

Sawai Group Holdings Co., Ltd.

FY2022 Financial Results for the 3rd Quarter

Feb 13, 2023

4887.T, TSE 1st section

sawai

Consolidated

- **Although sales increased year-on-year, income accounts fell below the same period of the previous fiscal year.**

In Japan

- **Sales are on par and core operating income decreased compared to the same period of the previous fiscal year.**

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

1. Decline in unit prices due to the NHI drug
2. Upfront cost for the cumulative third quarter of FY2022 of Trust Pharmatech Co., Ltd. (hereinafter, "Trust Pharmatech"): 3.7 billion yen
3. Recorded 700 million yen as a refund liability for returned Oseltamivir products, an anti-influenza virus drug

- **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, the adjustment was lifted 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 218, as of February 8, 2023.

(452, 347 and 258 items at the end of Mar. 2022, Jun. 2022 and Sep. 2022 respectively)

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

Production volume of the cumulative third quarter of FY2022, including the volume of contract manufacturing, increased 11% year-on-year, to approx. 12.5 billion tablets.

(Annual plan of production volume for FY2022 is approx. 16.5 billion.)

- **Impact of rising raw material costs on cost of sales**

Although the impact of the cumulative third quarter results is limited, it is gradually expanding from the second half.

In the United States

- **Steady sales for brand products**
- **Core operating profit significantly exceeded year-on-year due to cost reduction efforts.**

- **Consolidated:** Although sales increased year-on-year, income accounts fell below the same period of the previous fiscal year.
- **Japan:** Despite the impact of NHI drug price revision and rebound from increase in sales on account of extraordinary factors in the 1st half of the previous year, sales recovered to the same level as the previous fiscal year due to the growth in sales of new products and the adjustment lifting of the product for which shipments have been limited. Core operating income decreased from the same period last year, due to upfront cost for Trust Pharmatech, etc.
- **United States:** Sales increased year-on-year, due to the steady growth of products including brands in addition to the effect of the weak yen. Despite the negative impact on sales and income accounts from transient extraordinary factors in 3Q, core operating income increased year-on-year due to cost reduction efforts.

(JPY,MM)

	FY 2022 3Q			FY 2023 3Q			YoY
		Japan	US		Japan	US	
Net Sales	148,627	125,291	23,336	151,091	123,230	27,861	+1.7% (+2,464)
Core Operating Income	24,181	23,737	436	19,250	17,664	1,583	-20.4% (-4,931)
Core Operating Income (Excluding Trust Pharmatech)	-	-	-	22,975	21,389	-	-
Operating Income	23,936	21,210	2,726	14,379	14,672	-293	-39.9% (-9,557)
Operating Income (Excluding Trust Pharmatech)	-	-	-	17,960	18,253	-	-
Profit before tax	23,731	-	-	14,269	-	-	-39.9% (-9,461)
Profit attributable to owners of the parent	15,883	-	-	10,845	-	-	-31.7% (-5,037)

