Securities Code: 4506

Supplementary Financial Data (IFRS) for the Third Quarter of the Year Ending March 31, 2019

January 31, 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)

	Q3 FY2017	Q3 FY2018	Change % YoY	FY2017	Change % YoY	FY2018 (Forecast)	Change % YoY
Revenue	355.2	**346.9**	(2.3)	466.8	14.3	467.0	0.0
Cost of sales	88.4	**85.2**	(3.7)	112.3	18.9	112.5	0.1
Gross profit	266.7	**261.7**	(1.9)	354.5	13.0	354.5	0.0
SG&A expenses *1	134.8	**144.0**	6.8	186.2	8.6	190.5	2.3
R&D expenses	63.1	**62.0**	(1.7)	86.9	6.8	87.0	0.1
Other operating income/expenses (Core Basis)*2	9.2	**0.1**	(98.5)	9.2	178.2	0.0	—
Core operating profit	78.0	**55.9**	(28.4)	90.6	40.8	77.0	(15.0)
Changes in fair value of contingent consideration (negative number indicates loss)	(4.3)	**(5.5)**		6.4		(20.0)	
Other non-recurring items *3 (negative number indicates loss)	(2.8)	**(3.6)**		(8.8)		(4.0)	
Operating profit	70.9	**46.8**	(33.9)	88.2	118.9	53.0	(39.9)
Net profit attributable to owners of the parent	43.9	**40.0**	(8.9)	53.4	70.7	35.0	(34.5)
Basic earnings per share (yen)	110.48	100.60		134.53		88.10	
Net profit/ Equity attributable to owners of the parent (ROE)	10.1%	8.4%		12.4%		7.5%	

*1 Exclude non-recurring items (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 losses, etc.)

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

(Billions of yen)

	Q3 FY2017	Q3 FY2018	Change % YoY
Revenue	355.2	**346.9**	(2.3)
Cost of sales	88.4	**85.2**	(3.7)
Gross profit	266.7	**261.7**	(1.9)
SG&A expenses	139.1	**149.5**	7.4
R&D expenses	63.1	**62.0**	(1.7)
Other operating income/expenses	6.4	**(3.4)**	
Operating profit	70.9	**46.8**	(33.9)
Finance income/costs	2.9	**6.3**	
Profit before taxes	73.8	**53.2**	(27.9)
Net profit attributable to owners of the parent	43.9	**40.0**	(8.9)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	Q3 FY2017	Q3 FY2018
Net cash provided by operating activities	54.7	**19.2**
Net cash provided by (used in) investing activities	(7.1)	**(4.2)**
Net cash used in financing activities	(17.4)	**(27.6)**
Cash and cash equivalents at the end of period	136.8	**139.6**

4. Foreign Exchange Rates

	FY2017 Apr.-Dec.		FY2018 Apr.-Dec.		FY2018 assumption	Forex sensitivity FY2018 (Impact of yen depreciation by 1 yen)	
	Period end rate	Average rate	**Period end rate**	**Average rate**		Revenue	Core operating profit
Yen / USD	113.0	111.7	**111.0**	**111.2**	**110.0**	2.4	(0.0)
Yen / RMB	17.3	16.6	**16.2**	**16.6**	**16.5**	1.4	0.2

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization

	Q3 FY2017	Q3 FY2018	Change	FY2018 (Forecast)	Change
Capital expenditures	6.3	**10.3**	4.0	12.0	1.8
Property, plant and equipment	5.8	**5.5**	(0.3)	7.3	(0.3)
Intangible assets	3.6	**5.0**	1.4	8.0	2.8

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

Major capital expenditure project in FY2018

Workspace reform (Osaka/Tokyo head office), total budget ¥1.5billion, to be completed in FY2018

II. Consolidated Statement of Profit or Loss

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

(Billions of yen)

