therapeutic agent for asthma	2.1	2.0	(0.2)	(8.1)	2.5	4.6	2.1	4.1
China								
MEROPEN [®]	9.8	12.0	2.2	22.2	11.4	21.2	11.1	[24.0] 23.1
Other Regions								
MEROPEN [®]	5.1	2.8	(2.3)	(44.7)	2.8	7.9	4.2	7.0

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

(Millions of dollar)

品目	Q2 FY2018	Q2 FY2019	Change	Change %	FY2018 2nd Half	FY2018	FY2019 2nd Half (Forecast)	FY2019 (Forecast)
LATUDA [®]	813	873	60	7.4	850	1,663	848	1,721
BROVANA [®]	152	152	(0)	(0.0)	152	304	148	300
APTIOM [®]	88	100	12	13.7	97	185	105	205
LONHALA [®] MAGNAIR [®]	4	13	9	247.1	9	13	25	38
XOPENEX [®]	19	18	(1)	(6.7)	22	42	19	37

Note: The forecasts of some products have been revised. Figures in parentheses [] are previous forecasts.

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar.31 2019	Jun. 30 2019	Change	
Assets	834.7	805.0	(29.7)	
Non-current assets	461.4	422.4	(39.1)	
Property, plant and equipment	59.5	69.0	9.5	
Buildings and structures	36.9	36.5	(0.4)	
Machinery, equipment and carrier	10.7	8.3	(2.4)	
Tools, equipment and fixtures	4.9	4.7	(0.2)	
Land	5.0	5.0	(0.0)	
Construction in progress	2.0	1.9	(0.1)	Adopted IFRS 16 "Leases" from the beginning of FY2019
Right-of-use asset	—	12.6	12.6	
Goodwill	99.3	96.6	(2.7)	
Intangible assets	171.4	147.7	(23.7)	
Patent rights/Marketing rights	24.0	22.6	(1.4)	
In-process research & development	141.4	118.9	(22.5)	
Others	5.9	6.1	0.2	
Other financial assets	74.7	69.9	(4.8)	
Other non-current assets	5.8	5.3	(0.6)	
Deferred tax assets	50.7	33.9	(16.8)	Reversal of deferred tax assets in U.S.
Current assets	373.3	382.7	9.4	
Inventories	66.9	66.6	(0.3)	
Trade and other receivables	118.8	119.4	0.6	
Other financial assets	43.8	23.7	(20.0)	Decrease in short-term loan receivable
Other current assets	6.6	8.3	1.8	
Cash and cash equivalents	137.3	164.7	27.4	
Liabilities	336.6	293.4	(43.2)	
Non-current liabilities	138.4	100.2	(38.2)	
Bonds and borrowings	28.0	26.5	(1.5)	Total bonds and borrowings 30.9 → 29.5 [Repayment 1.5]
Other financial liabilities	80.4	45.9	(34.5)	
Retirement benefit liabilities	23.6	23.9	0.3	
Other non-current liabilities	6.4	3.9	(2.6)	
Deferred tax liabilities	—	0.0	0.0	
Current liabilities	198.2	193.2	(5.0)	
Bonds and borrowings	3.0	3.0	—	
Trade and other payables	49.2	48.9	(0.3)	
Other financial liabilities	8.7	13.7	5.1	
Income taxes payable	15.7	17.2	1.5	
Provisions	92.2	86.2	(5.9)	
Other current liabilities	29.4	24.1	(5.3)	
Equity	498.1	511.7	13.5	
Share capital	22.4	22.4	—	
Capital surplus	15.9	15.9	—	
Treasury shares	(0.7)	(0.7)	(0.0)	
Retained earnings	431.8	451.6	19.8	
Other components of equity	28.8	22.5	(6.3)	
Equity attributable to owners of the parent	498.1	511.7	13.5	

Goodwill	19/3	19/9
Sunovion	75.0	73.0
Oncology	24.3	23.6

IPR&D	19/3	19/9
apomorphine	55.2	53.6
BBI products	30.0	*27.4
Tolero products	44.4	*25.9
Others	11.9	12.0

*Decrease mainly due to impairment loss

Contingent consideration liabilities	19/3	19/9	Total probable payment (Max)
LONHALA®MAGNAIR®	8.9	9.1	\$210M
BBI	44.5	*15.3	\$1,390M
Tolero	27.9	*13.1	\$580M
Total	81.4	37.6	

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

* Decrease by revising business plans

FX rate 19/3 19/9
USD ¥111.0 ⇒ ¥107.9
RMB ¥16.5 ⇒ ¥15.1

VI. Changes in Quarterly Results

(Billions of yen)

