



# **Fiscal Year 2022 (Period Ending March 2023) First Half Financial Results Briefing**

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**November 8, 2022**

**TSE Prime 4559**

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

# **I. Consolidated Financial Highlights for the First Half of Fiscal Year 2022**

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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 2021 Results	First Half of Fiscal Year 2022 Results	Year-on-Year Difference	Forecast Announced in May	Difference With Publicly Announced Forecast
Net Sales		28,606	33,712	17.9%	33,000	2.2%
Gross Profit		20,143	24,335	20.8%	—	
Selling, General, and Administrative Expenses		17,470	18,441	5.6%	—	
	R&D Expenses	2,986	1,607	-46.2%	—	
	Advertising Expenses	816	1,175	44.1%	—	
Operating Profit		2,672	5,894	120.6%	3,500	68.4%
Ordinary Profit		3,116	5,182	66.3%	3,500	48.1%
Profit Attributable to Owners of Parent		2,115	3,998	89.0%	2,800	42.8%

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

- ◆ The top three products, including Asacol, performed well
- ◆ Dificlir made a significant contribution to sales growth

		First Half of Fiscal Year 2021	First Half of Fiscal Year 2022	
		Results	Results	Year-on-Year Growth
(Unit: Million yen)				
Ethical Pharmaceuticals Business		17,997	21,505	19.5%
	Asacol	8,506	9,881	16.2%
	Dificlir	2,279	3,895	70.9%
	Entocort	2,245	2,935	30.7%
	Acofide	1,580	1,541	-2.4%
	Others	3,386	3,251	-4.0%

## Factors Causing Changes from Previous Year

	Year-on-Year Comparison	Factors Causing Change	
		Domestic	Overseas
Asacol	+16.2%	Sales declined owing to the impact of competing products and drug price revisions	<ul style="list-style-type: none"> <li>• Robust performance in major markets such as the UK and Northern Europe</li> <li>• Good performance of 1600mg tablets</li> </ul>
Dificlir	+70.9%		Performed well thanks to the success of aggressive sales resource investment
Entocort	+30.7%	Robust performance despite being impacted by drug price revisions	Performed well in markets such as Canada and Northern Europe
Acofide	-2.4%	Although there were temporary sales accompanying the beginning of independent promotion in the previous year, there were no such temporary sales in this year	
Others	-4.0%	Although sales of Ferinject, etc., grew, overall sales declined owing to the suspension of sales of some products	

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

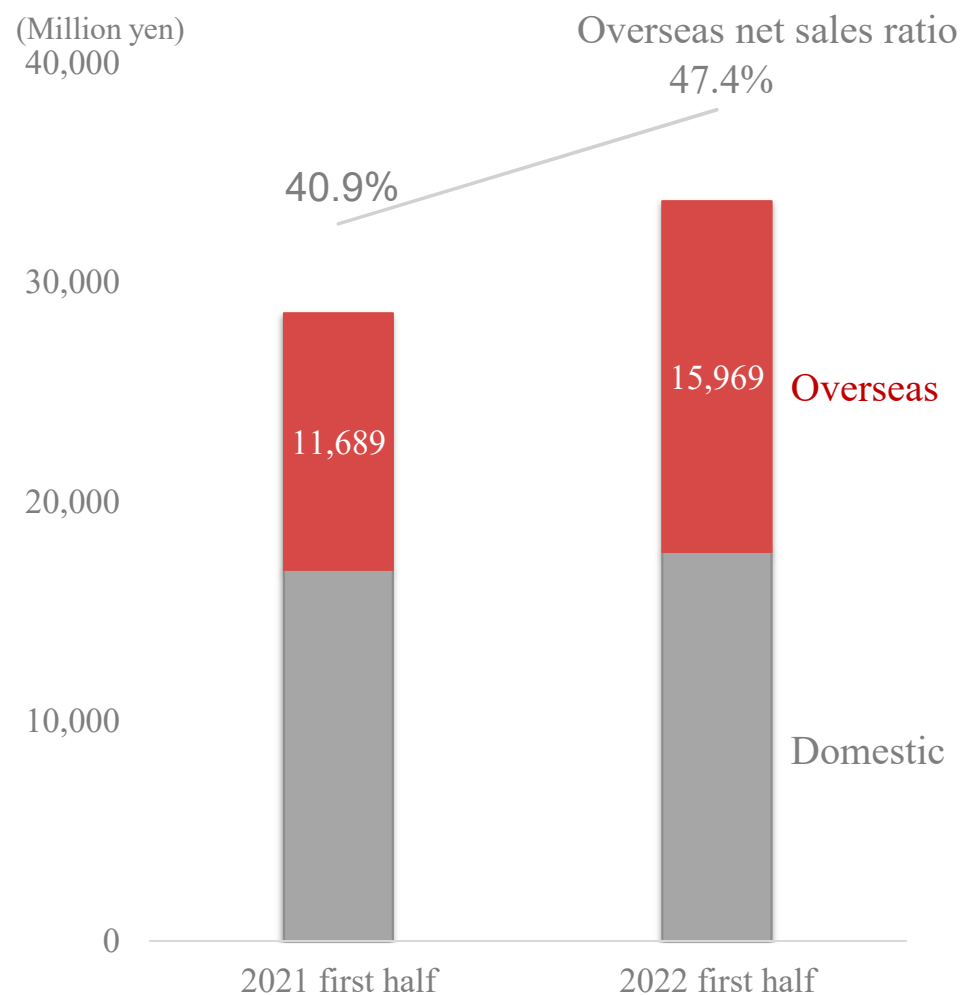
- ◆ Sales of the Hepalyse range are trending toward recovery
- ◆ In particular, there has been a notable recovery in the convenience store market

