

Supplementary Financial Data  
for the Third Quarter of the Year Ending March 31, 2017

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January 27, 2017

Sumitomo Dainippon Pharma Co., Ltd.

- Forecasts provided in this document are based on the management's assumptions and beliefs, made in light of information available up to the day of announcement. Actual financial results may differ materially from those presented in this document, being dependent upon a number of factors.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

## I. Consolidated Financial Highlights

### 1. Consolidated Statement of Income

(Billions of yen)

	FY2015	FY2016	Change (%)	FY2015	Change (%)	FY2016		Change (%)
	Apr.-Dec.	Apr.-Dec.		(Forecast)		Note 3		
Net sales	304.5	305.5	0.3	403.2	8.6	[398.0]	404.0	0.2
Cost of sales	79.1	74.3	(6.0)	104.5	3.2	[95.5]	98.5	(5.7)
SG&A expenses	194.4	186.9	(3.8)	261.8	6.1	[256.5]	259.5	(0.9)
SG&A expenses less R&D costs	135.4	129.8	(4.2)	179.8	2.4	[173.5]	178.5	(0.7)
R&D costs	59.0	57.2	(3.0)	82.0	15.0	[83.0]	81.0	(1.3)
Operating income	31.1	44.2	42.3	36.9	58.7		46.0	24.6
Ordinary income	31.1	49.9	60.2	35.2	51.0	[44.0]	46.0	30.6
Net income attributable to owners of the parent	23.3	29.6	26.7	24.7	59.9	[25.0]	26.0	5.3

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Change (%) represents ratio of changes from the corresponding period of the previous year.

3: The forecasts have been revised. Figures in parentheses [ ] are previously disclosed forecasts. Change (%) represents ratio of changes to the revised forecasts.

EBITDA (Billions of yen)	46.6	63.9	55.8	65.5
Earnings per share (yen)	58.76	74.43	62.16	65.44
Return on equity (ROE)	5.1%	6.4%	5.5%	5.7%

### 2. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2015	FY2016
	Apr.-Dec.	Apr.-Dec.
Net cash provided by (used in) operating activities	32.5	(1.8)
Net cash provided by (used in) investing activities	26.8	(33.7)
Net cash provided in (used in) financing activities	(12.2)	9.9
Cash and cash equivalents at the end of period	167.7	107.4

### 3. Foreign Exchange Rates

(Billions of yen)

	FY2015 Apr.-Dec.		FY2016 Apr.-Dec.		FY2016 Assumed rate	Forex sensitivity FY2016 (Impact of yen appreciation by 1yen/USD)	
	End of period rate	Average rate	End of period rate	Average rate			
Yen / USD	120.5	121.8	116.5	106.6	108.0	Net Sales	(1.8)
Yen / RMB	18.3	19.3	16.8	15.9	16.0	Operating Income	0.2

Note: Net sales and Operating income in FY2016 Apr.- Dec. decreased by 23.1 billion yen and increased by 0.2 billion yen respectively, compared to FY2015 Apr.- Dec. due to exchange rate fluctuation.

### 4. Capital Expenditures

(Billions of yen)

	FY2015	FY2016	Change	FY2016	
	Apr.-Dec.	Apr.-Dec.		Forecast	Change
Capital expenditures	5.5	4.4	(1.1)	7.1	(0.3)

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

Major capital expenditure project continuing in FY2016

Establishment of cell processing center in Central Research Laboratories (Suita city in Osaka)

Total expenditures ¥3.6billion, to start operation in FY2017

### 5. Depreciation and Amortization

(Billions of yen)

	FY2015	FY2016	Change	FY2016	
	Apr.-Dec.	Apr.-Dec.		Forecast	Change
Property, plant and equipment	5.8	5.6	(0.3)	7.5	(0.3)
Intangible assets	3.5	3.7	0.2	4.9	0.1
Goodwill	4.5	4.0	(0.6)	5.7	(0.3)

6. Valuations and accounting procedures following the acquisition of Cynapsus (October 2016)  
(Millions of dollar)

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible Assets)	—	669	669	Capitalize (Amortize after launch)
Other assets & liabilities (Net)	(57)	(74)	(17)	Lisence fee payable in future and other liabilities
Goodwill	—	12	12	Amortization for 20 years
Total	(57)	607	664	

## II. Consolidated Statement of (Comprehensive) Income

### 1. Consolidated Statement of Income

(Billions of yen)