	Q3 FY2017	Q3 FY2018	Change	Change %
Revenue	355.2	**346.9**	(8.3)	(2.3)
Overseas revenue	208.9	**218.6**	9.7	4.6
% of Revenue	58.8%	**63.0%**		
Cost of sales	88.4	**85.2**	(3.2)	(3.7)
% of Revenue	24.9%	**24.6%**		
Gross profit	266.7	**261.7**	(5.0)	(1.9)
SG&A expenses	134.8	**144.0**	9.2	6.8
Labor costs	57.0	**57.1**	0.1	0.1
Advertising and promotion costs	16.7	**19.1**	2.4	14.4
Sales promotion costs	11.7	**11.5**	(0.2)	(1.8)
Amortization/Depreciation	4.6	**5.9**	1.3	28.7
Others	44.8	**50.4**	5.6	12.5
R&D expenses	63.1	**62.0**	(1.1)	(1.7)
% of Revenue	17.8%	**17.9%**		
Other operating income/expenses (Core Basis)	9.2	**0.1**	(9.0)	(98.5)
Core operating profit	78.0	**55.9**	(22.1)	(28.4)
Changes in fair value of contingent consideration *	(4.3)	**(5.5)**	(1.2)	
Other non-recurring items *	(2.8)	**(3.6)**	(0.7)	
Operating profit	70.9	**46.8**	(24.1)	(33.9)
Finance income	3.2	**6.5**	3.3	
Finance costs	0.4	**0.2**	(0.2)	
Profit before taxes	73.8	**53.2**	(20.6)	(27.9)
Income tax expenses	29.9	**13.2**	(16.7)	
Net profit	43.9	**40.0**	(3.9)	(8.9)
Net profit attibutable to owners of the parent	43.9	**40.0**	(3.9)	(8.9)

* Negative number indicates loss.

・Japan Segment (¥12.3B)
・North America Segment ¥8.2B
[incl. FX rate impact (¥0.9B)]
・China Segment ¥0.9B
[incl. FX rate impact (¥0.0B)]
・Other Regions Segment (¥0.4B)
・Other (¥4.7B)

・Increase mainly in cost for LATUDA®

・FY17: Profit on business transfer

Changes in fair value of contingent consideration	Q3 FY17	Q3 FY18
LONHALA®MAGNAIR®	(6.9)	2.7
BBI	3.8	(3.8)
Tolero	(1.1)	(4.3)

・Restructuring cost (FY17: 1.9 FY18: 2.6)

・Foreign exchange gain on financial assets denominated in USD

2. Adjustmnents to Core Operating Profit

(Billions of yen)

Q3FY2018 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	346.9	**346.9**	-	
Cost of sales	85.2	**85.2**	-	
Gross profit	261.7	**261.7**	-	
SG&A expenses	149.5	**144.0**	(5.5)	Changes in fair value of contingent consideration (5.5)
R&D expenses	62.0	**62.0**	-	
Other operating income	0.6	**0.1**	(0.5)	Other operating income except for "profit on business transfer" and "share of profit of associates accounted for using equity method" is excluded from core operating profit (0.5)
Other operating expenses	(4.1)	**(0.0)**	4.1	Other operating expenses including restructuring cost are excluded from core operating profit 4.1
Operating profit	46.8	**55.9**	9.0	

III. Segment Information (Core Basis)

(Billions of yen)

Q3 FY2018 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	100.6	190.6	16.3	10.2	317.8	29.1	346.9
Cost of sales	39.6	15.7	2.9	4.4	62.6	22.6	85.2
Gross profit	61.1	174.9	13.4	5.8	255.2	6.5	261.7
SG&A expenses	37.9	92.4	6.8	2.8	139.9	4.1	144.0
Core segment profit	**23.2**	**82.5**	**6.7**	**3.0**	**115.4**	**2.3**	**117.7**
R&D expenses *1					61.2	0.8	62.0
Other operating income/expenses (Core basis)*2					0.1	0.0	0.1
Core operating profit					**54.3**	**1.6**	**55.9**

(Billions of yen)

Q3 FY2017 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	113.0	182.4	15.4	10.6	321.3	33.8	355.2
Cost of sales	40.1	13.3	3.3	5.0	61.7	26.7	88.4
Gross profit	72.9	169.1	12.1	5.6	259.7	7.0	266.7
SG&A expenses	37.8	83.3	6.3	2.7	130.0	4.8	134.8
Core segment profit	**35.1**	**85.8**	**5.8**	**2.9**	**129.6**	**2.2**	**131.9**
R&D expenses *1					62.3	0.8	63.1
Other operating income/expenses (Core basis)*2					9.2	0.0	9.2
Core operating profit					**76.5**	**1.5**	**78.0**

