

Sawai Group Holdings Co., Ltd.

FY2022 Financial Results for the 1st Half

Nov 8, 2022

4887.T, TSE Prime

sawai

In Japan

- **Although sales and core operating income decreased from the same period last year, core operating income progressed as forecasted.**

The factors behind the decline from the same period of the previous fiscal year were as follows:

1. Decline in unit prices due to the NHI drug
2. Decrease due to rebound from the significant increase in sales due to extraordinary factors in the 1st half of the previous year
→ Responded to an increased demand due to supply stoppages etc. of products from other generics companies by releasing inventory, and this backlash led to a year-on-year decline.
3. Recorded 700 million yen as a refund liability for returned Oseltamivir products, an anti-influenza virus drug
4. Upfront cost for the first half of FY2022 of Trust Pharmatech Co., Ltd. (hereinafter, "Trust Pharmatech") : 2.4 billion yen

- **Status of the product for which shipments have been limited**

While continuing limiting shipments of products, which are selected based on the inventory status following the increased demand due to supply stoppages etc. from other generics companies, lifted the adjustment from time to time in consideration of supply status of other companies, supply and demand of limited shipment items, inventory status, etc.

*The number of items that are limited for shipment is 222, as of November 8, 2022. (452 and 347 items at the end of March 2022 and June 2022 respectively)

- **The quantity of products manufactured progressed as planned.**

Production volume of the 1st half of FY2022, including the volume of contract manufacturing, increased 14% year on year, to approx. 8.4 billion tablets. (Annual plan of production volume for FY2022 is approx. 16.5 billion.)

- **Impact of rising raw material costs**

Limited impact on the first half results.

In the United States

- **Steady progress of the sales including the products launched in 2021. Revenue increased both on a yen and dollar bases.**
- **Both core operating profit and operating profit returned to profitability due to cost reduction efforts.**

- **Consolidated:** Sales and all income accounts fell below the same period of the previous fiscal year. Although sales fell slightly short of the 1H forecast, core operating income achieved.
- **Japan:** Sales and core operating income decreased from the same period last year, due to the impact of NHI drug price revision, rebound from increase in sales on account of extraordinary factors in the 1st half of the previous year, and upfront cost for Trust Pharmatech, etc.
- **United States:** Sales increased from the same period of the previous fiscal year both on a yen and dollar basis due to the steady growth of the new products launched in FY2021. Both core operating profit and operating profit returned to profitability due to cost reduction efforts.

