Securities Code: 4506

Supplementary Financial Data for the Second Quarter of the Year Ending March 31, 2018

October 30, 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)

	FY2016 Apr.-Sep.	FY2017 Apr.-Sep.	Change (%)	FY2016	Change (%)	FY2017 (Forecast)	Change (%)
Net sales	198.1	240.5	21.4	411.6	2.1	[464.0] 474.0	15.1
Cost of sales	47.9	60.5	26.4	100.1	(4.2)	[117.0] 118.5	18.4
SG&A expenses	123.5	132.7	7.5	258.8	(1.1)	[282.0] 283.5	9.5
SG&A expenses less R&D costs	85.7	92.3	7.7	178.0	(1.0)	[194.0] 194.5	9.3
R&D costs	37.7	40.4	7.0	80.8	(1.5)	[88.0] 89.0	10.1
Operating income	26.7	47.2	76.7	52.8	42.9	[65.0] 72.0	36.5
Ordinary income	23.9	48.4	102.6	54.3	54.3	[65.0] 72.0	32.5
Net income attributable to owners of the parent	10.9	34.9	219.4	29.0	17.4	[44.0] 47.0	62.1

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)	33.1	58.1	72.8	92.0
Earnings per share (yen)	27.49	87.81	72.97	118.3
Return on equity (ROE)	2.5%	7.3%	6.4%	9.8%

2. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2016 Apr.-Sep.	FY2017 Apr.-Sep.
Net cash provided by operating activities	13.5	44.8
Net cash provided by (used in) investing activities	31.6	(6.6)
Net cash used in financing activities	(26.5)	(12.4)
Cash and cash equivalents at the end of period	140.4	132.2

3. Foreign Exchange Rates

(Billions of yen)

	FY2016 Apr.-Sep.		FY2017 Apr.-Sep.		FY2017 Assumed rate	Forex sensitivity FY2017 (Impact of yen depreciation by 1 yen)	
	End of peiod rate	Average rate	End of peiod rate	Average rate		Net Sales	Operating Income
Yen / USD	101.1	105.2	112.7	111.1	110.0	2.3	(0.2)
Yen / RMB	15.1	15.9	17.0	16.4	16.5	1.2	0.1

4. Capital Expenditures

(Billions of yen)

	FY2016 Apr.-Sep.	FY2017 Apr.-Sep.	Change	FY2017	
				Forecast	Change
Capital expenditures	3.2	3.1	(0.1)	9.7	3.0

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

Major capital expenditure project continuing in FY2017
Establishment of a cell processing center in Central Research Labolatories (Suita city in Osaka)
Total expenditures ¥3.6billion, to start operation in FY2017

5. Depreciation and Amortization

(Billions of yen)

	FY2016 Apr.-Sep.	FY2017 Apr.-Sep.	Change	FY2017	
				Forecast	Change
Property, plant and equipment	3.7	3.5	(0.2)	6.7	(0.8)
Intangible assets	2.4	2.4	(0.0)	5.8	0.9
Goodwill	2.6	3.3	0.7	6.4	0.8

II. Consolidated Statement of (Comprehensive) Income

1. Consolidated Statement of Income

(Billions of yen)

