



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows

# **Press Conference Presentation for Q2 FY2019 (April 1 to September 30, 2019)**

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October 28, 2019

Hiroshi Nomura, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

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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 FY2019

## Financial Results for Q2 FY2019



# Financial Results for Q2 FY2019 (Core Basis)

Billions of yen

	Q2 FY2018 Results	Q2 FY2019 Results	Change			Q2 FY2019 (Apr.-Sep.)		FY2019	
			Value	FX impact	%	Forecasts	%	Forecasts	%
<b>Revenue</b>	226.2	230.6	4.4	(2.9)	2.0	228.5	100.9	475.0	48.5
Cost of sales *1	55.6	56.1	0.5	(0.8)	0.9	55.5	101.1	126.0	44.5
Gross profit	170.6	174.5	3.9	(2.2)	2.3	173.0	100.9	349.0	50.0
SG&A expenses *1	92.2	88.8	(3.4)	(1.1)	(3.7)	92.5	96.0	186.0	47.7
R&D expenses *1	41.3	41.0	(0.3)	(0.4)	(0.7)	41.0	100.0	86.0	47.7
Other operating income and expenses *2	0.1	0.1	(0.0)	—	(33.8)	0.0	—	0.0	—
<b>Core operating profit</b>	<b>37.2</b>	<b>44.8</b>	<b>7.6</b>	<b>(0.7)</b>	<b>20.5</b>	<b>39.5</b>	<b>113.3</b>	<b>77.0</b>	<b>58.1</b>
Changes in fair value of contingent consideration (negative number indicates loss)	(6.9)	① 41.8	48.6			17.0		12.0	
Other non-recurring items *3 (negative number indicates loss)	(0.7)	② (19.7)	(19.0)			(0.5)		(1.0)	
<b>Operating profit</b>	<b>29.6</b>	<b>66.8</b>	<b>37.2</b>		<b>125.7</b>	<b>56.0</b>	<b>119.3</b>	<b>88.0</b>	<b>75.9</b>
Profit before taxes	37.6	64.1	26.5		70.6	58.0	110.6	91.0	70.5
Income tax expenses	9.7	33.8	24.1			36.0		55.0	
<b>Net profit attributable to owners of the parent</b>	<b>27.9</b>	<b>30.3</b>	<b>2.5</b>		<b>8.8</b>	<b>22.0</b>	<b>137.9</b>	<b>36.0</b>	<b>84.3</b>

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

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

\*3 Non-recurring items (Other operating income and expenses except for \*2 items, impairment losses, etc.)

FX rates: Q2FY2018 Results : 1US\$ = ¥ 110.3, 1RMB = ¥16.7  
Q2FY2019 Results : 1US\$ = ¥ 108.6, 1RMB = ¥15.7

① Changes in fair value (cost reversal) due to:

- Discontinued P3 study for napabucasin pancreatic cancer (Q1)
- Revised business plans for alvocidib (Q2)
- Discontinued development for amcasertib (Q2)

② Non-recurring items recorded due to:

Impairment losses from

- Revised business plans for alvocidib (Q2)
- Discontinued development for amcasertib (Q2)

## Financial Results for Q2 FY2019

# Revenue of Major Products in Japan



Billions of yen

	Q2 FY2018	Q2 FY2019	Change		Q2 FY2019 (Apr.-Sep.)	
	Results	Results	Value	%	Forecasts	%
Trulicity®*	10.7	14.5	3.7	34.8	14.0	103.5
TRERIEF®	7.9	8.3	0.4	4.6	8.6	96.4
REPLAGAL®	6.3	7.0	0.7	11.1	6.1	115.5
METGLUCO®	5.1	4.9	(0.2)	(3.8)	4.7	104.6
SUREPOST®	3.0	3.4	0.5	15.8	3.1	111.3
AmBisome®	2.0	2.1	0.1	3.9	1.8	113.9
LONASEN® Tape	—	0.1	0.1	—	0.2	48.7
<b>Promoted products Total</b>	<b>35.1</b>	<b>40.3</b>	<b>5.2</b>	<b>14.8</b>	<b>38.5</b>	<b>104.7</b>
AMLODIN®	4.7	4.0	(0.7)	(15.1)	4.1	97.0
LONASEN® tablet/powder	6.3	3.9	(2.4)	(38.4)	4.0	96.9
AIMIX®	5.8	2.1	(3.7)	(63.3)	2.0	106.0
PRORENAL®	2.1	1.7	(0.4)	(19.3)	1.8	95.3
GASMOTIN®	2.0	1.6	(0.4)	(18.8)	1.6	100.4
AG products	2.3	3.8	1.4	61.3	3.4	111.0
Others	8.1	6.8	(1.3)	(16.2)	7.6	88.9
<b>Total</b>	<b>66.4</b>	<b>64.2</b>	<b>(2.2)</b>	<b>(3.3)</b>	<b>63.0</b>	<b>101.9</b>

Trulicity® continued to grow.