	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)			
			(B)-(A)	Change (%)	
Net sales	304.5	305.5	1.0	0.3	<ul style="list-style-type: none"> <li>•Japan Segment (¥5.9B)</li> <li>•North America Segment ¥6.3B</li> <li>[ incl. FX rate impact (¥20.4B) ]</li> <li>•China Segment (¥1.5B)</li> <li>[ incl. FX rate impact (¥2.7B) ]</li> </ul>
Overseas sales [% of net sales]	158.9 52.2%	164.3 53.8%	5.4	3.4	
Cost of sales [% of net sales]	79.1 26.0%	74.3 24.3%	(4.7)	(6.0)	<ul style="list-style-type: none"> <li>•Segment mix</li> <li>•Cost of sales decreased because unrealized profit of inventory on FY2015 FX rate realized in this period with stronger yen.</li> </ul>
Gross profit	225.5	231.2	5.7	2.5	
SG&A expenses	194.4	186.9	(7.5)	(3.8)	
Labor costs	57.6	55.1	(2.6)	(4.4)	•Decrease due to FX rate impact
Advertising and promotion costs	22.6	19.0	(3.6)	(16.1)	•Decrease in North America and FX rate impact
Sales promotion costs	10.4	9.1	(1.3)	(12.5)	
Amortization of goodwill, etc. *3	2.7	5.2	2.5	91.0	•Increase due to cost reversal from fair value adjustment of contingent consideration liabilities in FY2015
Other costs	42.1	41.4	(0.7)	(1.6)	
SG&A expenses less R&D costs	135.4	129.8	(5.7)	(4.2)	
R&D costs [% of net sales]	59.0 19.4%	57.2 18.7%	(1.8)	(3.0)	
Operating income	31.1	44.2	13.2	42.3	
Non-operating income	3.1	6.8	3.8		•Increase due to foreign exchange gains
Non-operating expenses	3.0	1.2	(1.8)		
Ordinary income	31.1	49.9	18.7	60.2	
Extraordinary income	6.1	4.8	(1.3)		
Gain on sales of investment securities	6.1	4.8	(1.3)		<ul style="list-style-type: none"> <li>•FY2015 : Sale of listed stock (North America)</li> <li>•FY2016 : Sale of listed stock (Japan)</li> </ul>
Extraordinary loss	0.3	10.0	9.7		
Business structure improvement expenses	—	10.0	10.0		•Additional retirement payments related to offering the early retirement program (Japan)
Impairment loss	0.3	—	(0.3)		
Income before income taxes	36.9	44.7	7.7	21.0	
Income taxes	13.6	15.1	1.5		
Net income	23.3	29.6	6.2	26.7	
Net income attributable to owners of the parent	23.3	29.6	6.2	26.7	

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Overseas sales includes exports of non-Pharmaceutical products.

\*3: Amortization of goodwill and patent rights, fair value change of contingent consideration liability

### 2. Consolidated Statement of Comprehensive Income

(Billions of yen)

	FY2015 Apr.-Dec.	FY2016 Apr.-Dec.	
Net income	23.3	29.6	
Other comprehensive income	3.8	4.6	
Unrealized gains (losses) on available-for-sale securities, net of tax	3.5	(4.2)	
Deferred gains or losses on hedges	(0.0)	0.0	
Foreign currency translation adjustments	(0.1)	8.6	<ul style="list-style-type: none"> <li>FX rate 16/3 16/12</li> <li>USD ¥112.6 ⇒ ¥116.5</li> <li>RMB ¥17.4 ⇒ ¥16.8</li> </ul>
Remeasurements of defined benefit plans	0.4	0.2	
Comprehensive income	27.2	34.2	

## 3. Segment Information (FY2016 Apr.-Dec.)

(Billions of yen)

	Pharmaceuticals Business					Subtotal	Other Business *2	Total
	Japan	North America	China	Other Regions				
Net sales	108.6	143.6	12.9	7.4	272.5	33.0	305.5	
Sales to customers	108.6	143.6	12.9	7.4	272.5	33.0	305.5	
Intersegment	0.0	—	—	—	0.0	(0.0)	—	
Cost of sales	35.1	7.0	2.3	3.6	48.0	26.3	74.3	
Gross profit	73.5	136.6	10.6	3.8	224.6	6.6	231.2	
SG&A expenses less R&D costs	42.2	74.5	6.0	2.2	124.9	4.8	129.8	
<i>Amortization included in above*1</i>	—	5.2	—	—	5.2	—	5.2	
Income (loss) of segment	31.2	62.1	4.6	1.6	99.6	1.8	101.4	
R&D costs*3	56.5					0.7	57.2	
Operating income	43.1					1.1	44.2	

## Segment Information (FY2015 Apr.-Dec.)

(Billions of yen)

	Pharmaceuticals Business					Subtotal	Other Business *2	Total
	Japan	North America	China	Other Regions				
Net sales	114.5	137.3	14.5	6.7	273.1	31.5	304.5	
Sales to customers	114.5	137.3	14.5	6.7	273.0	31.5	304.5	
Intersegment	0.0	—	—	—	0.0	(0.0)	—	
Cost of sales	35.0	12.3	2.6	3.8	53.7	25.3	79.1	
Gross profit	79.5	125.0	11.8	3.0	219.3	6.1	225.5	
SG&A expenses less R&D costs	44.1	78.6	6.2	1.9	130.7	4.7	135.4	
<i>Amortization included in above*1</i>	—	2.7	—	—	2.7	—	2.7	
Income (loss) of segment	35.4	46.4	5.7	1.1	88.6	1.4	90.0	
R&D costs*3	58.3					0.6	59.0	
Operating income	30.3					0.8	31.1	

## Segment Information (FY2016 Forecasts) \*4

(Billions of yen)

	Pharmaceuticals Business					Subtotal	Other Business *2	Total
	Japan	North America	China	Other Regions				
Net sales	139.5	193.5	16.8	10.8	360.6	43.4	404.0	
Sales to customers	139.5	193.5	16.8	10.8	360.6	43.4	404.0	
Intersegment	—	—	—	—	—	—	—	
Cost of sales	46.0	9.5	3.1	5.1	63.7	34.8	98.5	
Gross profit	93.5	184.0	13.7	5.7	296.9	8.6	305.5	
SG&A expenses less R&D costs	57.3	103.8	7.7	3.1	171.9	6.6	178.5	
<i>Amortization included in above*1</i>	—	7.3	—	—	7.3	—	7.3	
Income (loss) of segment	36.2	80.2	6.0	2.6	125.0	2.0	127.0	
R&D costs*3	80.0					1.0	81.0	
Operating income	45.0					1.0	46.0	

Notes \*1: Amortization of goodwill and patent rights, fair value change of contingent consideration liability

\*2: Including elimination of intersegment transaction.

\*3: R&amp;D costs are controlled globally and not allocated to each segment.

\*4: FY2016 forecasts have been revised.

#### 4. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)	
Japan	114.5	108.6	(5.9)	(5.2)	78.1	[139.0]	139.5
North America	137.3	143.6	6.3	4.6	76.4	[188.0]	193.5
China	14.5	12.9	(1.5)	(10.5)	77.0		16.8
Other Regions	6.7	7.4	0.7	9.8	68.4		10.8

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

#### 5. Sales of Major Products

##### Japan (Strategic Products)

(Invoice price sales basis, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)	
AIMIX <sup>®</sup> (irbesartan/amlodipine) Therapeutic agent for hypertension	11.9	13.1	1.1	9.6	81.1		16.1
LONASEN <sup>®</sup> (blonanserin) Atypical antipsychotic	9.8	10.1	0.3	2.7	72.8		13.8
TRERIEF <sup>®</sup> (zonisamide) Parkinson's disease drug	10.1	11.7	1.6	15.7	80.9		14.5

##### Japan (Other Products)

(Invoice price sales basis, Billions of yen)

REPLAGAL <sup>®</sup> (agalsidase alfa) Anderson-Fabry disease drug	7.9	8.2	0.3	3.9	77.7		10.5
AmBisome <sup>®</sup> (amphotericin B) Therapeutic agent for systemic fungal infection	3.3	3.5	0.2	5.5	81.1		4.3
AVAPRO <sup>®</sup> (irbesartan) Therapeutic agent for hypertension	8.4	8.1	(0.4)	(4.6)	80.5		10.0
SUREPOST <sup>®</sup> (repaglinide) Rapid-acting insulin secretagogue	2.7	3.3	0.6	24.3	72.1		4.6
METGLUCO <sup>®</sup> (metformin) Biguanide oral hypoglycemic	12.0	8.7	(3.4)	(27.9)	80.1		10.8
AMLODIN <sup>®</sup> (amlodipine) Therapeutic agent for hypertension and angina pectoris	12.9	10.2	(2.7)	(21.0)	83.7		12.2
PRORENAL <sup>®</sup> (limaprost alfadex) Vasodilator	6.9	5.2	(1.8)	(25.3)	74.2		7.0
GASMOTIN <sup>®</sup> (mosapride citrate) Gastroprokinetic	6.7	4.8	(1.9)	(28.3)	79.8		6.0
MEROPEN <sup>®</sup> (meropenem) Carbapenem antibiotic	5.0	3.4	(1.6)	(31.3)	76.2		4.5

## North America

(Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)
LATUDA <sup>®</sup> (lurasidone) Atypical antipsychotic	88.8	97.1	8.3	9.3	76.4	[127.1] 130.7
APTIOM <sup>®</sup> (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	5.4	8.0	2.6	48.6	65.2	[12.3] 11.8
BROVANA <sup>®</sup> (arformoterol tartrate) Long-acting beta-agonist	22.2	24.8	2.7	12.0	82.7	[30.0] 32.7
Ciclesonide * Inhaled corticosteroid / corticosteroid nasal spray	5.6	3.9	(1.6)	(29.3)	77.4	[5.1] 5.3
XOPENEX <sup>®</sup> (levalbuterol HCl) Short-acting beta-agonist	5.1	4.0	(1.1)	(22.1)	72.9	[5.5] 5.6
LUNESTA <sup>®</sup> (eszopiclone) Sedative hypnotic	3.6	(0.8)	(4.4)	—	—	[0.7] (0.4)
Industrial property revenues	3.7	3.5	(0.2)	(5.1)	88.8	[3.9] 4.0

## China

(Billions of yen)

Brand name (Generic name)	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)
MEROPEN <sup>®</sup> (meropenem)	12.2	11.3	(0.9)	(7.4)	78.3	14.4

## Other Regions

(Billions of yen)

Brand name (Generic name)	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)
MEROPEN <sup>®</sup> (meropenem) (Export)	3.7	4.3	0.5	13.8	69.8	6.1
Industrial property revenues	0.3	0.2	(0.1)	(29.8)	17.8	1.3

## (Reference) Sales of Products in North America Segment (based on local currency)

(Millions of dollar)

Brand name (Generic name)	FY2015 Apr.-Dec. (A)	FY2016 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2016 Forecasts(%)	FY2016 (Forecasts)
LATUDA <sup>®</sup> (lurasidone)	729	911	181	24.9	75.3	1,210
APTIOM <sup>®</sup> (eslicarbazepine acetate)	44	75	31	69.7	64.3	[117] 109
BROVANA <sup>®</sup> (arformoterol tartrate)	182	233	51	27.9	81.4	[286] 303
Ciclesonide *	46	37	(9)	(19.3)	75.6	49
XOPENEX <sup>®</sup> (levalbuterol HCl)	42	38	(5)	(11.0)	72.4	52
LUNESTA <sup>®</sup> (eszopiclone)	30	(7)	(37)	—	—	[7] (4)
Industrial property revenues	30	32	3	8.4	87.8	37

\* Total of 3 ciclesonide products (ALVESCO<sup>®</sup>, OMNARIS<sup>®</sup>, ZETONNA<sup>®</sup>)

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

Progress rate is against previous forecast.





LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2016 (A)	As of Dec. 31, 2016 (B)	(B)-(A)
[ Liabilities ]	261.2	277.2	16.0
Current liabilities:	179.7	211.6	31.9
Notes and accounts payable	12.2	15.0	2.8
Short-term loans payable	1.0	40.0	39.0
Current portion of bonds payable	10.0	—	(10.0)
Current portion of long-term loans payable	12.0	8.0	(4.0)
Income taxes payable	26.4	9.7	(16.0)
Reserve for bonuses	10.8	7.1	(3.8)
Reserve for sales returns	9.1	11.4	2.3
Reserve for sales rebates	49.2	59.3	10.1
Accounts payable-other	34.2	35.4	1.2
Others	14.9	25.8	10.9
Long-term liabilities:	81.5	65.6	(15.9)
Bonds payable	20.0	20.0	—
Long-term loans payable	8.0	—	(8.0)
Deferred tax liabilities	16.2	16.7	0.5
Liability for retirement benefit	16.2	14.9	(1.3)
Others	21.2	14.1	(7.0)
[ Net assets ]	446.5	473.7	27.2
Shareholders' equity:	379.0	401.8	22.8
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	341.4	364.2	22.8
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	67.5	71.9	4.4
Unrealized gains on available-for-sale securities, net of tax	25.3	20.9	(4.4)
Deferred gains or losses on hedges	(0.0)	0.0	0.0
Foreign currency translation adjustments	48.0	56.6	8.6
Remeasurement of defined benefit plans	(5.8)	(5.7)	0.2
Total liabilities and net assets	707.7	750.9	43.2

Total interest-bearing debt  
51.0→68.0  
[Short term loan +40.0]

← ·Decrease by payment

← ·Sales increase of Latuda  
Increase due to FX impact

FX rate    16/ 3            16/ 12  
USD    ¥ 112.6 ⇒ ¥ 116.5  
RMB    ¥ 17.4 ⇒ ¥ 16.8

#### IV. Quarterly Business Results

(Billions of yen)

	FY2015				FY2016		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Net sales	98.1	100.8	105.6	98.7	103.5	94.6	107.4
Cost of sales	26.4	25.7	27.0	25.4	23.9	24.0	26.5
SG&A expenses	67.3	62.7	64.4	67.4	65.0	58.5	63.4
SG&A expenses less R&D costs	47.2	42.6	45.6	44.3	45.7	40.1	44.0
R&D costs	20.1	20.1	18.8	23.1	19.3	18.4	19.4
Operating income (loss)	4.4	12.4	14.2	5.8	14.6	12.2	17.5
Non-operating income	0.9	1.6	0.6	0.2	1.0	0.4	5.5
Non-operating expenses	0.6	1.3	1.2	1.9	2.9	1.3	(3.0)
Ordinary income (loss)	4.7	12.8	13.6	4.1	12.7	11.2	26.0
Extraordinary income	6.0	0.1	(0.0)	0.0	—	3.8	1.0
Extraordinary loss	0.2	0.0	0.1	1.5	—	10.0	—
Income (Loss) before income taxes	10.6	12.8	13.5	2.6	12.7	5.0	27.0
Net income (loss) attributable to owners of the parent	5.9	7.3	10.1	1.4	8.4	2.6	18.6

Note: Cost of sales includes provision for (reversal of) reserve for sales returns.

#### V. Major Consolidated Subsidiaries (As of Dec. 31, 2016)

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	170	103	46
Businesses	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	Manufacturing, and sales of veterinary medicines, etc.	Manufacturing and sales of diagnostics, etc.
Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	December 2003
Ownership	100%	100%	100%
Number of employees	1,687	123	686
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

(Reference) Number of employees and MRs

	As of Mar. 31, 2015	As of Mar. 31, 2016	As of Dec. 31, 2016
consolidated	6,868	6,697	6,490
non-consolidated	4,126	4,000	3,615
MRs Japan	(excluding managers)	1,350	1,300
	(including managers)	1,530	1,460
MRs U.S.	(excluding managers)	700	710
	(including managers)	800	810
MRs China	(excluding managers)	370	300
	(including managers)	470	370

VI. Development Pipeline (As of January 27, 2017)

■ Submitted

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	Canada	Submitted in October 2014 Approved indication in the U.S.: Epilepsy (Adjunctive therapy / Monotherapy) Approved indication in Canada: Epilepsy (Adjunctive therapy)
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Submitted in December 2015 Approved in the U.S., Canada, Europe, etc.
	SUN-101 Inhalant	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	Submitted in July 2016 From the former Elevation Pharmaceuticals

■ Phase 3 (1/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 3	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Japan	Approved in the U.S., Canada, Europe, etc.
			Bipolar I depression			Approved in the U.S. and Canada
			Bipolar maintenance			

■ Phase 3 (2/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks	
Phase 3	BBI608 Oral	napabucasin	Gastric and Gastro-esophag eal junction adenocarcinoma (Combination therapy)	In-house	U.S., Canada, Japan, etc.	Global clinical study	
			Colorectal cancer (Combination therapy)		U.S., Canada, Japan		
			Pancreatic cancer (Combination therapy)		U.S.		
			Non-small cell lung cancer (Combination therapy)				
	SEP-225289 Oral	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.		
	APL-130277 Sublingual film	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	In-house	U.S.		From the former Cynapsus Therapeutics
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	Japan		Co-development with Nitto Denko Approved formulation: Oral
LONASEN® Transdermal Patch	(New formulation – Transdermal patch) Schizophrenia						
TRERIEF® Oral	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	In-house	Japan			

■ Phase 2 / 3

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 2 / 3	EPI-743 Oral	vatiquinone	Leigh syndrome	Edison Pharma- ceuticals	Japan	Phase 2 / 3 study completed, development strategy under consideration
	SEP-225289 Oral	dasotraline	Pediatric attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
Binge eating disorder (BED)						

■ Phase 2

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 2	BBI608 Oral	napabucasin	Colorectal cancer (Combination therapy)	In-house	U.S., Canada	
	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	Japan	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	Japan	
	BBI503 Oral	amcasertib	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	In-house	Canada	
			Hepatocellular carcinoma, Cholangio carcinoma (Monotherapy)			
			Gastrointestinal stromal tumor (Monotherapy)			
			Ovarian cancer (Monotherapy)		U.S.	
	SB623 Injection	TBD	Chronic Stroke	SanBio	U.S.	Co-development with SanBio
	EPI-589 Oral	TBD	Parkinson's disease	Edison Pharmaceuticals	U.S.	Conducted by Edison Pharmaceuticals
			Amyotrophic lateral sclerosis (ALS)			
SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.		
		Parkinson's disease psychosis				
alvocidib Injection	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven)	Sanofi	U.S.		