JPY, MM

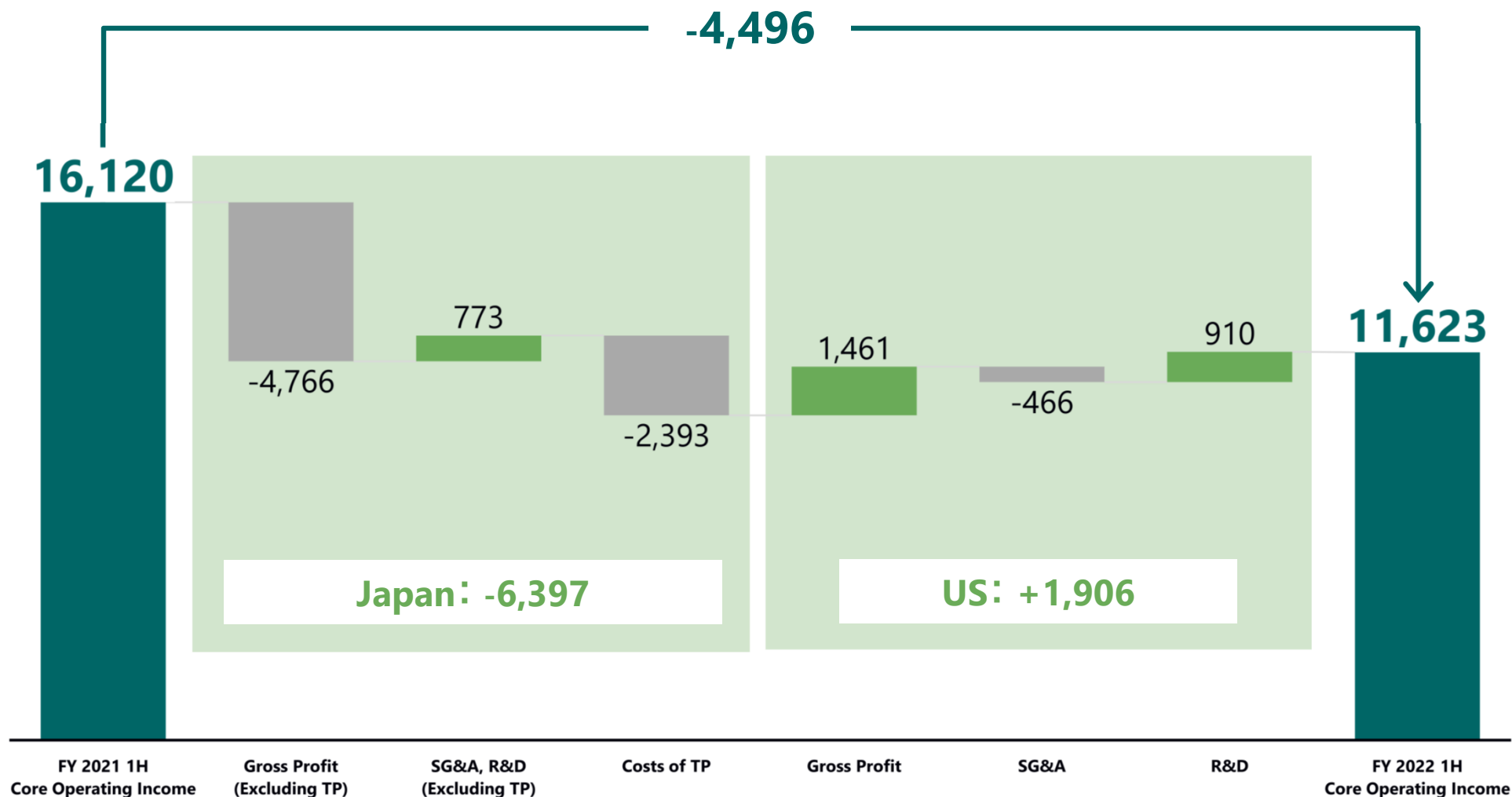
	FY 2022 1H			FY 2021 1H			YoY	FY2022 1H Forecast	Achievement
	Japan	US		Japan	US				
Net Sales	96,414	77,337	19,077	97,302	82,818	14,484	-0.9% (-888)	100,600	95.8%
Core Operating Income	11,623	9,822	1,799	16,120	16,219	-107	-27.9% (-4,496)	11,300	102.9%
Core Operating Income (Excluding Trust Pharmatech)	14,016	12,215	-	-	-	-	-	13,700	102.3%
Operating Income	8,817	8,297	519	13,822	14,431	-609	-36.2% (-5,005)	9,600	91.8%
Operating Income (Excluding Trust Pharmatech)	11,196	10,676	-	-	-	-	-	12,000	93.3%
Profit before tax	8,707	-	-	13,649	-	-	-36.2% (-4,942)	9,400	92.6%
Profit attributable to owners of the parent	6,660	-	-	9,422	-	-	-29.3% (-2,761)	7,900	84.3%

