



Sumitomo Dainippon
Pharma

Innovation today, healthier tomorrows

Investors Meeting Presentation for Q2 FY2020 (April 1 to September 30, 2020)

October 29, 2020

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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 FY2020

Financial Results for Q2 FY2020

Financial Results for Q2 FY2020 (Core Basis)



Billions of yen

	Q2 FY2019 Results	Q2 FY2020 Results	Change			FY2020	
			Value	FX impact	%	July 30 forecasts	%
Revenue	230.6	261.5	30.9	(2.6)	13.4	495.0	52.8
Cost of sales *1	56.1	70.7	14.6	0.2	26.0	140.0	50.5
Gross profit	174.5	190.8	16.3	(2.8)	9.3	355.0	53.7
SG&A expenses *1	88.8	93.6	4.8	(1.1)	5.4	219.0	42.7
R&D expenses *1	41.0	49.2	8.2	(0.6)	20.0	103.0	47.8
Core operating profit	44.8	48.0	3.2	(1.1)	7.2	33.0	145.4
Changes in fair value of contingent consideration (negative number indicates loss)	41.8	0.1	(41.7)			(24.0)	
Other non-recurring items *2 (negative number indicates loss)	(19.7)	(0.5)	19.2			15.0	
Operating profit	66.8	47.5	(19.3)		(28.9)	24.0	198.1
Profit before taxes	64.1	43.7	(20.5)		(31.9)	23.0	189.8
Income tax expenses	33.8	13.3	(20.5)			35.0	
Net profit	30.3	30.3	0.0		0.0	(12.0)	-
Net profit attributable to owners of the parent	30.3	37.3	7.0		23.0	9.0	414.4

Results of Sumitovant:

Q2 FY2020	¥B
Revenue	3.7
SG&A expenses	15.0
R&D expenses	13.8
Core operating profit	(25.1)
Operating profit	(25.1)
Net profit	(24.9)
Net profit attributable to owners of the parent	(18.0)

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

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

FX rates: Q2 FY2019 Results : 1US\$ = ¥ 108.6, 1RMB = ¥15.7
 Q2 FY2020 Results : 1US\$ = ¥ 106.9, 1RMB = ¥15.3
 FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

Financial Results for Q2 FY2020

Revenue of Major Products in Japan



Billions of yen

	Q2 FY2019	Q2 FY2020	Change		FY2020	
	Results	Results	Value	%	July 30 forecasts	%
Equa [®] /EquMet [®]	—	20.4	20.4	—	40.5	50.4
Trulicity [®] *	14.5	16.8	2.3	15.9	36.6	45.9
TRERIEF [®]	8.3	8.3	(0.0)	(0.3)	17.0	48.6
REPLAGAL [®]	7.0	6.9	(0.1)	(1.9)	13.3	51.9
METGLUCO [®]	4.9	4.7	(0.2)	(4.5)	8.8	53.4
AmBisome [®]	2.1	1.8	(0.2)	(10.2)	4.0	46.1
LATUDA [®]	—	0.9	0.9	—	2.2	39.8
LONASEN [®] Tape	0.1	0.6	0.5	470.6	2.5	22.2
Promoted products Total	36.9	60.4	23.5	63.6	124.9	48.3
AMLODIN [®]	4.0	3.3	(0.6)	(16.1)	6.1	54.7
SUREPOST [®]	3.4	2.7	(0.8)	(22.8)	3.5	76.1
AG products	3.8	3.8	(0.0)	(0.5)	7.2	52.1
Others	16.1	7.2	(8.9)	(55.1)	11.4	63.4
Total	64.2	77.3	13.2	20.5	153.1	50.5

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

Equa[®]/EquMet[®] contributed to increased revenue with sales recorded from November 2019