		First Half of Fiscal Year 2021	First Half of Fiscal Year 2022	
(Unit: Million yen)		Results	Results	Year-on-Year Growth
Consumer Healthcare Business		10,533	12,131	15.2%
	Hepalyse range	3,237	4,698	45.1%
	Pharmaceuticals	1,958	2,256	15.2%
	Soft Drinks Dietary Supplements	1,278	2,442	91.0%
	Chondroitin range	2,595	2,634	1.5%
	WithOne range	647	620	-4.1%
	Others	4,052	4,177	3.1%

## Factors Causing Changes from Previous Year

		Year-on-Year Comparison	Factors Causing Change
Hepalyse range	Pharmaceuticals	+15.2%	Secured new customers by promoting product features, such as “Fatigue recovery” and “Metabolism improvement/promotion”
	Soft Drinks Dietary Supplements	+91.0%	Significant increase in sales thanks to the easing of self-imposed restrictions related to COVID-19 and a recovery in social activities
Chondroitin range		+1.5%	Robust performance thanks to the impact of active advertising investment, etc.
WithOne range		-4.1%	Unable to attract new customers due to competing products resulting in a decrease
Others		+3.1%	Growth in cosmetics, etc.

**Asacol, Entocort, and Dificlir performed well, and overseas net sales grew significantly**





## **II. Consolidated Financial Forecast for Fiscal Year 2022**

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**II-1 Ethical Pharmaceuticals Business**

**II-2 Consumer Healthcare Business**

**II-3 Overview of Consolidated Financial Results**

**for Fiscal Year Ending March 31, 2023**

**II-4 Development Pipeline Status**

**II-5 Initiatives for Sustainable Growth**

- ◆ Significant growth in the overseas market in the first half of fiscal year 2022
- ◆ Continue to focus on rolling out the following products in Japan and overseas