Average rate US\$1 = ¥134 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

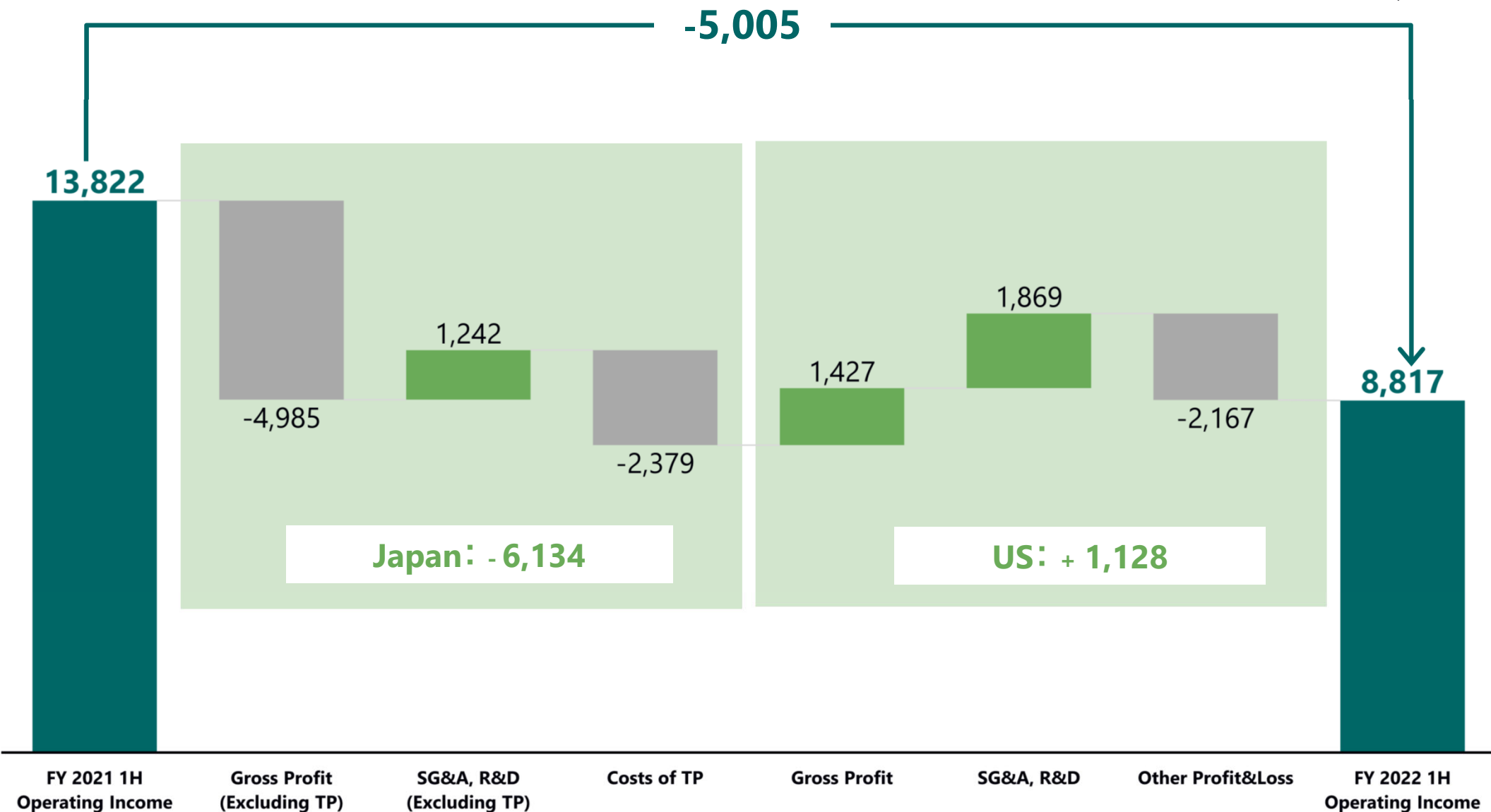
JPY, MM



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

Operating Income Analysis

JPY, MM



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

Sales by Channel in Japan

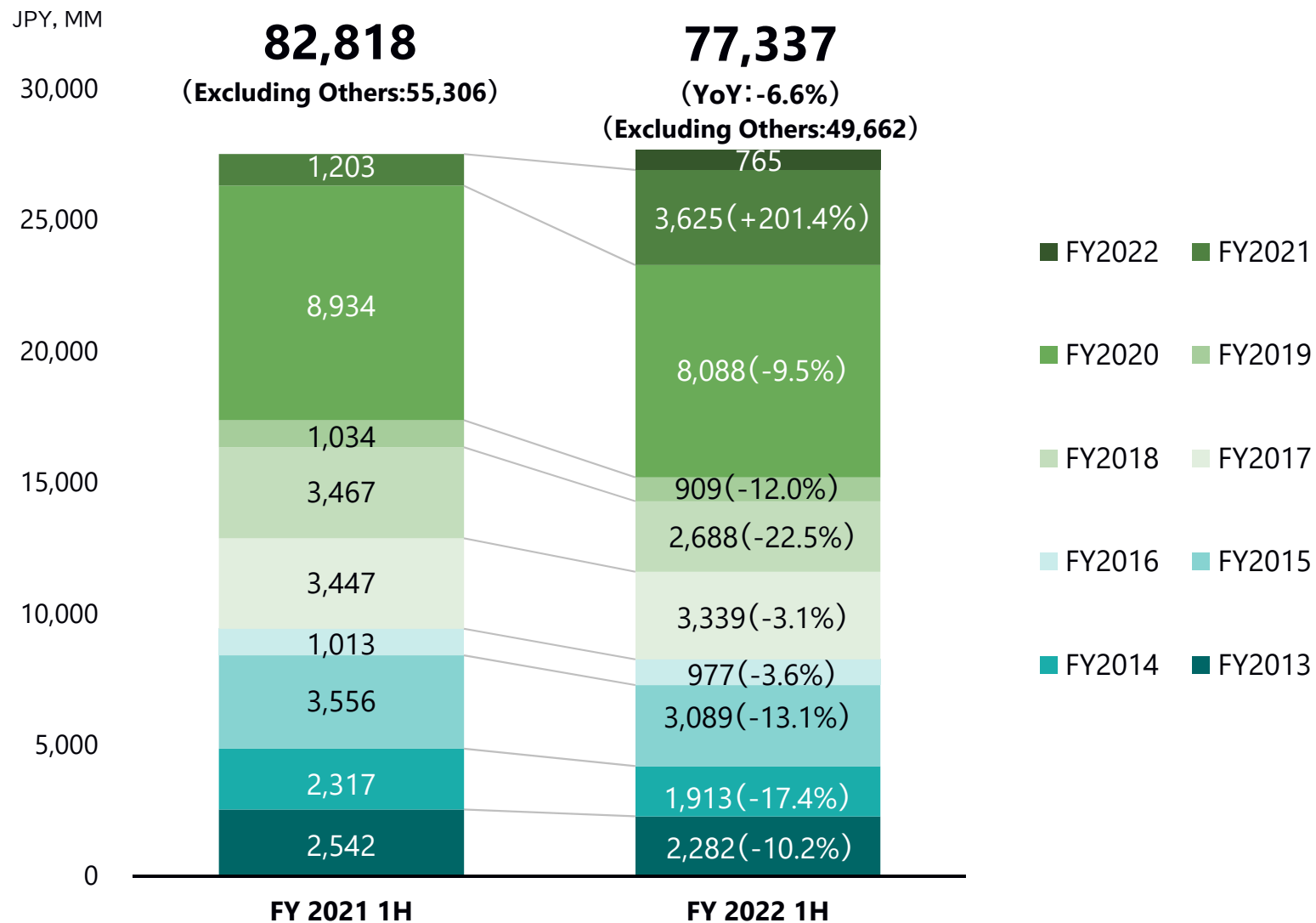
- In 1Q, sales decreased due to the extraordinary factors from the same period of the previous year, 2Q recovered to the same level as the previous fiscal year's.

