Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Investors Meeting Presentation for Q2 FY2018

(April 1 to September 30, 2018)

October 31, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Disclaimer Regarding Forward-looking Statements

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.
Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

Financial Results for Q2 FY2018

Financial Results for Q2 FY2018 (Core Basis)

Billions of yen

	Q2 FY2017 Results	Q2 FY2018 Results	Change			Q2 FY2018 (Apr.-Sep.)		FY2018	
			Value	FX rate impact	%	Forecasts	Achieve-ment %	Previous forecasts	Progress %
Revenue	231.4	226.2	(5.2)	(0.7)	(2.2)	230.0	98.3	467.0	48.4
Cost of sales	57.0	55.6	(1.4)	(1.5)	(2.5)	53.5	103.9	110.0	50.5
Gross profit	174.3	170.6	(3.8)	0.8	(2.2)	176.5	96.6	357.0	47.8
SG&A expenses *1	87.4	92.2	4.8	(0.4)	5.5	94.5	97.5	195.0	47.3
R&D expenses	40.3	41.3	1.0	(0.2)	2.6	41.0	100.8	85.0	48.6
Other operating income and expenses *2 (Core basis)	9.1	0.1	(9.0)	–	(99.2)	–	–	–	–
Core operating profit	55.8	37.2	(18.6)	1.4	(33.4)	41.0	90.6	77.0	48.2
Changes in fair value of contingent consideration (negative number indicates loss)	4.1	(6.9)	(10.9)			(8.5)		(19.0)	
Other non-recurring items *3 (negative number indicates loss)	(0.4)	(0.7)	(0.3)			(0.5)		(5.0)	
Operating profit	59.5	29.6	(29.9)		(50.2)	32.0	92.5	53.0	55.9
Net profit attributable to owners of the parent	45.3	27.9	(17.5)		(38.5)	22.0	126.7	35.0	79.6

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

FX rates: Q2FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.4
Q2FY2018 Results : 1US$ = ¥ 110.3, 1RMB = ¥16.7
FY2018 Previous Forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.5

Revenue of Major Products in Japan

Billions of yen

	Q2 FY2017 Results	Q2 FY2018 Results	Change		Q2 FY2018 (Apr.-Sep.)	
			Value	%	Forecasts	Achievement %
Trulicity® *	7.1	10.7	3.6	50.8	10.8	99.5
TRERIEF®	8.1	7.9	(0.1)	(1.6)	7.2	110.1
LONASEN®	6.5	6.3	(0.2)	(3.5)	6.4	98.4
REPLAGAL®	5.8	6.3	0.6	9.5	6.2	102.2
METGLUCO®	5.6	5.1	(0.5)	(8.2)	5.6	91.3
SUREPOST®	2.5	3.0	0.5	21.2	2.9	102.7
AmBisome®	2.2	2.0	(0.2)	(9.8)	2.2	89.7
Promoted products Total	37.7	41.4	3.7	9.7	41.3	100.2
AIMIX®	9.2	5.8	(3.5)	(37.5)	6.5	88.9
AMLODIN®	6.0	4.7	(1.3)	(21.3)	4.8	97.6
PRORENAL®	2.9	2.1	(0.8)	(26.3)	2.3	92.5
AVAPRO®	5.1	1.5	(3.5)	(70.0)	2.2	69.0
GASMOTIN®	2.6	2.0	(0.6)	(23.6)	2.1	94.3
Others	9.4	8.9	(0.5)	(5.3)	8.8	100.9
Total	72.8	66.4	(6.5)	(8.9)	68.0	97.6

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

Trulicity® grew significantly.

TRERIEF® sales remain unchanged y-o-y due to impact of NHI price revision, but showed favorable progress to the forecast.

Erosion by AIMIX® GEs showed a stronger impact than expected after June 2018.

Erosion by AVAPRO® GEs showed a stronger impact than expected.

Impact of NHI price revision was 4.5 billion yen.