LONASEN® Tape was launched in September 2019.

GEs of LONASEN® tablet/powder were launched in June 2019. Revenue of the AG products we sold are included in “AG products”

Note: Sales of each product are shown by invoice price (\* Trulicity® is shown by NHI price).

## Financial Results for Q2 FY2019

# Revenue of Major Products in North America & China



	Q2 FY2018 Results	Q2 FY2019 Results	Change	Q2 FY2018 Results	Q2 FY2019 Results	Change			Q2 FY2019 (Apr.-Sep.)		
						Value	FX impact	%	Forecasts		Yen-basis %
<b>North America</b>	Million \$			Billion yen			Million \$	Billion yen			
LATUDA®	813	873	60	89.7	94.8	5.1	(1.4)	5.7	850	93.5	101.4
BROVANA®	152	152	(0)	16.7	16.5	(0.3)	(0.3)	(1.5)	151	16.6	99.2
APTIOM®	88	100	12	9.7	10.9	1.2	(0.2)	12.0	99	10.9	99.6
LONHALA® MAGNAIR®	4	13	9	0.4	1.4	1.0	(0.0)	241.9	12	1.3	106.4
XOPENEX®	19	18	(1)	2.1	2.0	(0.2)	(0.0)	(8.1)	20	2.2	88.9
Others	35	35	0	3.9	3.8	(0.1)	(0.1)	(1.3)	33	3.6	106.7
<b>Total</b>	<b>1,111</b>	<b>1,191</b>	<b>80</b>	<b>122.5</b>	<b>129.3</b>	<b>6.8</b>	<b>(2.0)</b>	<b>5.6</b>	<b>1,165</b>	<b>128.1</b>	<b>101.0</b>
<b>China</b>	Million RMB			Billion yen			Million RMB	Billion yen			
MEROPEN®	587	765	179	9.8	12.0	2.2	(0.8)	22.2	727	12.0	100.0
Others	94	130	36	1.6	2.0	0.5	(0.1)	29.4	103	1.7	120.2
<b>Total</b>	<b>681</b>	<b>896</b>	<b>215</b>	<b>11.4</b>	<b>14.0</b>	<b>2.6</b>	<b>(0.9)</b>	<b>23.2</b>	<b>830</b>	<b>13.7</b>	<b>102.5</b>

LATUDA® and APTIOM® sales showed growth.

MEROPEN® sales remained strong.

LATUDA® was launched in September 2019

FX rates: Q2FY2018 Results : 1US\$ = ¥ 110.3, 1RMB = ¥16.7  
Q2FY2019 Results : 1US\$ = ¥ 108.6, 1RMB = ¥15.7

## Financial Results for Q2 FY2019

# Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Q2 FY2019 Results	Revenue (Sales to customers)	64.2	129.3	14.0	4.3	211.9	18.7	230.6	
	Cost of sales	26.3	11.4	2.3	1.5	41.6	14.5	56.1	
	Gross profit	37.9	117.9	11.7	2.8	170.3	4.2	174.5	
	SG&A expenses	24.6	55.9	4.2	1.6	86.2	2.6	88.8	
	Core segment profit	13.3	62.1	7.5	1.2	84.2	1.6	85.7	
	R&D expenses						40.6	0.4	41.0
	Other operating income/expenses						0.1	(0.0)	0.1
	Core operating profit						43.6	1.1	44.8
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
Change	Revenue (Sales to customers)	(2.2)	6.8	2.6	(2.7)	4.6	(0.2)	4.4	
	SG&A expenses	(0.6)	(2.2)	(0.2)	(0.3)	(3.3)	(0.1)	(3.4)	
	Core segment profit	(2.0)	7.3	2.4	(0.5)	7.2	0.1	7.3	
	Core operating profit						7.4	0.2	7.6

In Japan segment, both revenue and profit decreased.

In North America and China segment, both revenue and profit increased.