LATUDA[®] is in line with forecast since launched in June 2020

Prescription days limit of LONASEN[®] Tape was lifted in October

Financial Results for Q2 FY2020

Revenue of Major Products in North America & China



	Q2 FY2019 Results	Q2 FY2020 Results	Change	Q2 FY2019 Results	Q2 FY2020 Results	Change			FY2020		
						Value	FX impact	%	July 30 forecasts		Yen-basis %
North America	Million \$			Billions of yen			Million \$	Billion yen			
LATUDA®	873	978	105	94.8	104.6	9.8	(1.6)	10.3	1,740	187.9	55.7
BROVANA®	152	141	(10)	16.5	15.1	(1.4)	(0.2)	(8.3)	275	29.7	50.9
APTIOM®	100	125	25	10.9	13.4	2.5	(0.2)	23.0	216	23.3	57.3
LONHALA® MAGNAIR®	13	9	(3)	1.4	1.0	(0.4)	(0.0)	(27.6)	28	3.0	33.4
XOPENEX®	18	24	6	2.0	2.5	0.6	(0.0)	29.1	43	4.6	54.8
KYNMOBI™	—	1	1	—	0.1	0.1	(0.0)	—	10	1.1	11.6
Sunovion Others	35	38	3	3.8	4.1	0.3	(0.1)	6.6	45	4.9	83.6
Sumitovant	—	34	34	—	3.7	3.7	(0.1)	—	37	4.0	92.0
Total	1,191	1,351	160	129.3	144.5	15.2	(2.3)	11.7	2,394	258.5	55.9
China	Million RMB			Billions of yen			Million RMB	Billion yen			
MEROPEN®	765	649	(116)	12.0	9.9	(2.1)	(0.3)	(17.5)	1,484	23.0	43.1
Others	130	157	26	2.0	2.4	0.3	(0.1)	17.0	355	5.5	43.5
Total	896	806	(90)	14.0	12.3	(1.7)	(0.3)	(12.4)	1,839	28.5	43.1

North America sales showed steady progress to forecasts, Impact of COVID-19 was smaller than anticipated

KYNMOBI™ was launched at the end of September

In China, sales are still recovering from Impact of COVID-19 and showed slow progress to forecast

FX rates: Q2 FY2019 Results : 1US\$ = ¥ 108.6, 1RMB = ¥15.7
 Q2 FY2020 Results : 1US\$ = ¥ 106.9, 1RMB = ¥15.3
 FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

Financial Results for Q2 FY2020

Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Q2 FY2020 Results	Revenue (Sales to customers)	77.3	144.5	12.3	9.3	243.5	18.0	261.5	
	Cost of sales	40.2	11.5	2.2	3.2	57.1	13.6	70.7	
	Gross profit	37.2	133.0	10.1	6.2	186.4	4.4	190.8	
	SG&A expenses	23.8	62.2	3.8	1.3	91.1	2.5	93.6	
	Core segment profit	13.3	70.8	6.3	4.9	95.3	1.9	97.2	
	R&D expenses						48.8	0.4	49.2
	Core operating profit						46.5	1.5	48.0
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
	Core operating profit						43.6	1.1	44.8
Change	Revenue (Sales to customers)	13.2	15.2	(1.7)	5.0	31.6	(0.7)	30.9	
	SG&A expenses	(0.7)	6.3	(0.3)	(0.3)	4.9	(0.1)	4.8	
	Core segment profit	(0.0)	8.8	(1.3)	3.7	11.2	0.3	11.5	
	R&D expenses						8.2	(0.0)	8.2
	Core operating profit						2.9	0.4	3.2

Japan:
Product mix decreased margins, but core segment profit is unchanged due to decreased costs

North America:
Profit increased due to higher revenue and reduced costs at Sunovion which covered the incremental costs of Sumitovant

China:
Similar to Q1, decreased revenue drove the decreased profit

Financial Forecasts for FY2020

Financial Forecasts for FY2020

Financial Forecasts for FY2020 (Core Basis)



Billions of yen

	FY2020 July 30 forecasts	FY2020 Revised forecasts	Change
Revenue	495.0	506.0	11.0
Cost of sales	140.0	141.0	1.0
Gross profit	355.0	365.0	10.0
SG&A expenses	219.0	215.0	(4.0)
R&D expenses	103.0	103.0	—
Core operating profit	33.0	47.0	14.0
Changes in fair value of contingent consideration (negative number indicates loss)	(24.0)	(4.0)	20.0
Other non-recurring items (negative number indicates loss)	15.0	15.0	—
Operating profit	24.0	58.0	34.0
Income tax expenses	35.0	36.0	1.0
Net profit	(12.0)	21.0	33.0
Net profit attributable to owners of the parent	9.0	42.0	33.0
R O E (%)	1.7	7.7	
R O I C (%)	(0.2)	1.2	

FX rates: Unchanged

FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

Revised full-year forecasts considering Q2 performance trend and future outlook

- Revenue revised up by ¥11.0b in North America and other segment

- SG&A expenses revised down in all segments (¥4.0b) due to impact of COVID-19

- Changes in fair value of contingent consideration revised down by ¥20.0b due to review of napabucasin development schedule