	FY2018				FY2019	
	1Q	2Q	3Q	4Q	1Q	2Q
Revenue	115.9	110.2	120.7	112.4	117.5	113.1
Cost of sales	28.9	26.7	29.6	27.9	28.8	27.3
Gross profit	87.0	83.6	91.1	84.5	88.6	85.9
SG&A expenses	47.8	44.4	51.8	42.1	46.3	42.4
R&D expenses	20.9	20.5	20.6	20.9	20.0	21.0
Other operating income/expenses (Core Basis)	0.0	0.0	0.1	0.0	0.0	0.0
Core operating profit	18.4	18.7	18.7	21.4	22.3	22.5
Changes in fair value of contingent consideration (negative number indicates loss)	(2.5)	(4.4)	1.4	14.6	18.5	23.3
Other non-recurring items (negative number indicates loss)	(0.1)	(0.6)	(2.9)	(25.0)	(0.3)	(19.4)
Operating profit	15.8	13.8	17.2	11.1	40.4	26.4
Net profit attributable to owners of the parent	15.2	12.6	12.1	8.7	6.7	23.6

VII. Major Consolidated Subsidiaries (As of September 30, 2019)

Domestic	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Promo Co., Ltd.	
Establishment	October 1947	July 2010	June 1998	
Ownership	100%	100%	100%	
Number of employees	195	90	51	
Businesses	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	Manufacturing, and sales of veterinary medicines, etc.	Manufacturing and sales of pharmaceuticals, etc.	
Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Tolero Pharmaceuticals, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	June 2011	December 2003
Ownership	100%	100%	100%	100%
Number of employees	1,686	128	50	713
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

(Reference) Number of employees and MRs

	As of Mar. 31, 2018	As of Mar. 31, 2019	As of Sep. 30, 2019
consolidated	6,268	6,140	6,166
non-consolidated	3,402	3,067	3,062
MRs			
Japan (excluding managers)	1,130	1,120	1,140
(including managers)	1,260	1,240	1,260
U.S. (excluding managers)	830	720	720
(including managers)	930	820	810
China (excluding managers)	330	340	330
(including managers)	400	400	400

Number of contracted MRs is included in MRs.

VIII. Shareholder Positioning (As of September 30, 2019)

1. Total number of authorized shares: 1,500,000,000
2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 604,444)
3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	57	94,964	23.87
Securities companies	54	4,392	1.10
Other Japanese corporations	282	233,690	58.73
Corporations outside Japan, etc.	607	44,066	11.08
Individuals and others (Including treasury stock)	20,774	20,786	5.22
Total	21,774	397,900	100

Note: The numbers of shares are rounded down to the nearest thousand shares.

4. Major shareholders:

Shareholders	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	205,634	51.76
The Master Trust Bank of Japan, Ltd. (Trust account)	29,126	7.33
Inabata & Co., Ltd.	19,282	4.85
Japan Trustee Services Bank, Ltd. (Trust account)	11,701	2.95
Nippon Life Insurance Company	7,581	1.91
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Trust & Custody Services Bank, Ltd. (Securities investment trust account)	3,106	0.78
Japan Trustee Services Bank, Ltd. (Trust account 7)	3,058	0.77

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (604,444 stocks).

2: The numbers of shares held are rounded down to the nearest thousand shares.

IX. Development Pipeline (As of October 28, 2019)

- 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
SM-13496 (lurasidone hydrochloride)	Schizophrenia	Japan	Submitted in July 2019
	Bipolar depression	Japan	Submitted in July 2019
SEP-225289 (dasotraline)	Binge eating disorder (BED)	U.S.	Submitted in May 2019
	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Submitted in August 2017 Received Complete Response Letter in August 2018
		Japan	Phase 1
APL-130277 (apomorphine hydrochloride)	OFF episodes associated with Parkinson's disease	U.S.	Submitted in March 2018 Received Complete Response Letter in January 2019
LONASEN® (blonanserin)	(New usage: pediatric) Schizophrenia	Japan	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

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
RETHIO® (thiotepa)	(New indication) Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for malignant lymphoma * Development for the use of unapproved or off-labeled drugs	Japan	Submitted in March 2019
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) (Combination therapy) (Refractory or relapsed patients)	U.S.	Phase 2
	Myelodysplastic syndromes (MDS) (Combination therapy)	U.S.	Phase 1/2
	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed patients)	U.S.	Phase 1
	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed and refractory or relapsed patients)	Japan	Phase 1
DSP-7888 (adegramotide/ nelatimotide)	Glioblastoma (Combination therapy)	U.S., Japan	Phase 2 (Global clinical study)
	Myelodysplastic syndromes (MDS) (Monotherapy)	Japan	Phase 1/2
	Pediatric malignant gliomas (Monotherapy)	Japan	Phase 1/2
	Solid tumors (Combination therapy)	U.S.	Phase 1
TP-0903 (dubermatinib)	Chronic lymphocytic leukemia (CLL) (Monotherapy / Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy / Combination therapy)	U.S., Japan	Phase 1
DSP-0509	Solid tumors (Monotherapy / Combination therapy)	U.S.	Phase 1/2
TP-0184	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

3. Regenerative medicine / cell therapy

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
SB623	Chronic stroke	U.S.	Phase 2
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
PXL008 (imeglimin)	Type 2 diabetes	Japan	Phase 3