Medical institutions		FY2021 1H		FY2022 1H			YoY	
Channel	Total, Nationwide	# of Customers	Sales Share	# of Customers	Coverage Rate	Sales Share	# of Customers	Sales Growth
Hospital	8,183	7,975	9.9%	7,984	97.6%	10.0%	+9	-6.2%
DPC Hospital	1,764	1,749	6.0%	1,760	99.8%	6.1%	+11	-5.8%
Clinic	110,139	36,768	8.5%	37,949	34.5%	8.7%	+1,181	-5.4%
Pharmacy	90,111	59,821	80.5%	60,676	67.3%	80.3%	+855	-7.5%
Dispensing	63,207	59,538	80.0%	60,398	95.6%	79.8%	+860	-7.5%
Drug Stores, etc	26,904	283	0.5%	278	1.0%	0.5%	-5	-10.8%
Others	-	-	1.1%	-	-	1.0%	-	-8.1%
Total	208,433	104,564	100.0%	106,609	51.1%	100.0%	+2,045	-5.5%

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

Sales by Product Launch Year, Japan

- Steady growth in sales of products launched in FY2021 as projected.



- Overall sales increased by 8.0% on a dollar basis with the steady growth of products launched in FY2021 and brand products.
- Significant increase in sales on a yen basis of 31.7%, partly due to the impact of the sharp depreciation of the yen.

By segment

(JPY, MM)

	FY 2021 1H		FY 2022 1H		YoY
	Actual	Comp.	Actual	Comp.	
Generic Products	10,263	70.9%	13,280	69.6%	+29.4%
Main products*1	4,675	32.3%	5,042	26.4%	+7.9%
Products launched in FY2021	351	2.4%	2,460	12.9%	+600.7%
Others	5,237	36.2%	5,778	30.3%	+10.3%
Brand Products*2	4,221	29.1%	5,797	30.4%	+37.4%
Total	14,484	100.0%	19,077	100.0%	+31.7%

*1 Klor-Con®, Chlorpromazine, Qudexy® XR

*2 Zembrace Symtouch®, Tosymra®, Vigadrone®

By therapeutic areas

(JPY, MM)

	FY2021 1H		FY2022 1H		YoY
	Actual	Comp.	Actual	Comp.	
Central nervous system	7,171	49.5%	9,693	50.8%	+35.2%
Cardiovascular	4,948	34.2%	4,897	25.7%	-1.0%
Dermatologic agents	616	4.3%	2,349	12.3%	+281.1%
Hormone preparations	583	4.0%	749	3.9%	+28.5%
Agents for urogenital organs and the anus	360	2.5%	359	1.9%	-0.1%
Others	806	5.5%	1,029	5.5%	+27.6%
Total	14,484	100.0%	19,077	100.0%	+31.7%

Average rate

US\$1 = ¥110

US\$1 = ¥134

Progress towards FY2022 Forecasts, Consolidated

- Sales progresses slightly below the forecast, but core operating income makes progress as forecasted.
- In the second half, the full-year forecast remains unchanged, considering the impact of the yen depreciation, while anticipating an increase in sales of new and existing products in Japan.