■ Phase 1 / 2

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1 / 2	BBI608 Oral	napabucasin	Solid tumors (Combination therapy)	In-house	U.S., Canada	Phase 2 : Ovarian cancer, Breast cancer, Melanoma, etc.
			Malignant pleural mesothelioma (Combination therapy)		Japan	Phase 2
			Glioblastoma (Combination therapy)		Canada	
			Hepatocellular carcinoma (Combination therapy)		U.S.	
			Solid tumors (Combination therapy)		U.S.	
			Gastrointestinal cancer (Combination therapy)		U.S., Canada	
	BBI503 Oral	amcasertib	Solid tumors (Monotherapy)	In-house	U.S., Canada	Phase 2 : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.
			Hepatocellular carcinoma (Combination therapy)		U.S.	
			Solid tumors (Combination therapy)		U.S., Canada	
	DSP-7888 Injection	TBD	Myelodysplastic syndromes	In-house	Japan	Phase 2
			Pediatric malignant gliomas			
	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharma- ceutical	Japan	Independent development after April 2013

■ Phase 1 (1/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1	WT4869 Injection	TBD	Solid tumors	Joint research with Chugai Pharma- ceutical	Japan	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors, Hematologic malignancies	Joint research with Chugai Pharma- ceutical	U.S.	Independent development after April 2013
			Solid tumors		Japan	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S., Japan	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	Japan	
	BBI608 Oral	napabucasin	Pancreatic cancer (Combination therapy)	In-house	U.S.	
			Hematologic malignancies (Monotherapy / Combination therapy)			
			Hepatocellular carcinoma (Combination therapy)		Japan	
	DSP-3748 Oral	TBD	Cognitive impairment associated with schizophrenia	In-house	U.S.	
	BBI503 Oral	amcasertib	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	In-house	Japan	

■ Phase 1 (2/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1	BBI608+BBI503 Oral	napabucasin amcasertib	Solid tumors (Combination therapy)	In-house	U.S.	
	DSP-7888 Injection	TBD	Solid tumors, Hematologic malignancies	In-house	U.S.	
	DSP-1200 Oral	TBD	Treatment- resistant depression	In-house	U.S.	
	DSP-1958 Injection	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT)	In-house	Japan	Development for the use of unapproved and off-labelled drugs
	DSP-6745 Oral	TBD	Parkinson's disease psychosis	In-house	U.S.	
	TP-0903 Oral	TBD	Solid tumors	In-house	U.S.	

[Main revisions since the announcement of October 2016]

Napabucasin (Pancreatic cancer / Combination therapy)  
 Alvocidib (Acute myeloid leukemia / Combination therapy)  
 Napabucasin (Glioblastoma / Combination therapy)  
 DSP-6745 (Parkinson's disease psychosis)  
 TP-0903 (Solid tumors)

Newly added in Phase 3 in the U.S.  
 Newly added in Phase 2 in the U.S.  
 Started Phase 2 of Phase 1/2 in Canada  
 Newly added in Phase 1 in the U.S.  
 Newly added in Phase 1 in the U.S.



### Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed indications	Status of development
vosaroxin AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003. Multinational Phase 3 study completed by Sunesis (Sunesis' product code: SNS-595) in October 2014. Sunesis submitted an MAA in Europe for Acute Myeloid Leukemia (AML) in December 2015.
amrubicin hydrochloride (CALSED <sup>®</sup> )	Small cell lung cancer	Out-licensed to Celgene (former Pharmion) for the U.S. and European territories in June 2005. Phase 3 study completed in the U.S. and Europe by Celgene.
lurasidone hydrochloride SM-13496	Schizophrenia Bipolar disorder	Out-licensed to Daiichi Sankyo for rights or option rights for commercialization in four South American countries in January 2014. Daiichi Sankyo submitted an NDA in Venezuela for schizophrenia in December 2014 and in Brazil for schizophrenia and bipolar I depression in September 2015.

[Main revisions since the announcement of October 2016]

Lurasidone hydrochloride (SM-13496)

DKSH obtained approvals for schizophrenia in Thailand in October 2016 and Hong Kong in November 2016 following Singapore. Deleted from the list since DKSH obtained approvals in all partnering territory.

