

Sawai Group Holdings Co.,Ltd.

FY2023 Financial Results for the 1st Quarter

Aug 9, 2023

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Consolidated

- **Steady growth was made in line with the forecast.**

In Japan

- **Sales increased 11.5% year on year and core operating income slightly exceeded the same period of the previous year.**

(+) Increase in sales of products launched in FY2022

(+) Reflected the impact of rising costs on prices, mainly on low-priced generics

(-) Decline in unit prices due to the NHI drug revision

(-) Impact of soaring prices of energy, API and materials

(-) Cost of recall of several items

- **Status of the products for which shipments have been limited.**

Reviewed products under shipment limitation as needed 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 259, as of Aug. 9, 2023.

(452 and 300 items at the end of Mar. 2022 and Mar. 2023 respectively)

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

Production volume of the first quarter of FY2023, including the volume of contract manufacturing, was approx. 4.1 billion tablets. (Annual plan of production volume for FY2023 is approx. 17.1 billion; progress rate: 24%)

In the United States

- **Sales of products launched since FY2021 grew.**

- **Core operating income progressed as planned, while it decreased year-on-year due to the cost associated with the structural changes related to the divestiture of the brand products.**

- **Consolidated:** Core operating income is making a steady progress toward the annual plan, despite the decrease from the previous year.
- **Japan:** Sales increased 11.5% year-on-year due to the increase in sales of products launched in FY2022. Core operating income slightly exceeded the same period of the previous year.
- **United States:** Sales of products launched since FY2021 grew. Core operating income progressed as planned, while it decreased year-on-year due to the cost associated with the structural changes related to the divestiture of the brand products.

JPY, MM

	FY 2022 1Q			FY 2023 1Q			YoY
		Japan	US		Japan	US	
Net Sales	48,231	38,704	9,527	52,989	43,153	9,836	+9.9% (+4,758)
Core Operating Income	6,146	5,220	924	5,977	5,318	658	-2.8% (-169)
Core Operating Income (Excluding Trust Pharmatech)	7,214	6,289	-	7,395	6,735	-	+2.5% (+181)
Operating Income	4,820	4,570	250	4,603	4,629	-25	-4.5% (-217)
Operating Income (Excluding Trust Pharmatech)	5,888	5,638	-	6,011	6,036	-	+2.0% (+123)
Profit before tax	4,815	-	-	4,613	-	-	-4.2% (-202)
Profit attributable to owners of the parent	3,672	-	-	3,518	-	-	-4.2% (-154)

Average rate

US\$1 = ¥130

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.

Sales by Channel in Japan

- Sales increased due to the steady growth in sales of main products and products launched in FY2022.