### Domestic:

#### Ethical Pharmaceuticals Business

Asacol

Acofide

Ferinject

### Overseas:

#### Ethical Pharmaceuticals Business

Asacol

Dificlir

Entocort

## II-1 Ethical Pharmaceuticals Business: Overseas Business Development



### 8 Subsidiaries Established

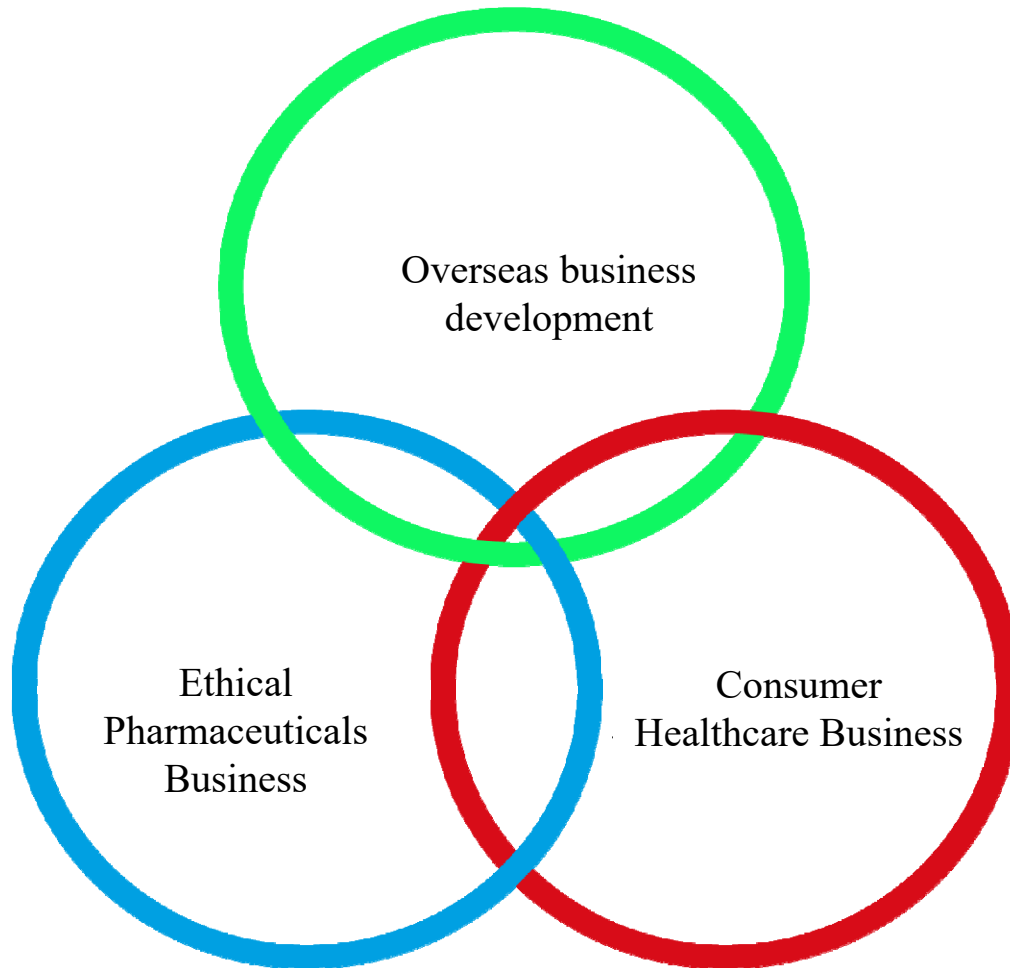
2004 Ireland  
2008 Sweden  
2010 UK, Czechoslovakia  
2011 Spain  
2013 Germany  
2016 France  
2021 Italy