(Billions of yen)

FY2018 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	130.0	261.3	23.3	14.4	429.0	38.0	467.0
Cost of sales	51.2	22.1	3.8	6.0	83.1	29.4	112.5
Gross profit	78.8	239.2	19.5	8.4	345.9	8.6	354.5
SG&A expenses	52.4	119.3	9.2	3.5	184.4	6.1	190.5
Core segment profit	**26.4**	**119.9**	**10.3**	**4.9**	**161.5**	**2.5**	**164.0**
R&D expenses *1					86.0	1.0	87.0
Other operating income/expenses (Core basis)*2					0.0	0.0	0.0
Core operating profit					**75.5**	**1.5**	**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

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	Q3 FY2017	**Q3 FY2018**	Change	Change %	Progress %	FY2018 (Forecast)
Japan	113.0	**100.6**	(12.3)	(10.9)	77.4	130.0
North America	182.4	**190.6**	8.2	4.5	72.9	261.3
China	15.4	**16.3**	0.9	5.8	70.1	23.3
Other Regions	10.6	**10.2**	(0.4)	(3.8)	70.7	14.4

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	Q3 FY2017	**Q3 FY2018**	Change	Change %	Progress %	FY2018 (Forecast)
Japan						
Promoted products						
Trulicity® * Therapeutic agent for type 2 diabetes (Launch:Sep. 2015)	11.8	**17.4**	5.6	47.5	76.3	22.8
TRERIEF® Therapeutic agent for Parkinson's disease	12.7	**12.2**	(0.5)	(3.7)	76.5	16.0
LONASEN® Atypical antipsychotic	10.0	**9.6**	(0.4)	(4.1)	77.0	12.5
REPLAGAL® Anderson-Fabry disease	9.0	**9.7**	0.7	7.8	78.1	12.4
METGLUCO® Therapeutic agent for type 2 diabetes	8.5	**7.8**	(0.7)	(7.9)	75.5	10.4
SUREPOST® Therapeutic agent for type 2 diabetes	3.9	**4.6**	0.8	20.6	78.7	5.9
AmBisome® Therapeutic agent for systemic fungal infection	3.4	**3.1**	(0.3)	(8.6)	72.4	4.3
Other products						
AMLODIN® Therapeutic agent for hypertension and angina pectoris	9.1	**7.2**	(2.0)	(21.4)	78.7	9.1
AIMIX® Therapeutic agent for hypertension	14.6	**7.1**	(7.4)	(51.0)	82.1	8.7
PRORENAL® Vasodilator	4.4	**3.2**	(1.2)	(26.9)	74.4	4.3
GASMOTIN® Gastroprokinetic	4.0	**3.0**	(1.0)	(24.2)	76.8	3.9
AVAPRO® Therapeutic agent for hypertension	7.6	**2.2**	(5.4)	(70.5)	77.5	2.9

* Revenue of Trulicity® is shown on NHI price basis.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	Q3 FY2017	**Q3 FY2018**	Change	Change %	Progress %	FY2018 (Forecast)
North Amrerica						
LATUDA® Atypical antipsychotic	135.1	**139.6**	4.5	3.3	72.2	193.5
BROVANA® Therapeutic agent for COPD	25.3	**25.3**	0.0	0.0	73.0	34.7
APTIOM® Antiepileptic (Launch: Apr. 2014)	11.4	**15.5**	4.2	36.5	76.9	20.2
LONHALA® MAGNAIR® Therapeutic agent for COPD (Launch: Apr. 2018)	—	**0.9**	0.9	—	77.6	1.2
Therapeutic agent for COPD (in-licensed 3 products) *	0.4	**0.4**	0.0	6.8	67.8	0.6
XOPENEX® Therapeutic agent for asthma	2.7	**3.3**	0.6	20.4	79.6	4.1
China						
MEROPEN®	13.3	**13.9**	0.6	4.4	69.5	20.0
Other Regions						
MEROPEN®	7.3	**6.5**	(0.7)	(10.1)	88.5	7.4

