

# Fiscal Year 2023 (Period Ending March 2024) First Half Financial Results Briefing

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November 8, 2023

TSE Prime 4559

Mitsuhiro Ibe, Representative Director, President  
Zeria Pharmaceutical Co., Ltd.

# **I. Consolidated Financial Highlights for the First Half of Fiscal Year 2023**

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**I-1 Overview**

**I-2 Ethical Pharmaceuticals Business**

**I-3 Consumer Healthcare Business**

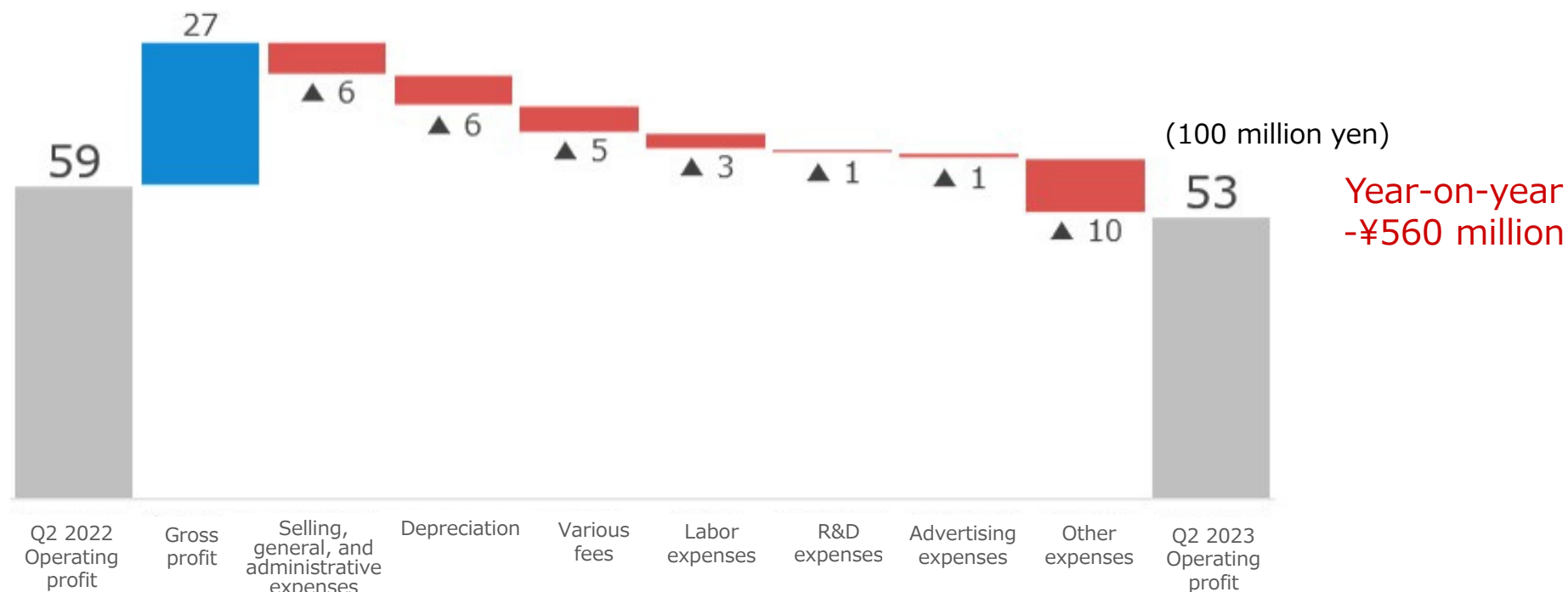
**I-4 Overseas Net Sales**

# I-1 Overview

(Unit: Million yen)	First Half of Fiscal Year 2022 Results	First Half of Fiscal Year 2023 Results	Year-on- Year Difference	Forecast Announced in May	Difference with Publicly Announced Forecast
Net Sales	33,712	36,678	8.8%	35,000	4.8%
Gross Profit	24,335	27,046	11.1%	—	
Selling, General, and Administrative Expenses	18,441	21,719	17.8%	—	
Operating Profit	5,894	5,327	-9.6%	5,500	-3.1%
Ordinary Profit	5,182	5,495	6.1%	5,500	-0.1%
Profit Attributable to Owners of Parent	3,998	5,396	35.0%	4,500	19.9%

# I-1 Factors Causing Changes in Operating Profit

Operating profit decreased due to promotional expenses, e.g., from sales activities, as well as increased depreciation



Selling, general, and administrative expenses

Enhanced promotion activities in the Oversea Ethical Pharmaceuticals Business

Depreciation

Increase in expense due to start of trademark amortization (Entocort)

Various fees

Royalties, etc.

Labor expenses

Increased hiring at overseas subsidiaries, wage increases

Other expenses

Increased expenses due to partial revision of the U.K. drug price regulation system, etc.