(JPY, MM)

	FY2022 Forecast			FY2022 1H Actual			Progress rate for full-year forecasts
		Japan	US	Japan	US		
Net Sales	207,000	174,800	32,200	96,414	77,337	19,077	46.6%
Core Operating Income	24,800 ^{*3}	22,300	2,500	11,623	9,822	1,799	46.9%
Core Operating Income (Excluding Trust Pharmatech)	29,600	27,100	-	14,016	12,215	-	47.4%
Operating Income	21,400	20,800	600	8,817	8,297	519	41.2%
Operating Income (Excluding Trust Pharmatech)	26,200	25,600	-	11,196	10,676	-	42.7%
Profit before tax	21,100	-	-	8,707	-	-	41.3%
Profit attributable to owners of the parent	17,700	-	-	6,660	-	-	37.6%

Average rate

US\$1= ¥120

US\$1= ¥134

*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 1,300, other income and expenditure -300

- US: SG&A expenses 1,500, R&D expenses 400

Progress of the Mid-
Term Business Plan,
“START 2024”

- Factories of Trust Pharmatech is proceeding as planned for commencement of operations.
- Initial release is scheduled in April 2023.

Current Situation

- Preparation for the start of commercial production for products to be launched in 2023 is proceeding steadily.
- Completed selection and preparation for submitting manufacturing permit application of the first product
- Technology transfer is in progress for second or more products.
- Progress of training for its employees is as planned (see details on the next page)

Schedule

Preparation for Manufacturing

From Apr. 2022

Start Shipping

From Apr. 2023

Manufacturing / Research Facilities



- Steady progress in training for employees at Trust Pharmatech.
- To be able to acquire the equivalent skills as the employees of Sawai Pharmaceutical's factories, achievement level is and continue to be evaluated regularly.

■ Training at HQs and Factories of Trust Pharmatech

- GMP* and other training are conducted monthly based on annual plans of each division.
- On-site trainings are implemented as planned, guided by experts from Reliability Assurance and Manufacturing divisions at Sawai Pharmaceutical.
- Disseminate information and provide procedural guidance regarding management, confirmation, and approval schemes for managers and supervisors.
- Assessment of performance records regarding GMP is also carried out monthly at the same level as audits and recommendations are made monthly by Reliability Assurance division and Quality Assurance department of each factory of Sawai Pharmaceutical.



■ Training at Factories at Sawai Pharmaceutical

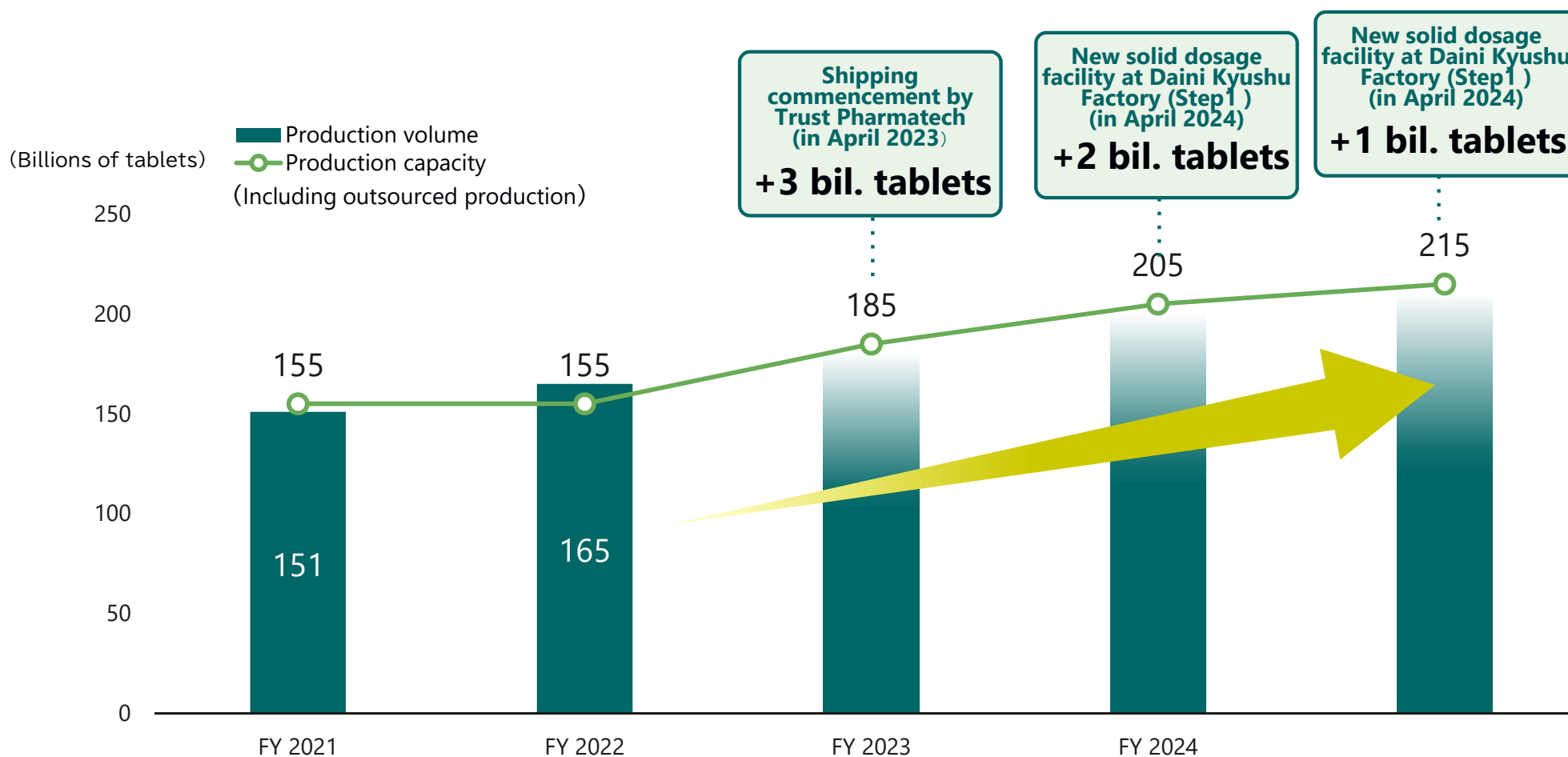
- 130 employees of Trust Pharmatech, who will work at its factories later, are undergoing on-the-job training at the existing factories of Sawai Pharmaceutical since May 2022. Training underway to practice Sawai criterion production methods
- Conduct GMP and other training in classes, and conduct on-the-job-training according to actual experience and individual proficiency for each task in charge.
- Steady progress in training in each division, including manufacturing, packaging, and back-office operation.