## VII. Profile of Major Products under Development (As of January 27, 2017)

### LATUDA® (lurasidone hydrochloride) Atypical antipsychotic

- Developed in-house
- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT<sub>1A</sub> receptor and has no appreciable affinity for histamine or muscarinic 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  
Bipolar I depression 2013: U.S., 2014: Canada

- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Venezuela	Daiichi Sankyo
	Schizophrenia, Bipolar I depression	Brazil	
	Schizophrenia	Turkey	In-house
	Schizophrenia	China	
Phase 3	Schizophrenia	Japan	
	Bipolar I depression, Bipolar maintenance	Japan	

### glycopyrronium bromide (SUN-101) Chronic obstructive pulmonary disease (COPD)

- Developed in-house (Sunovion Pharmaceuticals Inc., From the former Elevation Pharmaceuticals)
- SUN-101 is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, proprietary investigational eFlow nebulizer closed system. It is a portable, hand-held nebulizer system and is designed to deliver the medication in approximately two to three minutes. A standard jet nebulizer typically takes up to 10 minutes. Currently, there are no LAMAs delivered via nebulizer that are approved by the U.S. Food and Drug Administration (FDA). SUN-101 is a nebulizer delivered LAMA for COPD at the most advanced development stage.
- Development stage: NDA submitted in the U.S. in July 2016

### napabucasin (BBI608) Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is an orally-administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways by targeting 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	Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy)	U.S., Canada, Japan, etc.	paclitaxel	BRIGHTER
	Colorectal cancer (combination therapy)	U.S., Canada, Japan	FOLFIRI <sup>*2</sup> , FOLFIRI <sup>*2</sup> + bevacizumab	CanStem303C
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel	CanStem111P
	Non-small cell lung cancer (combination therapy)	U.S.	paclitaxel	CanStem43L
Phase 2	Colorectal cancer (combination therapy)	U.S., Canada	cetuximab, panitumumab, capecitabine	224
Phase 1 / 2	Solid tumors <sup>*1</sup> (combination therapy)	U.S., Canada	paclitaxel	201
	Malignant pleural mesothelioma (combination therapy)	Japan	cisplatin + pemetrexed	D8807005
	Hepatocellular carcinoma (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 <sup>*2</sup> , FOLFOX <sup>*2</sup> + bevacizumab, CAPOX <sup>*2</sup> , FOLFIRI <sup>*2</sup> , FOLFIRI <sup>*2</sup> + bevacizumab, regorafenib, irinotecan	246
Phase 1	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel, FOLFIRINOX <sup>*2</sup> , FOLFIRI <sup>*2</sup> , irinotecan liposome injection + fluorouracil + leucovorin	118
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone, bortezomib, imatinib, lbrutinib	103HEME
	Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	D8808001
	Solid tumors (combination therapy)	U.S.	amcasertib	401-101

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

\*2 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

### **dasotraline (SEP-225289) Attention-deficit hyperactivity disorder (ADHD), Binge eating disorder (BED)**

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- 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 by dosing at 24-hour intervals.
- Development stage:  
Adult attention-deficit hyperactivity disorder (ADHD): Phase 3 in the U.S.  
Pediatric attention-deficit hyperactivity disorder (ADHD): Phase 2 / 3 in the U.S.  
Binge eating disorder (BED): Phase 2 / 3 in the U.S.

**apomorphine hydrochloride (APL-130277)      Parkinson's disease**

- Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics)
- APL-130277 is a sublingual film formulation including apomorphine, a dopamine agonist, which is the only molecule approved in the United States 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: Phase 3 in the U.S.

**vatiquinone (EPI-743)      Mitochondrial disease**

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

**obeticholic acid (DSP-1747)      Nonalcoholic steatohepatitis (NASH), Primary biliary cholangitis (PBC)**

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is an agonist for farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. The compound is expected to be effective for hepatic dysfunction and hepatic fibrosis associated with an increase of bile acid in the liver.
- Development stage: Phase 2 in Japan for NASH, Phase 2 for PBC is under consideration.