Revenue of Major Products in North America & China

	Q2 FY2017 Results	Q2 FY2018 Results	Change	Q2 FY2017 Results	Q2 FY2018 Results	Change			Q2 FY2018 (Apr.-Sep.)		
						Value	FX rate impact	%	Forecasts		Yen-based progress
North America	Million $			Billion yen					Million $	Billion yen	%
LATUDA®	779	813	35	86.5	89.7	3.2	(0.6)	3.7	863	90.6	99.0
BROVANA®	147	152	4	16.4	16.7	0.4	(0.1)	2.2	156	16.4	102.0
APTIOM®	66	88	22	7.3	9.7	2.4	(0.1)	32.9	95	10.0	97.0
LONHALA® MAGNAIR®	–	4	4	–	0.4	0.4	–	–	10	1.0	40.5
Therapeutic agent for COPD (in-licensed 3 products) *	2	3	1	0.2	0.3	0.1	(0.0)	48.4	10	1.0	28.8
XOPENEX®	17	19	3	1.9	2.1	0.3	(0.0)	14.3	17	1.8	118.2
Others	55	33	(22)	6.0	3.6	(2.4)	(0.0)	(40.1)	37	3.9	92.5
Total	1,064	1,111	47	118.2	122.5	4.3	(0.9)	3.7	1,188	124.7	98.3
China	Million RMB			Billion yen					Million RMB	Billion yen	%
MEROPEN®	610	587	(24)	10.0	9.8	(0.2)	0.2	(2.0)	606	10.0	98.2
Others	90	94	4	1.5	1.6	0.1	0.0	6.6	91	1.5	105.3
Total	701	681	(20)	11.5	11.4	(0.1)	0.2	(0.9)	697	11.5	99.1

LATUDA® and APTIOM® sales were unfavorable than forecast, but showed growth y-o-y.

LONHALA® MAGNAIR® made slow progress during Q2.

Therapeutic agent for COPD remains in slow progress.

* UTIBRON®, SEEBRI®, ARCAPTA®

FX rates: Q2FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.4
Q2FY2018 Results : 1US$ = ¥ 110.3, 1RMB = ¥16.7

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
Q2 FY2018 Results	Revenue (Sales to customers)	66.4	122.5	11.4	7.0	207.3	18.8	226.2
	Cost of sales	25.9	9.7	1.9	3.5	41.0	14.6	55.6
	Gross profit	40.5	112.8	9.5	3.6	166.4	4.2	170.6
	SG&A expenses	25.1	58.1	4.4	1.9	89.4	2.7	92.2
	Core segment profit	15.4	54.8	5.1	1.7	76.9	1.5	78.4
	R&D expenses					40.8	0.5	41.3
	Other operating income/expenses					0.1	0.0	0.1
	Core operating profit					36.2	1.0	37.2
Q2 FY2017 Results	Revenue (Sales to customers)	72.8	118.2	11.5	6.8	209.3	22.0	231.4
	Cost of sales	26.2	8.0	2.3	3.1	39.6	17.4	57.0
	Gross profit	46.7	110.2	9.2	3.7	169.8	4.6	174.3
	SG&A expenses	25.2	53.4	3.7	1.8	84.2	3.2	87.4
	Core segment profit	21.5	56.8	5.5	1.8	85.6	1.4	87.0
	R&D expenses					39.8	0.5	40.3
	Other operating income/expenses					9.1	0.0	9.1
	Core operating profit					54.9	0.8	55.8
Change	Revenue (Sales to customers)	(6.5)	4.3	(0.1)	0.3	(2.0)	(3.2)	(5.2)
	SG&A expenses	(0.0)	4.7	0.6	0.0	5.3	(0.5)	4.8
	Core segment profit	(6.2)	(2.0)	(0.3)	(0.1)	(8.7)	0.1	(8.6)
	Core operating profit					(18.7)	0.1	(18.6)

Core segment profit in Japan decreased mainly due to NHI price revision.

Core segment profit in North America decreased due to increase in sales cost for new products, etc.

Other operating income for Q2 FY2017 includes profit on business transfer.

Financial Results for Q2 FY2018 (Full Basis)

Billions of yen

	Q2 FY2017 Results	Q2 FY2018 Results	Change	
			Value	%
Revenue	231.4	226.2	(5.2)	(2.2)
Cost of sales	57.0	55.6	(1.4)	(2.5)
Gross profit	174.3	170.6	(3.8)	(2.2)
SG&A expenses	83.3	99.0	15.7	18.9
R&D expenses	40.3	41.3	1.0	2.6
Other operating income and expenses	8.7	(0.6)	(9.3)	
Operating profit	59.5	29.6	(29.9)	(50.2)
Finance income and costs	1.5	8.0	6.5	
Net profit attributable to owners of the parent	45.3	27.9	(17.5)	(38.5)

Financial Forecasts for FY2018

Financial Forecasts for FY2018 (Core Basis)