## I-2 Ethical Pharmaceuticals Business: Net Sales by Product

Continued significant growth in Dificlir driving earnings

		First Half of Fiscal Year 2022	First Half of Fiscal Year 2023	
(Unit: Million yen)		Results	Results	Year-on-Year Growth
Ethical Pharmaceuticals Business		21,505	23,900	11.1%
	Asacol	9,881	10,097	2.2%
	Dificlir	3,895	6,545	68.0%
	Entocort	2,935	2,447	-16.6%
	Acofide	1,541	1,522	-1.3%
	Others	3,251	3,287	1.1%

## I-2 Ethical Pharmaceuticals Business

### Factors Causing Changes from Previous Year

	Year-on-Year Change (Million yen)	Factors Causing Change	
		Domestic	Overseas
Asacol	216	Impact from drug price revision	Growth in 1600mg tablets in the UK, Germany, and others
Dificlir	2,650	Start of shipments of Dafclir Tablets in April	Significant growth in France, UK, Italy, and Spain
Entocort	-488	Impact from drug price revision	Launch of generic products in Europe
Acofide	-19	Impact from drug price revision	
Others	36	Market penetration of Ferinject	

# I-3 Consumer Healthcare Business: Net Sales by Product

- ◆ Hepalyse range sales increased significantly in pharmaceutical category products
- ◆ Chondroitin range sales increased, while WithOne range sales decreased slightly

		First Half of Fiscal Year 2022	First Half of Fiscal Year 2023	
(Unit: Million yen)		Results	Results	Year-on-Year Growth
Consumer Healthcare Business		12,131	12,700	4.7%
	Hepalyse Range	4,698	5,190	10.5%
	Pharmaceuticals	2,256	2,676	18.6%
	Soft Drinks Dietary Supplements	2,442	2,513	2.9%
	Chondroitin Range	2,634	2,862	8.7%
	WithOne Range	620	612	-1.3%
	Others	4,177	4,034	-3.4%

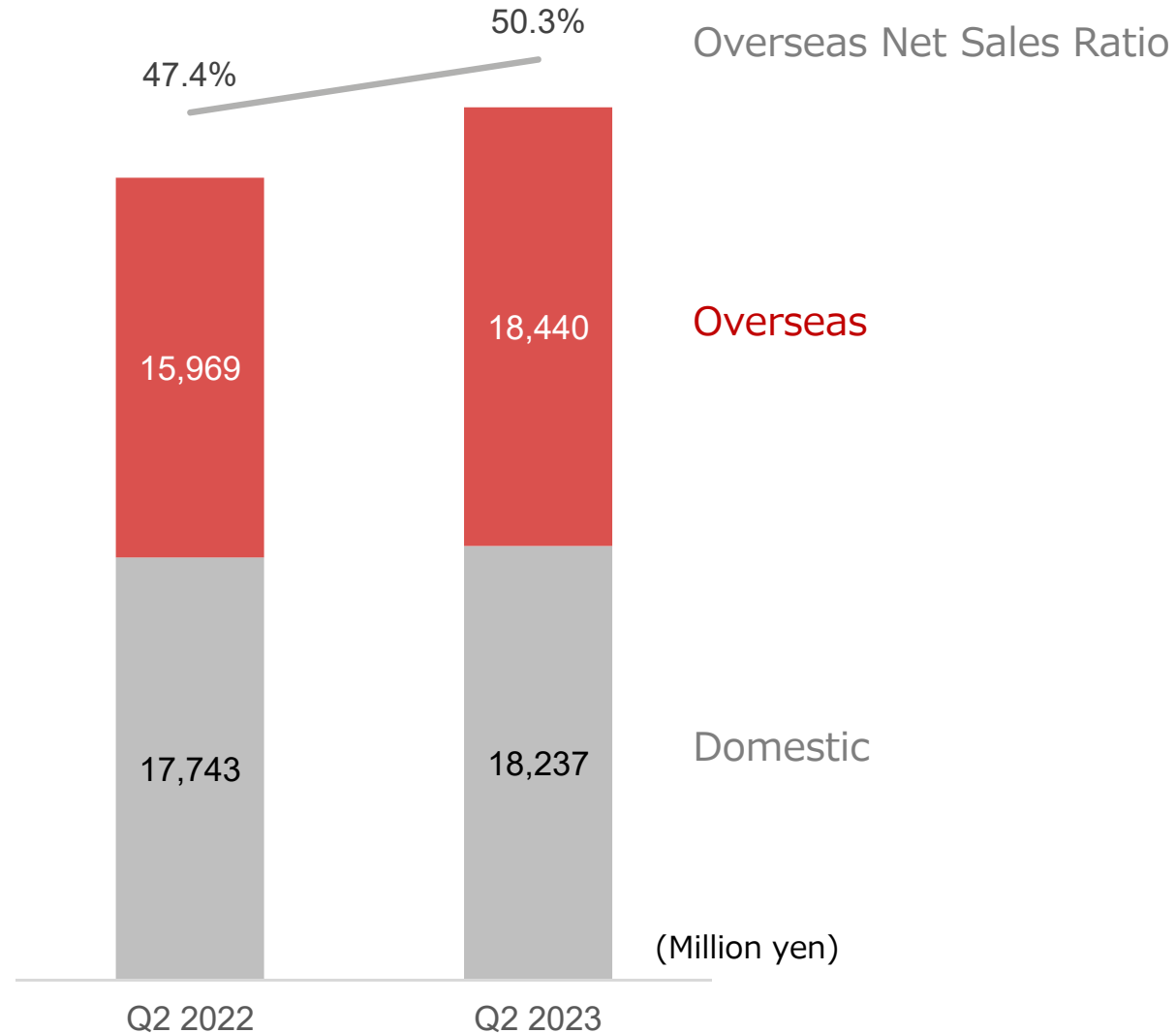
## Factors Causing Changes from Previous Year

		Year-on-Year Change (Million yen)	Factors Causing Change
Hepalyse Range	Pharmaceutical Hepalyse	420	COVID-19: Easing restrictions on activity and recovered flow of people Broader understanding of benefits for fatigue recovery and metabolism improvement/promotion
	Soft Drinks Dietary Supplements	70	COVID-19: Easing restrictions on activity and recovered flow of people
Chondroitin Range		228	Advertising effects
WithOne Range		-8	Impact of competing products
Others		-143	Decline in some health foods and other products despite growth in the Masdent range and European herbal preparation range



## I-4 Overseas Net Sales

**Dificlir contributed to sales growth,  
with overseas net sales exceeding 50% of total sales**



## **II. Consolidated Financial Forecast for Fiscal Year 2023**

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**II-1 Ethical Pharmaceuticals Business**

**II-2 Consumer Healthcare Business**

**II-3 Development Pipeline Status**

**II-4 Consolidated Full-Year Financial Forecast for Fiscal Year 2023**

### ◆ First Half of Fiscal Year 2023

#### Domestic market

Asacol

Struggling due to drug price revisions and intense market competition

Acofide

Slight decrease in sales due to drug price revisions

Ferinject

Continuing market penetration

Dafclir

Started shipments in April

Other long-listed products, etc.

Most products struggling due to drug price revisions and intense market competition

#### Overseas markets

Asacol

Good performance of 1600mg tablets.

