

Sawai Group Holdings Co., Ltd.

FY2021 Financial Results for the 1st Half

Nov 12, 2021

4887.T, TSE 1st section

sawai

- **Japan:** Despite the impact of the NHI drug price revision, both sales and core operating income exceeded the same period of the previous fiscal year due to increased sales of products launched in FY2020 and increased demand for Sawai Pharmaceutical products due to the supply stoppages etc. of products from other generics companies.
- **United States:** Both sales and core operating income decreased from the same period last year, due to the impact of competitor entries into key USL generic product markets.

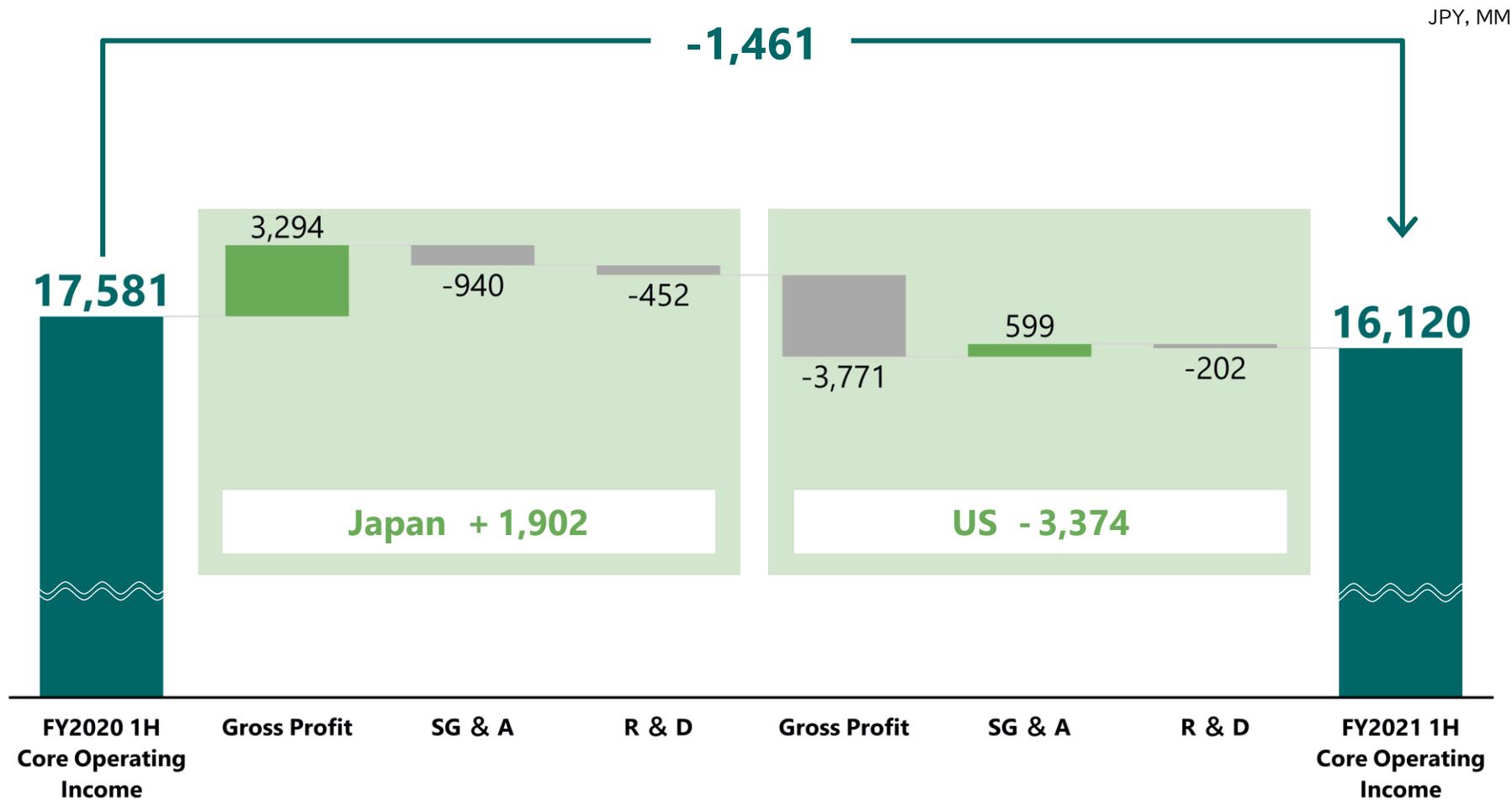
JPY, MM

	FY 2020 1H			FY 2021 1H			YoY
		Japan	US		Japan	US	
Net Sales	90,172	72,098	18,074	97,302	82,818	14,484	+7.9% (+7,130)
Core Operating Income	17,581	14,307	3,268	16,120	16,219	-107	-8.3% (-1,461)
Operating Income	14,012	13,397	615	13,822	14,431	-609	-1.4% (-190)
Profit before tax	13,812	-	-	13,649	-	-	-1.2% (-163)
Profit attributable to owners of the parent	10,800	-	-	9,422	-	-	-12.8% (+1,378)
Average rate	US\$1 = ¥107			US\$1 = ¥110			

- Results by segment in Japan and the U.S. are not consistent with the overall figures, as each segment profit includes inter-segment transactions.

- Core operating income is calculated by excluding profits and losses attributed to non-recurring factors from operating income.