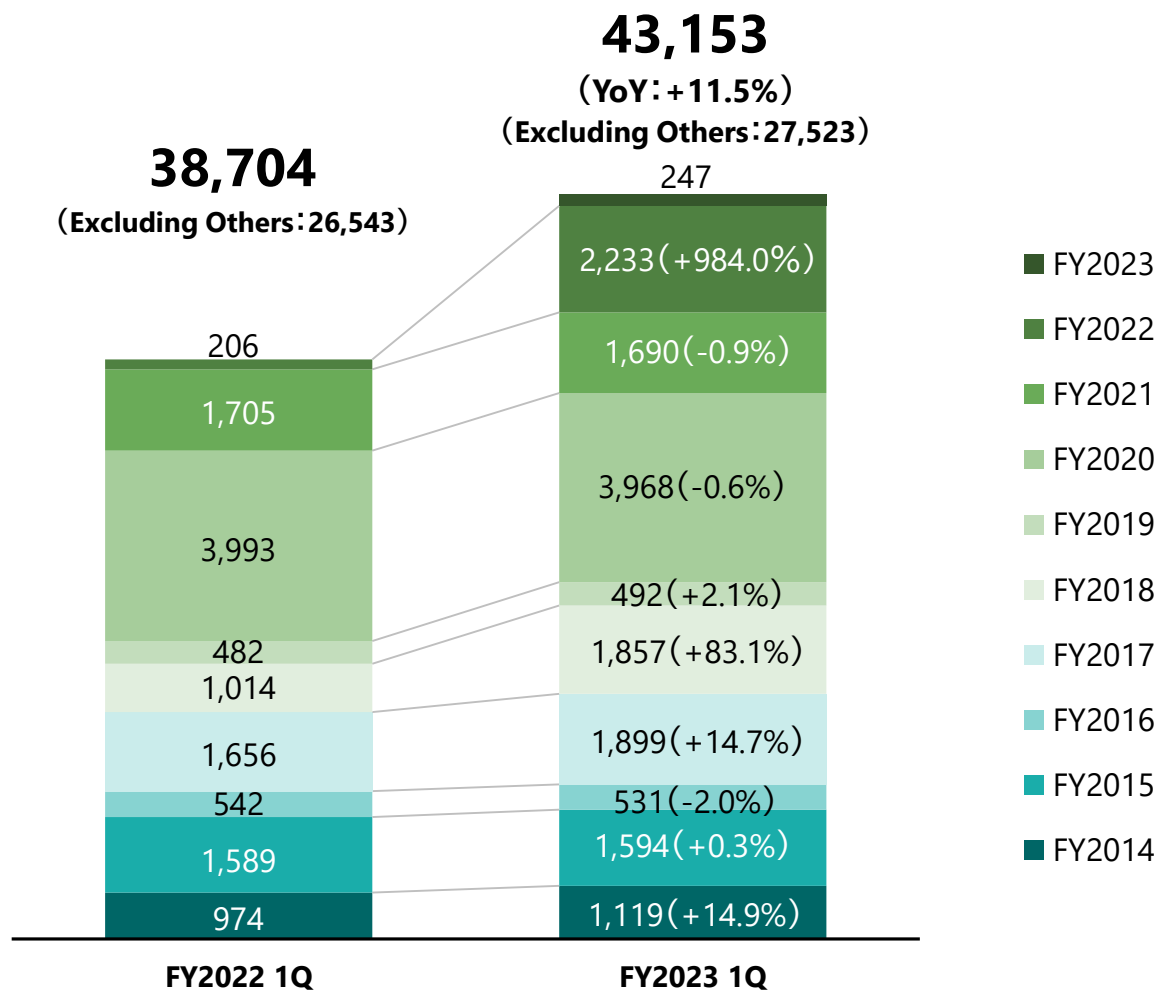
Medical institutions		FY2022 1Q		FY2023 1Q			YoY	
Channel	Total, Nationwide	# of Customers	Sales Share	# of Customers	Coverage Rate	Sales Share	# of Customers	Sales Growth
Hospital	8,162	7,901	9.9%	7,912	96.9%	10.8%	+11	+24.0%
DPC Hospital	1,761	1,757	6.0%	1,755	99.7%	6.9%	-2	+29.2%
Clinic	110,742	32,800	8.5%	34,253	30.9%	8.9%	+1,453	+19.2%
Pharmacy	90,163	60,029	80.6%	60,593	67.2%	79.3%	+564	+11.7%
Dispensing	63,518	59,779	80.0%	60,334	95.0%	78.9%	+555	+11.9%
Drug Stores, etc	26,645	250	0.5%	259	1.0%	0.4%	+9	-13.1%
Others	-	-	1.0%	-	-	1.0%	-	+11.4%
Total	209,067	100,730	100.0%	102,758	49.2%	100.0%	+2,028	+13.8%

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

Sales by Product Launch Year, Japan

- Steady growth in sales of products launched in FY2022.

(JPY, MM)



- Sales of products launched since FY2021 increased due to the launch of new products and other factors.
- Steady progress as planned. (Sales progress rate:26.3%)

By Segment

JPY, MM

	FY2022 1Q		FY2023 1Q		YoY
	Actual	Comp.	Actual	Comp.	
Generic products	5,777	60.6%	6,469	65.8%	+12.0%
Main products*1	2,352	24.7%	2,735	27.8%	+16.3%
New products launched since FY2021*2	442	4.6%	1,032	10.5%	+133.4%
Others	2,983	31.3%	2,702	27.5%	-9.4%
Specialty products*3	3,750	39.4%	3,367	34.2%	-10.2%
Total	9,527	100.0%	9,836	100.0%	+3.2%

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

*2 Excluding Isotretinoin Capsules (Private Label)

*3 Zembrace® Symtouch®, Tosymra®, Vigadrone®, Isotretinoin Capsules (Private Label)

By therapeutic areas

JPY, MM

	FY2022 1Q		FY2023 1Q		YoY
	Actual	Comp.	Actual	Comp.	
Central nervous system	4,585	48.1%	4,944	50.3%	+7.8%
Cardiovascular	2,549	26.8%	2,505	25.5%	-1.7%
Dermatologic agents	1,337	14.0%	1,096	11.1%	-18.0%
Hormone preparations	436	4.6%	334	3.4%	-23.4%
Antineoplastic agents	112	1.2%	227	2.3%	+102.0%
Others	508	5.3%	731	7.4%	+44.0%
Total	9,527	100.0%	9,836	100.0%	+3.2%

Average rate

US\$1 = ¥130

US\$1 = ¥137

Progress towards FY2023 Forecasts, Consolidated

- Net sales and core operating income are on track to achieve forecast.

(JPY, MM)

	FY2023 Forecast			FY2023 1Q Actual			Progress rate for full-year forecasts
		Japan	US		Japan	US	
Net Sales	217,200	180,500	36,700	52,989	43,153	9,836	24.4%
Core Operating Income	19,900 ^{*3}	16,300	3,600	5,977	5,318	658	30.0%
Core Operating Income (Excluding Trust Pharmatech)	25,300	21,700	-	7,395	6,735	-	29.2%
Operating Income	15,100	13,500	1,600	4,603	4,629	-25	30.5%
Operating Income (Excluding Trust Pharmatech)	20,500	18,900	-	6,011	6,036	-	29.3%
Profit before tax	14,800	-	-	4,613	-	-	31.2%
Profit attributable to owners of the parent	11,300	-	-	3,518	-	-	31.1%

Average rate

US\$1 = ¥135

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 300, R&D expenses 2,500
- US : SG&A expenses 1,600, R&D expenses 400



Reference Materials

- Listed two ingredients and eight products in the NHI drug price.

Product name	Brand products
Azilsartan Tablets: 10mg, 20mg, 40mg OD Tablets: 10mg, 20mg, 40mg	AZILVA® Tablets 10mg, 20mg, 40mg
Zinc Acetate Hydrate 25mg, 50mg	NOBELZIN® Tablets 25mg, 50mg

Comparison of Sales Volume by Therapeutic Area, Japan

- Steady growth in "central nervous system drugs", due to sales of launched newly launched products and mainstay products.

	FY2022 1Q	FY2023 1Q	YoY (volume)	YoY (value)
	Comp.	Comp.		
Cardiovascular drugs	27.9%	28.5%	+9.3%	+11.7%
Gastro-intestinal drugs	16.7%	16.2%	+4.0%	+8.5%
Central nervous system drugs	14.5%	15.2%	+11.5%	+16.0%
Blood/body fluid pharmaceutical products	9.3%	8.3%	-4.1%	-8.4%
Other metabolic drugs	8.1%	8.3%	+9.3%	+6.6%
Vitamin drugs	5.8%	5.8%	+8.7%	+4.1%
Respiratory organ agents	5.4%	5.4%	+8.2%	+14.1%
Antibiotics drugs	3.0%	3.2%	+13.6%	+12.5%
Agents for urogenital organs and the anus	1.9%	2.1%	+18.0%	+25.1%
Others	7.4%	7.1%	+1.0%	+27.1%
Total	100.0%	100.0%	+7.1%	+11.5%

Divestiture of Products

- Completed divestiture of marketing authorization rights for Tosymra® and Zembrace® SymTouch® in June 2023.

Products	<ul style="list-style-type: none"> Tosymra® (Sumatriptan nasal spray) 10 mg (Generic name: Sumatriptan succinate) Zembrace® SymTouch® (Sumatriptan injection) 3mg (Generic name: Sumatriptan succinate)
Purchaser	Tonix Pharmaceuticals Holding Corp.
Financial terms	<p>Approx. \$25M</p> <ul style="list-style-type: none"> -\$12M as a lump-sum payment upon completion of the divestiture -Approx. \$10M for the divestiture of inventory -Expect to receive \$3M in March 2024 or at the end of the divestiture, whichever comes first.
Objectives	As a result of aiming to optimize the value of these two migraine medications.

New Products

- Products launched since April

Therapeutic Area	Products	Brand products
Central nervous system	Fluphenazine Hydrochloride Tablets 1mg/2.5mg/5mg/10mg	Prolixin®
Agents affecting sensory organs	Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution 0.2%/0.5%	Combigan®
Gastro-intestinal drugs	Dicyclomine Hydrochloride Capsules, USP 10mg	Bentyl®
Dermatologic agents	Isotretinoin Capsules, USP 10mg/20mg/30mg/40mg	Accutane®
Central nervous system	VIGADRONE® (vigabatrin) Tablets, USP 500 mg	Sabril®

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 : To be considered after completion of the study in the U.S.

| **SWD002** (DTx for NASH)

- Digital Therapeutic App for NASH* that entered into a development and marketing license agreement with CureApp, Inc. Phase 3 study is scheduled to start in FY2023.

*NASH: non-alcoholic steatohepatitis

| **SaluDi (Personal Health Record (PHR) app)**

- Established the Japan Wellbeing Consortium with Hitachi Systems and two other companies to promote wellbeing.
- Aiming to expand its services and partners.

Health food business

| **Foods with Functional Claims**

- Launched “Kukkiri ryoku ai”, supplement for eye protection, in July 2023.
- Continue to develop products and services in the pre-disease and prevention fields.

New Drug Businesses (Orphan diseases)

| **Orphan Drugs**

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

Consolidated Financial Highlights-1

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Key Income Statements Data

JPY, MM

	FY2022 Actual		FY2023 Actual			FY2023 Forecast				
	1Q	/Sales (%)	1Q	/Sales (%)	YoY	1H	/Sales (%)	Full Year	/Sales (%)	YoY
Net Sales	48,231	100.0%	52,989	100.0%	+9.9%	105,700	100.0%	217,200	100.0%	+8.4%
Cost of Sales	32,853	68.1%	36,831	69.5%	+12.1%	72,600	68.7%	151,100	69.6%	+9.7%
Gross Profit	15,378	31.9%	16,158	30.5%	+5.1%	33,100	31.3%	66,100	30.4%	+5.5%
SG&A Expenses	7,326	15.2%	8,726	16.5%	+19.1%	17,800	16.8%	34,900	16.1%	+15.7%
R&D Expenses	3,197	6.6%	2,795	5.3%	-12.6%	8,300	7.9%	16,100	7.4%	+0.1%
Other income(expenses)	-35	-	-34	-	-	0	-	0	-	-
Core operating income	6,146	12.7%	5,977	11.3%	-2.8%	9,500	9.0%	19,900	9.2%	-13.7%
Core Operating Income (Excluding Trust Pharmatech)	7,214	15.0%	7,395	14.0%	+2.5%	12,200	11.5%	25,300	11.6%	-9.8%
Operating Income	4,820	10.0%	4,603	8.7%	-4.5%	7,000	6.6%	15,100	7.0%	-11.1%
Operating Income (Excluding Trust Pharmatech)	5,888	12.2%	6,011	11.3%	+2.0%	9,700	9.2%	20,500	9.4%	-5.0%
Profit before tax	4,815	10.0%	4,613	8.7%	-4.2%	6,800	6.4%	14,800	6.8%	-11.8%
Profit attributable to owners of the parent	3,672	7.6%	3,518	6.6%	-4.2%	5,100	4.8%	11,300	5.2%	-10.8%
EBITDA *1	9,378	19.4%	9,370	17.7%	-0.1%	16,200	15.3%	34,000	15.7%	-6.7%

Key Balance Sheets Data

	As of June 30, 2022	As of June 30, 2023
Total Assets	365,359	389,404
Equity	207,336	219,443
Ratio of equity attributable to owners of the company to total assets (%)	53.7%	53.3%

Amounts Per Common Share

	FY2022 1Q Actual	FY2023 1Q Actual	FY2023 Full Year Forecast
Basic earnings per share	83.86	80.33	257.97
Diluted earnings per Share	83.74	80.12	-
Dividend(interim)	-	-	130.00

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

Consolidated Financial Highlights-2

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(JPM, MM)

Sales and Operating Income by Area, Japan

	FY2022 Actual		FY2023 Actual			FY2023 Forecast				
	1Q	/Sales(%)	1Q	/Sales(%)	YoY	1H	/Sales(%)	Full Year	/Sales(%)	YoY
Net Sales	38,704	100.0%	43,153	100.0%	+11.5%	87,800	100.0%	180,500	100.0%	+10.3%
Cost of Sales	26,774	69.2%	30,259	70.1%	+13.0%	60,700	69.1%	126,800	70.2%	+11.8%
Gross Profit	11,930	30.8%	12,893	29.9%	+8.1%	27,100	30.9%	53,700	29.8%	+6.9%
SG&A Expenses	5,219	13.5%	6,154	14.3%	+17.9%	13,600	15.5%	27,500	15.2%	+23.6%
R&D Expenses	2,243	5.8%	2,099	4.9%	- 6.4%	6,300	7.2%	12,700	7.0%	+1.5%
Other income(expenses)	103	0.3%	-11	-	-	0	-	0	-	-
Core operating income	5,220	13.5%	5,318	12.3%	+ 1.9%	8,700	9.9%	16,300	9.0%	-23.9%
Core Operating Income (Excluding Trust Pharmatech)	6,289	16.2%	6,735	15.6%	+ 7.1%	11,400	13.0%	21,700	12.0%	-17.9%
Operating Income	4,570	11.8%	4,629	10.7%	+ 1.3%	7,200	8.2%	13,500	7.5%	-15.8%
Operating Income (Excluding Trust Pharmatech)	5,638	14.6%	6,036	14.0%	+ 7.1%	9,900	11.3%	18,900	10.5%	-8.5%
EBITDA *	8,155	21.1%	8,338	19.3%	+ 2.2%	14,900	17.0%	29,500	16.3%	-12.0%