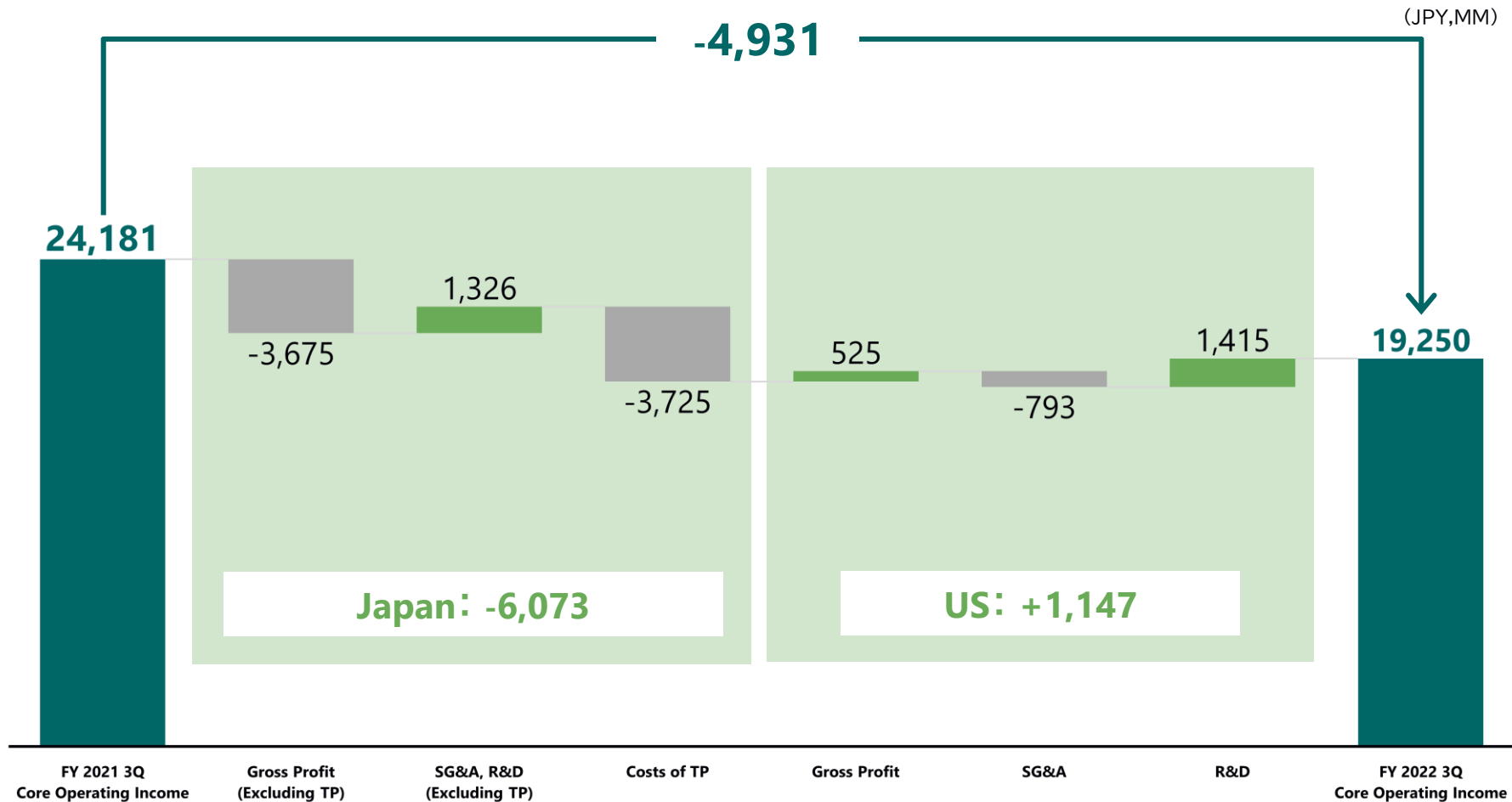
Average rate

US\$1 = ¥111

US\$1 = ¥137

- 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.

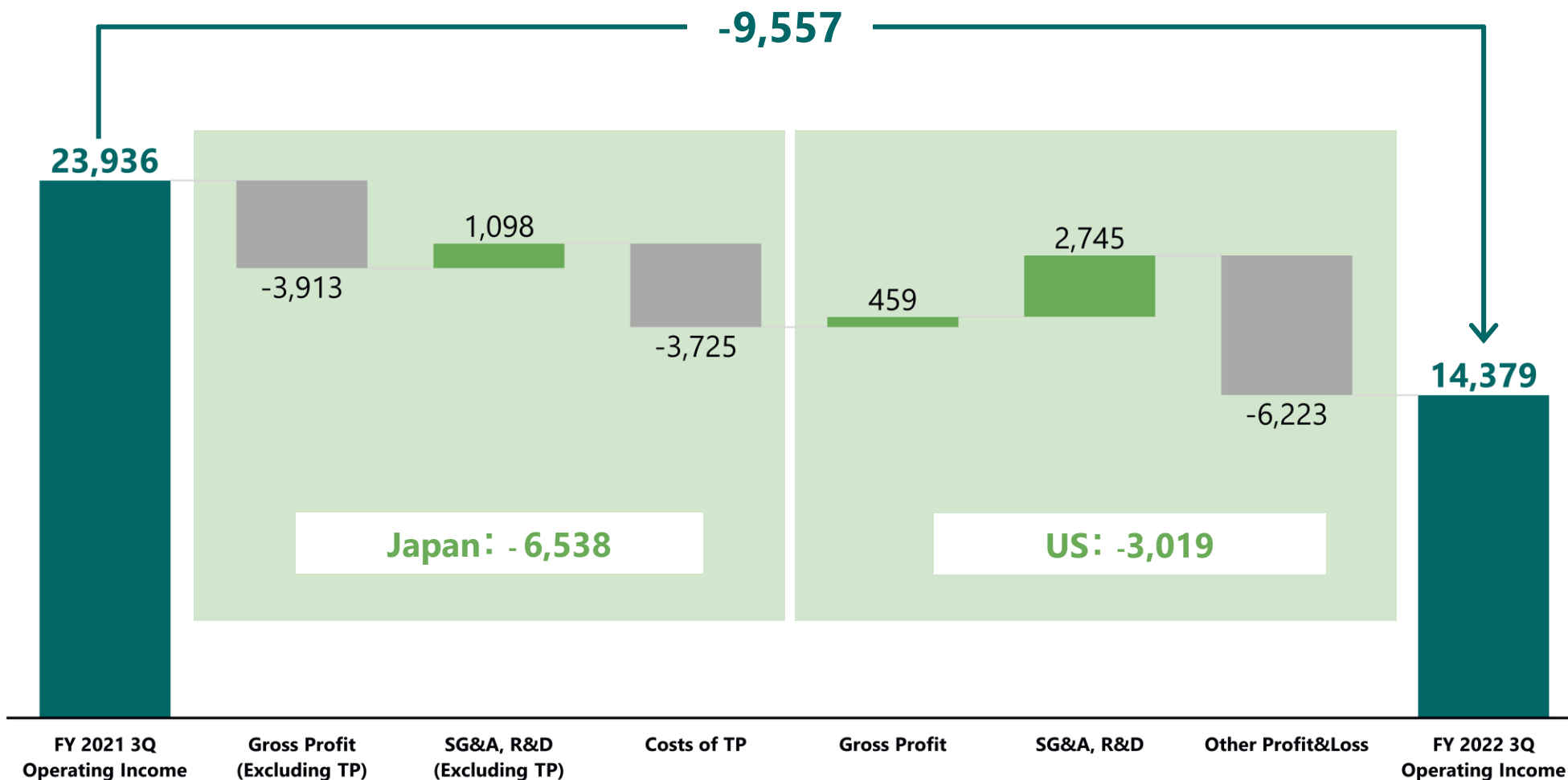
Core Operating Income Analysis



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

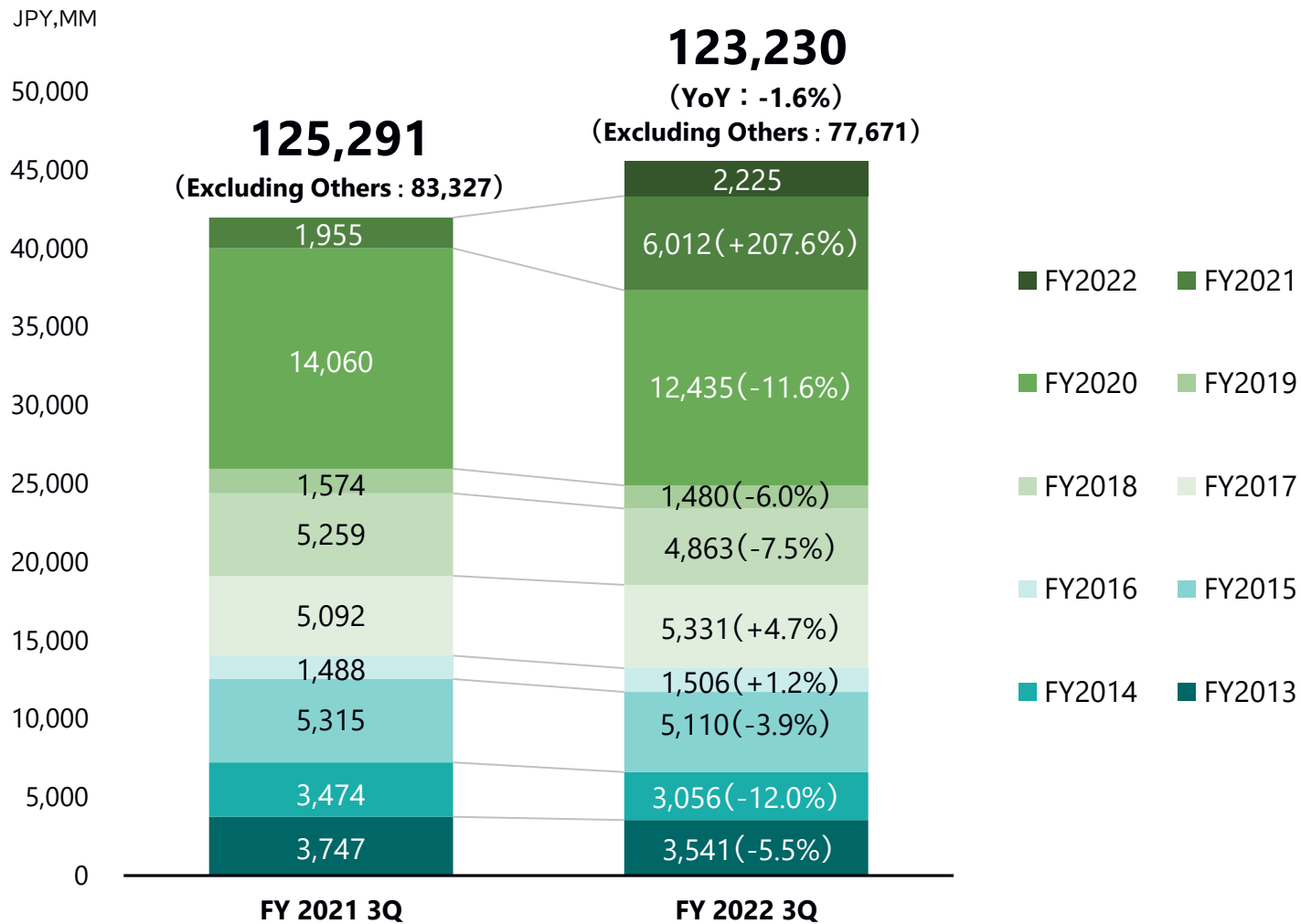
- Sales growth in new products and the adoption increase of products that lifted shipping adjustment contributed to the recovery from the decline caused by the previous fiscal year's extraordinary factors.