*GMP: Good Manufacturing Practice

Future Production Capacity to Strengthen Stable Supply Capabilities

- Steady progress to the production target for FY2022, approx. 16.5 billion tablets (including the volume of contract manufacturing), as production volume of 1st half was approx. 8.4 billion tablets.
- From the next fiscal year (fiscal 2023) onward, factories of Trust Pharmatech and the new solid dosage facility at Daini Kyushu factory will begin operations progressively.
- Aim to further expand market share in Japanese generics market.



- Steady progress in strengthening product pipeline through new and existing partnerships and in the preparation of commercial production in the new plant.

Product Development Strategy

- Increased pipeline products through engagements with several partners. Added 6 products to the pipeline in 1st half of FY2022.
- Currently 27 products in pipeline. USL will keep increasing its pipeline by selecting products with emphasis on ROI.

Progress of New Plant Project

- Starting commercial manufacturing in the new plant located at Maple Grove, MN in January 2023 as planned.
- Upsher-Smith is exploring expansion of the business through contract manufacturing service opportunities.



◆ New plant located at Maple Grove, MN

Digital medical devices business

Joint development of DTx for NASH

- Entered into a licensing agreement with CureApp, Inc. to develop and sell the digital therapeutics of NASH in July 2022.
- Phase 3 studies will be conducted based on data from multicenter clinical studies based on data acquired from the joint clinical studies at multiple facilities.

SWD001 (non-invasive neuromodulation device)

- Preparing for application for approval in 2022 and launch in 2024 for migraine in 2022.

PHR (Personal Healthcare Record) app

- Considering and preparing to launch and expand a variety of services on SaluDi, a health management app launched in October 2021.

Health food business

Health food business, where we would support longer healthy lifespans

(e.g., locomotive syndrome/frailty measures, and dementia/lifestyle-related disease prevention)

- Test marketing is underway until November 2022.
- Plan to evaluate business feasibility based on test marketing results and prepare for full-scale rollout.

New Drug Businesses (Orphan diseases)

Orphan Drugs

- Strengthening the internal evaluation structure and continuing to consider expanding the pipeline.



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

- Sales of new products in FY2022 are expected to be JPY 6 billion, including products scheduled to be launched in December 2022.

Product name	Brand products
Esomeprazole Capsules 10mg, 20mg	Nexium® Capsules 10mg, 20mg
Escitalopram Oxalate Tablets 10mg, 20mg OD Tablets 10mg, 20mg	Lexapro® Tablets 10mg, 20mg
Ramelteon Tablets 8mg	Rozerem® Tablets 8mg
Tolvaptan OD Tablets 7.5mg, 15mg Granules 1%	Samsca® OD Tablets 7.5mg, 15mg granules 1%
Ibandronate Intravenous Injection Syringes 1mg	Bonviva® Syringes for Intravenous Injection 1mg
Daptomycin for Intravenous Injection 350mg	Cubicin® IV 350mg

Comparison of Sales Volume by Therapeutic Area, Japan

- Steady growth in "other metabolic drugs" line, due to contributions from products launched in FY2021 and 2022.