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

(Millions of dollar)

品目	Q3 FY2017	**Q3 FY2018**	Change	Change %	Progress %	FY2018 (Forecast)
LATUDA®	1,210	**1,256**	46	3.8	71.4	1,759
BROVANA®	227	**228**	1	0.5	72.4	315
APTIOM®	102	**140**	38	37.2	76.0	184
LONHALA® MAGNAIR®	—	**8**	8	—	76.1	11
Therapeutic agent for COPD (in-licensed 3 products) *	3	**4**	0	7.3	73.2	5
XOPENEX®	24	**29**	5	21.0	79.4	37

* UTIBRON®, SEEBRI®, ARCAPTA®

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar.31 2018	Dec. 31 2018	Change
Assets	**809.7**	**830.1**	**20.4**
Non-current assets	**461.1**	**481.9**	**20.8**
Property, plant and equipment	58.2	59.9	1.7
Buildings and structures	36.7	37.5	0.9
Machinery, equipment and carrier	9.7	10.7	1.0
Tools, equipment and fixtures	4.1	4.8	0.7
Land	5.1	5.0	(0.1)
Construction in progress	2.7	1.8	(0.9)
Goodwill	95.1	99.4	4.3
Intangible assets	189.7	194.8	5.1
Patent rights/Marketing rights	30.8	28.5	(2.3)
In-process research & development	153.9	160.5	6.6
Others	4.9	5.7	0.8
Other financial assets	71.0	84.1	13.1
Other non-current assets	5.5	5.6	0.1
Deferred tax assets	41.6	38.2	(3.4)
Current assets	**348.6**	**348.2**	**(0.4)**
Inventories	60.2	65.0	4.8
Trade and other receivables	113.0	121.5	8.5
Other financial assets	22.1	16.3	(5.8)
Other current assets	5.6	5.8	0.2
Cash and cash equivalents	147.8	139.6	(8.2)
Liabilities	**357.0**	**332.1**	**(24.9)**
Non-current liabilities	**146.7**	**149.3**	**2.5**
Bonds and borrowings	30.9	28.7	(2.2)
Other financial liabilities	88.4	94.5	6.1
Retirement benefit liabilities	20.7	20.8	0.1
Other non-current liabilities	6.6	5.2	(1.3)
Deferred tax liabilities	0.1	0.1	(0.0)
Current liabilities	**210.2**	**182.8**	**(27.4)**
Bonds and borrowings	16.5	3.0	(13.5)
Trade and other payables	58.7	52.0	(6.7)
Other financial liabilities	6.3	9.2	2.9
Income taxes payable	14.4	3.6	(10.8)
Provisions	84.4	90.2	5.7
Other current liabilities	30.0	24.9	(5.1)
Equity	**452.7**	**498.0**	**45.3**
Share capital	22.4	22.4	—
Capital surplus	15.9	15.9	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	396.0	425.2	29.2
Other components of equity	19.1	35.2	16.1
Equity attributable to owners of the parent	**452.7**	**498.0**	**45.3**

Goodwill	18/3	18/12
Sunovion	71.8	75.1
Oncology	23.3	24.3

IPR&D	18/3	18/12
apomorphine	71.1	74.3
BBI products	28.7	30.0
Tolero products	42.5	44.4
Others	11.7	11.9

Rise in stock price

Total interest-bearing debt
47.4 → 31.7
[Redemption 10.0
Repayment 5.7]

Contingent consideration liabilities *	18/3	18/12	Total probable payment (Max)
LONHALA®MAGNAIR®	10.3	8.2	$210M
BBI	46.4	52.3	$2,405M
Tolero	29.8	35.5	$580M
Total	86.6	96.0	

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

FX rate	18/3		18/12
USD	¥106.3	⇒	¥111.0
RMB	¥ 16.9	⇒	¥ 16.2

VI. Change in Quarterly Results

(Billions of yen)