Billions of yen

	FY2017 Results	FY2018 Previous forecasts	FY2018 Revised forecasts	Change from previous forecasts		Change from FY2017		
				Value	%	Value	FX rate impact	Excl. FX rate impact
Revenue	466.8	467.0	**467.0**	0.2	0.0	–	12.0	(12.0)
Cost of sales	112.3	110.0	**112.5**	0.2	0.1	2.5	4.6	(2.1)
Gross profit	354.5	357.0	**354.5**	0.0	0.0	(2.5)	7.4	(9.9)
SG&A expenses	186.2	195.0	**190.5**	4.3	2.3	(4.5)	5.3	(9.8)
R&D expenses	86.9	85.0	**87.0**	0.1	0.1	2.0	2.2	(0.2)
Other operating income and expenses (Core basis)	9.2	–	**0.0**	(9.2)	–	0.0	–	0.0
Core operating profit	90.6	77.0	**77.0**	(13.6)	(15.0)	–	(0.1)	0.1
Changes in fair value of contingent consideration (negative number indicates loss)	6.4	(19.0)	**(20.0)**	(26.4)		(1.0)		
Other non-recurring items (negative number indicates loss)	(8.8)	(5.0)	**(4.0)**	4.8		1.0		
Operating profit	88.2	53.0	**53.0**	(35.2)	(39.9)	–		
Net profit attributable to owners of the parent	53.4	35.0	**35.0**	(18.4)	(34.5)	–		
R O E (%)	12.4	7.5	**7.5**					

Revenue is unchanged from previous forecast on JPY basis.

Excluding FX rate impact, revenue in Japan and North America was revised downward. In China was revised upside.

SG&A expenses are expected to reduce mainly in North America. R&D expenses revised upward only due to change in FX rate.

Core operating profit is unchanged from previous forecast.

FX rates: FY2017 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.7
FY2018 Previous forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.5
FY2018 Revised forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Revenue of Major Products in Japan

Billions of yen

	FY2017	FY2018 Previous Forecasts	FY2018 Revised Forecasts	Change from Previous Forecasts
Trulicity® *	15.9	22.8	22.8	–
TRERIEF®	16.1	14.5	16.0	1.5
LONASEN®	12.6	12.5	12.5	–
REPLAGAL®	11.7	12.2	12.4	0.2
METGLUCO®	10.9	11.1	10.4	(0.7)
SUREPOST®	5.0	5.9	5.9	–
AmBisome®	4.3	4.3	4.3	–
Promoted products Total	76.6	83.3	84.3	1.0
AIMIX®	18.8	10.4	8.7	(1.7)
AMLODIN®	11.4	9.1	9.1	–
PRORENAL®	5.4	4.3	4.3	–
AVAPRO®	8.4	4.0	2.9	(1.1)
GASMOTIN®	4.9	3.9	3.9	–
Others	17.9	16.8	16.8	–
Total	143.3	131.8	130.0	(1.8)

TRERIEF® sales are expected to offset impact of NHI price revision and revised upward to the level for FY2017.

AIMIX® and AVAPRO® were revised downward due to stronger impact of GEs erosion than expected.

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

Revenue of Major Products in North America & China

Billions of yen

	FY2017	FY2018 Previous Forecasts	FY2018 Revised Forecasts	Change from Previous Forecasts	FY2017	FY2018 Previous Forecasts	FY2018 Revised Forecasts	Change from Previous Forecasts
North America	Million $				Billion yen			
LATUDA®	1,611	1,759	1,759	–	178.6	184.7	193.5	8.8
BROVANA®	299	326	315	(11)	33.1	34.2	34.7	0.5
APTIOM®	141	210	184	(26)	15.7	22.1	20.2	(1.9)
LONHALA® MAGNAIR®	–	48	11	(37)	–	5.0	1.2	(3.8)
Therapeutic agent for COPD (in-licensed 3 products) *	5	28	5	(23)	0.5	2.9	0.6	(2.3)
XOPENEX®	36	34	37	3	4.0	3.6	4.1	0.5
Others	80	79	64	(15)	8.9	8.3	7.0	(1.3)
Total	2,172	2,484	2,375	(109)	240.8	260.8	261.3	0.5
China	Million RMB				Billion yen			
MEROPEN®	1,216	1,152	1,211	59	20.4	19.0	20.0	1.0
Others	185	181	200	19	3.1	3.0	3.3	0.3
Total	1,401	1,333	1,411	78	23.4	22.0	23.3	1.3

* UTIBRON®, SEEBRI®, ARCAPTA®

LATUDA® sales are unchanged from previous forecast because of taking measures including DTC-TV.