Medical institutions		FY2021 3Q		FY2022 3Q			YoY	
Channel	Total, Nationwide	# of Customers	Sales Share	# of Customers	Coverage Rate	Sales Share	# of Customers	Sales Growth
Hospital	8,177	8,018	10.0%	8,030	98.2%	10.2%	+12	-1.2%
DPC Hospital	1,764	1,751	6.1%	1,759	99.7%	6.3%	+8	-1.4%
Clinic	110,243	39,319	8.5%	41,535	37.7%	8.7%	+2,216	-0.3%
Pharmacy	90,279	60,362	80.4%	61,256	67.9%	79.9%	+894	-2.9%
Dispensing	63,319	60,059	79.9%	60,952	96.3%	79.4%	+893	-2.8%
Drug Stores, etc	26,960	303	0.5%	304	1.1%	0.5%	+1	-6.8%
Others	-	-	1.1%	-	-	1.2%	-	-1.3%
Total	208,699	107,699	100.0%	110,821	53.1%	100.0%	+3,122	-0.1%

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

Sales by Product Launch Year, Japan

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



- Steady sales for brand products.
- Decreased in sales by 2.8% on a dollar basis due to transient extraordinary factors in 3Q.
- 19.4% increase in sales on a yen basis, partly due to the impact of the sharp depreciation of the yen.

By Segment

(JPY:MM)

	FY2021 3Q		FY2022 3Q		YoY
	Actual	Comp.	Actual	Comp.	
Generic Products	16,931	72.6%	19,218	69.0%	+13.5%
Main Products*1	7,021	30.1%	7,930	28.5%	+12.9%
Products launched in FY21	1,958	8.4%	2,974	10.7%	+51.7%
Others	7,953	34.1%	8,315	29.8%	+4.6%
Brand Products	6,405	27.4%	8,643	31.0%	+34.9%
Total	23,336	100.0%	27,861	100.0%	+19.4%

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

By therapeutic areas

(JPY:MM)

	FY2021 3Q		FY2022 3Q		YoY
	Actual	Comp.	Actual	Comp.	
Central nervous system	11,004	47.2%	14,580	52.3%	+32.5%
Cardiovascular	7,269	31.1%	7,572	27.2%	+4.2%
Dermatologic agents	2,289	9.8%	2,773	10.0%	+21.1%
Hormone preparations (including antihormone preparations)	966	4.1%	921	3.3%	▲4.7%
Agents for urogenital organs and the anus	547	2.3%	525	1.9%	▲4.0%
Others	1,261	5.5%	1,490	5.3%	+18.1%
Total	23,336	100.0%	27,861	100.0%	+19.4%