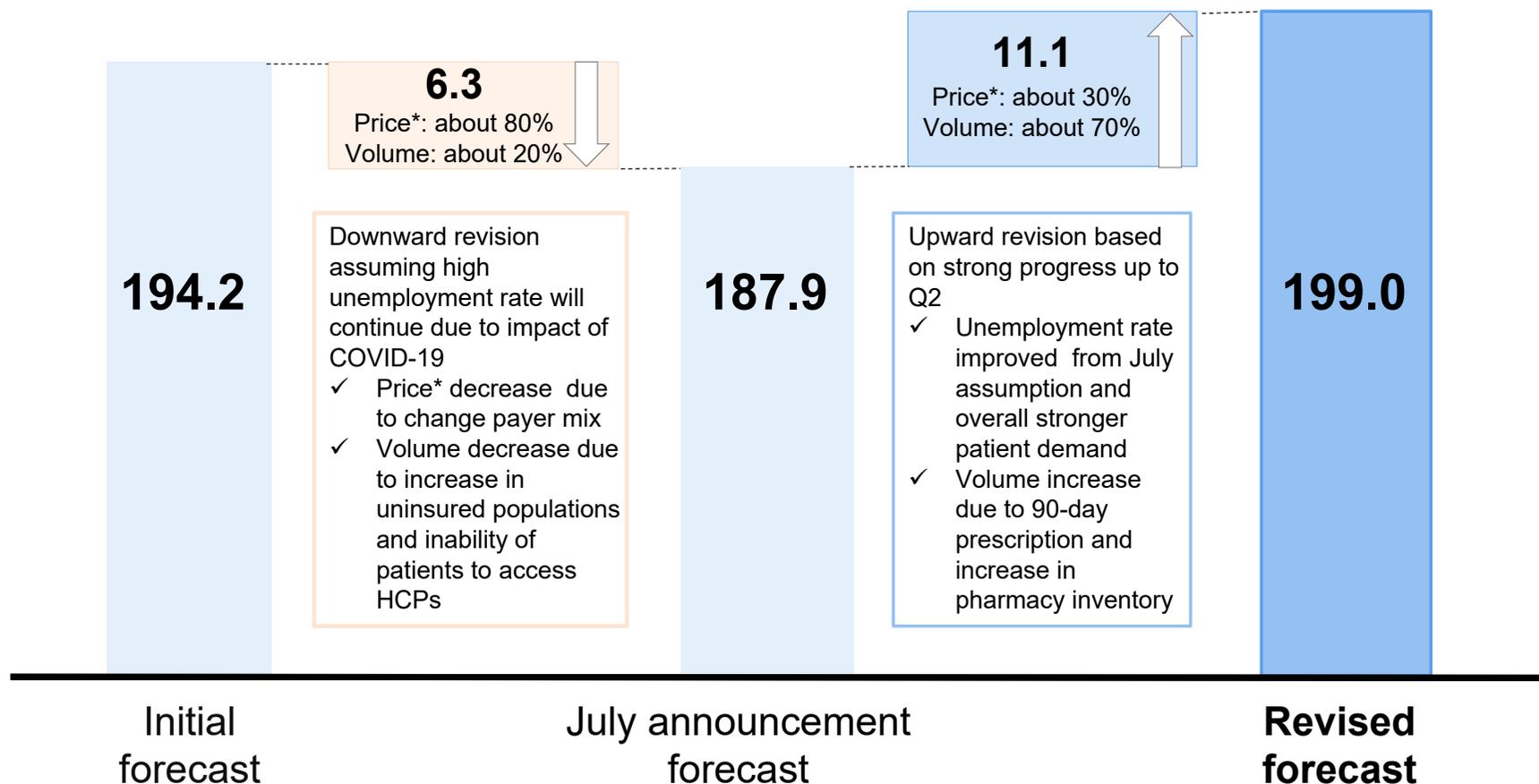
napabucasin :

NDA /launch target year revised due to delay of Phase 3 study result

- Launch target in U.S. : FY2021→FY2022
- Launch target in Japan : FY2022→FY2023

Upward Revision of LATUDA's Sales Forecast in North America

[Billions of yen]



*Price: average selling price

Financial Forecasts for FY2020

Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Revised forecasts FY2020	Revenue (Sales to customers)	153.3	272.1	27.7	16.9	470.0	36.0	506.0
	Cost of sales	79.1	23.9	5.4	5.1	113.5	27.5	141.0
	Gross profit	74.2	248.2	22.3	11.8	356.5	8.5	365.0
	SG&A expenses	52.0	146.1	8.5	2.9	209.5	5.5	215.0
	Core segment profit	22.2	102.1	13.8	8.9	147.0	3.0	150.0
	R&D expenses					102.0	1.0	103.0
	Core operating profit					45.0	2.0	47.0
July 30 forecasts FY2020	Revenue (Sales to customers)	153.1	258.5	28.5	16.9	457.0	38.0	495.0
	Cost of sales	77.9	22.5	5.3	5.0	110.7	29.3	140.0
	Gross profit	75.2	236.0	23.2	11.9	346.3	8.7	355.0
	SG&A expenses	52.5	148.2	9.4	3.2	213.3	5.7	219.0
	Core segment profit	22.7	87.8	13.8	8.7	133.0	3.0	136.0
	R&D expenses					102.0	1.0	103.0
	Core operating profit					31.0	2.0	33.0
Change	Revenue (Sales to customers)	0.2	13.6	(0.8)	—	13.0	(2.0)	11.0
	SG&A expenses	(0.5)	(2.1)	(0.9)	(0.3)	(3.8)	(0.2)	(4.0)
	Core segment profit	(0.5)	14.3	—	0.2	14.0	—	14.0
	R&D expenses					—	—	—
	Core operating profit					14.0	—	14.0

Japan segment

- Revenue up, profit down since REPLAGAL[®] sales revised up by ¥0.4b, cost of sales expected to increase and planned reduction in SG&A expenses

North America segment

- Profit revised upward due to anticipated higher sales (LATUDA[®] ¥11.1b, APTIOM[®] ¥1.3b), reduced SG&A expenses

China segment

- Considered further decrease in MEROPEN[®] sales and decrease in SG&A expenses due to longer than expected impact of COVID-19

Other Business

- Revenue related to food and chemical products revised down due to effects of COVID-19

Major Topics (North America & Japan Business)

North America: Sales Structure for New Products

Myovant

- **Relugolix** (NDA submitted)
 - ✓ Establishing marketing base, and hiring sales reps
 - Prostate cancer: About 100 sales reps to cover urologists and oncologists
 - Uterine fibroids: About 200 sales reps to cover obstetricians and gynecologists

Urovant

- **Vibegron** (NDA submitted)
 - ✓ Establishing marketing base, and hiring sales forces
 - Overactive bladder: About 160 sales reps to cover urologists, long-term care, and high prescribing PCPs

Sunovion

✓ Entered into a co-promotion agreement
Multi-specialty team about 80 people to cover PCPs across the US

✓ Entered into a commercial collaboration agreement to provide third-party logistics etc.

■ **KYNMOBI™** (Launched in September 2020)

- ✓ Aim to establish as the preferred on-demand treatment option for OFF episodes associated with Parkinson's disease
 - Focus on Morning OFF in FY2020, and promote all OFF episodes in FY2021
 - Sales structure: Conduct the promotion by utilizing personal and online, about 80 existing sales reps

Japan: Activities of Sales & Marketing Division

■ CNS Sales Department has been created (October 2020)

- A flat organization under direct control of the Sales & Marketing Division. The Executive Director of the Sales & Marketing Division also serves as the Senior Director, CNS Sales Department
 - ✓ Improve the efficiency of information sharing as well as instruction transmission, and rapidly develop a unified strategy
 - ✓ Aim for early maximization of sales of LATUDA® and LONASEN® Tape
- Strengthen branch management in the Diabetes area by removing Psychiatry & Neurology area from the jurisdiction of branch managers
 - ✓ Aim to strengthen Diabetes area for the launch of imeglimin

■ Efficient and effective sales activities

- Environmental changes: As a consequence of COVID-19, step up implementation of visit restrictions and appointment system introductions at medical institutions, thereby reducing face-to-face information provision
- Introduce optimal technology by promoting digital innovation, and promote information provision activities tailored to needs
 - ✓ Remote dedicated MR (iMR®), virtual MR (vMR™)
Provide information on-demand without face-to-face interaction
 - ✓ Started initiatives to develop a new communication platform using XR* (in cooperation with KDDI)
Smooth communication by utilizing 3D images and constructing a new communication space that utilizes virtual reality
 - ✓ Real MR
Utilize various communication means such as online interviews, briefing sessions, lectures, and e-promotion-linked approaches in addition to traditional face-to-face activities

Research and Development

Research and Development

Development Pipeline (as of October 28, 2020)



 : Psychiatry & Neurology
 : Oncology
 : Regenerative medicine / Cell therapy
 : Others
 : Frontier business
 Revisions since the announcement of July 2020 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	SEP-363856 (Schizophrenia)	dubermatinib (TP-0903) (Solid tumors)	SEP-4199 (Bipolar I depression)	EPI-743 (Leigh syndrome)	imeglimin (Type 2 diabetes)
	EPI-589 (ALS)		DSP-7888 (Solid tumors)	napabucasin (Colorectal cancer)	
	DSP-1181 (Obsessive compulsive disorder)		Allo iPS cell-derived products (Parkinson's disease) Investigator-initiated clinical study	SMC-01 (Type 2 diabetes)	
U.S.	DSP-6745 (Parkinson's disease psychosis)	alvocidib (MDS)	EPI-589 (Parkinson's disease/ALS)	SEP-363856 (Schizophrenia)	relugolix (Prostate cancer)
	SEP-378608 (Bipolar disorder)	dubermatinib (TP-0903) (Solid tumors)	SEP-363856 (Parkinson's disease psychosis)	napabucasin (Colorectal cancer)	RVT-802 (Pediatric congenital athymia) Received Complete Response Letter
	DSP-3905 (Neuropathic pain)	DSP-0509 (Solid tumors)	SEP-4199 (Bipolar I depression)	relugolix (Endometriosis)	vibegron (OAB)
	SEP-378614 (Treatment resistant depression)	TP-0184 (Solid tumors / Hematologic malignancies)	alvocidib (AML)	vibegron (OAB in men with BPH)	relugolix (Uterine fibroids)
	SEP-380135 (Agitation in Alzheimer's disease)	DSP-0337 (Solid tumors)	DSP-7888 (Solid tumors)		
		TP-1287 (Solid tumors)	vibegron (IBS-associated pain)		
		TP-3654 (Solid tumors/ Hematologic malignancies)	rodatristat ethyl (Pulmonary arterial hypertension)		
		TP-1454 (Solid tumors)	URO-902 (Overactive bladder)		
Europe					relugolix (Uterine fibroids)

New Action in Regenerative Medicine / Cell Therapy

■ S-RACMO Co., Ltd. established and started operations

Sumitomo Dainippon Pharma + Sumitomo Chemical: Established a joint venture company for CDMO business in the field of regenerative and cellular medicine, and started operations (October 2020)

CDMO: Contract Development and Manufacturing Organization

- Use part of the regenerative and cellular medicine manufacturing facility “SMaRT” owned by Sumitomo Dainippon Pharma, and a new manufacturing facility (scheduled to be completed in December 2021)
- Under negotiation to secure the contract for manufacturing corneal endothelial cells which CorneaGen Inc. aims to obtain approval for in Japan (planned indication: corneal diseases) and to develop the manufacturing method for this product

Sumitomo Dainippon Pharma

- ✓ Expertise in the development of manufacturing processes and formulations acquired through its involvement in regenerative medicine / cell therapy business
- ✓ Industry-leading regulatory affairs experience



Sumitomo Chemical

- ✓ Basic iPS/ES cell technologies
- ✓ Expertise in the operation of pharmaceutical contract manufacturing

S-RACMO

Aim for annual sales of over 10 billion yen globally in the future
CDMO market size: Approximately 1.2 trillion yen globally by 2030*

Investment ratio 51%

Investment ratio 49%

Aim to gain a solid share of this market and elevate the level of technology and expertise in CDMO business

Frontier Business Status

■ Mobile app for management of diabetic patients : SMC-01

Sumitomo Dainippon Pharma + Save Medical :

Reached a joint development agreement and commenced Ph3 study for type 2 diabetes in Japan (May 2020)

- Launch target in Japan set for FY2022 as a medical device

■ Device to automatically collect and store blood with minimal pain : OneDraw

Sumitomo Dainippon Pharma + Drawbridge Health :

Reached a joint research and development agreement for the diagnosis and effective management of diabetes, etc. (October 2020)

- Aim to complete non-clinical study in FY2020, commence clinical study in FY 2021, and submit NDA in Japan in FY2022

■ Digital devices for dementia and nursing care

Sumitomo Dainippon Pharma + SOMPO + Aikomi :

Agreed to collaborate on the research and development and commercialization for non-medical nursing care applications and medical applications (July 2020)

- Sumitomo Dainippon Pharma and Aikomi aim to develop medical devices to relieve behavioral and psychological symptoms of dementia (BPSD)

Aikomi and SOMPO aim to initiate official joint marketing in Japan in FY2021 as non-medical devices for nursing care

■ Virtual Reality for social anxiety disorder

Sunovion + BehaVR :

Reached a joint development agreement for social anxiety disorder utilizing virtual reality (June 2020)

- Launch target in the U.S. set for FY2022 as a non-medical device, aim to commercialize as a medical device in the future

Appendix

<Contents>

- P.19 Financial Results for Q2 FY2020 (Full Basis)
- P.20 Adjustments to Core Operating Profit
- P.21 Financial Position
- P.22 Execution of Hybrid Finance
- P.23 Revenue of Major Products in Japan
- P.24 Revenue of Major Products in North America & China
- P.25 Product Launch Target
- P.26 Main Event/Target for FY2020
- P.27 Regenerative Medicine/Cell Therapy Business Plan

Appendix (Financial Results for Q2 FY2020)



Financial Results for Q2 FY2020 (Full Basis)

Billions of yen

	Q2 FY2019 Results	Q2 FY2020 Results	Change	
			Value	%
Revenue	230.6	261.5	30.9	13.4
Cost of sales	56.3	70.7	14.4	25.6
Gross profit	174.3	190.8	16.5	9.5
SG&A expenses	47.0	94.2	47.1	100.2
R&D expenses	60.2	49.2	(10.9)	(18.2)
Other operating income and expenses	(0.3)	0.1	0.4	
Operating profit	66.8	47.5	(19.3)	(28.9)
Finance income and costs	(2.7)	(3.9)	(1.2)	
Income tax expenses	33.8	13.3	(20.5)	
Net profit	30.3	30.3	0.0	0.0
Net profit attributable to owners of the parent	30.3	37.3	7.0	23.0

Appendix (Financial Results for Q2 FY2020)

Adjustments to Core Operating Profit



Q2 FY2020 Results

Billions of yen

	IFRS Full Basis	Adjusted amount	IFRS Core Basis	Adjusted items
Revenue	261.5	-	261.5	
Cost of sales	70.7	-	70.7	
Gross profit	190.8	-	190.8	
SG&A expenses	94.2	(0.6)	93.6	Changes in fair value of contingent consideration 0.1 Business structure improvement expense (0.6)
R&D expenses	49.2	-	49.2	
Other operating income and expenses	0.1	(0.1)	(0.0)	Share of profit/loss of associates accounted for using equity method included in other operating income and expenses (Positive number indicates profit)
Operating profit	47.5	0.4	48.0	Core operating profit

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

Appendix (Financial Results for Q2 FY2020)

Financial Position



B / S	As of March 31,2020	As of September 30,2020	Change
Assets	1,252.9	1,238.5	(14.4)
Goodwill	169.0	164.3	(4.7)
Intangible assets	421.8	408.1	(13.7)
Other financial assets (Non-current)	200.9	189.0	(11.9)
Cash and deposit/ Short-term loan receivable	127.6	134.7	7.1
Liabilities	620.8	602.5	(18.3)
Bonds payable	—	118.9	118.9
Loan payable	298.0	178.5	(119.5)
Trade and other payable	62.3	53.0	(9.2)
Income tax payable	22.6	13.4	(9.3)
Provisions	84.6	93.8	9.1
Equity	632.1	636.0	3.9
Attributable to owners of the parent	529.5	543.5	14.0
Ratio of equity attributable to owners of the parent to total assets	42.3%	43.9%	
C / F	Q2 FY2019	Q2 FY2020	Change
Operating CF	31.8	26.1	(5.7)
Investment CF	10.8	19.4	8.6
Financial CF	(11.2)	(9.8)	1.4
Cash and cash equivalents	164.7	134.7	(30.0)
(Operating funds)	186.3	134.7	(51.6)

Billions of yen

Foreign exchange (stronger yen)
impact (26.2)

Refinanced 120 billion yen by issuing
subordinated bond out of the bridge
loan 270 billion yen