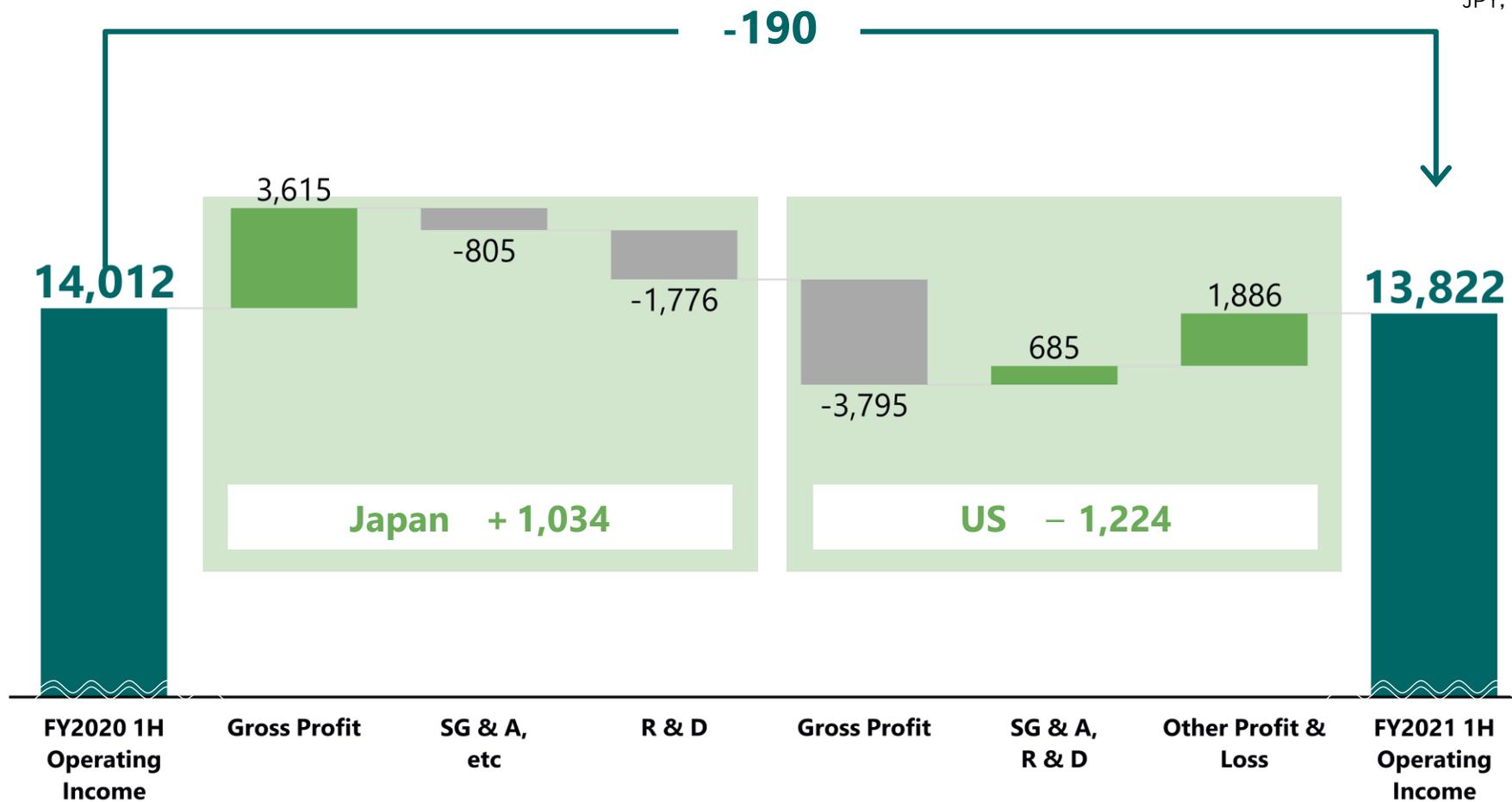
Core Operating Income Analysis



- Results by segment in Japan and the U.S. are not consistent with the overall figures, as each segment profit includes inter-segment transactions.

Operating Income Analysis

JPY, MM



Sales by Channel in Japan, Unconsolidated

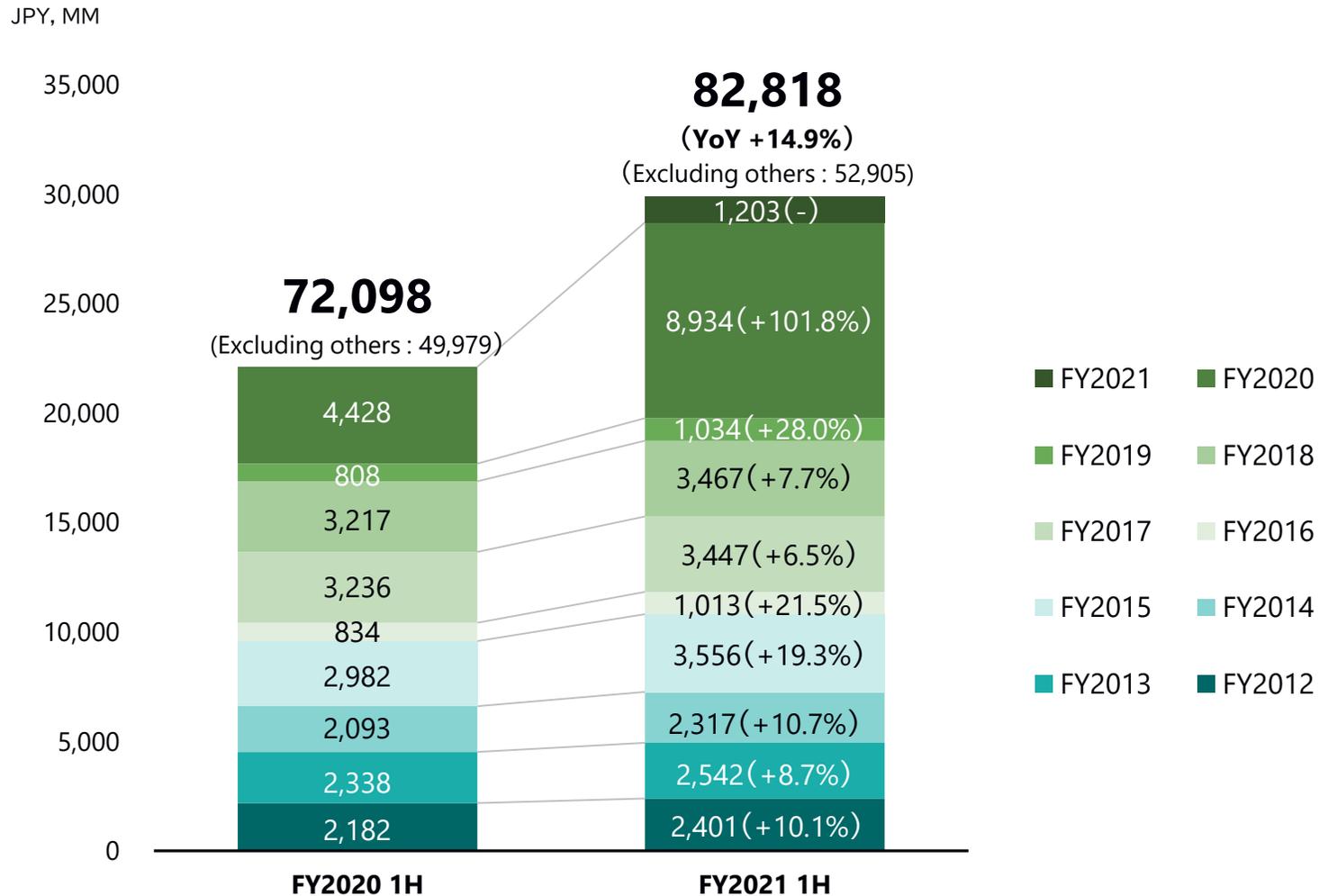
- Significant growth in sales due to the adoption of products launched in FY2020 and main products.

Medical institutions		FY2020 1H		FY2021 1H			YoY	
Channel	Total, Nationwide	# of Customers	Sales Share	# of Customers	Coverage Rate	Sales Share	# of Customers	Sales Growth
Hospital	8,249	7,978	10.9%	7,975	96.7%	9.9%	-3	+7.0%
DPC* Hospital	1,757	1,748	6.6%	1,749	99.5%	6.0%	+1	+7.3%
Clinic	106,677	35,249	9.0%	36,768	34.5%	8.5%	+1,519	+11.2%
Pharmacy	89,352	58,815	78.9%	59,821	66.9%	80.5%	+1,006	+20.1%
Dispensing	62,270	58,527	78.3%	59,538	95.6%	80.0%	+1,011	+20.3%
Drug Stores, etc.	27,082	288	0.6%	283	1.0%	0.5%	-5	+1.8%
Others	-	-	1.2%	-	-	1.1%	-	+7.9%
Total	204,278	102,042	100.0%	104,564	51.2%	100.0%	+2,522	+17.1%

*DPC: Diagnosis Procedure Combination, a fixed payment system for inpatients

Sales by Product Launch Year, Japan

- Steady growth in sales of products launched in FY2020



- Sales declined significantly, due to the impact of competitor entries into key USL generic product markets.
- Steady progress in brand products.
- Three products have launched in the first half of FY2021.

By Segment

JPY, MM

	FY2020 1H		FY2021 1H		YoY
	Actual	Comp.	Actual	Comp.	
Generic products	15,126	83.7%	10,263	70.9%	-32.1%
Main products*1	8,584	47.5%	4,675	32.3%	-45.5%
New products launched in FY2021	-	-	351	2.4%	-
Others	6,542	36.2%	5,237	36.2%	-19.9%
Brand products*2	2,948	16.3%	4,221	29.1%	+43.2%
Total	18,074	100.0%	14,484	100.0%	-19.9%

By therapeutic areas

JPY, MM

	FY2020 1H		FY2021 1H		YoY
	Actual	Comp.	Actual	Comp.	
Central nervous system	9,215	51.0%	7,171	49.5%	-22.2%
Cardiovascular	5,726	31.7%	4,948	34.2%	-13.6%
Dermatologic agents	341	1.9%	616	4.3%	+81.0%
Hormone preparations (including antihormone preparations)	613	3.4%	583	4.0%	-5.0%
Agents for urogenital organs and the anus	866	4.8%	360	2.5%	-58.5%
Others	1,312	7.2%	806	5.5%	-38.6%
Total	18,074	100.0%	14,484	100.0%	-19.9%

Average rate

US\$1 = ¥107

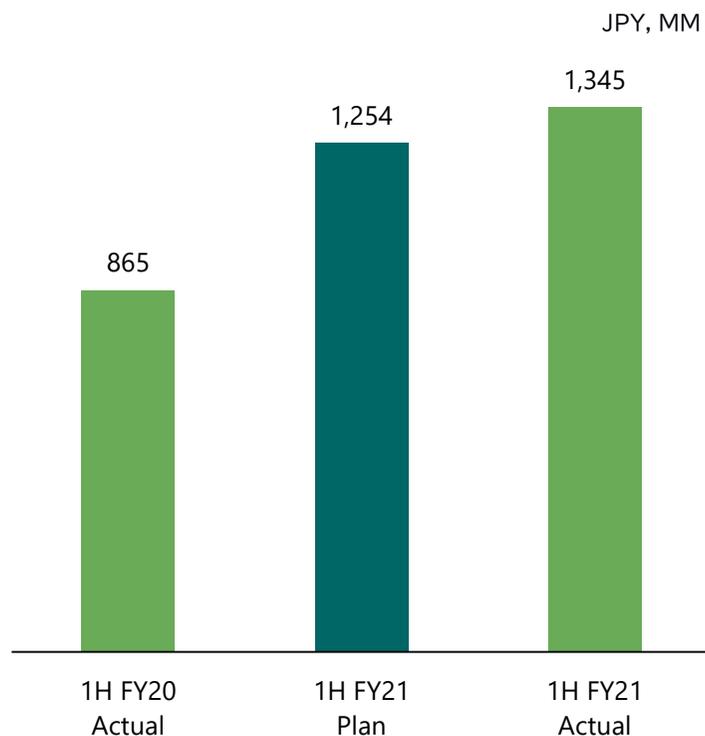
US\$1 = ¥110

*1 Klor-con®, Chlorpromazine, Qudexy®

*2 Zembrace® Symtouch®, Tosymra™, Vigadrone®

Combined performance for Zembrace and Tosymra is ahead of expectations for FY21; Tosymra volumes are in line with plan while Revenue is slightly behind plan due to lower than planned average selling price (ASP)

Net Sales (Zembrace & Tosymra)



Key Actions to Accelerate Tosymra Growth

- Drive improved Average Selling Price (ASP) through improved Prior Authorization (PA) performance (both submission rates and success rates for submitted PAs) and new Platinum Pass business rules
- Drive new prescription growth via new Direct-to-Consumer channel partnerships with Cove, an online migraine telemedicine company, and two regional pharmacies to conduct patient consultations on non-oral migraine solutions (Tosymra)
- Engage new managed care partner, Eversana, and leverage real world economic data to influence better coverage from managed care
- Continue to drive first fill success through specialty pharmacy channel with Blink Pharmacy

Progress towards FY2021 Forecasts, Consolidated

- The business in Japan grew steadily, while the sales in the US fell short of the initial forecast due to a sharp decline in sales of main generics products.
- On a consolidated basis, both net sales and core operating income slightly exceeded the FY2021 first half forecast.
- Our full-year forecast remains unchanged as the circumstances surrounding the business environment are unclear, considering shipment adjustments due to the supply stoppages of products from other generics companies etc.

JPY, MM

	FY 2021 Full Year Forecast			FY2021 1H Actual			Progress rate for full-year forecasts
		Japan	US		Japan	US	
Net Sales	196,400	163,700	32,700	97,302	82,818	14,484	49.5%
Core Operating Income	31,300 ^{*3}	27,900	3,400	16,120	16,219	-107	51.5%
Operating Income	26,400	26,400	0	13,822	14,431	-609	52.4%
Profit before tax	26,100	-	-	13,649	-	-	52.3%
Profit attributable to owners of the parent	19,500	-	-	9,422	-	-	48.3%

Average rate

US\$1 = ¥110

US\$1 = ¥110

*1 Results by segment in Japan and the U.S. are not consistent with the overall figures, as each segment profit includes inter-segment transactions.

*2 Core operating income is calculated by excluding profits and losses attributed to non-recurring factors from operating income.

*3 Adjust the followings from operating income

- Japan: SG&A expenses 500, R&D expenses 1,000

- US : SG&A expenses 4,600, R&D expenses 600, other income and expenditure -1,800

Progress of
the Mid-Term Business Plan,
"START 2024"

Investment to Increase Production Capacity in Japan

- Decided to invest in the construction of a new solid dosage form facility in order to increase production capacity
- As a result of this investment, the total in-house production capacity of Sawai Pharmaceutical increases by approximately 20% from the current capacity, 15.5 billion tablets per year

Overview

Purpose	In response to rising demand and further market expansion for generics in the future
Planned amount of Investment	STEP1 : approx. 35 billion yen STEP2 : approx. 5.5 billion yen
Production Capacity	STEP1 : 2 billion tablet capacity to be added in 2024 STEP2 : 1 billion tablet capacity to be added (Step 2 will be implemented without delay in consideration of market trends including other companies and the status of our new product development)
Number of new employment (plan)	STEP1 : 330 STEP2 : 490 (Total number including step 1)



Schedule



Project to Create a New Factory in the US



Project to Create a New Factory

We continue to be on schedule and budget for the consolidation of our Denver, CO and Plymouth, MN manufacturing facilities into a modern facility connected to our Maple Grove, MN HQ to lower operating expenses and improve quality and efficiency.

Expected Benefits

- Meaningful positive Net Income impact beginning in 2023 through consolidation of facilities and repatriation of CMO products
- Improved efficiencies driven by the long-term benefit of consolidating operations into modernized facility
- Improved quality through electronic batch records, better material and manufacturing flow and improved equipment

Cost Estimates & Deliverables

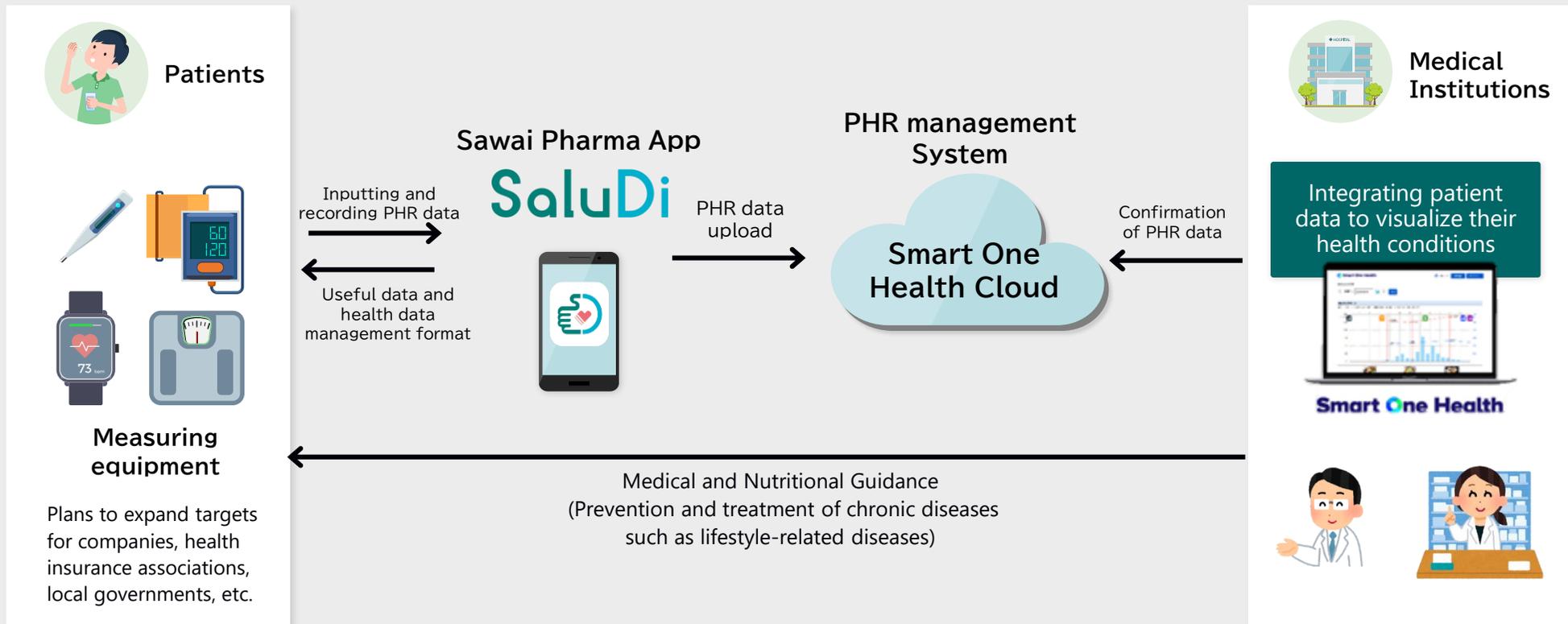
- Despite the environment due to COVID, we focused on cost/schedule control with external consultants and are on schedule and within expected budget
- Denver site sale completed in April 2021 with flexible lease-back to allow for certain transfer of Denver product to Maple Grove facility
- Maple Grove Pilot Plant is fully operational
- Phase 2 build-out to transfer Plymouth products and allow for sale of Plymouth plant will be considered in Q3 FY21

Key Milestones



New Businesses: Launch of Personal Health Record Management App, "SaluDi"

- This app features functions of recording and managing daily health conditions, making online medical care appointments, consultation, and access to information on pre-symptomatic illness and disease prevention.
- This is the first step to realize "Contributing to improving people's lifestyles, health, and quality of life by providing and utilizing medical and health information, not only pharmaceuticals" set in our medium-term business plan, "START 2024" announced in May 2021.



The background features a gradient of green shades from dark teal to light lime green, with several overlapping, wavy, semi-transparent bands. Two thin white horizontal lines are positioned on either side of the text, extending from the left and right edges towards the center.

R e f e r e n c e M a t e r i a l s

Comparison of Sales Volume by Therapeutic Area, Japan

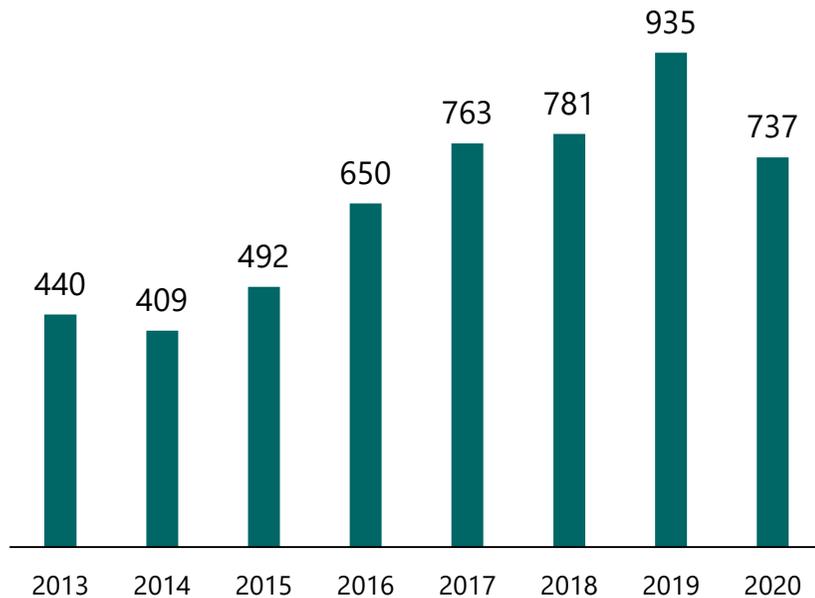
- Significant increase in sales volume for each therapeutic category.

(Unit: %)

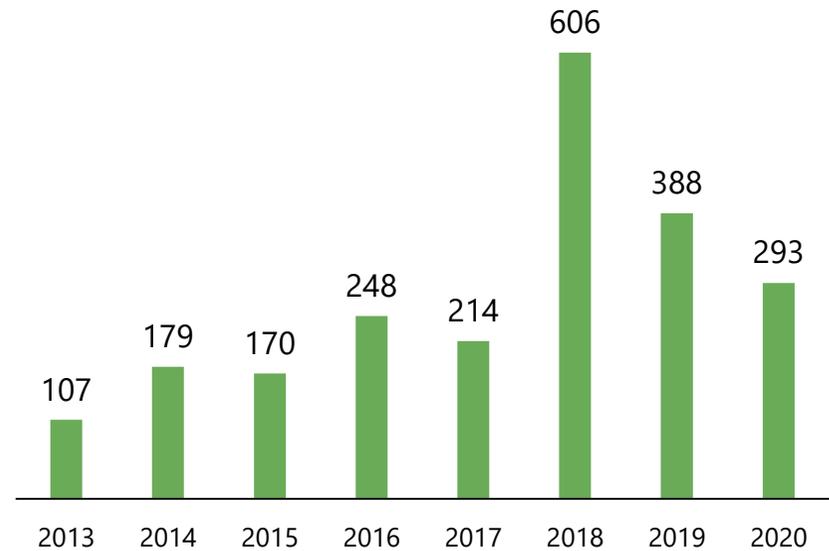
	FY2020 1H	FY2021 1H	YoY (volume)	YoY (value)
	Comp.	Comp.		
Cardiovascular drugs	30.0%	30.2%	+21.5%	+10.0%
Gastro-intestinal drugs	19.0%	17.2%	+8.9%	+2.7%
Central nervous system drugs	13.4%	13.8%	+23.9%	+27.2%
Blood/body fluid pharmaceutical products	8.4%	8.6%	+22.8%	+15.2%
Other metabolic drugs	6.9%	7.0%	+22.9%	+21.4%
Vitamin drugs	5.2%	6.0%	+38.4%	+51.9%
Respiratory organ agents	5.1%	4.9%	+16.2%	+14.2%
Antibiotics drugs	1.8%	1.9%	+23.9%	+20.7%
Agents for urogenital organs and the anus	1.5%	1.7%	+40.2%	+21.3%
Others	8.7%	8.7%	+21.7%	+9.0%
Total	100.0%	100.0%	+20.6%	+14.9%

The FDA approved 737 new ANDA products in their FY2020 (Oct 19-Sep 20), down from the record 935 approvals in FY2019. ANDA's withdrawn peaked in FY2018 and have declined the past two years. Approvals and withdrawn ANDA's are trending to end slightly lower for FDA's FY2021.