【Main revisions since the announcement of July 2019】

Changes	Brand name/ Product code (Generic name)	Proposed indication	Area	Development stage
Submitted	SM-13496 (lurasidone hydrochloride)	Schizophrenia, Bipolar depression	Japan	Submitted in July 2019
Newly added	DSP-0509	Solid tumors (Combination therapy)	U.S.	Started Phase 1/2 study
	TP-3654	Myelofibrosis (Monotherapy / Combination therapy)	U.S.	Started Phase 1 study
Deleted from the table due to the study completed	DSP-7888 (adegramotide/relatimotide)	Solid tumors, Hematologic malignancies (Monotherapy)	U.S.	Phase 1
Deleted from the table due to the study discontinued	BBI503 (amcasertib)	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
		Solid tumors (Monotherapy/Combination therapy)	U.S.	Phase 1/2
	BBI608+BBI503 (napabucasin +amcasertib)	Solid tumors (Combination therapy)	U.S.	Phase 1

X. Profiles of Major Products under Development (As of October 28, 2019)

1. Psychiatry & Neurology

dasotraline (SEP-225289) Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-225289 is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.
- Development stage:
Binge eating disorder (BED): NDA submitted in the U.S. in May 2019
Attention-deficit hyperactivity disorder (ADHD):
U.S.: NDA submitted in August 2017, Complete Response Letter received in August 2018, development strategy under consideration
Japan: Phase 1 in Japan

apomorphine hydrochloride (APL-130277) Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics), Formulation: sublingual film

- APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist, which is the molecule approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.
- Development stage: NDA submitted in the U.S. in March 2018.
Complete Response Letter received in January 2019

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 discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform and doesn't show affinity to dopamine D₂ receptors. The molecular target(s) responsible for the profile of effects is unknown, but may include agonist effects at serotonin 5-HT_{1A} and TAAR1 (trace amine-associated receptor 1) receptors. Results obtained with the preclinical models suggest that SEP-363856 may be able to treat the positive and negative symptoms of schizophrenia as well as Parkinson's disease psychosis. SEP-363856 is expected to have high efficacy in the treatment of schizophrenia and Parkinson's disease psychosis, with an improved safety profile compared with currently marketed antipsychotics.
- 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 BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.), 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 BioElectron Technology Corporation
(former Edison Pharmaceuticals, Inc.), 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. by BioElectron Technology Corporation
Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by BioElectron Technology Corporation
Amyotrophic lateral sclerosis (ALS): Phase 1 in Japan

SEP-4199

Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-4199 is investigated for the treatment of major depressive episodes associated with bipolar I disorder. The mechanism of action is not disclosed at this time.
- 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 D₂ 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 discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. 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 discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. Pre-clinical studies suggest that it showed rapid onset and long lasting antidepressant-like activity and neuroplasticity effects.
- 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 discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. Pre-clinical studies suggest that it 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.

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 which 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 2	Colorectal cancer (combination therapy)	U.S.	cetuximab, panitumumab, capecitabine	224
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 (combination therapy) (refractory or relapsed patients)	U.S.	cytarabine, mitoxantrone	TPI-ALV-201 (Zella 201)

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	TPI-ALV-102 (Zella 102)
Phase 1	Acute myeloid leukemia (combination therapy) (newly diagnosed patients)	U.S.	cytarabine, daunorubicin	TPI-ALV-101 (Zella 101)
	Acute myeloid leukemia (combination therapy) (newly diagnosed and refractory or relapsed patients)	Japan	newly diagnosed: cytarabine, daunorubicin refractory or relapsed : cytarabine, mitoxantrone	DC850101
	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	Myelodysplastic syndromes (monotherapy)*	Japan	-	DB650027
	Pediatric malignant gliomas (monotherapy)*	Japan	-	DB601001
Phase 1	Solid tumors (combination therapy)	U.S.	nivolumab, pembrolizumab	BBI-DSP7888-102CI

* Phase 2 stage

dubermatinib (TP-0903)

In-licensed from University of Utah, Formulation: oral

- TP-0903 is an 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:
Chronic lymphocytic leukemia (monotherapy / combination therapy): Phase 1/2 in the U.S.
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 inhibits activin A receptor type 1 (ACVR1, also known as ALK2) kinase, part of the transforming growth factor beta (TGF β) receptor superfamily. Mutations in the ACVR1 gene have been identified in various tumors, including diffuse intrinsic pontine glioma (DIPG; one of common pediatric brain tumors). TP-0184 has been shown to inhibit the growth of tumors harboring ACVR1 mutations in the pre-clinical studies.
- Development stage: 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.

3. Regenerative medicine / cell therapy

SB623 In-licensed from and co-developed with SanBio, Inc., Formulation: injection

- SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. SB623 is expected to be effective for chronic stroke, which has no effective treatments available, by promoting regeneration of central nerve cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, SB623 production can be scaled up from a single donor's cells, enabling delivery of uniform-quality products to a large number of stroke patients.
- Development stage: Chronic stroke: Phase 2 in the U.S. (Co-development with SanBio)

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

imeglimin (PXL008) In-licensed from and co-developed with Poxel SA, Formulation: oral

- Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. 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: Phase 3 in Japan (Co-development with Poxel)