North America sales were revised downward in light of 1H progress.

China sales are expected to remain steady.

FX rates:
FY2017 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.7
FY2018 Previous Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.5
FY2018 Revised Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
FY2018 Revised Forecasts	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					86.0	1.0	87.0
	Other operating income/expenses					0.0	0.0	0.0
	Core operating profit					75.5	1.5	77.0
FY2018 Previous Forecasts	Revenue (Sales to customers)	131.8	260.8	22.0	14.4	429.0	38.0	467.0
	Cost of sales	52.3	18.8	3.7	6.0	80.8	29.2	110.0
	Gross profit	79.5	242.0	18.3	8.4	348.2	8.8	357.0
	SG&A expenses	52.5	124.2	8.5	3.5	188.7	6.3	195.0
	Core segment profit	27.0	117.8	9.8	4.9	159.5	2.5	162.0
	R&D expenses					84.0	1.0	85.0
	Other operating income/expenses					–	–	–
	Core operating profit					75.5	1.5	77.0
Change	Revenue (Sales to customers)	(1.8)	0.5	1.3	–	–	–	–
	SG&A expenses	(0.1)	(4.9)	0.7	–	(4.3)	(0.2)	(4.5)
	Core segment profit	(0.6)	2.1	0.5	–	2.0	–	2.0
	Core operating profit					–	–	–

In Japan segment, revenue and profit were revised downward due to impact of GEs of AIMIX® and AVAPRO®.

In North America segment, sales expenses for dasotraline and 3 therapeutic agents for COPD are expected to reduce.

In China segment, revenue and profit were revised upward.

Total core operating profit is unchanged from previous forecast.

Major Topics (North America & Japan Business)

Status of LATUDA® ANDA litigations (U.S. Patent No.9,815,827 / 9,907,794)

Litigations filed in February 2018

Focused efforts concerning '827 patent, while reserving the right to dispute the court's construction of claim and assert infringement regarding '794 patent in an appeal

- ✓ Claim construction ruling (Markman Ruling) issued by the court on October 5, 2018
- ✓ Preparing for the trial, expected to be an intensive one for a week in late November to early December 2018

In parallel with the preparation for the trial, the court has required that, under its direction, DSP/Sunovion participate in separate settlement negotiation with each defendant

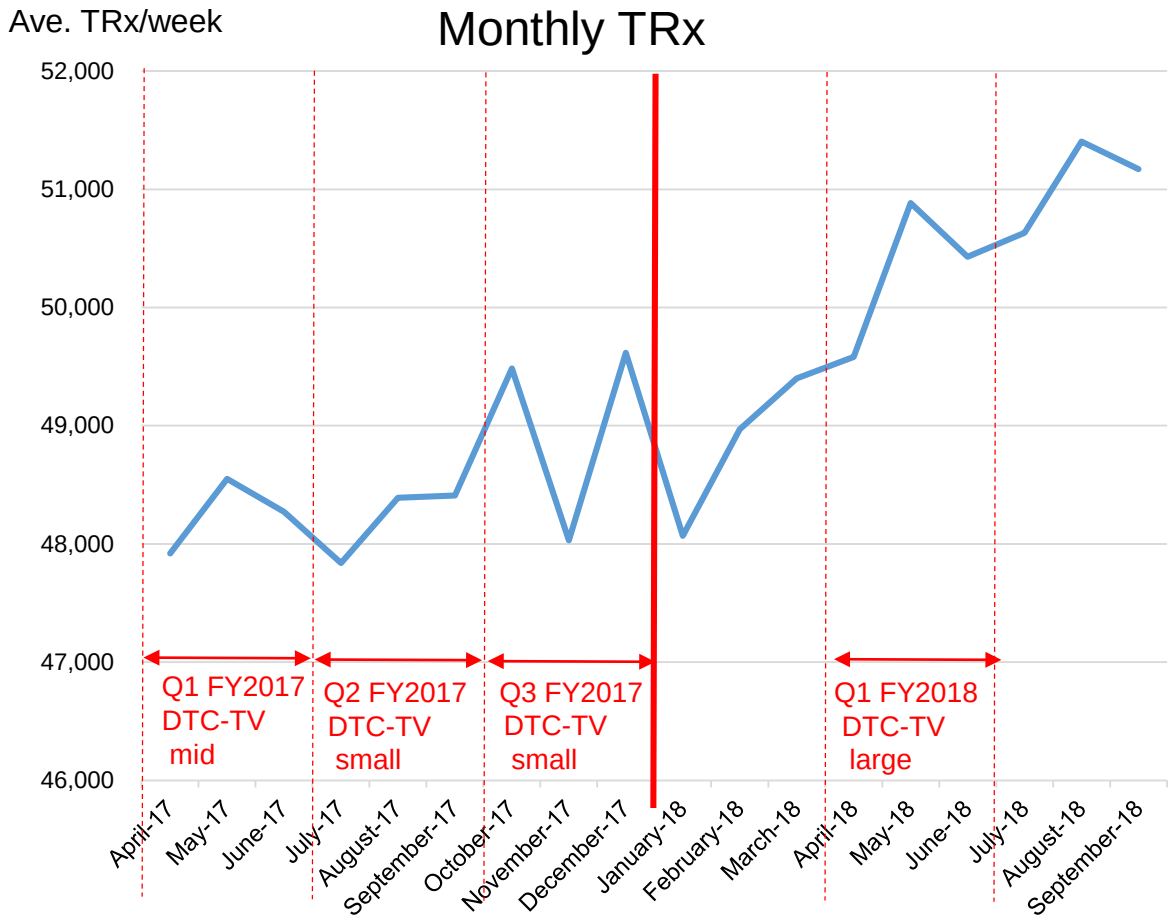
- ✓ Number of defendants has been reduced from the original 16 defendants to 10 defendants (as of October 29, EST), thanks to settlement efforts made so far