# Financial Forecasts for FY2019



## Financial Forecasts for FY2019

# Financial Forecasts for FY2019 (Core Basis)



Billions of yen

	FY2018 Results	FY2019 Previous forecasts	FY2019 Revised forecasts	Change from previous forecasts		Change from FY2018
				Value	%	Value
Revenue	459.3	475.0	<b>475.0</b>	15.7	3.4	—
Cost of sales	113.1	126.0	<b>125.0</b>	11.9	10.5	(1.0)
Gross profit	346.2	349.0	<b>350.0</b>	3.8	1.1	1.0
SG&A expenses	186.1	186.0	<b>187.0</b>	0.9	0.5	1.0
R&D expenses	82.9	86.0	<b>86.0</b>	3.1	3.8	—
Core operating profit	77.3	77.0	<b>77.0</b>	(0.3)	(0.4)	—
Changes in fair value of contingent consideration (negative number indicates loss)	9.1	12.0	<b>35.0</b>	25.9		23.0
Other non-recurring items (negative number indicates loss)	(28.5)	(1.0)	<b>(24.0)</b>	4.5		(23.0)
Operating profit	57.9	88.0	<b>88.0</b>	30.1	52.0	—
Income tax expense	16.4	55.0	<b>51.0</b>	34.6		(4.0)
Net profit attributable to owners of the parent	48.6	36.0	<b>36.0</b>	(12.6)	(26.0)	—
R O E (%)	10.2	7.1	<b>7.1</b>			
R O I C (%)	11.8	4.1	<b>4.8</b>			

Unchanged full-year forecasts for revenue and each profit item

Revised forecast of fair value of contingent consideration counts the change for Q2.

Revised forecast of other non-recurring items counts impairment losses and other items recorded in Q2.

FX rate assumption of RMB was updated.

FX rates: FY2018 Results : 1US\$ = ¥ 110.9, 1RMB = ¥16.5  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥16.5  
 FY2019 Revised forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5

## Financial Forecasts for FY2019

# Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)	
		Japan	North America	China	Other Regions	Subtotal			
Revised Forecasts	FY2019	Revenue (Sales to customers)	136.0	260.0	27.3	13.7	437.0	38.0	475.0
		Cost of sales	63.0	22.7	5.0	4.9	95.6	29.4	125.0
		Gross profit	73.0	237.3	22.3	8.8	341.4	8.6	350.0
		SG&A expenses	53.3	116.0	9.0	3.2	181.5	5.5	187.0
		Core segment profit	19.7	121.3	13.3	5.6	159.9	3.1	163.0
		R&D expenses					85.0	1.0	86.0
		Core operating profit					74.9	2.1	77.0
Previous Forecasts	FY2019	Revenue (Sales to customers)	135.0	260.0	28.3	13.7	437.0	38.0	475.0
		Cost of sales	62.0	23.2	6.2	5.2	96.6	29.4	126.0
		Gross profit	73.0	236.8	22.1	8.5	340.4	8.6	349.0
		SG&A expenses	53.8	114.0	9.5	3.2	180.5	5.5	186.0
		Core segment profit	19.2	122.8	12.6	5.3	159.9	3.1	163.0
		R&D expenses					85.0	1.0	86.0
		Core operating profit					74.9	2.1	77.0
Change		Revenue (Sales to customers)	1.0	–	(1.0)	–	–	–	–
		SG&A expenses	(0.5)	2.0	(0.5)	–	1.0	–	1.0
		Core segment profit	0.5	(1.5)	0.7	0.3	–	–	–
		Core operating profit					–	–	–

Japan segment  
- Incremental revenue of REPLAGAL®

North America segment  
- Incremental expenses related to strategic alliance with Roivant Sciences

China segment  
- Expected yen-based revenue decline due to update FX rate assumption despite strong sales trend

# Research and Development

# Main Event/Target for FY2019 (as of October 28, 2019)

✓ Done event / target    Revisions since the announcement of July 2019 are shown in red.

<b>Psychiatry &amp; Neurology</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> LONASEN® (New formulation : transdermal patch) : Obtain approval for schizophrenia in Japan</li> <li><input checked="" type="checkbox"/> Lurasidone : Submit NDA for schizophrenia and bipolar depression in Japan</li> <li><input checked="" type="checkbox"/> Dasotraline : NDA submission for BED in the U.S.</li> <li><input type="checkbox"/> Dasotraline : Determine development strategy for ADHD in the U.S.</li> <li><input type="checkbox"/> Apomorphine : Resubmit NDA for OFF episodes associated with Parkinson's disease in the U.S.</li> <li><input type="checkbox"/> SEP-363856* : Start next phase study ( <input checked="" type="checkbox"/> Phase 3 study in the U.S., <input type="checkbox"/> Phase 2 study in Japan )</li> </ul>
<b>Oncology</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Napabucasin : Promote global Phase 3 studies for colorectal cancer and pancreatic cancer ( <input checked="" type="checkbox"/> Completed interim analysis in H1 FY2019, interim analysis results: Phase 3 study for colorectal cancer to be continued, Phase 3 study for pancreatic cancer discontinued )</li> </ul>
<b>Regenerative medicine / Cell therapy</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> SB623 : Determine development policy for chronic stroke in the U.S.</li> <li><input type="checkbox"/> Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study</li> </ul>
<b>Other</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Imeglimin : Obtain two Phase 3 study results ( <input type="checkbox"/> TIMES 2, <input checked="" type="checkbox"/> TIMES 3 ) in Japan</li> </ul>
<b>Infectious Diseases</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Promote joint research with academia and others (antimicrobial resistance (AMR), universal influenza vaccines, malaria vaccines)</li> </ul>
<b>Frontier</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Promotion of the current themes (MELTIN, Aikomi), development of new themes</li> </ul>

\* Sunovion discovered SEP-363856 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform.

# Clinical Development Status (Major Changes since July 29, 2019)

## ■ Lurasidone

Japan: NDA for schizophrenia and bipolar depression submitted in July 2019

✓ Launch target: FY2020

## ■ Revised development strategy of alvocidib

U.S.: : Revised policy to prioritize Phase 1/2 study for myelodysplastic syndromes (MDS) which is highly MCL-1 dependent

Study design: Combination with decitabine in 1st line MDS patients, plan to add combination product azacitidine

✓ Plan to launch in FY2023

## ■ DSP-0509

U.S.: Started Phase 1/2 study for solid tumors (combination therapy)

## ■ TP-3654

U.S.: Started Phase 1 study for myelofibrosis (monotherapy/combotherapy)

## ■ Discontinuation

Amcasertib: solid tumors, hematologic malignancies (Japan and U.S.: Phase 2 study)

Obeticholic acid (DSP-1747): development in China (nonalcoholic steatohepatitis, Primary Biliary Cholangitis)

## ■ Update on progress of proposal to acquire Cynata Therapeutics Limited (announced on July 19, 2019)

Withdrawn after unable to reach the mutually agreed terms

# Product Launch Target (as of October 28, 2019)

Revisions since the announcement of July 2019 are shown in red.

Area	FY2019	FY2020	FY2021	FY2022	FY2023
Japan	<p><b>LONASEN®</b> (Schizophrenia/ Transdermal patch) <i>Launched in September 2019</i></p> <p><b>RETHIO®</b> (Conditioning treatment prior to autologous HSCT for malignant lymphoma)</p>	<p><b>lurasidone</b> (Schizophrenia/ Bipolar depression)</p>	<p><b>imeglimin</b> (Type 2 diabetes)</p>	<p><b>napabucasin</b> (Colorectal cancer)</p> <p><b>Allo iPS cell-derived products *2</b> (AMD)</p> <p><b>Allo iPS cell-derived products *2</b> (Parkinson's disease)</p>	
	<p><b>dasotraline</b> (ADHD) Launch target under consideration</p>	<p><b>Apomorphine</b> (OFF episodes associated with Parkinson's disease)</p> <p><b>dasotraline</b> (BED)</p>	<p><b>napabucasin</b> (Colorectal cancer)</p>	<p><b>SB623 *2</b> (Chronic stroke) Launch target under consideration</p>	<p><b>SEP-363856</b> (Schizophrenia)</p> <p><b>alvocidib *1</b> (MDS)</p> <p><b>dubernatinib (TP-0903)</b> (Solid tumors/ Hematologic malignancies) *1</p> <p><b>TP-0184 *1</b> (Solid tumors)</p>

: 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.

# Appendix

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## Appendix (Financial Results for Q2 FY2019)

# Financial Results for Q2 FY2019 (Full Basis)



Billions of yen

	Q2 FY2018 Results	Q2 FY2019 Results	Change	
			Value	%
Revenue	226.2	230.6	4.4	2.0
Cost of sales	55.6	56.3	0.7	1.2
Gross profit	170.6	174.3	3.8	2.2
SG&A expenses	99.0	47.0	(52.0)	(52.5)
R&D expenses	41.3	60.2	18.8	45.6
Other operating income and expenses	(0.6)	(0.3)	0.3	
Operating profit	29.6	66.8	37.2	125.7
Finance income and costs	8.0	(2.7)	(10.7)	
Net profit attributable to owners of the parent	27.9	30.3	2.5	8.8



## Appendix (Financial Results for Q2 FY2019)

# Adjustments to Core Operating Profit



### Q2 FY2019 Results

Billions of yen

IFRS Full Basis		Adjusted amount	IFRS Core Basis		Adjusted items
Revenue	230.6	—	Revenue	230.6	
Cost of sales	56.3	(0.2)	Cost of sales	56.1	
Gross profit	174.3	0.2	Gross profit	174.5	
SG&A expenses	47.0	41.8	SG&A expenses	88.8	Changes in fair value of contingent consideration 41.8
R&D expenses	60.2	(19.1)	R&D expenses	41.0	Impairment loss (19.1)
Other operating income and expenses	(0.3)	0.4	Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.1	
Operating profit	66.8	(22.1)	Core operating profit	44.8	
			Changes in fair value of contingent consideration (Positive number indicates profit)	41.8	From SG&A expenses 41.8
			Other non-recurring items *2 (Negative number indicates loss)	(19.7)	Impairment loss (19.1)

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.

## Appendix (Financial Results for Q2 FY2019)

# Financial Position / Cash Flows



Billions of yen

Financial Position	As of March 31, 2019	As of Sep. 30, 2019	Change
Assets	834.7	805.0	(29.7)
Non-current assets	461.4	422.4	(39.1)
Current assets	373.3	382.7	9.4
Liabilities	336.6	293.4	(43.2)
Non-current liabilities	138.4	100.2	(38.2)
Current liabilities	198.2	193.2	(5.0)
Equity	498.1	511.7	13.5
Shareholders' equity ratio	59.7%	63.6%	

Cash Flows	Q2FY2018	Q2FY2019	Change
Operating CF	7.0	31.8	24.8
Investment CF	(0.6)	10.8	11.5
Financial CF	(23.1)	(11.2)	11.9
Cash / Cash equivalents	137.6	(164.7)	27.1
Operating funds	152.4	186.3	33.9

### 【Assets】

#### Non-current

PP&E	9.5
Intangible assets	(23.7)
Deferred tax assets	(16.8)

#### Current

Other financial assets	(20.0)
Cash and cash equivalents	27.4

### 【Liabilities】

#### Non-current

Other financial liabilities	(34.5)
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#### Current

Provisions	(5.9)
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### 【Operating CF】

Change in trade and other payables	16.1
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### 【Investment CF】

Change in short-term loan receivable	13.1
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### 【Finance CF】

Repayment of loan and redemption of bonds	13.5
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## Appendix (Financial Forecasts for FY2019)

# Revenue of Major Products in Japan



Billions of yen

	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
Trulicity® *	23.1	28.2	28.2	—
TRERIEF®	15.7	17.1	17.1	—
Equa®/EquMet®	—	16.0	16.0	—
REPLAGAL®	12.5	11.8	12.6	0.8
METGLUCO®	10.1	9.3	9.3	—
SUREPOST®	6.1	6.2	6.2	—
AmBisome®	4.0	3.9	3.9	—
LONASEN® Tape	—	1.8	1.8	—
<b>Promoted products Total</b>	<b>71.5</b>	<b>94.3</b>	<b>95.1</b>	<b>0.8</b>
AMLODIN®	9.1	7.5	7.5	—
LONASEN® tablet/powder	12.2	5.2	5.2	—
AIMIX®	8.2	3.7	3.7	—
PRORENAL®	4.0	3.3	3.3	—
GASMOTIN®	3.8	3.1	3.1	—
AG products	5.5	6.9	6.9	—
Others	15.0	11.0	11.2	0.2
<b>Total</b>	<b>129.3</b>	<b>135.0</b>	<b>136.0</b>	<b>1.0</b>

Revised forecast of REPLAGAL® based on its 1<sup>st</sup> half progress

Note: Sales of each product are shown by invoice price (\* Trulicity® is shown by NHI price).

## Appendix (Financial Forecasts for FY2019)

# Revenue of Major Products in North America & China



	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
<b>North America</b>	Million \$				Billion yen			
LATUDA®	166.3	172.1	172.1	—	184.5	189.3	189.3	—
BROVANA®	30.4	30.0	30.0	—	33.7	33.0	33.0	—
APTIOM®	18.5	20.5	20.5	—	20.5	22.5	22.5	—
LONHALA® MAGNAIR®	1.3	3.8	3.8	—	1.4	4.2	4.2	—
XOPENEX®	4.2	3.7	3.7	—	4.6	4.1	4.1	—
Others	7.1	6.3	6.3	—	7.8	6.9	6.9	—
<b>Total</b>	<b>227.7</b>	<b>236.4</b>	<b>236.4</b>	<b>—</b>	<b>252.5</b>	<b>260.0</b>	<b>260.0</b>	<b>—</b>
<b>China</b>	Million RMB				Billion yen			
MEROPEN®	128.4	145.5	148.8	3.3	21.2	24.0	23.1	(0.9)
Others	21.2	26.6	27.3	0.7	3.5	4.3	4.2	(0.1)
<b>Total</b>	<b>149.6</b>	<b>171.5</b>	<b>176.1</b>	<b>4.6</b>	<b>24.7</b>	<b>28.3</b>	<b>27.3</b>	<b>(1.0)</b>

Unchanged in North America forecast

Revised downward in China due to FX impact though sales remained strong

FX rates: FY2018 Results : 1US\$ = ¥ 110.9, 1RMB = ¥16.5  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥16.5  
 FY2019 Revised forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5

## Appendix (Research and Development)



# Development Pipeline (as of October 28, 2019)

  : Psychiatry & Neurology 
   : Oncology 
   : Regenerative medicine / cell therapy 
   : Others 
 Revisions since the announcement of July 2019 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	<b>dasotraline</b> (ADHD)	<b>alvocidib</b> (AML)	<b>SEP-4199</b> (Bipolar I depression)	<b>EPI-743</b> (Leigh syndrome)	<b>lurasidone</b> (Schizophrenia/ Bipolar depression)
	<b>SEP-363856</b> (Schizophrenia)	<b>dubermatinib (TP-0903)</b> (Solid tumors)	<b>DSP-7888</b> (Solid tumors/ Hematologic malignancies)	<b>napabucasin</b> (Colorectal cancer)	<b>RETHIO®</b> (Conditioning treatment prior to autologous HSCT for malignant lymphoma)
	<b>EPI-589</b> (ALS)		<b>Allo iPS cell-derived products</b> (Parkinson's disease) Investigator-initiated clinical study	<b>imeglimin</b> (Type 2 diabetes)	
U.S.	<b>DSP-6745</b> (Parkinson's disease psychosis)	<b>alvocidib</b> (AML/MDS)	<b>EPI-589</b> (Parkinson's disease/ALS)	<b>SEP-363856</b> (Schizophrenia)	<b>dasotraline</b> (BED)
	<b>SEP-378608</b> (Bipolar disorder)	<b>dubermatinib (TP-0903)</b> (Solid tumors/ Hematologic malignancies)	<b>SEP-363856</b> (Parkinson's disease psychosis)	<b>napabucasin</b> (Colorectal cancer)	<b>dasotraline</b> (ADHD) Development strategy under consideration
	<b>DSP-3905</b> (Neuropathic pain)	<b>DSP-0509</b> (Solid tumors)	<b>SEP-4199</b> (Bipolar I depression)		<b>apomorphine</b> (OFF episodes associated with Parkinson's disease) Received Complete Response Letter
	<b>SEP-378614</b> (Treatment resistant depression)	<b>TP-0184</b> (Solid tumors)	<b>alvocidib</b> (r/r AML)		
	<b>SEP-380135</b> (Agitation in Alzheimer's disease)	<b>DSP-0337</b> (Solid tumors)	<b>DSP-7888</b> (Solid tumors)		
	<b>TP-1287</b> (Solid tumors)	<b>SB623</b> (Chronic stroke)			
	<b>TP-3654</b> (Solid tumors/ Hematologic malignancies)				

## Appendix (Research and Development)

### Regenerative Medicine/Cell Therapy Business Plan (as of October 28, 2019)



Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
<b>Chronic stroke (SB623)</b>	SanBio	North America	Allo mesenchymal stem cell	<b>Completed Phase 2b study Development strategy and launch target under consideration</b>
<b>AMD (age-related macular degeneration)</b>	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	<b>In progress: clinical research Preparing to start clinical study (Japan)</b>
<b>Parkinson's disease (Designated as a "SAKIGAKE")</b>	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	<b>In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)</b>
<b>Retinitis pigmentosa</b>	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	<b>Preparing to start clinical research</b>
<b>Spinal cord injury</b>	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	<b>In progress: clinical research</b>
<b>Kidney failure</b>	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	<b>In progress: pre-clinical study</b>

**Aim to launch in FY2022 \***

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



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