Products are sold in 64 countries  
around the world

**ASACOL**<sup>TM</sup>  
FIDAXOMICIN

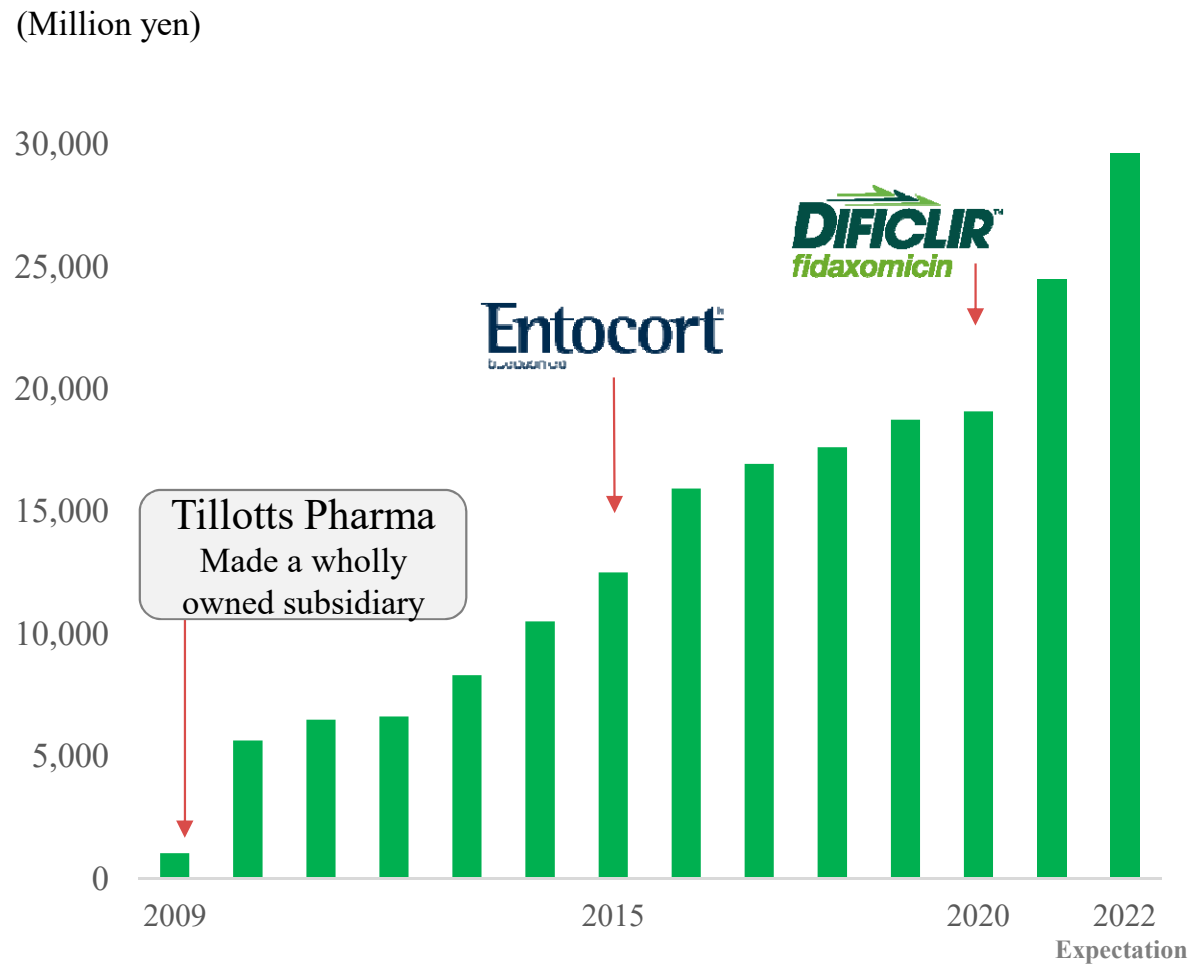
**Entocort**<sup>®</sup>  
Budesonide

**DIFICLIR**<sup>TM</sup>  
fidaxomicin

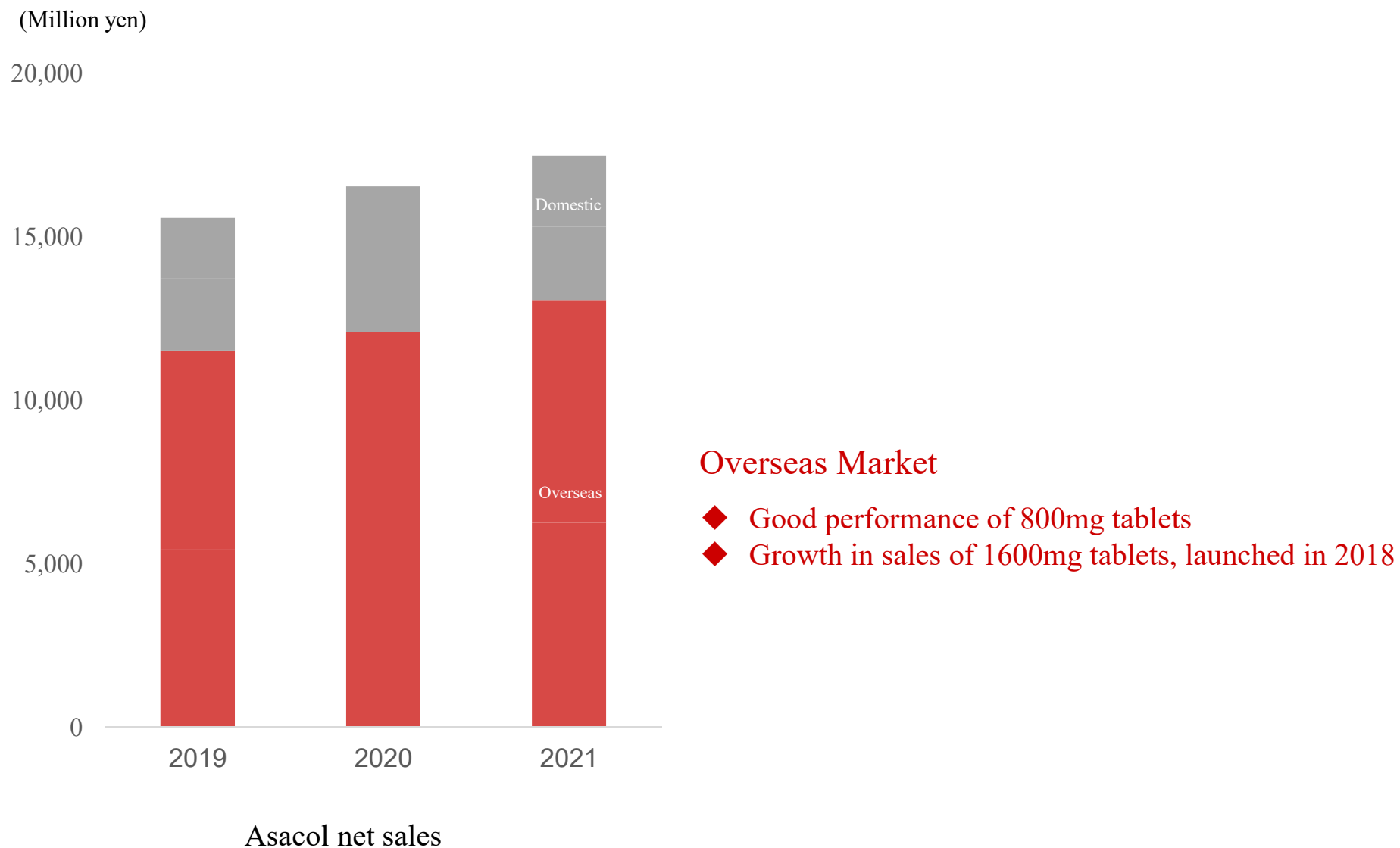


## II-1 Ethical Pharmaceuticals Business: Trends in Overseas Net Sales

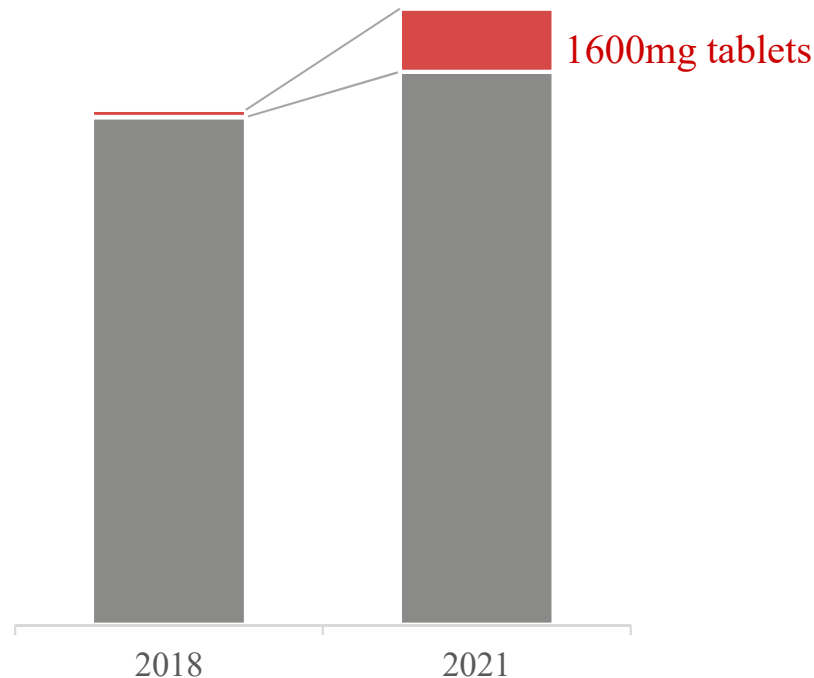
In addition to Asacol and Entocort, Dificlir has also contributed to sales growth



### Expect growth in the overseas market to continue



### Sales are growing, particularly in Europe



Asacol net sales in the overseas market  
(Swiss francs basis)

- Sales of 1600mg tablets are steadily increasing
- It is being promoted to encourage switching from competing high-dose formulations
- We plan to continue to expand sales to more countries

### A favorable market environment for Dificlir development is being prepared

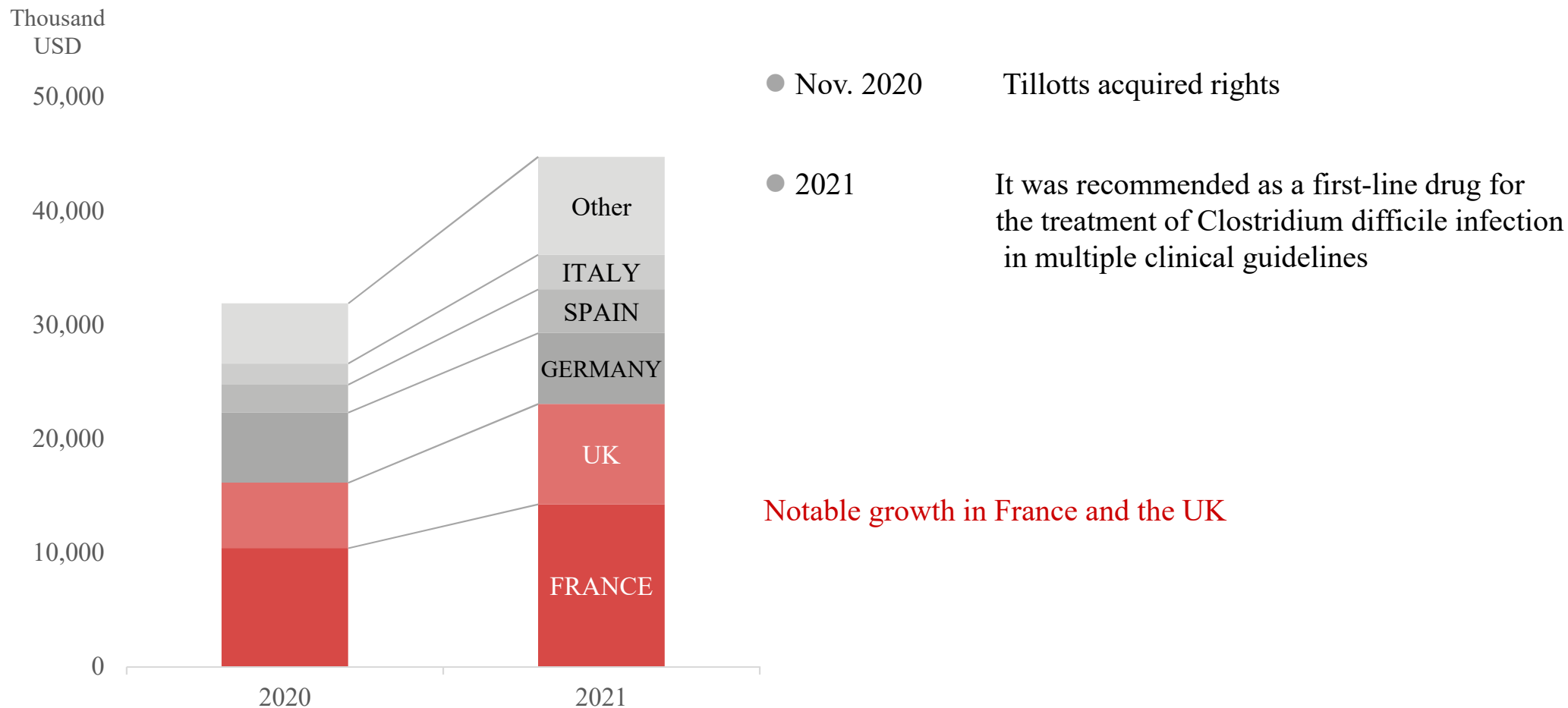


- It was recommended as a treatment for Clostridium difficile infection in multiple clinical guidelines published in 2021

European Society of Clinical Microbiology and Infectious Diseases (ESCMID)	Initial treatment Cases with high risk of recurrence	First-line drug
The Society for Healthcare Epidemiology of America (SHEA) / Infectious Diseases Society of America (IDSA)	Initial treatment First recurrence	First-line drug
National Institute for Health and Care Excellence (NICE)	Initial treatment Cases of recurrence	Second-line drug First-line drug

- We believe the recommendations in these guidelines will create a good environment for Dificlir in major European markets including France and the UK
- We will proactively invest sales resources to strengthen access to medical institutions

### Sales grew significantly in 2021



Source: Aggregated by the Company based on IQVIA Analytics Link data for 2020 and 2021  
(Market definitions according to the Company)  
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Conducted TV commercials and other mass media advertising  
and online advertising and promotional campaigns centered on SNS

Chondroitin range



Hepalyse range

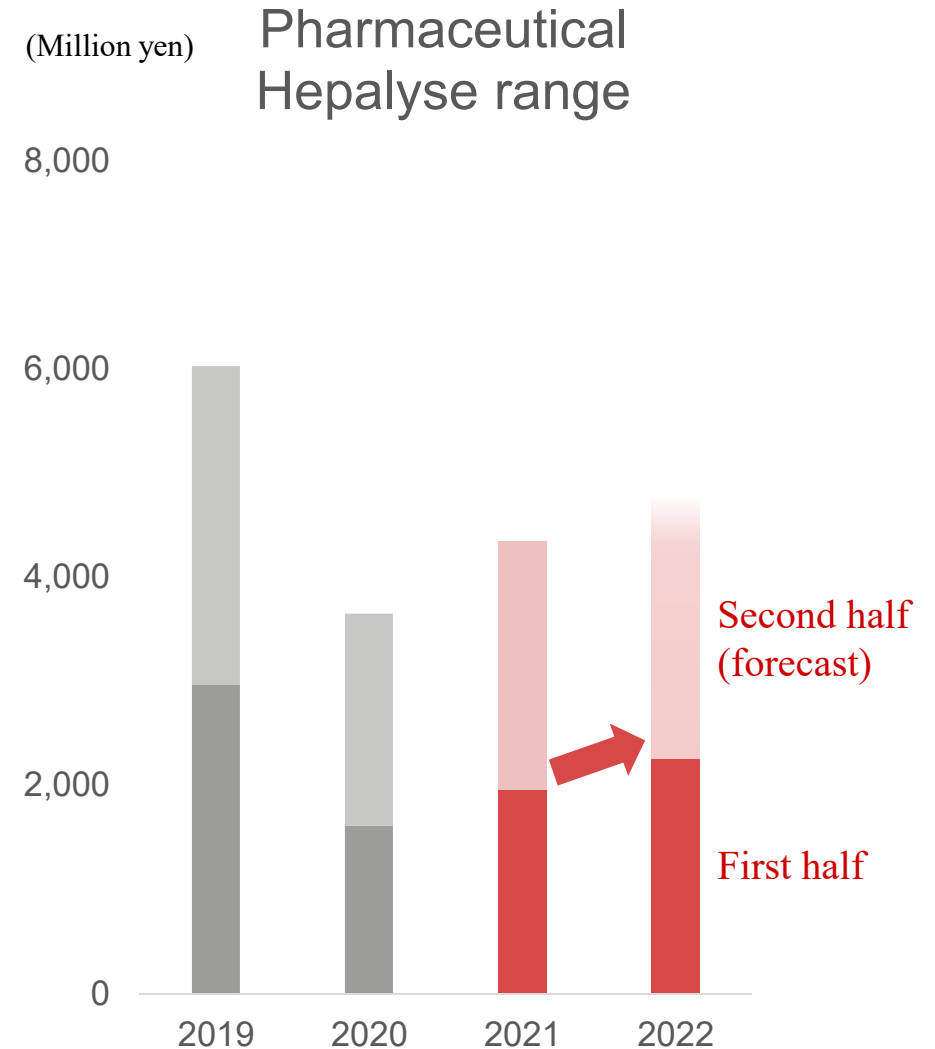
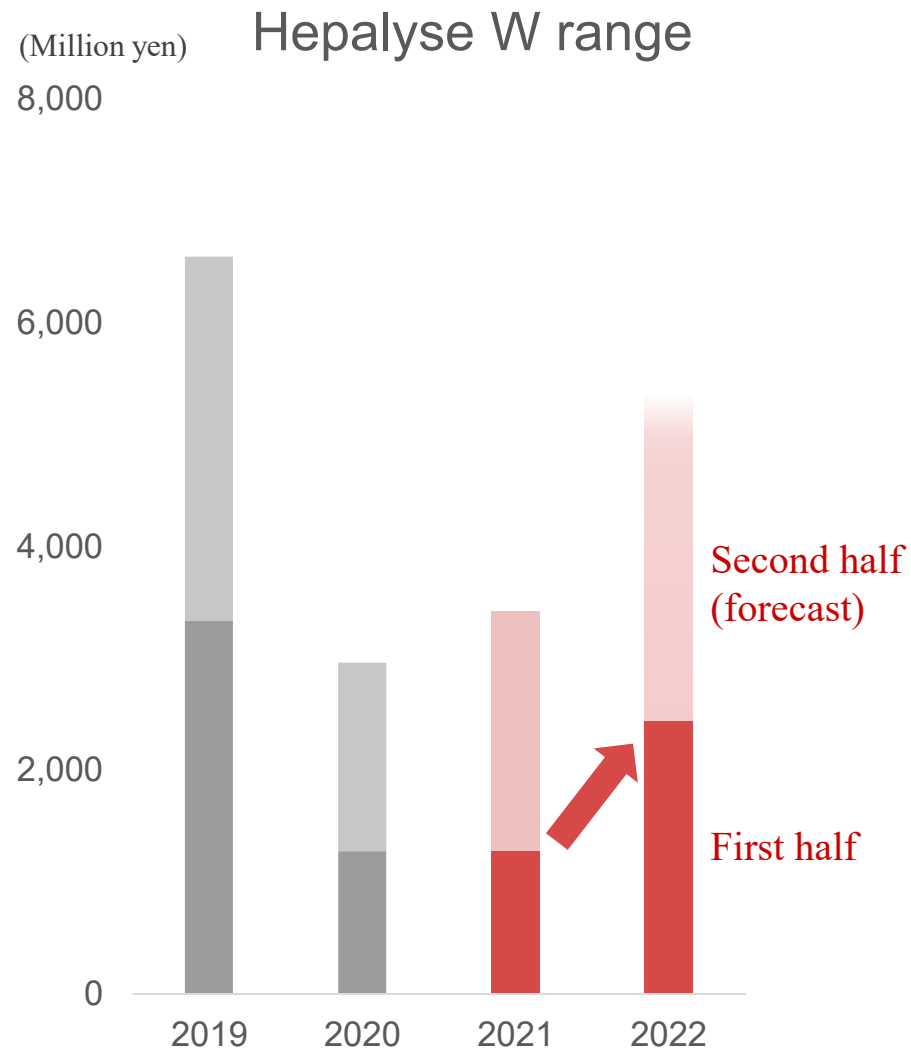