Average rate

US\$1 = ¥111

US\$1 = ¥137

Progress towards FY2022 Forecasts, Consolidated

- Although sales progresses slightly below the forecast, core operating income makes progress as forecasted.
- Aim to continue to increase sales through launching new products and expanding new adoption of products that lifted shipping adjustment in Japan, and cost control in both Japan and the US.

(JPY:MM)

	FY2022 Forecast			FY2022 3Q Actual			Progress rate for full-year forecasts
		Japan	US		Japan	US	
Net Sales	207,000	174,800	32,200	151,091	123,230	27,861	73.0%
Core Operating Income	24,800 ^{*3}	22,300	2,500	19,250	17,664	1,583	77.6%
Core Operating Income (Excluding Trust Pharmatech)	29,600	27,100	-	22,975	21,389	-	77.6%
Operating Income	21,400	20,800	600	14,379	14,672	-293	67.2%
Operating Income (Excluding Trust Pharmatech)	26,200	25,600	-	17,960	18,253	-	68.5%
Profit before tax	21,100	-	-	14,269	-	-	67.6%
Profit attributable to owners of the parent	17,700	-	-	10,845	-	-	61.3%

Average rate

US\$1 = ¥120

US\$1 = ¥137

*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

■ Future Policies

Implement a pricing policy reflected the rising cost of API and materials.

■ Current Environment

- Procurement price of API and materials including packaging material are rising due to inflation, soaring energy prices, and the depreciation of yen.
- In order to ensure a stable supply of generic drugs, the product cost increase must be reflected in the product price amid a steady increase in the cost of sales.



- In the Japanese market, generic drugs account for 50.3% of the total volume of ethical drugs, and are now essential in all fields of medical care.
- Generic drugs, for which maintaining a stable supply is essential, has become a part of social infrastructure now and are our core business.
- Require a pricing policy adapted to environmental changes to ensure long-term stable supply of generics that patients can use with peace of mind.

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

- Factories of Trust Pharmatech are proceeding as planned for initial shipment in April 2023.
- Preparing for providing products that patients can use with peace of mind and that are trusted by medical professionals.

Progress toward Initial Shipment

- Production of the first product is scheduled to start after obtaining approval for partial changes to add Trust Pharmatech to the column for manufacturing sites for products to be marketed.
- Planning to gradually transfer technology from factories at Sawai Pharmaceutical for existing Sawai products and the second and subsequent products.
- Preparing for technology transfer and production. Four products are scheduled to be produced in FY2024.



Training at Factories at Sawai Pharmaceutical

Training

- Training has been progressing according to a yearly schedule at both the HQ and factories of Trust Pharmatech and plants of Sawai Pharmaceutical.
- Efforts to promote compliance education and instillation of Sawai's corporate philosophy were done as needed by the department or team.

Schedule (from Apr. 2023)

- Approx. 40 employees assigned to Sawai Pharmaceutical factories returned and engaged in production at Trust Pharmatech.
- Approx. 90 employees including new trainees, are scheduled to join the training and production increase at factories of Sawai Pharmaceutical.

- Completed construction of new plant (Plant C) in Maple Grove, MN
- Closed Denver plant in December 2022 and started commercial manufacturing in the new plant in January 2023
- FDA Approved (FDA inspection August 2022)

Expected improvement by the new plant

- Repatriation of key intermediate processes are expected to save \$4 - \$6 million annually
- Continued optimization of gross margin will occur with increased utilization of new facility
- Exploring expansion of the business through contract manufacturing service opportunities utilizing Plant C

Summary of Plant C

Objectives	<ul style="list-style-type: none"> • Consolidate manufacturing facilities • Increase efficiency • Increase capacity
Location	Maple Grove, MN (Upsher-Smith HQ)
Investment	\$130 million
Manufacturing Capacity	5B doses per year; Tablets, Capsules, Powders, Liquids.
Square Footage	~270,000 square feet (~25,000 m ²)
USL manufacturing employees total	~150
depreciation in FY23	\$5 million