Litigations newly filed after May 2018

- ✓ Subsequent to May 2018, we filed, similarly to the above February litigation, three additional lawsuits to assert '827 and '794 patents (one filing each in August, September and October) against three generic manufacturers who newly filed ANDA
- ✓ The trial schedule of the February litigations not affected by these new litigations, as these litigations proceed independently of the above February litigations

TRx Growth of LATUDA®

- **DTC investments and TRx growth**
  - TRx demand for the 6 months from April through September 2018 grew 3.7% vs the previous 6 months ending in March 2018
  - TRx growth was driven through a combination of field execution in 1H and DTC which was executed in Q1 and continued to influence demand in Q2



* Source: NPA, IQVIA Weekly Audit Data

Activities of Japan Business Unit

Maximize the value of products and development pipeline by cross-sectional efforts

- **Formulate and execute strategy by cross-sectional project team**
  - ✓ Operate Launch Readiness Team for LONASEN® (transdermal patch) toward launch in FY2019
  - ✓ Prepare plans to maximize the value of imeglimin

Strengthening of Psychiatry & Neurology area

- **Boost sales force**
  - ✓ CNS MRs: approx. 350 (increased approx. 40 on October 1, 2018)
    - Reason for increase: More focus on Psychiatry & Neurology area in anticipation of launch of lurasidone and LONASEN® (transdermal patch)
    - Shifted from hypertension area
  - ✓ Enhance training program “MR camp” continuously in Psychiatry & Neurology area
    Plan to implement MR camp for general MRs (especially diabetic area) from 2H FY2018
    * MR camp : Practical multi-day training to learn everyday activities at clinical sites

- **Strong sales of TRERIEF®**
  - ✓ Thanks to effective promotion by CNS MRs (revised sales structure in December 2016)
  - ✓ Increase total MRs’ detailing for TRERIEF® due to the additional indication for Parkinsonism in dementia with Lewy bodies

Research and Development

Progress of Focus Research Areas & Frontier area (1)

Psychiatry & Neurology area

Dasotraline

- U.S. : Received Complete Response Letter for ADHD in August 2018
  Plan to discuss next steps for ADHD program with the FDA, launch target is TBD
- U.S. : Aim to submit NDA for BED in FY2018

LONASEN®

- Japan : NDA submitted for schizophrenia (transdermal patch) in July 2018, launch target is FY2019

Oncology area

Napabucasin

- To be completed enrollment of Phase 3 studies for colorectal cancer and pancreatic cancer by FY2018
- Changed the protocol of Phase 3 study protocol for colorectal cancer
  - ✓ Added overall survival (OS) of high p-STAT3 expression patients as primary endpoint