WithOne range



## II-2 Consumer Healthcare Business: Hepalyse Range

- ◆ Sales of the Hepalyse range are trending toward recovery
- ◆ In particular, there has been a notable recovery in the convenience store market



### Focusing on cultivating chondroitin, Hepalyse, WithOne, and European herbal preparation



Chondroitin range  
(arthritis, lumbago therapeutic agent)



Pharmaceutical Hepalyse range  
(nutrient tonics)



WithOne range  
(laxatives)



Prefemin  
(therapeutic agent for premenstrual syndrome (PMS))



Belfemin  
(treatment for ameliorating foot swelling)



Colpermin  
(treatment to improve irritable bowel syndrome (IBS))

### Main OTC drug product ranges



Hi Jelly range  
(nutrient tonics)



Prevaline range  
(drug for the skin)



Viewclear range  
(eye drops)



Masdent range  
(medicated toothpaste)



IONA Cosmetics



Hepalyse W series

### Other OTC drugs

### Oral care

### Cosmetics

### Soft drinks

### Domestic: Ethical Pharmaceuticals Business

- Asacol  
Decline in sales owing to the impact of drug price revisions and competing products
- Acofide  
Further relaxation of patient consultation restraints, spread of gastroscopy  
Increase in sales based on aggressive sales resource investment
- Ferinject  
Increase in sales based on aggressive sales resource investment

### Overseas: Ethical Pharmaceuticals Business

- Asacol  
Increase in sales of 800mg and 1600mg tablets, addition of new pharmaceutical preparations in launch countries, etc.
- Dificlir  
Favorable change in the market environment amid prescriptions being recommended by clinical guidelines
- Entocort  
Good performance to continue in Canada, Northern Europe, etc.

### Consumer Healthcare Business

- Hepalyse range

We expect sales to recover as the impact of the spread of COVID-19 eases and we enter the year-end/New Year period of peak demand

- Pharmaceutical Hepalyse range

Continue promotion activities that clearly communicate product features

- Hepalyse W range

Implement sales promotion campaigns via SNS and tie-up projects with convenience stores

- Chondroitin range

Increase in sales by implementing promotion activities that clearly communicate the ingredient features

- WithOne range

Implement promotion activities that clearly communicate the ingredient features through new TV commercials, etc.

- European herbal preparation range

Acquire potential customers by expanding awareness of “European Herbal Preparation drugs”

## II-3 Consolidated Financial Forecast for Fiscal Year Ending March 31, 2023

(Million yen)	Fiscal Year Ended March 31, 2022	Fiscal Year Ending March 31, 2023	
	Results	Expectation	Year-on-Year Growth Rate
<b>Net Sales</b>	59,532	66,000	10.9%
<b>Operating Profit</b>	6,366	7,000	10.0%
<b>Ordinary Profit</b>	5,935	7,000	17.9%
<b>Profit Attributable to Owners of Parent</b>	3,961	5,600	41.4%
<b>Dividend Per Share</b>	35 yen	36 yen (expected)	
<b>R&amp;D Expenses</b>	4,789	5,000	4.4%
<b>Advertising Expenses</b>	1,963	2,900	47.7%
<b>Overseas Net Sales</b>	24,668	29,650	20.2%

## II-4 Development Pipeline Status

### Domestic Development

Development Code/Name	Development Company/Institution	Indication	Phase1	Phase2	Phase3	Application	Approval Acquisition	Sales
Z-338 (Acofide)	Zeria	Pediatric functional dyspepsia						
ZG-801	Zeria	Hyperkalemia						
Z-338 (Acofide)	Kyushu University	Esophagogastric junction outflow obstruction (Investigator initiated trial)						

### Overseas Development

Development Code / Name	Development Company/Institution	Indication	Phase1	Phase2	Phase3	Application	Approval Acquisition	Sales
Z-338 (Acofide)	Zeria	Functional dyspepsia	Europe					
Z-338 (Acofide)	Meiji Seika Pharma	Functional dyspepsia	Thailand and Indonesia					
Z-338 (Acofide)	Faes Farma	Functional dyspepsia	Mexico and Honduras					
			8 Latin-American countries*					

\* Chile, Colombia, Peru, Ecuador, Dominican Republic, Costa Rica, Guatemala, and Panama

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