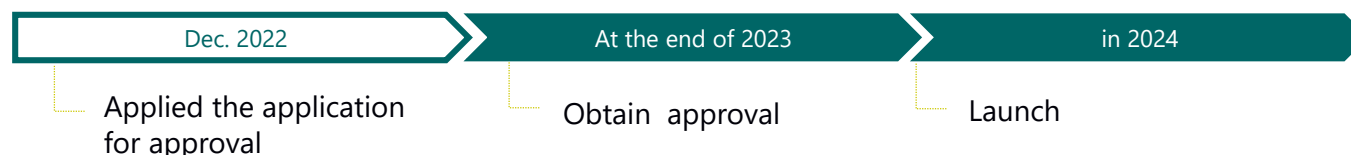
New Businesses: Application for Marketing and Manufacturing Approval for SWD001

- Applied for marketing and manufacturing approval for SWD001, a non-invasive neuromodulation device, as a medical device for acute treatment of migraine in December 2022.
- Aiming to launch as the first neuromodulation device in the migraine field in Japan.

About SWD001

Features	<ul style="list-style-type: none">● SWD001 doesn't require surgery to use.● In January 2021, Sawai Pharmaceutical and Neuroliief (Head office: Netanya, Israel, CEO: Scott Drees) entered into an exclusive development and marketing agreement to make SWD001 available in Japan.● SWD001 delivers unparalleled stimulation to the occipital and trigeminal nerves and creates a cumulative effect by releasing neurotransmitters in the brainstem and modulating brain networks associated with control of pain and mood.● Patients can use SWD001 at home, and can share treatment data with their physician, uploading the data to the cloud database through a dedicated app. Utilizing the uploaded data, patients can also receive advice from their doctors.
Targeted Market	Japan
Competitors	No Approved non-invasive neuromodulation devices have been identified in Japan. (as of February 2023)
Note	Neuromodulation is recommended in the Headache Practice Guideline 2021* and is expected to be a new option for patients who are inoperative to conventional treatments. *The guideline was created based on current medical knowledge to assist clinicians in making clinical judgments for appropriate and valid practice.

Planned Schedule



Digital medical devices business

| SWD001 (non-invasive neuromodulation device)

- Acute treatment of migraine : Applies for marketing and manufacturing approval in December 2022. Preparing for launch.
- Depression : Preparing to file for approval in 2023

| SWD002 (DTx for NASH)

- Digital Therapeutic App for NASH* that entered into a development and marketing license agreement with CureApp, Inc. Phase 3 studies are in preparation.

*NASH: non-alcoholic steatohepatitis

| SaluDi (Personal Health Record (PHR) app)

- Adoption to the "Digital Healthy Aging Project in Yabu City" in Yabu City, Hyogo Prefecture, scheduled to start operation in April 2023.



Health food business

| “Triple Seikatsu Shukan (Triple lifestyle habit)” (Foods with Functional Claims)

- Test marketing completed in November 2022.
- Evaluating business feasibility based on test marketing results and being under consideration for full-scale development.



New Drug Businesses (Orphan diseases)

| Orphan Drugs

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



Reference Materials

Comparison of Sales Volume by Therapeutic Area, Japan

- Steady growth in "central nervous system drugs" and "other metabolic drugs" lines, due to contributions from products launched in FY2021 and FY2022.

	FY2021 3Q	FY2022 3Q	YoY (volume)	YoY (value)
	Comp.	Comp.		
Cardiovascular drugs	29.7%	27.4%	-7.8%	-10.0%
Gastro-intestinal drugs	17.0%	16.6%	-2.6%	-5.0%
Central nervous system drugs	13.8%	15.3%	+10.1%	+10.7%
Blood/body fluid pharmaceutical products	8.5%	8.6%	+0.8%	-4.3%
Other metabolic drugs	7.0%	8.2%	+16.9%	+18.4%
Vitamin drugs	6.2%	5.7%	-7.7%	-19.5%
Respiratory organ agents	5.3%	5.7%	+7.2%	+4.0%
Antiallergic drug	3.1%	2.9%	-5.2%	-9.2%
Antibiotics drugs	1.9%	2.0%	+2.2%	+7.9%
Others	7.5%	7.6%	-0.5%	+0.8%
Total	100.0%	100.0%	-0.4%	-1.6%

Consolidated Financial Highlights-1

sawai

Key Income Statements Data

(JPY,MM)