TP-1287 U.S.: Started Phase 1 study for solid tumors (monotherapy)

- Small molecule oral inhibitor of cyclin-dependent kinase 9 (CDK9)
- Yield alvocidib by cleave enzymatically in body

Progress of Focus Research Areas & Frontier area (2)

- **Regenerative medicine / Cell therapy field**
  - **Allo iPS cell-derived dopamine neural progenitor**
    Japan : Kyoto University Hospital started Phase 1 / 2 study of investigator-initiated clinical study for Parkinson's disease
  - **Allo iPS cell-derived retinal pigment epithelium**
    Japan : Preparing for start of clinical study with Healios K.K. in FY2018
- **Frontier area**
  - Invested JPY700 million in MELTIN MMI and signed a joint research and development agreement as part of our efforts to pioneer frontier areas in October 2018
    - Conduct joint research and development of medical devices, etc. through utilizing our many years of knowledge in the pharmaceutical business and MELTIN's bio-signal processing and robotic technologies
    - Aim to deliver new value that benefits patients

Activities in FY2018 : Clinical Development Status

Area	Products	Proposed indication	Area	FY2018 target (Revised in July 27, 2018)	Status as of October 30, 2018
Psychiatry & Neurology	TRERIEF®	Parkinsonism in dementia with Lewy bodies (DLB)	Japan	Approval	**Approved in July 2018**
	dasotraline	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Approval and launch	**NDA submitted, received Complete Response Letter**
		Binge eating disorder (BED)	U.S.	NDA submission	**Preparing NDA submission**
	apomorphine (APL-130277)	OFF episodes associated with Parkinson's disease	U.S.	Approval (Previous target : Approval and launch)	**NDA submitted**
	LONASEN®	(New formulation: Transdermal patch) Schizophrenia	Japan	NDA submission	**NDA submitted**
Oncology	alvocidib	Acute myeloid leukemia (AML) (Refractory or relapsed patients)	U.S.	Promotion of Phase 2 study (Previous target : NDA submission for accelerated approval)	**Stage 2 of Phase 2 study ongoing**
	napabucasin	Pancreatic cancer, Colorectal cancer	U.S., Japan	Promotion of Phase 3 studies	**Phase 3 study ongoing**
Regenerative medicine / Cell therapy	SB623	Chronic stroke	U.S.	Obtain Phase 2b study results in 1H 2019	**Phase 2b study ongoing**
	Allo iPS cell-derived products	AMD (age-related macular degeneration)	Japan	Start a clinical study (corporate-initiated)	**Preparing for start of clinical study**
	Allo iPS cell-derived products	Parkinson's disease	Japan	Start a clinical study (investigator-initiated)	**Phase 1 / 2 study ongoing (investigator-initiated clinical study)**

Development Pipeline (as of October 2018)

: Psychiatry & Neurology : Oncology : Regenerative medicine / cell therapy : Others

Revisions since the announcement of July 2018 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**dasotraline** (ADHD) **SEP-363856** (Schizophrenia) **DSP-2230** (Neuropathic pain) **EPI-589** (ALS) **SEP-4199** (Bipolar I depression)	**alvocidib** (AML)	**amcasertib** (Solid tumors) **DSP-7888** (Solid tumors / Hematologic malignancies) **DSP-6952** (IBS with constipation / Chronic idiopathic constipation)	**lurasidone** (Schizophrenia / Bipolar I depression / Bipolar maintenance) **EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes)	**LONASEN®** (Schizophrenia /Transdermal patch) **thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)
U.S.	**DSP-2230** (Neuropathic pain) **DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain)	**alvocidib** (AML / MDS) **TP-0903** (Solid tumors / Hematologic malignancies) **DSP-0509** (Solid tumors) **TP-0184** (Solid tumors) **DSP-0337** (Solid tumors) **TP-1287** (Solid tumors)	**EPI-589** (Parkinson's disease / ALS) **SEP-363856** (Schizophrenia / (Parkinson's disease psychosis) **SEP-4199** (Bipolar I depression) **alvocidib** (r/r AML) **amcasertib** (Solid tumors) **DSP-7888** (Solid tumors / Hematologic malignancies) **SB623** (Chronic stroke)	**dasotraline** (BED) **napabucasin** (Colorectal cancer / Pancreatic cancer)	**dasotraline** (ADHD) * Received Complete Response Letter **apomorphine** (OFF episodes associated with Parkinson's disease)