	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)
Net sales	198.1	240.5	42.4	21.4
Overseas sales	106.0	145.8	39.8	37.5
[% of net sales]	53.5%	60.6%		
Cost of sales	47.9	60.5	12.6	26.4
[% of net sales]	24.2%	25.2%		
Gross profit	150.2	179.9	29.7	19.8
SG&A expenses	123.5	132.7	9.2	7.5
Labor costs	37.0	37.6	0.6	1.8
Advertising and promotion costs	12.3	10.2	(2.1)	(17.1)
Sales promotion costs	5.9	7.5	1.5	25.9
Amortization of goodwill, etc. *3	3.4	5.0	1.6	46.8
Other costs	27.0	31.9	4.9	18.2
SG&A expenses less R&D costs	85.7	92.3	6.6	7.7
R&D costs	37.7	40.4	2.6	7.0
[% of net sales]	19.1%	16.8%		
Operating income	26.7	47.2	20.5	76.7
Non-operating income	1.4	1.8	0.5	
Non-operating expenses	4.2	0.7	(3.5)	
Ordinary income	23.9	48.4	24.5	102.6
Extraordinary income	3.8	—	(3.8)	
Gain on sales of investment securities	3.8	—	(3.8)	
Extraordinary loss	10.0	—	(10.0)	
Business structure improvement expenses	10.0	—	(10.0)	
Income before income taxes	17.7	48.4	30.7	173.5
Income taxes	6.8	13.5	6.7	
Net income	10.9	34.9	24.0	219.4
Net income attributable to owners of the parent	10.9	34.9	24.0	219.4

・Japan Segment ¥2.3B
・North America Segment ¥35.9B
[incl. FX rate impact ¥6.7B]
・China Segment ¥2.3B
[incl. FX rate impact ¥0.4B]
・Other Regions ¥1.5B

・Japan segment + ¥3.7B
Increase in sales / Cost of sales ratio increase due to product mix
・North America segment +¥7.4B
incl. FX impact related to unrealized gain of inventory +¥4.1B

・Decrease mainly related to LATUDA in North America

・Increase mainly related to new COPD products in North America

・Decrease in foreign exchange loss

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)

	FY2016 Apr.-Sep.	FY2017 Apr.-Sep.
Net income	10.9	34.9
Other comprehensive income	(35.2)	4.8
Unrealized gains (losses) on available-for-sale securities, net of tax	(5.1)	2.6
Deferred gains or losses on hedges	(0.1)	0.0
Foreign currency translation adjustments	(30.1)	2.3
Remeasurements of defined benefit plans	0.1	(0.1)
Comprehensive income	(24.2)	39.7

FX rate 17/ 3 17/9
USD ¥ 112.2 ⇒ ¥ 112.7
RMB ¥ 16.3 ⇒ ¥ 17.0

3. Segment Information (FY2017 Apr.-Sep.) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	72.9	127.3	11.5	6.8	218.5	22.0	240.5
Sales to customers	72.8	127.3	11.5	6.8	218.4	22.0	240.5
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	26.2	11.5	2.3	3.1	43.1	17.4	60.5
Gross profit	46.7	115.8	9.2	3.7	175.4	4.6	179.9
SG&A expenses less R&D costs	25.0	58.5	3.7	1.9	89.1	3.2	92.3
*Amortization included in above*1*	—	*5.0*	—	—	*5.0*	—	*5.0*
Income (loss) of segment	21.7	57.3	5.5	1.8	86.3	1.4	87.6
R&D costs*3					39.9	0.5	40.4
Operating income					46.4	0.8	47.2

Segment Information (FY2016 Apr.-Sep.) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	70.6	91.4	9.2	5.3	176.4	21.7	198.1
Sales to customers	70.5	91.4	9.2	5.3	176.4	21.7	198.1
Intersegment	0.0	—	—	—	0.0	(0.0)	—
Cost of sales	22.5	4.1	1.4	2.5	30.5	17.3	47.9
Gross profit	48.1	87.2	7.8	2.7	145.8	4.4	150.2
SG&A expenses less R&D costs	28.5	49.0	3.5	1.5	82.5	3.2	85.7
*Amortization included in above*1*	—	*3.4*	—	—	*3.4*	—	*3.4*
Income (loss) of segment	19.6	38.3	4.3	1.2	63.4	1.1	64.5
R&D costs*3					37.3	0.5	37.7
Operating income					26.1	0.6	26.7

Segment Information (FY2017 Forecasts) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	141.6	251.8	19.7	15.9	429.0	45.0	474.0
Sales to customers	141.6	251.8	19.7	15.9	429.0	45.0	474.0
Intersegment	—	—	—	—	—	—	—
Cost of sales	51.0	21.4	3.8	6.4	82.6	35.9	118.5
Gross profit	90.6	230.4	15.9	9.5	346.4	9.1	355.5
SG&A expenses less R&D costs	52.0	124.2	7.8	3.7	187.7	6.8	194.5
*Amortization included in above*1*	—	*13.8*	—	—	*13.8*	—	*13.8*
Income (loss) of segment	38.6	106.2	8.1	5.8	158.7	2.3	161.0
R&D costs*3					88.0	1.0	89.0
Operating income					70.7	1.3	72.0

Notes *1: Amortization of goodwill and patent rights, change in fair value of contingent consideration liability
*2: Including elimination of intersegment transaction.
*3: R&D costs are controlled globally and not allocated to each segment.
*4: FY2017 forecasts have been revised.

4. Sales of Pharmaceuticals Business (Sales to customers) (Billions of yen)

	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
Japan	70.5	72.8	2.3	3.3	70.3	140.8	68.8	[139.2]	141.6
North America	91.4	127.3	35.9	39.3	106.5	197.9	124.5	[245.6]	251.8
China	9.2	11.5	2.3	25.4	8.4	17.6	8.2	[18.3]	19.7
Other Regions	5.3	6.8	1.5	28.1	6.3	11.6	9.1		15.9

5. Sales of Major Products

Japan (Promoted Products) (Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
AIMIX® Therapeutic agent for hypertension	8.3	9.2	0.9	11.1	8.8	17.1	8.3		17.5
TRERIEF® Therapeutic agent for Parkinson's disease	7.6	8.1	0.5	6.3	7.5	15.1	7.9		16.0
LONASEN® Atypical antipsychotic	6.7	6.5	(0.1)	(1.8)	6.2	12.8	6.7		13.2
METGLUCO® Biguanide oral hypoglycemic	5.7	5.6	(0.1)	(2.1)	5.5	11.2	5.7		11.3
REPLAGAL® Anderson-Fabry disease	5.3	5.8	0.5	9.0	5.4	10.7	5.5		11.3
Trulicity® * GLP-1 receptor agonist (Launch:Sep. 2015)	2.1	7.1	5.0	235.2	4.6	6.8	7.4	[11.0]	14.5
AVAPRO® Therapeutic agent for hypertension	5.3	5.1	(0.2)	(4.0)	5.1	10.3	2.9		8.0
SUREPOST® Rapid-acting insulin secretagogue	2.2	2.5	0.3	13.9	2.2	4.3	2.8		5.3
AmBisome® Therapeutic agent for systemic fungal infection	2.2	2.2	(0.0)	(1.1)	2.2	4.4	2.3		4.5

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

Japan (Other Products) (Invoice price sales basis, Billions of yen)

AMLODIN® Therapeutic agent for hypertension and angina pectoris	6.7	6.0	(0.8)	(11.6)	6.3	13.0	4.6		10.6
PRORENAL® Vasodilator	3.5	2.9	(0.6)	(16.8)	3.1	6.5	2.2		5.1
GASMOTIN® Gastroprokinetic	3.2	2.6	(0.6)	(18.8)	2.8	6.0	2.4		5.0
MEROPEN® Carbapenem antibiotic	2.3	1.8	(0.5)	(23.2)	2.0	4.3	1.5	[4.1]	3.3

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

North America (Billions of yen)

Brand name Therapeutic indication	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
LATUDA® Atypical antipsychotic	61.4	86.5	25.0	40.8	74.5	135.9	91.5	[169.2]	178.0
BROVANA® Long-acting beta-agonist	16.1	16.4	0.3	1.7	17.0	33.1	18.0		34.4
APTIOM® Antiepileptic (Launch: Apr. 2014)	5.0	7.3	2.3	46.8	6.6	11.6	9.4		16.7
Ciclesonide Inhaled corticosteroid / corticosteroid nasal spray	2.4	1.4	(1.0)	(40.0)	2.7	5.1	—	[1.7]	1.4
XOPENEX® Short-acting beta-agonist	2.6	1.9	(0.8)	(28.9)	2.5	5.1	1.3		3.2
New products for COPD *	—	0.2	0.2	—	0.0	0.0	0.5	[4.1]	0.7
Industrial property revenues	2.4	9.8	7.4	313.9	1.7	4.1	0.5	[9.5]	10.3