Execution of Hybrid Finance

Issuance of Hybrid Bonds

Hybrid Bonds

A form of hybrid financing that forms a hybridization of equity and debt. There is no dilution of the equity value, whereas they are similar to equity in features and characteristics, such as an option to defer interest payments, extremely long-term redemption periods, and subordination in liquidation or bankruptcy proceedings

Name of bonds	Sumitomo Dainippon Pharma Co., Ltd. unsecured subordinated bonds with interest payment deferrable clause and optional early redemption conditions
Issue amount	1st series: ¥60 billion, 2nd series: ¥60 billion
Initial interest rate	1st series: 1.39% p.a., 2nd series: 1.55% p.a.
Issue date	September 10, 2020
Maturity date	September 9, 2050 (30 years)
First call date	1st series: September 10, 2027 2nd series: September 10, 2030
Rating	BBB+ (Rating and Investment Information, Inc.)
Equity credit	“Class3 - equity credit 50” (Rating and Investment Information, Inc.)

- ✓ Finance the funds for partial repayment of bridge loan (¥270b) raised for the Strategic Alliance with Roivant
- ✓ The balance of the bridge loan will be refinanced by bank loan, etc.

Appendix (Financial Forecasts for FY2020)

Revenue of Major Products in Japan



Billions of yen

	FY2020 July 30 forecast	FY2020 Revised forecasts	Change
Equa [®] /EquMet [®]	40.5	40.5	—
Trulicity [®] *	36.6	36.6	—
TRERIEF [®]	17.0	17.0	—
REPLAGAL [®]	13.3	13.7	0.4
METGLUCO [®]	8.8	8.8	—
LONASEN [®] Tape	2.5	2.5	—
AmBisome [®]	4.0	4.0	—
LATUDA [®]	2.2	2.2	—
Promoted products Total	124.9	125.3	0.4
AMLODIN [®]	6.1	6.1	—
SUREPOST [®]	3.5	3.5	—
AG products	7.2	7.2	—
Others	11.4	11.2	(0.2)
Total	153.1	153.3	0.2

Revised up REPLAGAL[®]

Impact of NHI price revision :
About 10 billion
(Change from April 2019 price, FY2020 forecast basis)

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

Appendix (Financial Forecasts for FY2020)



Revenue of Major Products in North America & China

	FY2020 July 30 forecasts	FY2020 Revised forecasts	Change	FY2020 July 30 forecasts	FY2020 Revised forecasts	Change
North America	Million \$			Billions of yen		
LATUDA®	1,740	1,843	103	187.9	199.0	11.1
BROVANA®	275	275	—	29.7	29.7	—
APTIOM®	216	228	12	23.3	24.6	1.3
LONHALA®MAGNAIR®	28	28	—	3.0	3.0	—
XOPENEX®	43	43	—	4.6	4.6	—
KYNMOBI™	10	10	—	1.1	1.1	—
Sunovion Others	45	55	10	4.9	6.1	1.2
Sumitovant	37	37	—	4.0	4.0	—
Total	2,394	2,519	125	258.5	272.1	13.6
China	Million RMB			Billions of yen		
MEROPEN®	1,484	1,452	(32)	23.0	22.5	(0.5)
Others	355	335	(20)	5.5	5.2	(0.3)
Total	1,839	1,787	(52)	28.5	27.7	(0.8)

Revised up LATUDA® and APTIOM® because impact of COVID-19 is lower than anticipated