	FY2021 1H	FY2022 1H	YoY (volume)	YoY (value)
	Comp.	Comp.		
Cardiovascular drugs	30.2%	27.5%	-11.9%	-15.9%
Gastro-intestinal drugs	17.2%	16.8%	-5.6%	-8.5%
Central nervous system drugs	13.8%	15.1%	+6.2%	+3.9%
Blood/body fluid pharmaceutical products	8.6%	8.9%	+0.6%	-7.6%
Other metabolic drugs	7.0%	8.2%	+13.7%	+13.8%
Vitamin drugs	6.0%	5.8%	-5.7%	-16.0%
Respiratory organ agents	4.9%	5.5%	+9.2%	+1.7%
Antibiotics drugs	1.9%	1.9%	-2.1%	+1.4%
Agents for urogenital organs and the anus	1.7%	1.7%	-3.1%	+1.7%
Others	8.7%	8.6%	-5.6%	-10.2%
Total	100.0%	100.0%	-3.2%	-6.6%

Consolidated Financial Highlights-1

Key Income Statements Data

(単位:百万円)

	FY2021 Actual		FY2022 Actual				FY2022 Forecast				
	1H	/Sales (%)	1H	/Sales (%)	YoY	Achievement	1H	/Sales (%)	Full Year	/Sales (%)	YoY
Net Sales	97,302	100.0%	96,414	100.0%	-0.9%	46.6%	100,600	100.0%	207,000	100.0%	+6.8%
Cost of Sales	61,414	63.1%	65,914	68.4%	+7.3%	47.6%	68,600	68.2%	138,500	66.9%	+8.9%
Gross Profit	35,888	36.9%	30,500	31.6%	-15.0%	44.5%	32,000	31.8%	68,500	33.1%	+2.8%
SG&A Expenses	16,196	16.6%	15,155	15.7%	-6.4%	44.4%	16,700	16.6%	34,100	16.5%	-27.0%
R&D Expenses	8,118	8.3%	6,429	6.7%	-20.8%	48.3%	5,800	5.8%	13,300	6.4%	-45.5%
Other income(expenses)	2,247	2.3%	-99	-	-	-	100	0.1%	300	0.1%	-
Core operating income	16,120	16.6%	11,623	12.1%	-27.9%	46.9%	11,300	11.2%	24,800	12.0%	-5.8%
Core Operating Income (Excluding Trust Pharmatech)	-	-	14,016	14.5%	-	47.4%	13,700	13.6%	29,600	14.3%	-
Operating Income	13,822	14.2%	8,817	9.1%	-36.2%	41.2%	9,600	9.5%	21,400	10.3%	-
Operating Income (Excluding Trust Pharmatech)	-	-	11,196	11.6%	-	42.7%	12,000	11.9%	26,200	12.7%	-
Profit before tax	13,649	14.0%	8,707	9.0%	-36.2%	41.3%	9,400	9.3%	21,100	10.2%	-
Profit attributable to owners of the parent	9,422	9.7%	6,660	6.9%	-29.3%	37.6%	7,900	7.9%	17,700	8.6%	-
EBITDA *1	21,464	22.1%	18,157	18.8%	-15.4%	48.3%	17,800	17.7%	37,600	18.2%	+1.6%

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

Key Balance Sheets Data

	As of March 31, 2022	As of Sep 30, 2022
Total Assets	349,502	381,984
Equity	200,083	214,204
Ratio of equity attributable to owners of the company to total assets (%)	54.4%	52.9%

Amounts Per Common Share

	FY2021 1H Actual	FY2022 1H Actual	FY2022 Full Year Forecast
Basic earnings per share	215.15	152.09	404.19
Diluted earnings per Share	214.96	151.80	-
Dividend(interim)	65.00	65.00	130.00

Consolidated Financial Highlights-2

Sales and Operating Income by Area, Japan

(JPY, MM)

	FY 2021 Actual		FY 2022 Actual				FY 2022 Forecast		
	1H	/Sales (%)	1H	/Sales (%)	YoY	Achievement	Full Year	/Sales (%)	YoY
Net Sales	82,818	100.0%	77,337	100.0%	-6.6%	44.2%	174,800	100.0%	+6.7%
Cost of Sales	52,544	63.4%	53,877	69.7%	+2.5%	45.2%	119,300	68.2%	+12.5%
Gross Profit	30,275	36.6%	23,460	30.3%	-22.5%	42.3%	55,500	31.8%	-3.9%
SG&A Expenses	10,861	13.1%	10,587	13.7%	-2.5%	41.8%	25,300	14.5%	+16.0%
R&D Expenses	5,210	6.3%	4,607	6.0%	-11.6%	47.5%	9,700	5.5%	-22.6%
Other income(expenses)	215	0.3%	31	0.0%	-85.4%	10.4%	300	0.2%	-96.7%
Core operating income	16,219	19.6%	9,822	12.7%	-39.4%	44.0%	22,300	12.8%	-17.5%
Core Operating Income (Excluding Trust Pharmatech)	-	-	12,215	15.8%	-	45.1%	27,100	15.5%	-
Operating Income	14,431	17.4%	8,297	10.7%	-42.5%	39.9%	20,800	11.9%	-35.7%
Operating Income (Excluding Trust Pharmatech)	-	-	10,676	13.8%	-	41.7%	25,600	14.6%	-
EBITDA *	21,008	25.4%	15,753	20.4%	-25.0%	46.3%	34,000	19.5%	-7.1%