Sales and Operating Income by Area, US

	FY2022 Actual		FY2023 Actual			FY2023 Forecast				
	1Q	/Sales(%)	1Q	/Sales(%)	YoY	1H	/Sales(%)	Full Year	/Sales(%)	YoY
Net Sales	9,527	100.0%	9,836	100.0%	+3.2%	17,900	100.0%	36,700	100.0%	+0.2%
Cost of Sales	6,080	63.8%	6,572	66.8%	+8.1%	11,900	66.5%	24,300	66.2%	+0.2%
Gross Profit	3,448	36.2%	3,265	33.2%	- 5.3%	6,000	33.5%	12,400	33.8%	+0.2%
SG&A Expenses	2,108	22.1%	2,573	26.2%	+22.1%	4,200	23.5%	7,400	20.2%	-6.5%
R&D Expenses	955	10.0%	696	7.1%	- 27.1%	2,000	11.2%	3,400	9.3%	-5.0%
Other income(expenses)	-136	-	-21	-	-	0	-	0	-	-
Core operating income	924	9.7%	658	6.7%	- 28.8%	800	4.5%	3,600	9.8%	+119.5%
Operating Income	250	2.6%	-25	-	-	-200	-	1,600	4.4%	+72.1%
EBITDA *	1,220	12.8%	1,031	10.5%	- 15.6%	1,300	7.3%	4,500	12.3%	+54.5%

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

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Consolidated Financial Highlights-3

Adjusted from Full basis to Core basis

(JPY, MM)

	FY2022 1Q Actual				FY2023 1Q Actual			
	Full Basis	Adjusting		Core Basis	Full Basis	Adjusting		Core Basis
		Japan	US			Japan	US	
Net Sales	48,231	-	-	48,231	52,989	-	-	52,989
Cost of Sales	-32,853	18	29	-32,807	- 36,831	0	0	-36,830
Inventory step-up	-1	-	1	-	- 0	-	0	-
Others	-46	18	28	-	-0	0	-	-
Gross Profit	15,378	18	29	15,425	16,158	0	0	16,159
SG&A Expenses	-7,326	148	401	-6,777	- 8,726	152	547	- 8,027
Amortization of intangible assets	-555	148	407	-	- 581	152	428	-
Others	6	0	-6	-	- 118	-	118	-
R&D Expenses	-3,197	587	109	-2,501	- 2,795	525	115	- 2,155
Amortization of intangible assets	-448	339	109	-	- 568	452	115	-
Impairment loss	-222	222	-	-	-	-	-	-
Others	-26	26	-	-	- 73	73	-	-
Other income	124	-120	-4	-	87	- 27	- 60	-
Other expenses	-159	18	141	-	- 120	38	82	-
Operating Income	4,820	651	676	6,146	4,603	690	684	5,977

Selling General and Administrative Expenses

(JPY,MM)

	FY2022 Actual		FY2023 Actual			FY2023 Forecast	
	1Q	/Sales (%)	1Q	/Sales (%)	YoY	Full year	/Sales (%)
R&D Expenses	3,197	6.6%	2,795	5.3%	-12.6%	16,100	7.4%
Japan	2,243	5.8%	2,099	4.9%	-6.4%	12,700	7.0%
US	955	10.0%	696	7.1%	-27.1%	3,400	9.0%
Advertisement Expenses	307	0.6%	201	0.4%	-34.5%	2,100	1.0%

Capital Expenditure & Depreciation and Amortization

	FY2022 1Q Actual	FY2023 1Q Actual	FY2023 Full Year Forecast
Capital Expenditure	2,655	12,166	28,900
Japan	2,083	12,005	27,800
US	572	161	1,100
Depreciation and Amortization	4,234	4,541	19,300
Japan	3,422	3,625	15,700
Manufacturing Division	2,255	2,378	10,300
R&D Division	639	759	3,600
Administration Div. & Business Div.	529	488	1,800
US	812	916	3,600

Personnel Information Number of Employees

	FY2022 Actual		FY2023 Actual	
	As of June 30, 2022	Comp.(%)	As of June 30, 2023	Comp.(%)
Japan	2,962	86.6%	3,075	87.0%
Manufacturing Division	2,038	59.6%	2,124	60.1%
R&D Division	303	8.8%	301	8.5%
Administration Div. & Business Div.	621	18.2%	650	18.4%
(MRs)	383	-	375	-
US	457	13.4%	458	13.0%
Total	3,419	100.0%	3,533	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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