Sales in China revised down due to impact of COVID-19

FX rates: Unchanged

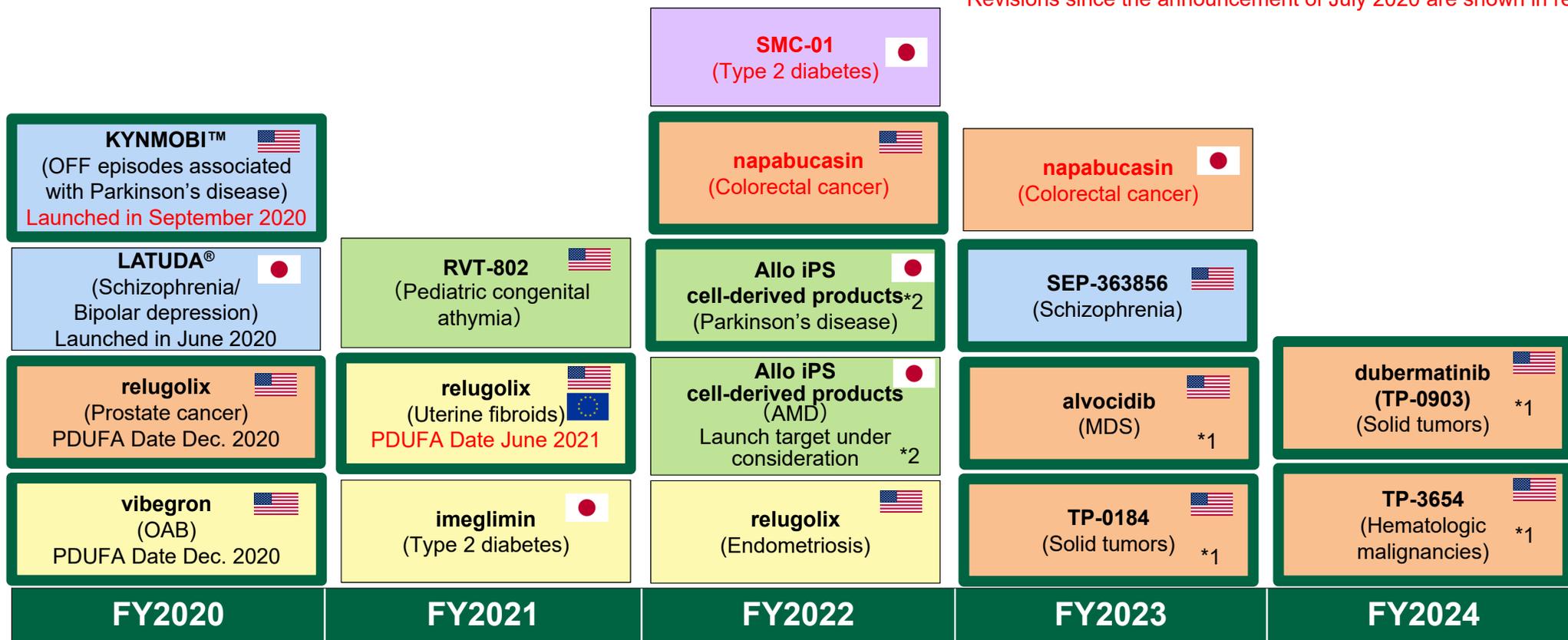
FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

Appendix (Research and Development)



Product Launch Target (as of October 28, 2020)

Revisions since the announcement of July 2020 are shown in red



- : Psychiatry & Neurology
- : Oncology
- : Regenerative medicine / cell therapy
- : Others
- : Frontier business

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 (Research and Development)



Main Event / Target for FY2020 (as of October 28, 2020)

✓ Completed action / target

Psychiatry & Neurology	<ul style="list-style-type: none"> ✓ Apomorphine : Obtain approval for OFF episodes associated with Parkinson's disease in the U.S. □ SEP-363856 : □ Determine new indication for development (global study) <ul style="list-style-type: none"> □ Start Phase 2/3 study for schizophrenia in Asia including Japan and China ✓ SEP-4199 : Obtain results from Phase 2 study for Bipolar I depression
Oncology	<ul style="list-style-type: none"> □ Napabucasin : Obtain results from global Phase 3 study for colorectal cancer ✓ Relugolix : Submit NDA for prostate cancer in the U.S.
Regenerative medicine / Cell therapy	<ul style="list-style-type: none"> □ RVT-802 : Resubmit BLA for pediatric congenital athymia in the U.S. □ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study □ Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated clinical study
Infectious Diseases	<ul style="list-style-type: none"> □ Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines (transmission-blocking/blood-stage) : Promote research and development projects
Others	<ul style="list-style-type: none"> □ Vibegron : Obtain approval for overactive bladder in the U.S. □ Relugolix : ✓ Obtain results from Phase 3 study for endometriosis (SPRIT 1, SPIRIT 2) <ul style="list-style-type: none"> ✓ Submit NDA for uterine fibroids in the U.S. □ Obtain approval for uterine fibroids in Europe ✓ Imeglimin : Submit NDA for type 2 diabetes in Japan
Frontier	<ul style="list-style-type: none"> □ Promotion of the current themes (MELTIN, Aikomi, Drawbridge and internal themes), development of new themes

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of October 28, 2020)



Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	Under preparation to resubmit BLA
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	In progress: pre-clinical study

Aim to start clinical study in FY2020

Aim to launch in FY2022 *

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



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