	FY2017				FY2018		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Revenue	116.2	115.2	123.8	111.7	115.9	110.2	**120.7**
Cost of sales	27.5	29.5	31.4	23.9	28.9	26.7	**29.6**
Gross profit	88.7	85.7	92.4	87.8	87.0	83.6	**91.1**
SG&A expenses	44.2	43.1	47.5	51.3	47.8	44.4	**51.8**
R&D expenses	19.9	20.4	22.8	23.8	20.9	20.5	**20.6**
Other operating income/expenses (Core Basis)	0.2	8.9	0.1	(0.0)	0.0	0.0	**0.1**
Core operating profit	24.8	31.0	22.2	12.6	18.4	18.7	**18.7**
Changes in fair value of contingent consideration (negative number indicates loss)	7.1	(3.0)	(8.3)	10.7	(2.5)	(4.4)	**1.4**
Other non-recurring items (negative number indicates loss)	(0.2)	(0.2)	(2.5)	(6.0)	(0.1)	(0.6)	**(2.9)**
Operating profit	31.6	27.8	11.4	17.3	15.8	13.8	**17.2**
Net profit attributable to owners of the parent	24.6	20.7	(1.4)	9.7	15.2	12.6	**12.1**

VII. Major Consolidated Subsidiaries (As of Dec. 31, 2018)

Domestic	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.
Establishment	October 1947	July 2010	June 1998
Ownership	100%	100%	100%
Number of employees	187	82	42
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 and diagnostics, 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	1,701	112	47	688
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, 2017	As of Mar. 31, 2018	As of Dec. 31, 2018
consolidated		6,492	6,268	**6,208**
non-consolidated		3,572	3,402	**3,116**
MRs				
Japan	(excluding managers)	1,130	1,130	**1,120**
	(including managers)	1,260	1,260	**1,240**
U.S.	(excluding managers)	870	830	**720**
	(including managers)	990	930	**830**
China	(excluding managers)	340	330	**330**
	(including managers)	410	400	**400**

Number of contracted MRs is included in MRs.

VIII. Development Pipeline (As of January 31, 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	Phase 3
	Bipolar I depression	Japan	Phase 3
SEP-225289 （dasotraline）	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Submitted in August 2017 Received Complete Response Letter in August 2018
		Japan	Phase 1
	Binge eating disorder (BED)	U.S.	Phase 3
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 formulation – Transdermal patch) Schizophrenia	Japan	Submitted in July 2018
	(New usage: pediatric) Schizophrenia	Japan	Phase 3
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-363856	Schizophrenia	U.S.	Phase 2
		Japan	Phase 1
	Parkinson’s disease psychosis	U.S.	Phase 2
SEP-4199	Bipolar I depression	U.S., Japan	Phase 2 (Global clinical study)
DSP-2230	Neuropathic pain	U.S., Japan	Phase 1
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

2. Oncology (1/2)

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
DSP-1958 (thiotepa)	Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for Pediatric Solid Tumors (Monotherapy) * Development for the use of unapproved or off-labeled drugs	Japan	Submitted in July 2018
BBI608 (napabucasin)	Colorectal cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Pancreatic cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Malignant pleural mesothelioma (Combination therapy)	Japan	Phase 1/2
	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
	Hematologic malignancies (Monotherapy / Combination therapy)	U.S.	Phase 1
BBI503 (amcasertib)	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy/ Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan	Phase 1
DSP-2033 （alvocidib）	Acute myeloid leukemia (AML) (Combination therapy) (Refractory or relapsed patients)	U.S.	Phase 2 (Global clinical study)
	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

3. Oncology (2/2)

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
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, Hematologic malignancies (Monotherapy)	U.S.	Phase 1
	Solid tumors (Combination therapy)	U.S.	Phase 1
BBI608+BBI503 (napabucasin +amcasertib)	Solid tumors (Combination therapy)	U.S.	Phase 1
TP-0903	Chronic lymphocytic leukemia (CLL) (Monotherapy / Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy / Combination therapy)	U.S.	Phase 1
DSP-0509	Solid tumors (Monotherapy)	U.S.	Phase 1
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