Product Launch Target (as of October 2018)

Area	FY2018	FY2019	FY2020	FY2021	FY2022
Japan	**TRERIEF®** (Parkinsonism in dementia with Lewy bodies) * Approved in July 2018	**LONASEN®** (Schizophrenia / Transdermal patch) **thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)	**lurasidone** (Schizophrenia / Bipolar I depression /Bipolar maintenance)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes) **DSP-6952** (IBS with constipation / Chronic idiopathic constipation)	**Allo iPS cell-derived products** *2 (AMD) **Allo iPS cell-derived products** *2 (Parkinson's disease) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)
U.S.	**dasotraline** (ADHD) * Launch target under consideration	**Apomorphine** (OFF episodes associated with Parkinson's disease) **dasotraline** (BED)	**alvocidib** *1 (AML)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)	**SB623** *2 (Chronic stroke)

: Psychiatry & Neurology : Oncology
: Regenerative medicine / cell therapy : Others

Expect peak annual sales to be 50 billion yen or more (described in the first launch)

*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

*2 Launch schedule is based on our goal pending agreement with partners.

Appendices

＜**Contents**＞

Adjustments to Core Operating Profit

Q2FY2018 Results

Billions of yen

IFRS Full Basis		Adjusted amount
Revenue	226.2	
Cost of sales	55.6	
Gross profit	170.6	
SG&A expenses	99.0	(6.9)
R&D expenses	41.3	
Other operating income and expenses	(0.6)	0.7
Operating profit	29.6	7.5

IFRS Core Basis		Adjusted items
Revenue	226.2	
Cost of sales	55.6	
Gross profit	170.6	
SG&A expenses	92.2	Changes in fair value of contingent consideration (6.9)
R&D expenses	41.3	
Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.1	
Core operating profit	37.2	
Changes in fair value of contingent consideration (Positive number indicates profit)	(6.9)	From SG&A expenses (6.9)
Other non-recurring items *2 (Negative number indicates loss)	(0.7)	

IFRS Full Basis : Each item is shown by original financial value under IFRS

IFRS Core Basis : Each item is shown by value after adjustment for calculating core operating profit

*1 "P/L on business transfer" and "share of P/L of associates accounted for using equity method" included in "other operating income and expenses" are used for calculation for core operating profit.

*2 Non-recurring items including "other operating income and expenses" except for *1 items, and impairment losses, etc.

Financial Position / Cash Flows

Billions of yen

Financial Position	As of March 31, 2018	As of Sep. 30, 2018	Change
Assets	809.7	836.4	26.8
Non-current assets	461.1	487.4	26.3
Current assets	348.6	349.0	0.4
Liabilities	357.0	345.3	(11.6)
Non-current liabilities	146.7	154.0	7.3
Current liabilities	210.2	191.3	(19.0)
Equity	452.7	491.1	38.4
Shareholders' equity ratio	55.9%	58.7%	

Cash Flows	Q2FY2017	Q2FY2018	Change
Operating CF	35.7	7.0	(28.7)
Investment CF	3.0	(0.6)	(3.6)
Financial CF	(12.8)	(23.1)	(10.2)
Cash / Cash equivalents	132.2	137.6	5.4
Operating funds	146.8	152.4	5.5

【Assets】

Non-current	PP&E	2.4
	Intangible assets	10.1
	Other financial assets	7.4
Current	Inventories	8.3
	Cash/Cash equivalents	(10.2)

【Liabilities】

Non-current		
	Bonds/Borrowings	(1.5)
	Other financial liabilities	10.7
Current	Bonds/Borrowings	(13.5)
	Trade and other payables	(9.5)
	Provisions	7.6

【Operating CF】

Decrease in profit before tax (23.4)

【Financial CF】

Decrease in interest-bearing debt (7.0)

Regenerative Medicine/Cell Therapy Business Plan (as of October 2018)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	Clinical research	Clinical study
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell		In progress *2 (Phase 2b study)
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell-derived retinal pigment epithelium	In progress	Preparing for start
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto Univ CiRA	Global	Allo iPS cell-derived dopamine neural progenitor		In progress of investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor	Preparing for start	
Spinal cord injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	Preparing for start	

Aim to launch in FY2022*1

*1 Launch schedule is based on our goal that is not agreed with partners.
*2 Plan to conduct Phase 3 study, but aim to utilize the application of accelerated approval program depending on Phase 2b study result.

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows