Sawai Group Holdings Co., Ltd. -

# **FY2022 Financial Results for the 1st Quarter**

Aug 10, 2022 4887.T, TSE Prime

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# Summary

#### In Japan

• Although sales and core operating income decreased from the same period last year, steady growth was made in line with the forecast.

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 1Q 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 (including the amount that is expected to be returned.)
- 4. Upfront cost for 1Q of Trust Pharmatech Co., Ltd. (hereinafter, "Trust Pharmatech"): 1.1 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 315, as of August 10, 2022. (452 items at the end of March 2022)

#### • The quantity of products manufactured progressed as planned.

Production volume of 1Q, including the volume of contract manufacturing, was approx. 4.3 billion tablets (Annual plan of production volume for FY2022 is approx. 16.5 billion tablets)

#### Status of efforts toward Stable Supply

- → Construction of both Injection Production Facilities at Kyusyu Plant (Shipments to start in June 2023) and New Solid Dosage Facility at Daini Kyushu Factory (Shipments to start in April 2024) are on track.
- → At Trust Pharmatech, 130 employees, who will work at its factories later, are undergoing on-the-job training at the existing factories of Sawai Pharmaceutical since May 2022. The remaining members are continuing to organize what needs to be done to comply with GMP, while preparing to manufacture products

#### 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 restored profitability due to cost reductions.

Overview



- Consolidated: Even though the performance declined on a year-on-year basis, progress is on track to meet the forecast.
- **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 1Q of the previous year, and upfront cost for Trust Pharmatech, etc.

• **United States:** Sales increased from a year earlier both on a yen and dollar basis and core operating income turned profitable, due to the steady growth of the new products launched in FY2021 and cost reduction efforts.

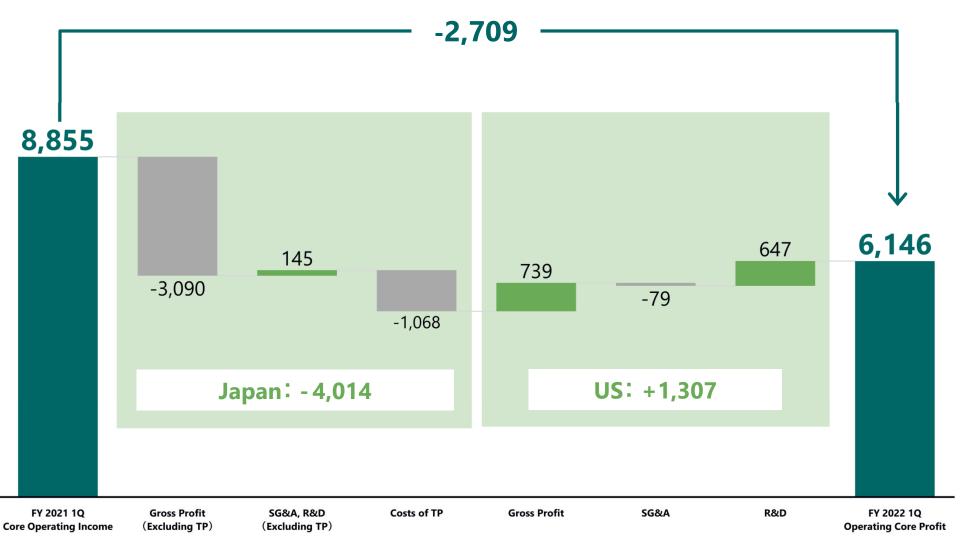
		FY 2021 1	IQ	F	Y 2022 1Q		YoY
		Japan	US		Japan	US	101
Net Sales	50,486	43,487	6,999	48,231	38,704	9,527	-4.5% (-2,254)
Core Operating Income	8,855	9,233	-383	6,146	5,220	924	-30.6% (-2,709)
Core Operating Income (Excluding Trust Pharmatech)	-	-	-	7,214	6,289	-	-
Operating Income	8,483	8,091	392	4,820	4,570	250	-43.2% (-3,663)
Operating Income (Excluding Trust Pharmatech)	-	-	-	5,888	5,638	-	-
Profit before tax	8,433	-	-	4,815	-	-	-42.9% (-3,618)
Profit attributable to owners of the parent	6,307	-	-	3,672	-	-	-41.8% (-2,635)

Average rate US\$1 = \$109 US\$1 = \$130

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

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

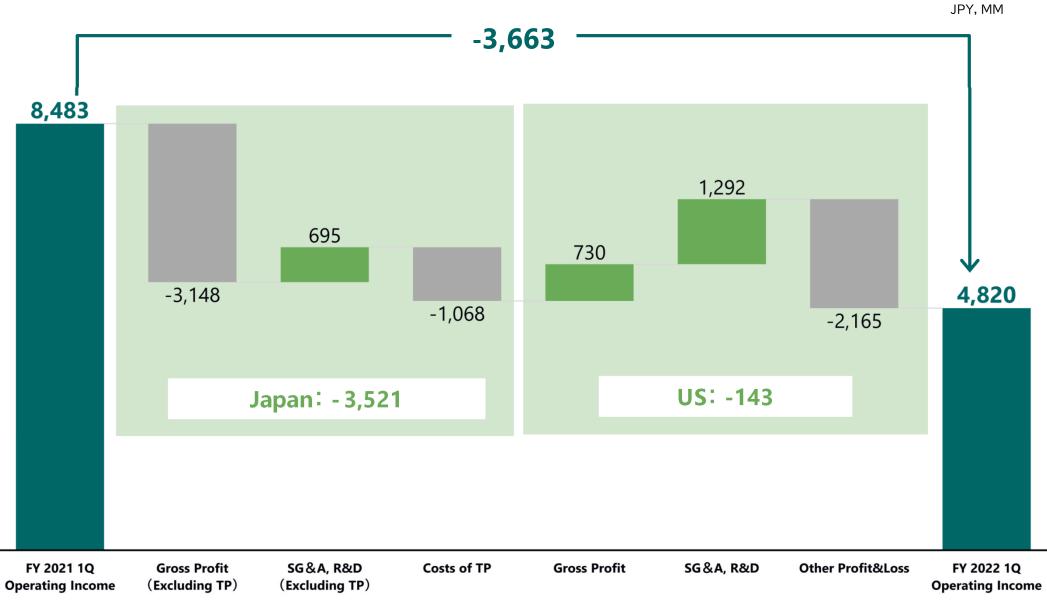
JPY, MM



- 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**





- 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. © 2022 SAWAI GROUP HOLDINGS Co., Ltd. | 5

# Sales by Channel in Japan

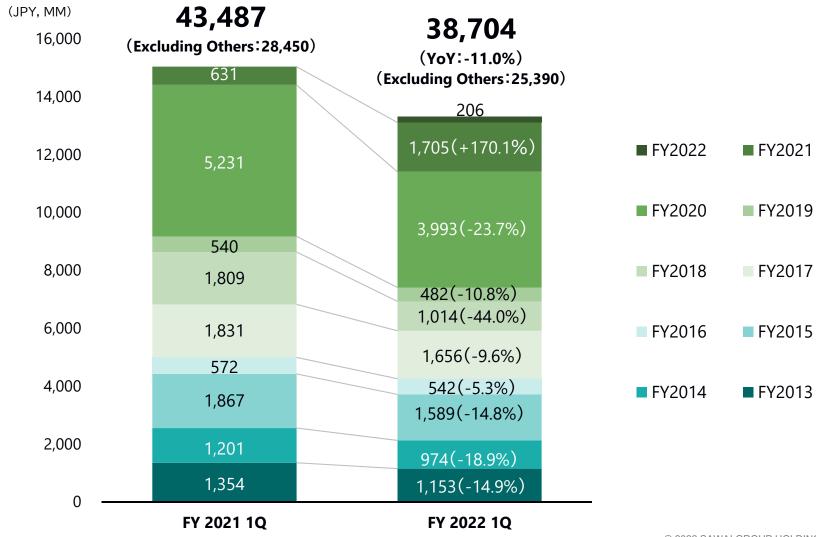
• Sales decreased due to the extraordinary factors from 1Q of the previous year, etc.

	Medical insti	itutions	FY202	21 1Q		FY2022 1Q		Yc	Υ
	Channel	Total, Nationwide	# of Customers	Sales Share	# of Customers	Coverage Rate	Sales Share	# of Customers	Sales Growth
Но	ospital	8,198	7,908	9.6%	7,901	96.4%	9.9%	-7	-9.6%
	DPC Hospital	1,764	1,743	5.8%	1,757	99.6%	6.0%	+14	-9.5%
Cl	inic	108,805	33,134	8.6%	32,800	30.1%	8.5%	-334	-13.6%
Ph	narmacy	90,125	59,153	80.7%	60,029	66.6%	80.6%	+876	-11.1%
	Dispensing	63,098	58,898	80.1%	59,779	94.7%	80.0%	+881	-11.1%
	Drug Stores, etc	27,027	255	0.6%	250	0.9%	0.5%	-5	-15.4%
Ot	thers	-	-	1.1%	-	-	1.0%	-	-16.4%
Тс	otal	207,128	100,195	100.0%	100,730	48.6%	100.0%	+535	-11.1%

<sup>\*</sup>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.



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# **US Sales Analysis**



- Overall sales increased by 15.0% 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 36.1%, partly due to the impact of the sharp depreciation of the yen.

## By segment

(JPY, MM)

		FY20	21 1Q	FY20	22 1Q	YoY	
		Actual	Comp.	Actual	Comp.	YOY	
Gene	ric Products	4,965	70.9%	6,723	70.6%	+35.4%	
	Main products <sup>*1</sup>	2,450	35.0%	2,352	24.7%	-4.0%	
	Products launched in FY2021	2	0.0%	1,388	14.6%	+91604.9%	
	Others	2,513	35.9%	2,983	31.3%	+18.7%	
Bran Prod	d ucts <sup>*2</sup>	2,034	29.1%	2,804	29.4%	+37.9%	
Total		6,999	100.0%	9,527	100.0%	+36.1%	

<sup>\*1</sup> Klor-Con®, Chlorpromazine, Qudexy® XR

## ■ By therapeutic areas

(JPY, MM)

	FY202	21 1Q	FY202	22 1Q	YoY	
	Actual	Comp.	Actual	Comp.	101	
Central nervous system	3,411	48.7%	4,585	48.1%	+34.4%	
Cardiovascular	2,544	36.3%	2,549	26.8%	+0.2%	
Dermatologic agents	142	2.0%	1,337	14.0%	+844.9%	
Hormone preparations	312	4.5%	436	4.6%	+39.5%	
Agents for urogenital organs and the anus	164	2.3%	166	1.7%	+1.0%	
Others	426	6.2%	455	4.8%	+6.8%	
Total	6,999	100.0%	9,527	100.0%	+36.1%	

Average rate US\$1 = \$109 US\$1 = \$130

<sup>\*2</sup> Zembrace Symtouch®, Tosymra®, Vigadrone®

# Progress towards FY2022 Forecasts, Consolidated

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

(JPY, MM)

	FY2022 Forecast			F		Progress rate	
		Japan	US		Japan	US	for full-year forecasts
Net Sales	207,000	174,800	32,200	48,231	38,704	9,527	23.3%
Core Operating Income	24,800 <sup>*3</sup>	22,300	2,500	6,146	5,220	924	24.8%
Core Operating Income (Excluding Trust Pharmatech)	29,600	27,100	-	7,214	6,289	-	24.4%
Operating Income	21,400	20,800	600	4,820	4,570	250	22.5%
Operating Income (Excluding Trust Pharmatech)	26,200	25,600	-	5,888	5,638	-	22.5%
Profit before tax	21,100	-	-	4,815	-	-	22.8%
Profit attributable to owners of the parent	17,700	-	-	3,672	-	ı	20.7%

Average rate

US\$1= ¥109

US\$1= ¥130

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

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

<sup>\*3</sup> Adjust the followings from operating income

<sup>-</sup> Japan: SG&A expenses 500, R&D expenses 1,300, other income and expenditure -300

<sup>-</sup> US: SG&A expenses 1,500, R&D expenses 400

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

- Entered into a licensing agreement with CureApp, Inc. (CureApp) to develop and sell the digital therapeutics of NASH.
- Initiatives in accordance with "Cultivating new growth areas", one of the three categories of START2024, the Sawai's Mid-Term Business Plan.
- Expected to be a promising treatment option for NASH for which there is currently no established drug treatment.

#### Overview

Indications	NASH (Non-Alcoholic Steatohepatitis)
Estimated Number of Patients of NASH	About 2 million people in Japan alone who have been diagnosed with NASH (the preliminary population is estimated to be about 10 million people)
Roles	CureApp and Sawai Group Holdings will jointly develop the app to obtain regulatory approval. After obtaining regulatory approval, the app will be sold by Sawai Pharmacautical in Japan.
Amount of Investment	<ul> <li>R&amp;D expenses for phase III clinical trials, etc.</li> <li>Up to 10.5 billion yen of future milestone payments for development and sales</li> <li>Sales-based royalties</li> </ul>

## **About the App for NASH**

### Current Treatment Option

There is no established drug therapy, and daily life guidance including diet therapy and exercise therapy aimed at weight loss is mainly given.

- Even if appropriate guidance is provided during outpatient visits, the challenge is to continue diet therapy and exercise therapy with the patient's own efforts alone.
- Cognitive-behavioral therapy with the app
  - Provide guidance that is optimized for individual patients on a daily basis.
  - Reducing the burden on both patients and healthcare professionals by visualizing the patient's state

## Synergy with Sawai Pharmaceutical

 Expectations for business development in collaboration with Sawai Pharmaceutical, which has strengths in the lifestyle-related disease field

#### **Current Status**

 CureApp has conducted joint clinical trials at multiple institutions and confirmed improvements of treatment with cognitive behavioral therapy provided guidances by the app.

## **Next Step**

 The app will be improved based on data acquired from the joint clinical studies at multiple facilities and taken to the phase III clinical trials.



# New Products, Japan

• 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
Febuxostat Tablets 10mg, 20mg, 40mg OD Tablets 10mg, 20mg	Feburic <sup>®</sup> Tablets 10mg, 20mg, 40mg
Aripiprazole Tablets 1mg, Oral Solution 1mg	ABILIFY® tablets 1mg, ABILIFY® oral solution 0.1%
Dasatinib Hydrate Tablets 20mg, 50mg	SPRYCEL <sup>®</sup> Tablets 20mg, 50mg
Azacitidine Injection 100mg	Vidaza <sup>®</sup> for Injection 100mg
Teriparatide Acetate Injection: 56.5μ	Teribone <sup>®</sup> Injection 56.5μg

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# 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 1Q	FY2022 1Q	YoY	YoY
	Comp.	Comp.	(volume)	(value)
Cardiovascular drugs	30.5%	27.9%	-15.5%	-18.4.%
Gastro-intestinal drugs	16.9%	16.7%	-8.3%	-10.2%
Central nervous system drugs	13.5%	14.5%	-0.2%	+1.4%
Blood/body fluid pharmaceutical products	8.5%	9.3%	+0.9%	-6.7%
Other metabolic drugs	6.9%	8.1%	+8.9%	+10.7%
Vitamin drugs	6.6%	5.8%	-19.1%	-36.5%
Respiratory organ agents	4.8%	5.4%	+3.8%	-2.9%
Antibiotics drugs	1.8%	1.9%	-6.8%	-1.8%
Agents for urogenital organs and the anus	1.8%	1.7%	-12.5%	-8.9%
Others	8.7%	8.7%	-7.1%	-16.5%
Total	100.0%	100.0%	-7.5%	-11.0%

# Consolidated Financial Highlights-1



#### ■ Key Income Statements Data

JPY, MM

	FY2021	1 Actual		FY2022	Actual				FY2022 Forecast		
	1Q	/Sales (%)	1Q	/Sales ( % )	YoY	Achievement	1H	/Sales (%)	Full Year	/Sales (%)	YoY
Net Sales	50,486	100.0%	48,231	100.0%	-4.5%	23.3%	100,600	100.0%	207,000	100.0%	+6.8%
Cost of Sales	31,777	62.9%	32,853	68.1%	+3.4%	23.7%	68,600	68.2%	138,500	66.9%	+8.9%
Gross Profit	18,709	37.1%	15,378	31.9%	-17.8%	22.4%	32,000	31.8%	68,500	33.1%	+2.8%
SG&A Expenses	8,106	16.1%	7,326	15.2%	-9.6%	21.5%	16,700	16.6%	34,100	16.5%	-27.0%
R&D Expenses	4,185	8.3%	3,197	6.6%	-23.6%	24.0%	5,800	5.8%	13,300	6.4%	-45.5%
Other income( expenses)	2,065	4.1%	-35	-	-	-	100	0.1%	300	0.1%	-
Core operating income	8,855	17.5%	6,146	12.7%	-30.6%	24.8%	11,300	11.2%	24,800	12.0%	-5.8%
Core Operating Income (Excluding Trust Pharmatech)	-	-	7,214	15.0%	-	24.4%	13,700	13.6%	29,600	14.3%	-
Operating Income	8,483	16.8%	4,820	10.0%	-43.2%	22.5%	9,600	9.5%	21,400	10.3%	-
Operating Income (Excluding Trust Pharmatech)	-	-	5,888	12.2%	-	22.5%	12,000	11.9%	26,200	12.7%	-
Profit before tax	8,433	16.7%	4,815	10.0%	-42.9%	22.8%	9,400	9.3%	21,100	10.2%	-
Profit attributable to owners of the parent	6,307	12.5%	3,672	7.6%	-41.8%	20.7%	7,900	7.9%	17,700	8.6%	_
EBITDA *1	11,537	22.9%	9,378	19.4%	-18.7%	24.9%	17,800	17.7%	37,600	18.2%	+1.6%

## ■ Key Balance Sheets Data

# As of March 31, 2021 Total Assets 349,502 365,359 Equity 200,083 207,336 Ratio of equity attributable to owners of the company to total assets (%) 54.4% 53.7%

#### Amounts Per Common Share

	FY2021 1Q Actual	FY2022 1Q Actual	FY2022 Full Year Forecast
Basic earnings per share	144.03	83.86	404.19
Diluted earnings per Share	143.93	83.74	-
Dividend(interim)	-	-	130.00

<sup>\*1</sup> 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

	FY202 <sup>-</sup>	l Actual	FY2022 Actual				FY2022 Forecast		
	1Q	/Sales(%)	1Q	/Sales(%)	YoY	Achievement	Full Year	/Sales(%)	YoY
Net Sales	43,487	100.0%	38,704	100.0%	-11.0%	22.1%	174,800	100.0%	+6.7%
Cost of Sales	27,496	63.2%	26,774	69.2%	-2.6%	22.4%	119,300	68.2%	+12.5%
Gross Profit	15,991	36.8%	11,930	30.8%	-25.4%	21.5%	55,500	31.8%	-3.9%
SG&A Expenses	5,442	12.5%	5,219	13.5%	-4.1%	20.6%	25,300	14.5%	+16.0%
R&D Expenses	2,500	5.7%	2,243	5.8%	-10.3%	23.1%	9,700	5.5%	-22.6%
Other income( expenses)	42	0.1%	103	0.3%	+146.3%	34.2%	300	0.2%	-96.7%
Core operating income	9,233	21.2%	5,220	13.5%	-43.5%	23.4%	22,300	12.8%	-17.5%
Core Operating Income (Excluding Trust Pharmatech)	-	-	6,289	16.2%	-	23.2%	27,100	15.5%	-
Operating Income	8,091	18.6%	4,570	11.8%	-43.5%	22.0%	20,800	11.9%	-35.7%
Operating Income (Excluding Trust Pharmatech)	-	-	5,638	14.6%	-	22.0%	25,600	14.6%	-
EBITDA *	11,633	26.8%	8,155	21.1%	-29.9%	24.0%	34,000	19.5%	-7.1%

#### ■ Sales and Operating Income by Area, US

	FY2021	l Actual		FY2022	2 Actual			FY2022 Forecast	
	1Q	/Sales(%)	1Q	/Sales(%)	YoY	Achievement	Full Year	/Sales(%)	YoY
Net Sales	6,999	100.0%	9,527	100.0%	+36.1%	29.6%	32,200	100.0%	+7.4%
Cost of Sales	4,281	61.2%	6,080	63.8%	+42.0%	31.7%	19,200	59.6%	-8.9%
Gross Profit	2,718	38.8%	3,448	36.2%	+26.9%	26.5%	13,000	40.4%	+46.1%
SG&A Expenses	2,665	38.1%	2,108	22.1%	-20.9%	23.9%	8,800	27.3%	-64.6%
R&D Expenses	1,689	24.1%	955	10.0%	-43.5%	26.5%	3,600	11.2%	-69.7%
Other income( expenses)	2,029	29.0%	-136	-	-	-	0	-	-
Core operating income	-383	-	924	9.7%	-	37.0%	2,500	7.8%	-
Operating Income	392	5.6%	250	2.6%	-36.4%	41.6%	600	-	-
EBITDA *	-101	-	1,220	12.8%	-	33.9%	3,600	11.2%	+779.1%

<sup>\*</sup> 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)

	FY2021 1Q Actual			FY2022 1Q Actual				
	Full	Adjusting		Core	Full	Adjusting		Core
	Basis	Japan	US	Basis	Basis	Japan	US	Basis
Net Sales	50,486	-	-	50,486	48,231	-	-	48,231
Cost of Sales	-31,777	-40	20	-31,797	-32,853	18	29	-32,807
Inventory step-up	-4	-	4	-	-1	-	1	-
Others	24	-40	16	-	-46	18	28	-
Gross Profit	18,709	-40	20	18,688	15,378	18	29	15,425
SG&A Expenses  Amortization of intangible assets	-8,106	132	1,038	-6,936	-7,326	148	401	-6,777
	-1,171	132	1,039	-	-555	148	407	-
Others	1	-	-1	-	6	0	-6	-
R&D Expenses	-4,185	1,092	196	-2,897	-3,197	587	109	-2,501
Amortization of intangible assets	-461	265	196	-	-448	339	109	-
Impairment loss	-826	826	-	-	-222	222	-	-
Other income	2,067	-42	-2,025	-	124	-120	-4	-
Other expenses	-1	1	-	-	-159	18	141	-
Operating Income	8,483	1,143	-771	8,855	4,820	651	676	6,146

# **Consolidated Financial Date**

#### ■ Selling General and Administrative Expenses

(JPY, MM)

		FY2021 Actual		FY2022 Actual			FY2022 Forecast	
		1Q	/Sales(%)	1Q	/Sales(%)	YoY	Full year	/Sales(%)
R&D	Expenses	4,185	8.3%	3,197	6.6%	-23.6%	13,300	6.4%
	Japan	2,500	5.7%	2,243	5.8%	-10.3%	9,700	5.5%
	US	1,689	24.1%	955	10.0%	-43.5%	3,600	11.2%
	ertisement enses	539	1.1%	307	0.6%	-43.0%	2,800	1.4%

## ■ Capital Expenditure & Depreciation and Amortization

#### FY2022 Full FY2022 1Q Year Forecast Actual Capital Expenditure 4,501 2,655 24,600 Japan 2.979 2,083 22,300 US 572 2,300 1,522 Depreciation and 16,700 4,314 4,234 Amortization Japan 2,797 3,422 13,500 Manufacturing 2,255 9,300 1,840 Division **R&D** Division 2,500 527 639 Administration Div. & Business 430 529 1,700 Div. US 1,517 812 3,200

## Personnel Information Number of Employees

		FY2021 Actual		FY2022 Actual		
		As of June 30, 2021	Comp.(%)	As of June 30, 2022	Comp.(%)	
Japan		2,495	81.9%	2,962	86.6%	
	Manufacturing Division	1,650	54.2%	2,038	59.6%	
	R&D Division	250	8.2%	303	8.8%	
	Administration Div. & Business Div.	595	19.5%	621	18.2%	
	(MRs)	383	-	383	-	
US		550	18.1%	457	13.4%	
Tota	al	3,045	100.0%	3,419	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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