	FY2021 Actual		FY2022 Actual				FY2022 Forecast		
	3Q	/Sales (%)	3Q	/Sales (%)	YoY	Achievement	Full Year	/Sales (%)	YoY
Net Sales	148,627	100.0%	151,091	100.0%	+1.7%	73.0%	207,000	100.0%	+6.8%
Cost of Sales	94,133	63.3%	102,930	68.1%	+9.3%	74.3%	138,500	66.9%	+8.9%
Gross Profit	54,494	36.7%	48,161	31.9%	-11.6%	70.3%	68,500	33.1%	+2.8%
SG&A Expenses	24,088	16.2%	23,173	15.3%	-3.8%	68.0%	34,100	16.5%	-27.0%
R&D Expenses	12,867	8.7%	10,825	7.2%	-15.9%	81.4%	13,300	6.4%	-45.5%
Other income(expenses)	6,398	4.3%	216	0.1%	-96.6%	71.9%	300	0.1%	-
Core operating income	24,181	16.3%	19,250	12.7%	-20.4%	77.6%	24,800	12.0%	-5.8%
Core Operating Income (Excluding Trust Pharmatech)	-	-	22,975	15.2%	-	77.6%	29,600	14.3%	-
Operating Income	23,936	16.1%	14,379	9.5%	-39.9%	67.2%	21,400	10.3%	-
Operating Income (Excluding Trust Pharmatech)	-	-	17,960	11.9%	-	68.5%	26,200	12.7%	-
Profit before tax	23,731	16.0%	14,269	9.4%	-39.9%	67.6%	21,100	10.2%	-
Profit attributable to owners of the parent	15,883	10.7%	10,845	7.2%	-31.7%	61.3%	17,700	8.6%	-
EBITDA *1	32,201	21.7%	29,253	19.4%	-9.2%	77.8%	37,600	18.2%	+1.6%

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

Key Balance Sheets Data

(JPY, MM)

	As of March 31, 2022	As of Dec 31, 2022
Total Assets	349,502	364,815
Equity	200,083	210,139
Ratio of equity attributable to owners of the company to total assets (%)	54.4%	54.6%

Amounts Per Common Share

(JPY)

	FY2021 3Q Actual	FY2022 3Q Actual	FY2022 Full Year Forecast
Basic earnings per share	362.69	247.66	404.19
Diluted earnings per Share	362.35	247.13	-
Dividend(interim)*2	65.00*2	65.00*2	130.00

*2 FY2022 1H Actual

Consolidated Financial Highlights-2

sawai

Sales and Operating Income by Area, Japan

(JPY,MM)

	FY 2021 Actual		FY 2022 Actual				FY 2022 Forecast		
	3Q	/Sales (%)	3Q	/Sales (%)	YoY	Achievement	Full Year	/Sales (%)	YoY
Net Sales	125,291	100.0%	123,230	100.0%	-1.6%	70.5%	174,800	100.0%	+6.7%
Cost of Sales	80,031	63.9%	84,763	68.8%	+5.9%	71.1%	119,300	68.2%	+12.5%
Gross Profit	45,259	36.1%	38,467	31.2%	-15.0%	69.3%	55,500	31.8%	-3.9%
SG&A Expenses	15,909	12.7%	16,047	13.0%	+0.9%	63.4%	25,300	14.5%	+16.0%
R&D Expenses	8,371	6.7%	8,016	6.5%	-4.2%	82.6%	9,700	5.5%	-22.6%
Other income(expenses)	232	0.2%	268	0.2%	+15.6%	89.2%	300	0.2%	-96.7%
Core operating income	23,737	18.9%	17,664	14.3%	-25.6%	79.2%	22,300	12.8%	-17.5%
Core Operating Income (Excluding Trust Pharmatech)	-	-	21,389	17.4%	-	78.9%	27,100	15.5%	-
Operating Income	21,210	16.9%	14,672	11.9%	-30.8%	70.5%	20,800	11.9%	-35.7%
Operating Income (Excluding Trust Pharmatech)	-	-	18,253	14.8%	-	71.3%	25,600	14.6%	-
EBITDA *	30,919	24.7%	26,748	21.7%	-13.5%	78.7%	34,000	19.5%	-7.1%