4. 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

5. 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 October 2018】

Changes	Brand name/ Product code (Generic name)	Proposed indication	Area	Development stage
Approval	SM-13496 (lurasidone hydrochloride)	Schizophrenia	China	Approved in January 2019
Changed	SEP-4199	Bipolar I depression	Japan	Started Phase 2 study
New	SEP-378614	Treatment resistant depression	U.S.	Started Phase 1 study
	TP-3654	Solid tumors (Monotherapy)	U.S.	Started Phase 1 study
Completed	SM-13496 (lurasidone hydrochloride)	Bipolar maintenance (Not to be submitted for the indication)	Japan	Phase 3
Discontinued	DSP-6952 (minesapride)	IBS with constipation, Chronic idiopathic constipation	Japan	(Phase 2)

IX. Profile of Major Products under Development (As of January 31, 2019)

1. Psychiatry & Neurology

LATUDA® (lurasidone hydrochloride) Developed in-house, Formulation: oral

- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine H_1 or muscarinic M_1 receptors.
- Approved country and area:
  Schizophrenia 2010: U.S., 2012: Canada, 2013: Switzerland, 2014: Europe and Australia, 2016: Taiwan, Russia, Singapore, Thailand and Hong Kong, 2017: Brazil and UAE 2019: China
  Bipolar I depression 2013: U.S., 2014: Canada, 2017: Russia, Brazil and Taiwan
- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Colombia	Daiichi Sankyo
	Bipolar I depression		
	Schizophrenia	Turkey	In-house
	Bipolar I depression	Switzerland	
Phase 3	Schizophrenia	Japan	In-house
	Bipolar I depression	Japan	
	Schizophrenia	Korea	Bukwang Pharmaceutical

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:
  Attention-deficit hyperactivity disorder (ADHD): NDA submitted in the U.S. in August 2017
  Complete Response Letter received in August 2018
  Binge eating disorder (BED): Phase 3 in the U.S.
  Attention-deficit hyperactivity disorder (ADHD): 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 only molecule approved in the U.S. 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

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-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 D_2 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 2 in the U.S.
  Parkinson's disease psychosis: Phase 2 in the U.S.
  Schizophrenia: 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-2230 Developed in-house, Formulation: oral

- DSP-2230 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, DSP-2230 has demonstrated antiallodynic effects in preclinical models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce central nervous system or cardiovascular system side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.
- Development stage: Neuropathic pain: Phase 1 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 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, which has a high selectivity for Nav1.7 expressed in peripheral neuron, is expected not to 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.

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 designed to inhibit cancer stemness pathways such as STAT3. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI608 has been shown to inhibit STAT3 pathways, Nanog pathways and β-catenin pathways in pre-clinical studies.
- 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
	Pancreatic cancer (combination therapy)	U.S., Japan	gemcitabine + nab-paclitaxel	CanStem111P
Phase 2	Colorectal cancer (combination therapy)	U.S.	cetuximab, panitumumab, capecitabine	224
Phase 1 / 2	Solid tumors[*1] (combination therapy)	U.S.	paclitaxel	201
	Malignant pleural mesothelioma[*2] (combination therapy)	Japan	cisplatin + pemetrexed	D8807005
	Hepatocellular carcinoma[*2] (combination therapy)	U.S.	sorafenib	HCC-103
	Glioblastoma (combination therapy)	Canada	temozolomide	251
	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
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone, bortezomib, imatinib, Ibrutinib	103HEME
	Solid tumors (combination therapy)	U.S.	amcasertib	401-101

*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

amcasertib（BBI503） Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI503 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways, including Nanog, by targeting stemness kinases. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI503 has been shown to inhibit multiple kinases in pre-clinical studies.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy)	Canada	-	205b
	Gastrointestinal stromal tumor (monotherapy)	Canada	-	205c
Phase 1 / 2	Solid tumors* (monotherapy)	U.S.	-	101
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S.	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	201
Phase 1	Solid tumors (monotherapy), Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	DA101003
	Solid tumors (combination therapy)	U.S.	napabucasin	401-101

* Phase 2 stage: Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

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)
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, Hematologic malignancies (monotherapy)	U.S.	-	BBI-DSP7888-101
	Solid tumors (combination therapy)	U.S.	nivolumab, atezolizumab	BBI-DSP7888-102CI

* Phase 2 stage

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. TP0903 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.

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): Phase 1 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), part of the transforming growth factor beta (TGFβ) 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 to inhibit cancer stemness pathways such as STAT3. 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.

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 liver, muscles, and the pancreas, 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)