China (Billions of yen)

Brand name	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
MEROPEN®	8.0	10.0	2.0	24.7	7.3	15.4	6.9	[15.8]	16.9

Other Regions (Billions of yen)

Brand name	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
MEROPEN® (Export)	2.9	4.8	1.8	62.5	3.8	6.8	4.4		9.2
Industrial property revenues	0.2	0.0	(0.2)	(85.6)	1.0	1.3	2.5		2.5

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

Brand name	FY2016 Apr.-Sep. (A)	FY2017 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2016		FY2017 (Forecasts)		
					2nd Half	Full Year	2nd Half	Full Year	
LATUDA®	584	779	195	33.4	670	1,254	839	[1,538]	1,618
BROVANA®	153	147	(6)	(3.6)	152	305	166		313
APTIOM®	47	66	18	39.1	59	107	86		152
Ciclesonide	23	13	(10)	(43.2)	25	47	-	[16]	13
XOPENEX®	25	17	(8)	(32.6)	22	47	12		29
New products for COPD *	—	2	2	—	0	0	4	[37]	6
Industrial property revenues	22	88	65	292.1	15	37	5	[86]	93

* Four products (UTIBRON™, SEEBRI™, ARCAPTA®, glycopyrronium bromide(SUN-101, under review by FDA))

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

III. Consolidated Balance Sheet

ASSETS

(Billions of yen)

	As of Mar. 31, 2017 (A)	As of Sep. 30, 2017 (B)	(B)-(A)
[Assets]	794.0	828.5	34.6
Current assets:	376.5	406.2	29.8
Cash and time deposits	71.4	92.3	20.9
Notes and accounts receivable	110.9	118.3	7.3
Marketable securities	34.2	39.9	5.7
Inventories	68.8	66.9	(1.9)
Deferred tax assets	61.0	59.1	(1.9)
Short-term loans receivable	16.7	14.7	(2.1)
Others	13.4	15.2	1.8
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)
Fixed assets:	417.5	422.3	4.8
Property, plant and equipment:	59.3	58.3	(1.0)
Buildings and structures	38.6	38.0	(0.6)
Machinery, equipment and carriers	6.8	6.6	(0.1)
Land	6.3	6.3	0.0
Construction in progress	3.1	2.9	(0.2)
Others	4.6	4.5	(0.0)
Intangible assets:	304.3	300.6	(3.7)
Goodwill	90.6	87.9	(2.7)
In-process research & development	194.0	194.9	1.0
Others	19.8	17.8	(2.0)
Investments and other assets:	53.9	63.4	9.4
Investment securities	48.0	58.0	10.0
Asset for retirement benefit	0.6	0.8	0.2
Deferred tax assets	0.7	0.1	(0.6)
Others	4.6	4.5	(0.1)
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)
Total assets	794.0	828.5	34.6

Amortization (¥3.3B)
FX rate ¥0.6B

FX rate ¥1.0B

Increase by purchase and valuation

Accounts receivable turnover period (in months)	3.23	2.95

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2017 (A)	As of Sep. 30, 2017 (B)	(B)-(A)
[Liabilities]	333.3	332.5	(0.8)
Current liabilities:	228.4	236.3	7.8
Notes and accounts payable	14.5	15.8	1.3
Short-term loans payable	40.0	40.0	—
Current portion of bonds payable	10.0	20.0	10.0
Current portion of long-term loans payable	8.0	—	(8.0)
Income taxes payable	8.8	11.9	3.1
Reserve for bonuses	11.0	10.1	(0.9)
Reserve for sales returns	11.3	11.7	0.4
Reserve for sales rebates	65.7	72.8	7.2
Accounts payable-other	37.0	35.0	(2.0)
Others	22.2	18.9	(3.3)
Long-term liabilities:	104.8	96.3	(8.6)
Bonds payable	10.0	—	(10.0)
Deferred tax liabilities	32.6	33.3	0.7
Liability for retirement benefit	13.5	13.6	0.1
Others	48.8	49.4	0.6
[Net assets]	460.7	496.0	35.4
Shareholders' equity:	401.2	431.7	30.5
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	363.6	394.1	30.5
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	59.4	64.3	4.8
Unrealized gains on available-for-sale securities, net of tax	18.4	21.1	2.6
Deferred gains or losses on hedges	(0.0)	0.0	0.0
Foreign currency translation adjustments	45.7	48.1	2.3
Remeasurement of defined benefit plans	(4.7)	(4.8)	(0.1)
Total liabilities and net assets	794.0	828.5	34.6

Total interest-bearing debt
68.0 → 60.0 [Repayment 8.0]

← Increase in LATUDA sales

FX rate 17/ 3 17/ 9
USD ¥ 112.2 ⇒ ¥ 112.7
RMB ¥ 16.3 ⇒ ¥ 17.0

IV. Quarterly Business Results

(Billions of yen)

	FY2016				FY2017	
	Q1	Q2	Q3	Q4	Q1	Q2
Net sales	103.5	94.6	107.4	106.1	116.3	124.2
Cost of sales	23.9	24.0	26.5	25.7	29.5	31.0
SG&A expenses	65.0	58.5	63.4	71.9	67.0	65.7
SG&A expenses less R&D costs	45.7	40.1	44.0	48.2	47.1	45.2
R&D costs	19.3	18.4	19.4	23.7	19.9	20.4
Operating income (loss)	14.6	12.2	17.5	8.5	19.7	27.5
Non-operating income	1.0	0.4	5.5	(3.3)	0.7	1.2
Non-operating expenses	2.9	1.3	(3.0)	0.7	0.6	0.1
Ordinary income (loss)	12.7	11.2	26.0	4.5	19.8	28.6
Extraordinary income	—	3.8	1.0	0.9	—	—
Extraordinary loss	—	10.0	—	2.9	—	—
Income (Loss) before income taxes	12.7	5.0	27.0	2.5	19.8	28.6
Net income (loss) attributable to owners of the parent	8.4	2.6	18.6	(0.6)	14.4	20.5

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

V. Major Consolidated Subsidiaries (As of Sep 30, 2017)

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	177	99	48
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.	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	1,727	155	32	678
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, 2016	As of Mar. 31, 2017	As of Sep. 30, 2017
consolidated		6,697	6,492	6,548
non-consolidated		4,000	3,572	3,592
MRs Japan	(excluding managers)	1,300	1,130	1,140
	(including managers)	1,460	1,260	1,270
MRs U.S.	(excluding managers)	710	870	860
	(including managers)	810	990	970
MRs China	(excluding managers)	300	340	340
	(including managers)	370	410	420

Number of contracted MRs is included in MRs.

VI. Shareholder Positioning (As of September 30, 2017)

1. Total number of authorized shares: 1,500,000,000

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 600,993)

3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	60	82,665	20.78
Securities companies	72	4,900	1.23
Other Japanese corporations	332	235,566	59.20
Corporations outside Japan, etc.	536	43,178	10.85
Individuals and others (Including treasury stock)	29,872	31,589	7.94
Total	30,872	397,900	100

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

4. Major shareholders:

Shareholders	Status of ownership	
	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	203,034	51.10
Inabata & Co., Ltd.	23,682	5.96
The Master Trust Bank of Japan, Ltd. (Trust account)	13,735	3.46
Japan Trustee Services Bank, Ltd. (Trust account)	11,076	2.79
Nippon Life Insurance Company	7,581	1.91
Japan Trustee Services 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
Japan Trustee Services Bank, Ltd. (Trust account 9)	4,129	1.04
Sumitomo Dainippon Pharma Employee shareholders' association	3,496	0.88

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (600,993 stocks).
2: The numbers of shares held are rounded down to the nearest thousand shares.

Vll. Development Pipeline (As of October 30, 2017)

■ **Submitted**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	Canada	Submitted in October 2014 Approved indication in Canada: Epilepsy (Adjunctive therapy)
			(New usage: pediatric) Epilepsy (Monotherapy/ Adjunctive therapy)			Submitted in September 2017
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Submitted in December 2015 Approved in the U.S., Canada, Europe, etc.
			(New usage: pediatric) Bipolar l depression		U.S., Canada	Submitted in May 2017
	SUN-101 Inhalant	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	Submitted in July 2016 Resubmitted in June 2017 From the former Elevation Pharmaceuticals
	SEP-225289 Oral	Dasotraline	Adult, Pediatric attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	Submitted in August 2017
	TRERIEF® Oral	Zonisamide	(New indication) Parkinsonism in dementia with Lewy bodies (DLB)	In-house	Japan	Submitted in August 2017

■ **Phase 3**

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., Canada, etc.
			Bipolar maintenance			
	BBI608 Oral	napabucasin	Colorectal cancer (Combination therapy)	In-house	U.S., Canada, Japan	Global clinical study
			Pancreatic cancer (Combination therapy)		U.S., Japan	
	SEP-225289 Oral	Dasotraline	Binge eating disorder (BED)	In-house	U.S.	
	APL-130277 Sublingunal film	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	In-house	U.S.	From the former Cynapsus Therapeutics
	LONASEN® Oral	blonanserin	(New usage: pediatric) Schizophrenia	In-house	Japan	
	LONASEN® Transdermal Patch		(New formulation – Transdermal patch) Schizophrenia			Co-development with Nitto Denko Approved formulation: Oral

■ **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	BioElectron (former Edison Pharma-ceuticals)	Japan	Phase 2 / 3 study completed, development strategy under consideration

■ **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 Pharma-ceuticals	Japan	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	Japan	
	BBI503 Oral	amcasertib	Hepatocellular carcinoma, Cholangio carcinoma (Monotherapy)	In-house	Canada	
			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	BioElectron (former Edison Pharma-ceuticals)	U.S.	Conducted by BioElectron
			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)	Sanofi	U.S., Canada, etc.	Refractory or relapsed patients
	DSP-7888 Injection	adegramotide/ nelatimotide	Glioblastoma (Combination therapy)	In-house	U.S., Canada, Japan, etc.	Global clinical study

■ **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)			
			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	adegramotide/ nelatimotide	Myelodysplastic syndromes (Monotherapy)	In-house	Japan	Phase 2
			Pediatric malignant gliomas (Monotherapy)			
	WT4869 Injection	TBD	Myelodysplastic syndromes (Monotherapy)	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 (Monotherapy)	Joint research with Chugai Pharma-ceutical	Japan	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	Joint research with Chugai Pharma-ceutical	U.S.	Independent development after April 2013
			Solid tumors (Monotherapy)		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	
	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	adegramotide/ nelatimotide	Solid tumors, Hematologic malignancies (Monotherapy)	In-house	U.S., Canada	
			Solid tumors (Combination therapy)		U.S.	
	DSP-1958 Injection	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT) (Monotherapy)	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 (Monotherapy)	In-house	U.S.	
	SEP-378608 Oral	TBD	Bipolar disorder	In-house	U.S.	
	alvocidib Injection	alvocidib	Acute myeloid leukemia (AML) (Combination therapy)	Sanofi	U.S.	Newly diagnosed patients

[Main revisions since the announcement of July 2017]

APTIOM® (Addition of pediatric usage / Epilepsy) Deleted due to approval in the U.S. (September 2017)
dasotraline (Adult and pediatric ADHD) Submitted in the U.S. (August 2017)
TRERIEF® (New indication / Parkinsonism in DLB) Submitted in Japan (August 2017)
DSP-7888 (Solid tumors / Combination therapy) Started Phase 1 study in the U.S.
alvocidib (AML / Combination therapy / Newly diagnosed patients) Started Phase 1 study in the U.S.
DSP-1200 (Treatment-resistant depression) Deleted due to discontinued development in the U.S.