■ ANDA Approvals



■ Approved ANDAs Withdrawn

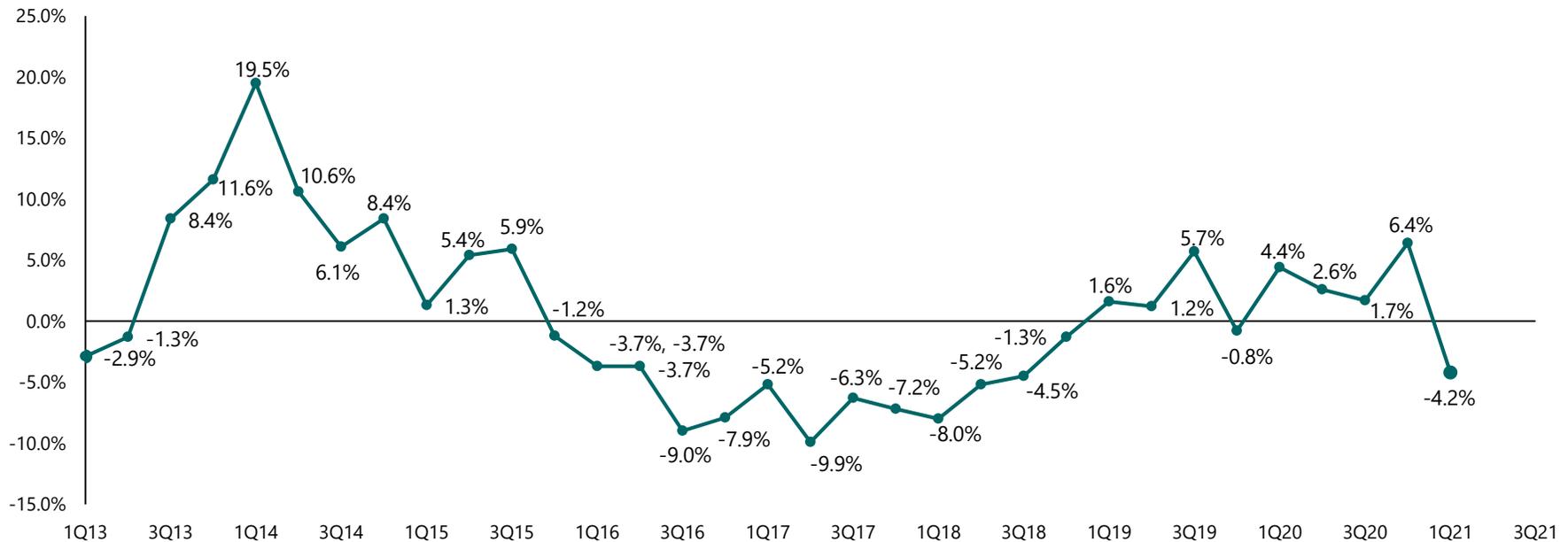


Source: US FDA

Year-over-year Generic price changes have leveled off close to 0% since 2019. Oral solid and topical products have performed better than injectables during this period.

Generic Price Per Rx Quarterly Yr/Yr % Change

(includes IQVIA calendar adjustment factors, but does NOT adjust 90-day Rx)



Source = IQVIA: Barclay's Bank Research Sep 1, 2021

Consolidated Financial Highlights-1

sawai

Key Income Statements Data

JPY, MM

	FY2020 Actual		FY2021 Actual			FY2021 Forecast				
	1Q	/Sales (%)	1Q	/Sales (%)	YoY	1H	/Sales (%)	Full Year	/Sales (%)	YoY
Net Sales	90,172	100.0%	97,302	100.0%	7.9%	94,800	100.0%	196,400	100.0%	+4.9%
Cost of Sales	54,103	60.0%	61,414	63.1%	13.5%	58,800	62.0%	120,600	61.4%	+5.1%
Gross Profit	36,069	40.0%	35,888	36.9%	-0.5%	36,000	38.0%	75,800	38.6%	+4.6%
SG&A Expenses	16,110	17.9%	16,196	16.6%	0.5%	17,100	18.0%	34,800	17.7%	-12.9%
R&D Expenses	6,148	6.8%	8,118	8.3%	32.0%	7,400	7.8%	16,400	8.4%	+18.1%
Other income(expenses)	202	0.2%	2,247	2.3%	1011.8%	1,800	1.9%	1,800	0.9%	+557.1%
Core operating income	17,581	19.5%	16,120	16.6%	-8.3%	14,800	15.6%	31,300	15.9%	-8.1%
Operating Income	14,012	15.5%	13,822	14.2%	-1.4%	13,300	14.0%	26,400	13.4%	+39.8%
Profit before tax	13,812	15.3%	13,649	14.0%	-1.2%	13,100	13.8%	26,100	13.3%	+41.4%
Profit attributable to owners of the parent	10,800	12.0%	9,422	9.7%	-12.8%	10,000	10.5%	19,500	9.9%	+58.0%
EBITDA *	23,364	25.9%	21,464	22.1%	-8.1%	20,400	21.5%	42,500	21.6%	-6.6%

* Core operating income + amortization and depreciation expenses included in core operating income

Key Balance Sheets Data

JPY, MM

	As of March 31, 2021	As of Sep 30, 2021
Total Assets	393,341	398,667
Equity	240,750	248,567
Ratio of equity attributable to owners of the company to total assets (%)	55.5%	56.7%

Amounts Per Common Share

JPY

	FY2020 1H Actual	FY2021 1H Actual	FY2021 Full Year Forecast
Basic earnings per share	246.65	215.15	445.29
Diluted earnings per Share	246.41	214.96	-
Dividend	65.00	65.00	130.00

Consolidated Financial Highlights-2

Sales and Operating Income by Area, Japan

JPY, MM

	FY2020 Actual		FY2021 Actual			FY2021 Forecast		
	1H	/Sales(%)	1H	/Sales(%)	YoY	Full Year	/Sales(%)	YoY
Net Sales	72,098	100.0%	82,818	100.0%	+14.9%	163,700	100.0%	+6.6%
Cost of Sales	45,437	63.0%	52,544	63.4%	+15.6%	103,600	63.3%	+6.4%
Gross Profit	26,660	37.0%	30,275	36.6%	+13.6%	60,100	36.7%	+7.0%
SG&A Expenses	9,885	13.7%	10,861	13.1%	+9.9%	23,300	14.2%	+6.8%
R&D Expenses	3,434	4.8%	5,210	6.3%	+51.7%	10,400	6.4%	+27.9%
Other income(expenses)	55	0.1%	215	0.3%	+291.9%	0	-	-
Core operating income	14,307	19.8%	16,219	19.6%	+13.4%	27,900	17.0%	-7.8%
Operating Income	13,397	18.6%	14,431	17.4%	+7.7%	26,400	16.1%	+0.4%
EBITDA *	19,552	27.1%	21,008	25.4%	+7.4%	37,900	23.2%	-6.7%

Sales and Operating Income by Area, US

JPY, MM

	FY2020 Actual		FY2021 Actual			FY2021 Forecast		
	1H	/Sales(%)	1H	/Sales(%)	YoY	Full Year	/Sales(%)	YoY
Net Sales	18,074	100.0%	14,484	100.0%	-19.9%	32,700	100.0%	-2.8%
Cost of Sales	8,665	47.9%	8,870	61.2%	+2.4%	17,000	52.0%	-2.2%
Gross Profit	9,409	52.1%	5,614	38.8%	-40.3%	15,700	48.0%	-3.4%
SG&A Expenses	6,228	34.5%	5,349	36.9%	-14.1%	11,500	35.2%	-36.5%
R&D Expenses	2,718	15.0%	2,913	20.1%	+7.2%	6,000	18.3%	+4.0%
Other income(expenses)	153	0.8%	2,039	14.1%	+1233.0%	1,800	5.5%	+649.3%
Core operating income	3,268	18.1%	- 107	-	-	3,400	10.4%	-9.7%
Operating Income	615	3.4%	- 609	-	-	0	-	-
EBITDA *	18,074	100.0%	14,484	100.0%	-19.9%	32,700	100.0%	-2.8%

* Core operating income + amortization and depreciation expenses included in core operating income

Consolidated Financial Highlights-3

Adjusted from Full basis to Core basis

JPY, MM

	FY2020 1H Actual				FY2021 1H Actual			
	Full Basis	Adjusting		Core Basis	Full Basis	Adjusting		Core Basis
		Japan	US			Japan	US	
Net Sales	90,172	-	-	90,172	97,302	-	-	97,302
Cost of Sales	-54,103	126	32	-53,944	-61,414	-196	57	-61,553
Inventory step-up	-21	-	21	-	- 6	-	6	-
Impairment loss	-	-	-	-	-	-	-	-
Others	-137	126	12	-	-38	38	0	-
Gross Profit	36,069	126	32	36,227	35,888	-196	57	35,750
SG&A Expenses	-16,110	264	2,361	-13,485	-16,196	300	2,080	-13,816
Amortization of intangible assets	-2,625	264	2,361	-	-2,382	296	2,086	-
Others	-	-	-	-	3	4	-6	-
R&D Expenses	-6,148	575	412	-5,161	-8,118	1,899	404	-5,814
Amortization of intangible assets	- 819	456	363	-	-972	568	404	-
Impairment loss	-168	119	49	-	-1,331	1,331	-	-
Other income	210	-57	-153	-	2,254	-220	-2,034	-
Other expenses	-9	6	3	-	-6	6	-	-
Operating Income	14,012	913	2,655	17,581	13,822	1,791	507	16,120

Selling General and Administrative Expenses

JPY, MM

	FY2020 Actual		FY2021 Actual			FY2021 Forecast	
	1H	/Sales(%)	1H	/Sales(%)	YoY	Full year	/Sales(%)
R&D Expenses	6,148	6.8%	8,118	8.3%	+32.0%	16,400	8.4%
Japan	3,434	4.8%	5,210	6.3%	+51.7%	10,400	6.4%
US	2,718	15.0%	2,913	20.1%	+7.2%	6,000	18.3%
Advertisement Expenses	1,291	1.4%	1,576	1.6%	+22.0%	3,800	1.9%

Capital Expenditure & Depreciation and Amortization

JPY, MM

	FY2020 1H Actual	FY2021 1H Actual	FY2021 Full Year Forecast
Capital Expenditure	7,509	7,266	12,300
Japan	4,860	4,494	7,800
US	2,649	2,771	4,500
Depreciation and Amortization	9,227	8,699	17,900
Japan	5,965	5,653	10,900
Manufacturing Division	4,184	3,686	7,400
R&D Division	962	1,095	1,800
Administration Div. & Business Div.	819	872	1,700
US	3,262	3,046	7,000

Personnel Information Number of Employees

	FY2020 Actual		FY2021 Actual	
	As of Sep 30, 2020	Comp.(%)	As of Sep 30, 2021	Comp.(%)
Japan	2,453	80.8%	2,474	82.0%
Manufacturing Division	1,609	53.0%	1,634	54.1%
R&D Division	249	8.2%	250	8.3%
Administration Div. & Business Div. (MRs)	595	19.6%	590	19.5%
(MRs)	394	-	379	-
US	584	19.2%	544	18.0%
Total	3,037	100.0%	3,018	100.0%

- The plans, forecasts, strategy and other information regarding the Sawai Group contained in this presentation are based on the Company's assumptions and judgments using information available at the time of publication. Therefore, due to potential risks and uncertainties, there is no guarantee of the accuracy of this information.
- Potential risks and uncertainties include, but are not limited to, the economic environment for prescription drugs, which is the main operating domain of the Sawai Group, market competition and services offered by the Group.

Contact
Information

Sawai Group Holdings Co., Ltd.
Group Public Relations & Investor Relations Office



ir@sawai.co.jp