Sales increased in UK, Germany, and other countries

Dificlir

Sales increased in France, UK, Italy, Spain, and other countries

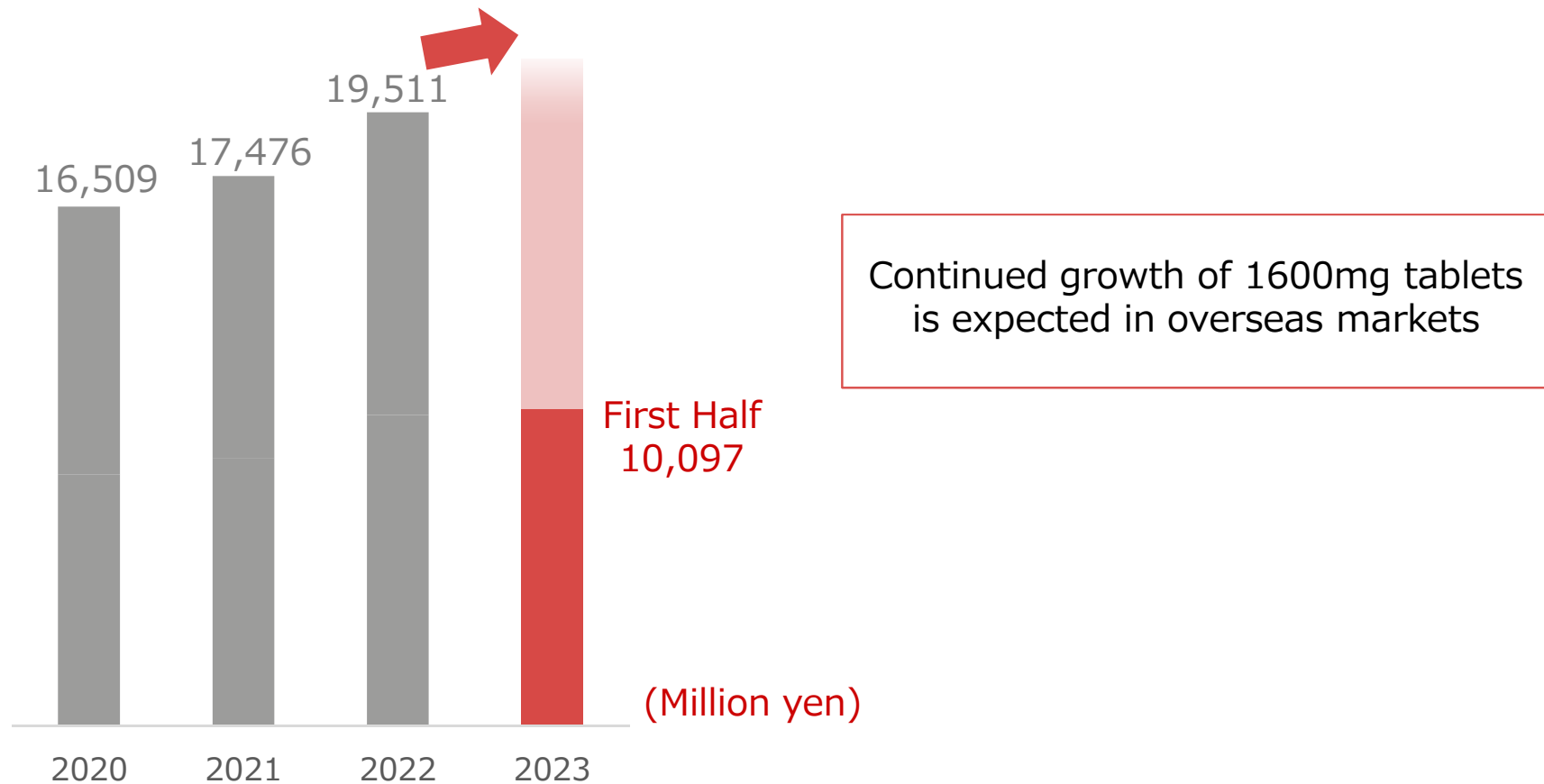
Entocort

Sales decreased due to the launch of generic products in the European market

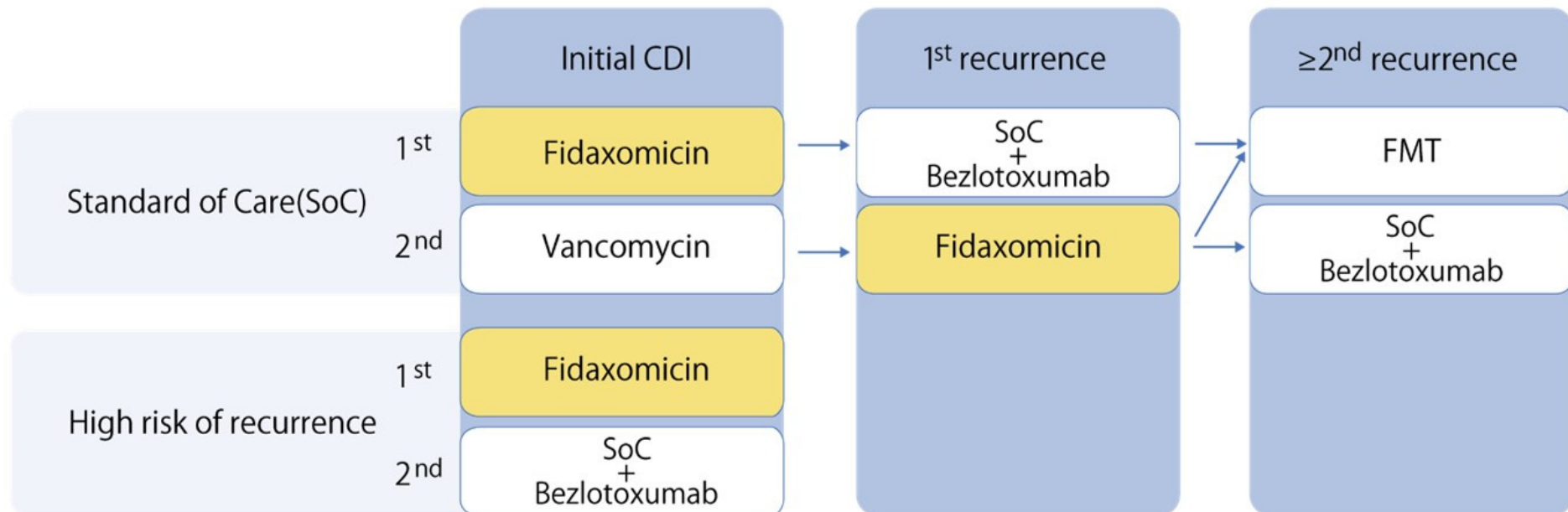
### ◆ Second Half of Fiscal Year 2023: Forecast

No major change factors are expected in either domestic or overseas markets, and progress is expected to be in line with initial expectations

### Continued growth in the UK and other overseas markets



### Dificlir (Fidaxomicin) recommended as a first-line drug for pharmacological treatment of first-episode *Clostridioides difficile* infections

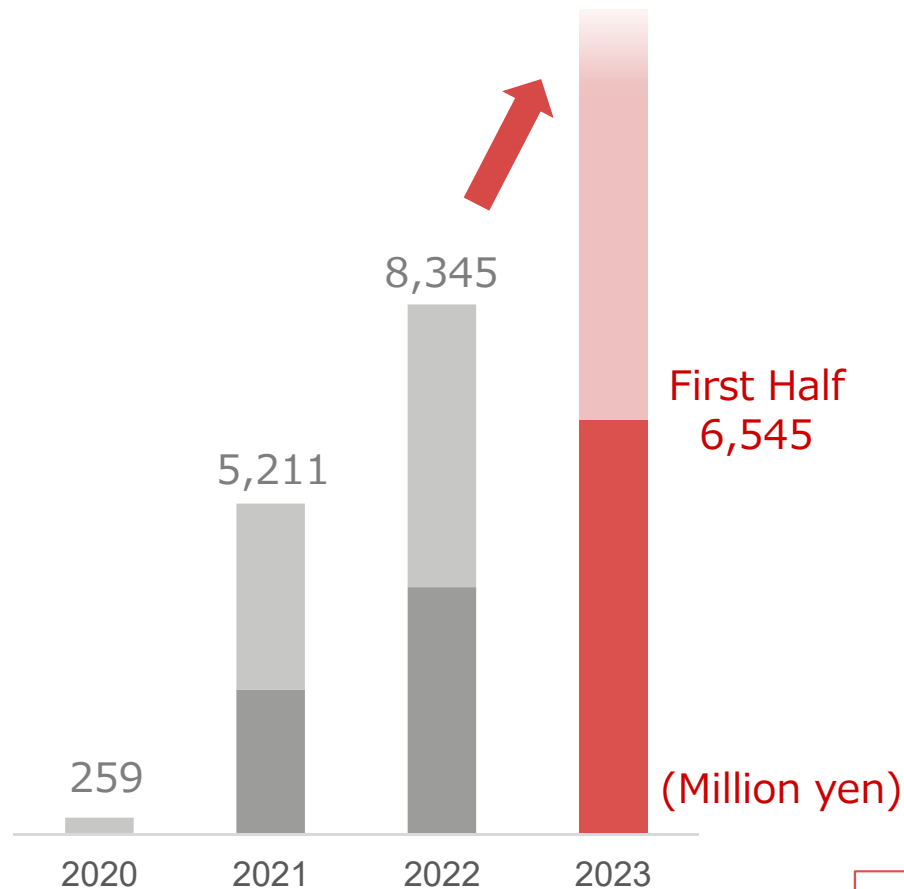


Recurrence Risk

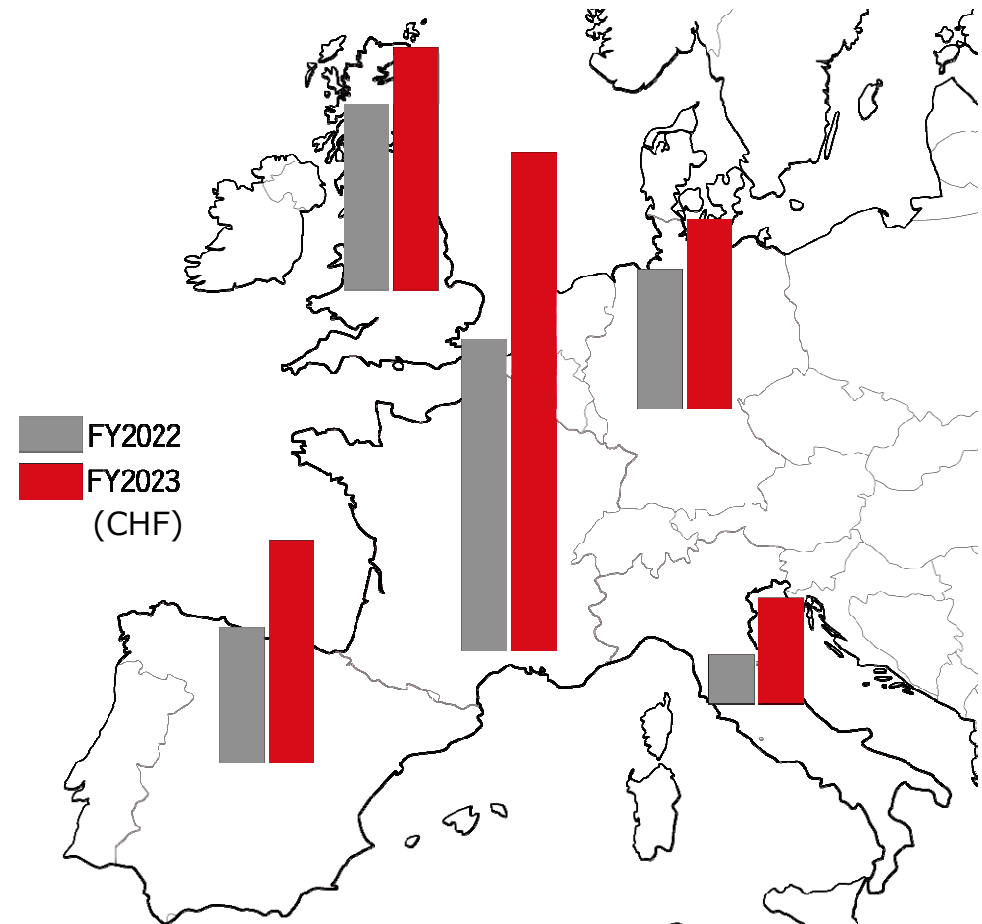
- (1) Senior citizens (age 65 to 70 and up)
- (2) Those with past hospitalization and/or using antibiotics
- (3) Those using proton pump inhibitors

Adapted from *Clinical Microbiology and Infection* 2021 27S1-S21 DOI: (10.1016/j.cmi.2021.09.038)

### Sustained growth after clinical guideline revision

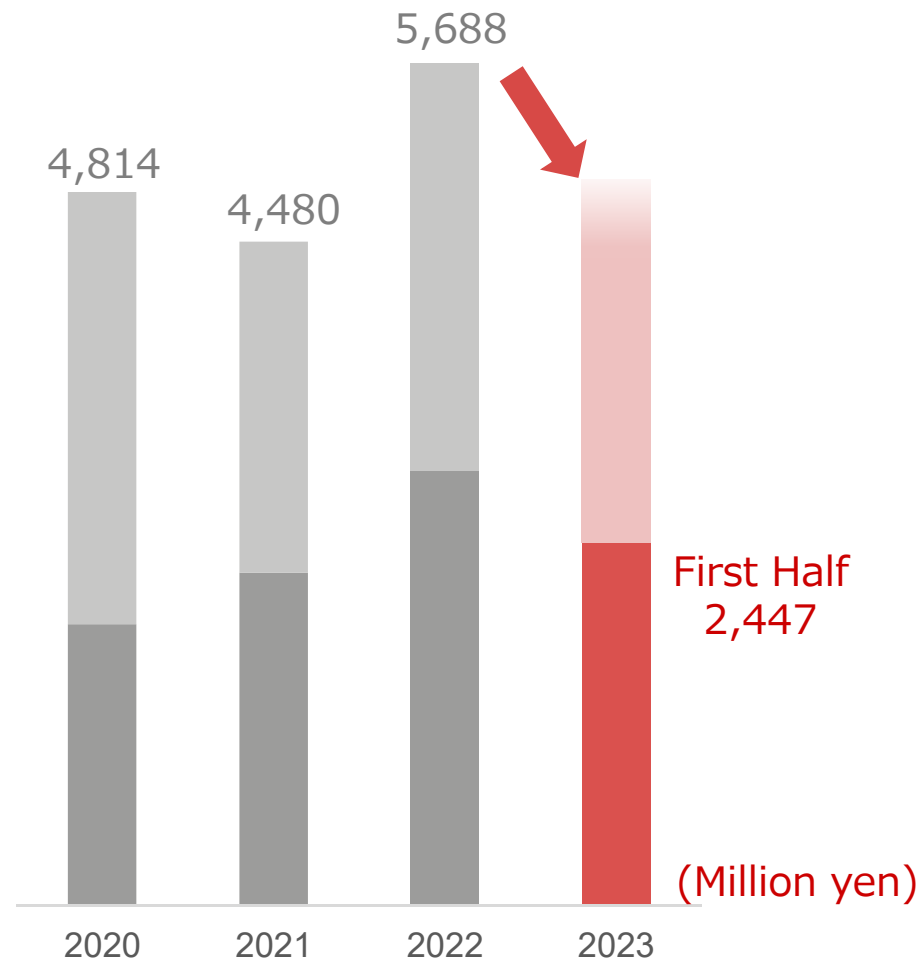


### Top 5 sales regions in fiscal year 2023 first half



- France drives sales growth
- Other countries are expected to follow France's lead as guidelines are issued and disseminated

### Europe: Sales decreased due to impact from of launch of generic products



Entocort generics (as of August 2023)

Launched in eight countries

### First Half of Fiscal Year 2023

- ◆ Hepalyse range  
Strong sales amid increased social activity  
Significant growth in pharmaceuticals promoting the benefit of fatigue recovery
- ◆ Chondroitin range  
Strong performance thanks to the impact of advertising investment, etc.
- ◆ European herbal preparation range  
Growth in sales of Prefemin with the transition to a Class II drug

### Second Half of Fiscal Year 2023: Forecast

- ◆ Hepalyse range  
Aggressive advertising activities to capture increased demand in Q3  
Year-on-year increase in sales expected
- ◆ Running TV commercials for the new Prevaline a Quick series of drug for the skin and the Masdent series of medicated toothpaste to focus on cultivating the market



In addition to mainstay products, focus on cultivating European herbal preparations, drugs for the skin, etc.

### Main OTC drug product ranges



Chondroitin range  
Arthritis, lumbago  
therapeutic agent

Pharmaceutical  
Hepalyse range  
Nutrient tonics

WithOne range  
Laxatives

### Hepalyse W range



Hepalyse W Premium  
soft drink

### IONA Cosmetics



IONA Spa & Mineral Essences

### European herbal preparation range



Prefemin

### Drug for the skin Prevaline range



Prevaline a Quick cream

### Medicated toothpaste Masdent range



Masdent Care

Apr. 2023: Transitioned  
to a Class II drug

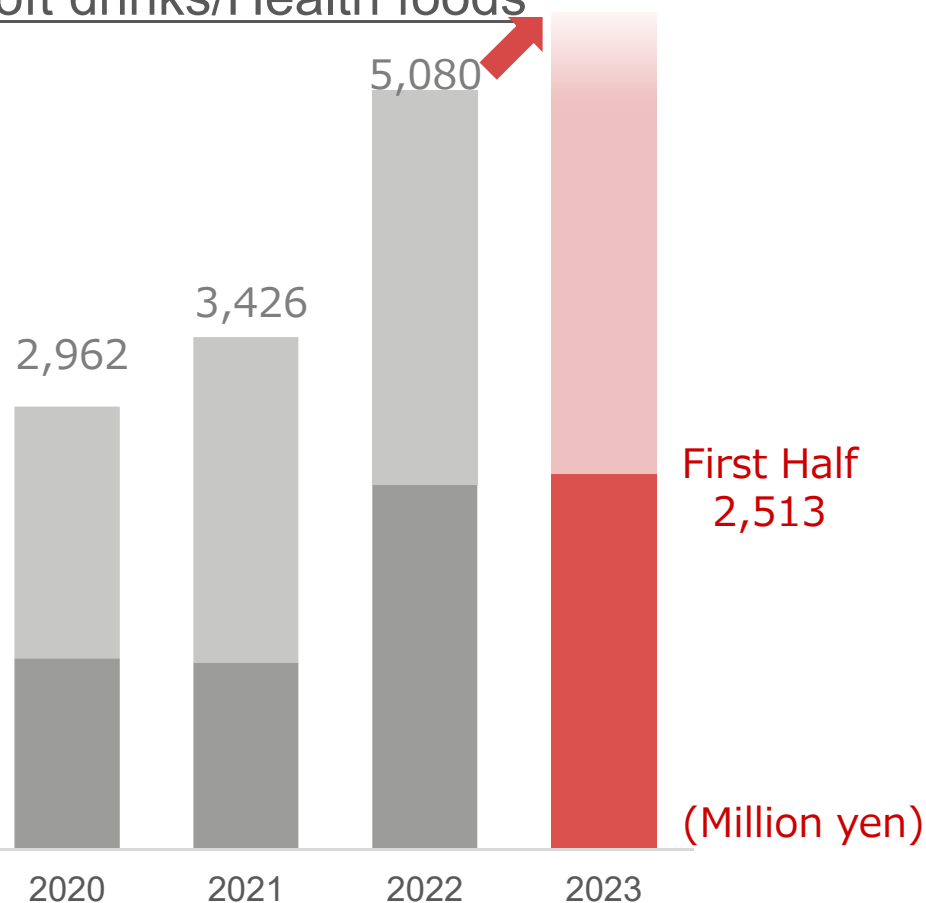
Prevaline a Quick series:  
Launched in November

Currently running a  
Masdent series TV  
commercial

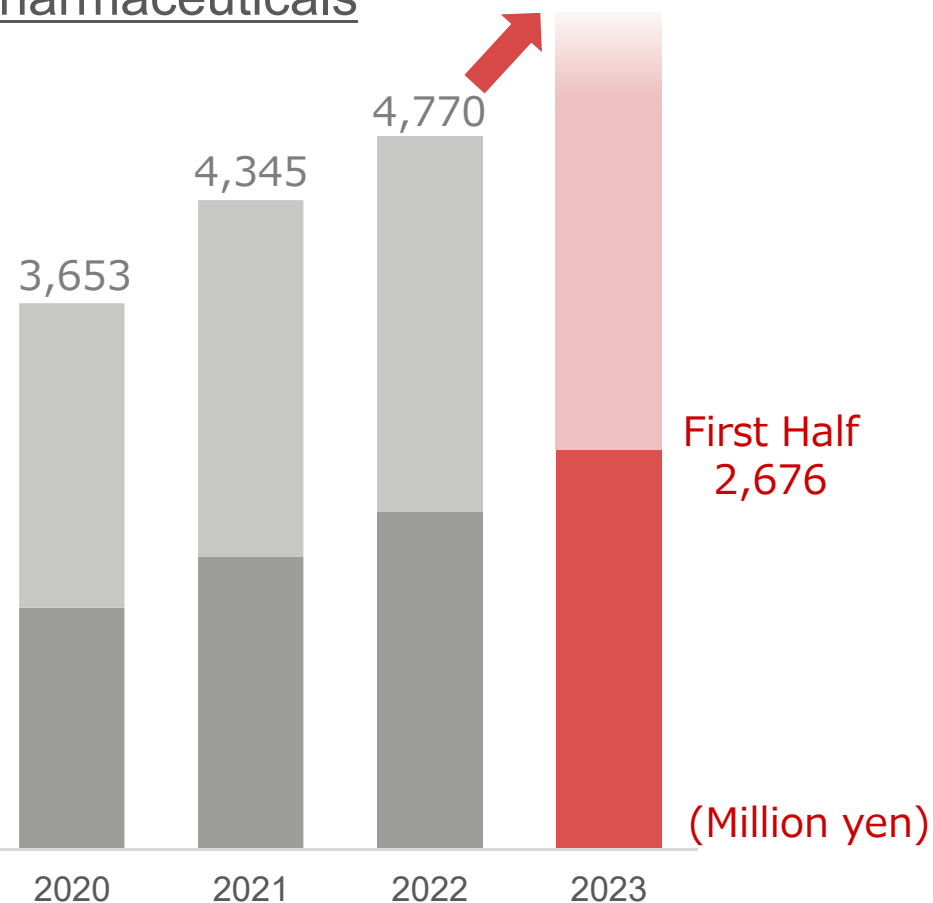
## II-2 Consumer Healthcare Business: Hepalyse Range

- ◆ Sales recovered nearly to pre-COVID-19 pandemic levels
- ◆ In the first half of the fiscal year, sales of pharmaceuticals to drugstores grew in particular
- ◆ Aggressive advertising in Q3 planned to capture demand

Soft drinks/Health foods



Pharmaceuticals



### Expanding sales with the transition to a Class II drug



＼ 日本で唯一の ／

# PMSのおくすりプレフェミン

(月経前症候群) ※OTC医薬品として

女性を悩ませるPMS。  
これからは、  
おくすりで緩和するにや

生理前が  
つらい、  
イライラ  
する。

薬局  
ドラッグストアで!

西洋ハーブ チェストベリーが効く  
30錠(30日分) [第2類医薬品]

【効能・効果】月経前の次の諸症状（月経前症候群）の緩和：乳房のはり、頭痛、イライラ、怒りっぽい、気分変動

Broadcasting of new TV commercials, information dissemination through social media, participation in Femtech events, etc.  
Aiming to increase the presence of Prefemin

## II-3 Development Pipeline Status

### Domestic Development

Development Code/Name	Development Company/Institution	Indication	Phase 1	Phase 2	Phase 3	NDA in Preparation	NDA Filed	NDA Approved
ZG-801	Zeria	Hyperkalemia						
Z-338 (Acotiamide)	Zeria	Pediatric functional dyspepsia						
ZG-802 (Acotiamide)	Zeria	Underactive bladder						
Z-338 (Acotiamide)	Kyushu University	Esophagogastric junction outflow obstruction (Investigator initiated trial)						