Sales and Operating Income by Area, US

	FY 2021 Actual		FY 2022 Actual				FY 2022 Forecast		
	3Q	/Sales (%)	3Q	/Sales (%)	YoY	Achievement	Full Year	/Sales (%)	YoY
Net Sales	23,336	100.0%	27,861	100.0%	+19.4%	86.5%	32,200	100.0%	+7.4%
Cost of Sales	14,101	60.4%	18,166	65.2%	+28.8%	94.6%	19,200	59.6%	-8.9%
Gross Profit	9,235	39.6%	9,694	34.8%	+5.0%	74.6%	13,000	40.4%	+46.1%
SG&A Expenses	8,182	35.1%	7,128	25.6%	-12.9%	81.0%	8,800	27.3%	-64.6%
R&D Expenses	4,502	19.3%	2,811	10.1%	-37.6%	78.1%	3,600	11.2%	-69.7%
Other income(expenses)	6,175	26.5%	-48	-	-	-	0	-	-
Core operating income	436	1.9%	1,583	5.7%	+263.2%	63.3%	2,500	7.8%	-
Operating Income	2,726	11.7%	-293	-	-	-	600	1.9%	-
EBITDA *	1,273	5.5%	2,501	9.0%	+96.4%	69.5%	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 3Q Actual				FY2022 3Q Actual			
	Full Basis	Adjusting		Core Basis	Full Basis	Adjusting		Core Basis
		Japan	US			Japan	US	
Net Sales	148,627	-	-	148,627	151,091	-	-	151,091
Cost of Sales	-94,133	-216	105	-94,243	-102,930	22	170	-102,737
Inventory step-up	-7	-	7	-	-2	-	2	-
Others	118	-216	98	-	-190	22	168	-
Gross Profit	54,494	-216	105	54,383	48,161	22	170	48,354
SG&A Expenses	-24,088	448	3,160	-20,480	-23,173	560	1,314	-21,299
Amortization of intangible assets	-3,613	444	3,168	-	-1,729	444	1,285	-
Others	4	4	-8	-	-145	116	29	-
R&D Expenses	-12,867	2,526	619	-9,722	-10,825	2,677	344	-7,805
Amortization	-1,498	878	619	-	-1,468	1,125	344	-
Impairment loss	-1,645	1,645	-	-	-1,523	1,523	-	-
Others	-	-	-	-	-29	29	-	-
Other income	6,407	-237	-6,170	-	393	-301	-91	-
Other expenses	-10	10	-	-	-177	36	142	-
Operating Income	23,936	2,530	-2,285	24,181	14,379	2,994	1,878	19,250

Selling General and Administrative Expenses

(JPY,MM)

	FY2021 Actual		FY2022 Actual			FY2022 Forecast	
	3Q	/Sales (%)	3Q	/Sales (%)	YoY	Full year	/Sales (%)
R&D Expenses	12,867	8.7%	10,825	7.2%	-15.9%	13,300	6.4%
Japan	8,371	6.7%	8,016	6.5%	-4.2%	9,700	5.5%
US	4,502	19.3%	2,811	10.1%	-37.6%	3,600	11.2%
Advertisement Expenses	2,091	1.4%	943	0.6%	-54.9%	2,800	1.4%

Capital Expenditure & Depreciation and Amortization

	FY2021 3Q Actual	FY2022 3Q Actual	FY2022 Full Year Forecast
Capital Expenditure	9,952	18,738	24,600
Japan	6,004	17,566	22,300
US	3,948	1,172	2,300
Depreciation and Amortization	13,130	13,199	16,700
Japan	8,505	10,653	13,500
Manufacturing Division	5,505	6,853	9,300
R&D Division	1,678	2,139	2,500
Administration Div. & Business Div.	1,322	1,660	1,700
US	4,625	2,547	3,200

Personnel Information Number of Employees

	FY2021 Actual		FY2022 Actual	
	As of December 31, 2021	Comp. (%)	As of December 31, 2022	Comp. (%)
Japan	2,467	82.2%	2,958	87.0%
Manufacturing Division	1,631	54.4%	2,022	59.5%
R&D Division	251	8.4%	297	8.7%
Administration Div. & Business Div.	585	19.5%	639	18.8%
(MRs)	381	-	378	-
US	533	17.8%	441	13.0%
Total	3,000	100.0%	3,399	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.
Public Relations & Investor Relations Corporate Communications



ir@sawai.co.jp