VIII. Profile of Major Products under Development (As of October 30, 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_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
  Bipolar I depression　2013: U.S., 2014: Canada, 2017: Russia and Brazil
- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Venezuela	Daiichi Sankyo
	Schizophrenia	Turkey	In-house
	Schizophrenia	China	
	Bipolar I depression,	Taiwan	Standard Chem. & Pharm.
Phase 3	Schizophrenia	Japan	In-house
	Bipolar I depression, Bipolar maintenance	Japan	
	Schizophrenia	Korea	Bukwang Pharmaceutical

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 proprietary investigational eFlow® closed system nebulizer. 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. NDA resubmitted in June 2017.

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 over the 24-hour dosing interval.
- Development stage:
  Adult and pediatric attention-deficit hyperactivity disorder (ADHD):NDA submitted in the U.S. in August 2017.
  Binge eating disorder (BED): Phase 3 in the U.S.

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	Colorectal cancer (combination therapy)	U.S., Canada, 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., Canada	cetuximab, panitumumab, capecitabine	224
Phase 1 / 2	Solid tumors*1 (combination therapy)	U.S., Canada	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
	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 Phase 2

*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

apomorphine hydrochloride (APL-130277)　Parkinson's disease

- Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics)
- 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:　Phase 3 in the U.S.

vatiquinone (EPI-743)　Mitochondrial disease

- In-licensed from BioElectron Technology Corporation (former 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, 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

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_4 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	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 BioElectron Technology Corporation (former 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 BioElectron Technology Corporation
  Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by BioElectron Technology Corporation

SEP-363856 Schizophrenia, Parkinson's disease psychosis

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-363856 is an antipsychotic agent with a novel mechanism of action, 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, 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 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 (AML) (combination therapy) (refractory or relapsed patients)	U.S., Canada, etc.	cytarabine, mitoxantrone	TPI-ALV-201
Phase 1	Acute myeloid leukemia (AML) (combination therapy) (newly diagnosed patients)	U.S.	cytarabine, daunorubicin	TPI-ALV-101

adegramotide / nelatimotide (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 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., Canada, Japan, etc.	bevacizumab	BBI-DSP7888-201G
Phase 1/2	Myelodysplastic syndromes (MDS) * (monotherapy)	Japan	-	DB650027
	Pediatric malignant gliomas * (monotherapy)	Japan	-	DB601001
Phase 1	Solid tumors, Hematologic malignancies (monotherapy)	U.S., Canada	-	BBI-DSP7888-101
	Solid tumors (combination therapy)	U.S.	nivolumab, atezolizumab	BBI-DSP7888-102CI

* Phase 2

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) (monotherapy): Phase 1 / 2 in Japan

  Solid tumors (monotherapy): 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 (monotherapy): Phase 1 in the U.S.
  Solid tumors (monotherapy): 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 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: Phase 1 in the U.K., the U.S. and Japan

DSP-6745 Parkinson's disease psychosis

- Developed in-house
- 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: Phase 1 in the U.S.

TP-0903 Cancer

- Developed in-house (Tolero Pharmaceuticals, Inc.)
- 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 effects 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:
  Solid tumors (monotherapy): Phase 1 in the U.S.

SEP-378608 Bipolar disorder

- Developed in-house
- SEP-378608 is a novel CNS-active molecule discovered using preclinical models phenotypic screening platform. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of brain associated with the regulation of mood.
- Development stage:
  Bipolar disorder: Phase 1 in the U.S.