### Overseas Development

Development Code/Name	Development Company/Institution	Indication	Phase 1	Phase 2	Phase 3	NDA in Preparation	NDA Filed	NDA Approved
Z-338 (Acotiamide)	Zeria	Functional dyspepsia	Europe					
Z-338 (Acotiamide)	Meiji Seika Pharma	Functional dyspepsia	Thailand					
Z-338 (Acotiamide)	Faes Farma	Functional dyspepsia	Mexico, Honduras, Dominican Republic, Ecuador, Chile, Peru, El Salvador*					
Z-338 (Acotiamide)	F.T. Pharma	Functional dyspepsia	Vietnam					

\*Launched in Mexico in October 2023  
 NDA filed in five countries (Colombia, Costa Rica, Guatemala, Panama, Nicaragua)

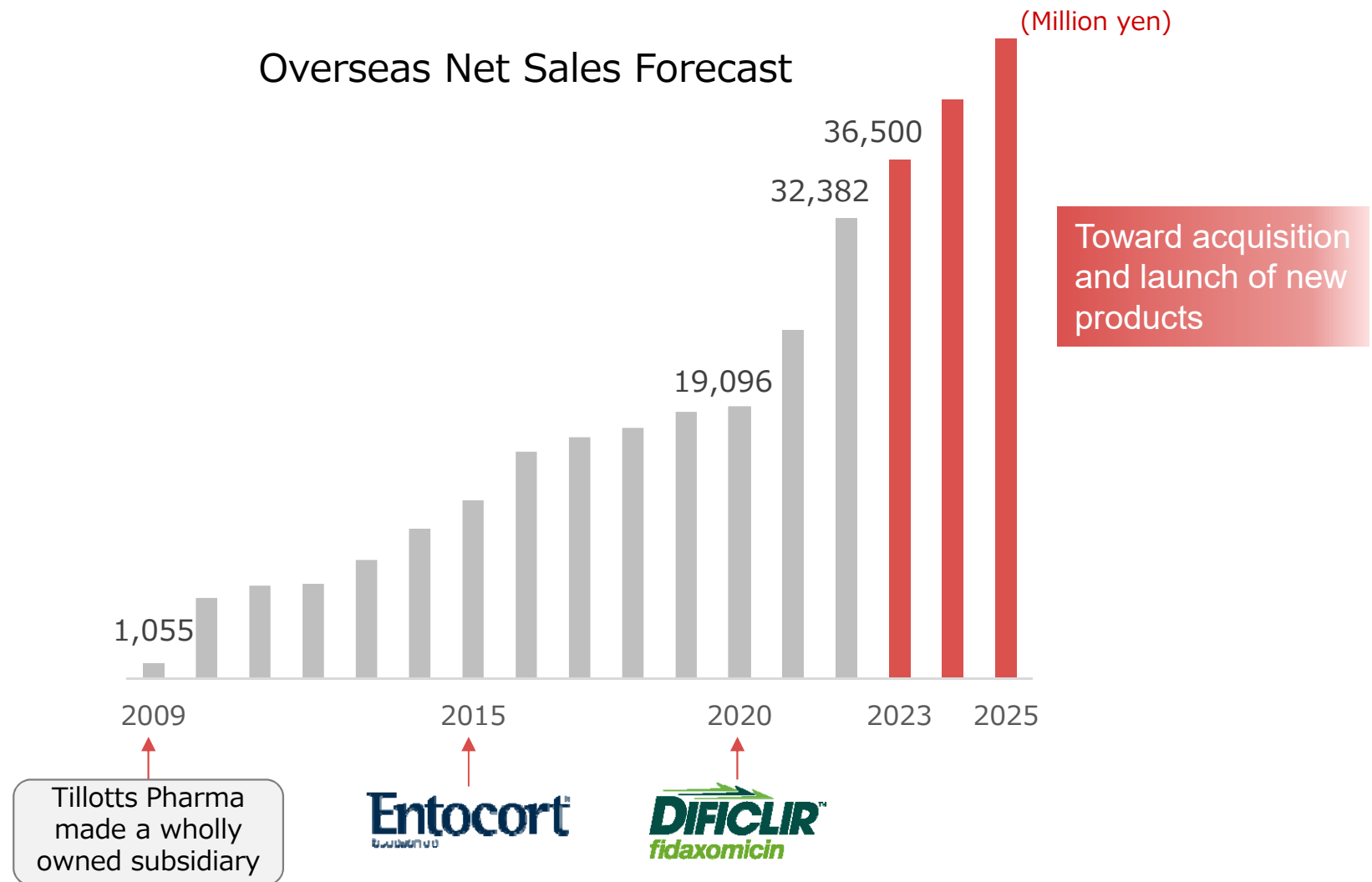
## II-4 Consolidated Full-Year Financial Forecast for Fiscal Year 2023

No change from forecast announced May 2023

	Fiscal Year 2022	Fiscal Year 2023	
	Results	Expectation	Year-on-Year Growth Rate
(Million yen)			
Net Sales	68,383	73,000	6.8%
Operating Profit	9,014	9,100	1.0%
Ordinary Profit	7,579	9,000	18.7%
Profit Attributable to Owners of Parent	6,195	7,000	13.0%
Dividend Per Share	40 yen	44 yen (expected)	
R&D Expenses	3,456	4,500	30.2%
Advertising Expenses	2,500	3,100	24.0%
Overseas Net Sales	32,382	36,500	12.7%

## II-4 Consolidated Full-Year Financial Forecast for Fiscal Year 2023

Continued growth expected in 2023 and beyond in overseas business  
Tillotts business growth to be the largest growth driver



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