**DSP-6952      IBS with constipation, Chronic idiopathic constipation**

- Developed in-house
- DSP-6952 is an enterokinetic agent with a high affinity for serotonin 5-HT<sub>4</sub> receptor where it has partial agonist effects. DSP-6952 is expected to be effective for IBS with constipation and chronic idiopathic constipation by increasing complete spontaneous bowel movement.
- Development stage: Phase 2 in Japan

**amcasertib (BBI503)      Cancer**

- Developed in-house (Boston Biomedical, Inc.)
- 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	Renal cell carcinoma, Urothelial carcinoma (monotherapy)	Canada	-	205a
	Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy)	Canada	-	205b
	Gastrointestinal stromal tumor (monotherapy)	Canada	-	205c
	Ovarian cancer (monotherapy)	U.S.	-	205GYN-M

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 1 / 2	Solid tumors* (monotherapy)	U.S., Canada	-	101
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S., Canada	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 : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

### **SB623                      Stroke**

- In-licensed from and co-developed with SanBio, Inc.
- 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 that 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: Phase 2 in the U.S.

### **EPI-589                      Neurodegenerative diseases**

- In-licensed from Edison Pharmaceuticals, Inc.
- EPI-589 is expected to show efficacy by removing the oxidative stress which 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 Edison Pharmaceuticals, Inc.  
Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by Edison Pharmaceuticals, Inc.

### **SEP-363856                      Schizophrenia, Parkinson's disease psychosis**

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-363856 is a psychotropic agent with a novel mechanism of action, and doesn't show affinity to dopamine D<sub>2</sub> receptors. The molecular target(s) responsible for the profile of effects is unknown, but may include agonist effects at serotonin 5-HT<sub>1A</sub> 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, while improving patients' QOL.
- Development stage:  
Schizophrenia: Phase 2 in the U.S.  
Parkinson's disease psychosis: Phase 2 in the U.S.  
Schizophrenia: Phase 1 in Japan

**alvocidib            Cancer**

- In-licensed from Sanofi S.A.
- Alvocidib targets cyclin-dependent kinase (CDK) 9, 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:  
Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven): Phase 2 in the U.S.

**DSP-7888            Cancer**

- Developed in-house
- 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 cancers 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:  
Myelodysplastic syndromes (MDS): Phase 2 of Phase 1 / 2 in Japan  
Pediatric malignant gliomas: Phase 2 of Phase 1 / 2 in Japan  
Solid tumors, Hematologic malignancies : Phase 1 in the U.S.

**WT4869            Cancer**

- Developed in-house (Joint research with Chugai Pharmaceutical Co.,Ltd.)
- WT4869 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. WT4869 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific cytotoxic T-lymphocytes that attack WT1-expressing cancer cells.
- Development stage:  
Myelodysplastic syndromes (MDS): Phase 1 / 2 in Japan  
Solid tumors: Phase 1 in Japan

**WT2725            Cancer**

- Developed in-house (Joint research with Chugai Pharmaceutical Co.,Ltd.)
- WT2725 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. WT2725 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific cytotoxic T-lymphocytes that attack WT1-expressing cancer cells.
- Development stage:  
Solid tumors, Hematologic malignancies: Phase 1 in the U.S.  
Solid tumors: Phase 1 in Japan

**DSP-2230            Neuropathic pain**

- Developed in-house
- 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 animal 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: Phase 1 in the U.K., the U.S. and Japan

**DSP-3748            Cognitive impairment associated with schizophrenia (CIAS)**

- Developed in-house
- DSP-3748 is a positive allosteric modulator (PAM) of  $\alpha 7$ -type nicotinic acetylcholine receptor ( $\alpha 7$ nAChR). DSP-3748 is expected to treat patients with cognitive impairment associated with schizophrenia (CIAS) by enhancing the ACh transmission via  $\alpha 7$ nAChR. DSP-3748 is expected to cause less desensitization compared with a conventional agonist.
- Development stage: Phase 1 in the U.S.

**DSP-1200            Treatment-resistant depression**

- Developed in-house
- DSP-1200 is a dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and adrenergic  $\alpha 2A$  receptors antagonist. DSP-1200 is expected to enhance acetylcholine, dopamine, and noradrenaline release in prefrontal cortex, which would provide stronger improvement of depressive symptoms and cognitive function, compared with the existing SDAs (serotonin-dopamine antagonists). DSP-1200 is expected to have fewer safety concerns compared with marketed antipsychotics, because it has low or negligible affinities for receptors associated with safety profile.
- Development stage: Phase 1 in the U.S.

**DSP-6745            Parkinson's disease psychosis**

- Developed in-house
- DSP-6745 is a serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>2C</sub> 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<sub>2</sub> receptors.
- Development stage: Phase 1 in the U.S.

**TP-0903            Cancer**

- Developed in-house (Tolero Pharmaceuticals, Inc.)
- TP-0903 is AXL receptor tyrosine kinase inhibitor. AXL is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 is expected to be an anti-cancer agent for a variety of cancer types.
- Development stage:  
Solid tumors: Phase 1 in the U.S.