Sales and Operating Income by Area, US

	FY 2021 Actual		FY 2022 Actual				FY 2022 Forecast		
	1H	/Sales (%)	1H	/Sales (%)	YoY	Achievement	Full Year	/Sales (%)	YoY
Net Sales	14,484	100.0%	19,077	100.0%	+31.7%	59.2%	32,200	100.0%	+7.4%
Cost of Sales	8,870	61.2%	12,037	63.1%	+35.7%	62.7%	19,200	59.6%	-8.9%
Gross Profit	5,614	38.8%	7,040	36.9%	+25.4%	54.2%	13,000	40.4%	+46.1%
SG&A Expenses	5,349	36.9%	4,570	24.0%	-14.6%	51.9%	8,800	27.3%	-64.6%
R&D Expenses	2,913	20.1%	1,823	9.6%	-37.4%	50.6%	3,600	11.2%	-69.7%
Other income(expenses)	2,039	14.1%	-128	-	-	-	0	-	-
Core operating income	-107	-	1,799	9.4%	-	72.0%	2,500	7.8%	-
Operating Income	-609	-	519	2.7%	-	86.6%	600	-	-
EBITDA *	449	3.1%	2,402	12.6%	+434.8%	66.7%	3,600	11.2%	+779.1%

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

Consolidated Financial Highlights-3

Adjusted from Full basis to Core basis

(JPY, MM)

	FY2021 1H Actual				FY2022 1H Actual			
	Full Basis	Adjusting		Core Basis	Full Basis	Adjusting		Core Basis
		Japan	US			Japan	US	
Net Sales	97,302	-	-	97,302	96,414	-	-	96,414
Cost of Sales	-61,414	-196	57	-61,553	-65,914	24	92	-65,799
Inventory step-up	-6	-	6	-	-2	-	2	-
Others	145	-196	51	-	-114	24	90	-
Gross Profit	35,888	-196	57	35,750	30,500	24	92	30,616
SG&A Expenses	-16,196	300	2,080	-13,816	-15,155	298	835	-14,022
Amortization of intangible assets	-2,382	296	2,086	-	-1,137	296	841	-
Others	3	4	-6	-	-4	1	-5	-
R&D Expenses	-8,118	1,899	404	-5,814	-6,429	1,235	225	-4,970
Amortization	-972	568	404	-	-947	722	225	-
Impairment loss	-1,331	1,331	-	-	-487	487	-	-
Others	-	-	-	-	-26	26	-	-
Other income	2,254	-220	-2,034	-	280	-213	-67	-
Other expenses	-6	6	-	-	-379	183	197	-
Operating Income	13,822	1,791	507	16,120	8,817	1,526	1,281	11,623

Selling General and Administrative Expenses

(JPY, MM)

	FY2021 Actual		FY2022 Actual			FY2022 Forecast	
	1H	/Sales(%)	1H	/Sales(%)	YoY	Full year	/Sales(%)
R&D Expenses	8,118	8.3%	6,429	6.7%	-20.8%	13,300	6.4%
Japan	5,210	6.3%	4,607	6.0%	-11.6%	9,700	5.5%
US	2,913	20.1%	1,823	9.6%	-37.4%	3,600	11.2%
Advertisement Expenses	1,576	1.6%	541	0.6%	-65.7%	2,800	1.4%

Capital Expenditure & Depreciation and Amortization

	FY2021 1H Actual	FY2022 1H Actual	FY2022 Full Year Forecast
Capital Expenditure	7,266	16,891	24,600
Japan	4,494	15,891	22,300
US	2,771	1,000	2,300
Depreciation and Amortization	8,699	8,617	16,700
Japan	5,653	6,949	13,500
Manufacturing Division	3,686	4,526	9,300
R&D Division	1,095	1,323	2,500
Administration Div. & Business Div.	872	1,099	1,700
US	3,046	1,669	3,200

Personnel Information Number of Employees

	FY2021 Actual		FY2022 Actual	
	As of September 30, 2021	Comp.(%)	As of September 30, 2022	Comp.(%)
Japan	2,474	82.0%	2,959	86.5%
Manufacturing Division	1,634	54.1%	2,028	59.3%
R&D Division	250	8.3%	299	8.7%
Administration Div. & Business Div.	590	19.5%	632	18.5%
(MRs)	379	-	379	-
US	544	18.0%	462	13.5%
Total	3,018	100.0%	3,421	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.

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