

# **Fiscal Year 2021 (Period Ended March 2022) Financial Results Briefing**

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**May 17, 2022**

**TSE Prime 4559**

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

# **I. Consolidated Financial Highlights for Fiscal Year 2021**

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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

	Fiscal Year 2020		Fiscal Year 2021		
	Results	Sales Ratio	Results	Sales Ratio	Year-on-Year Growth Rate
(Million yen)					
<b>Net Sales</b>	52,757	100.0%	59,532	100.0%	12.8%
<b>Gross Profit</b>	36,960	70.1%	42,148	70.8%	14.0%
<b>Selling, General, and Administrative Expenses</b>	33,484	63.5%	35,782	60.1%	6.9%
<b>R&amp;D Expenses</b>	5,411	10.3%	4,789	8.0%	-11.5%
<b>Advertising Expenses</b>	1,783	3.4%	1,963	3.3%	10.1%
<b>Operating Profit</b>	3,475	6.6%	6,366	10.7%	83.2%
<b>Ordinary Profit</b>	3,208	6.1%	5,935	10.0%	85.0%
<b>Profit Attributable to Owners of Parent</b>	3,143	6.0%	3,961	6.7%	26.0%
<b>Dividend Per Share</b>	34 yen		35 yen (planned)		

Note: The “Accounting Standard for Revenue Recognition” began to apply from Fiscal Year 2021. It is shown applied retroactively to Fiscal Year 2020.

## I-2 Ethical Pharmaceuticals Business

- ◆ Dificlir and Acofide contributed greatly to increased sales
- ◆ Other products including long-listed products stopped declining due to the growth of Ferinject

		Fiscal Year 2020	Fiscal Year 2021	
(Unit: Million yen)		Results	Results	Year-on-Year Growth
Ethical Pharmaceuticals Business		29,951	37,006	23.6%
	Asacol	16,509	17,476	5.9%
	Dificlir	259	5,211	1,906.3%
	Entocort	4,814	4,480	-7.0%
	Acofide	1,667	3,154	89.2%
	Others	6,699	6,684	-0.2%

## Factors Causing Changes from Previous Year

	Year-on-Year Comparison	Factors Causing Change	
		Domestic	Overseas
Asacol	+5.9%	(+) Increase in switching from generic prescriptions	(+) Good performance of 800mg tablets and 1600mg tablets
Dificlir	+1,906.3%		(+) Sales recorded throughout the year
Entocort	-7.0%	(+) Steady progress of Zentacort due to relaxing of consultation restraints	(-) Impact of inventory adjustments in Canada, Spain, and elsewhere
Acofide	+89.2%	(+) Resolved inventory adjustments by switching to independent promotion Impact from relaxing of consultation restraints, etc.	
Others	-0.2%	(+) Expansion of Ferinject (-) Decrease in some long-listed products, etc.	

## I-3 Consumer Healthcare Business

- ◆ Although sales of the Hepalyse range recovered, segment sales decreased due to difficulties with the Chondroitin range, WithOne range, and disinfectants

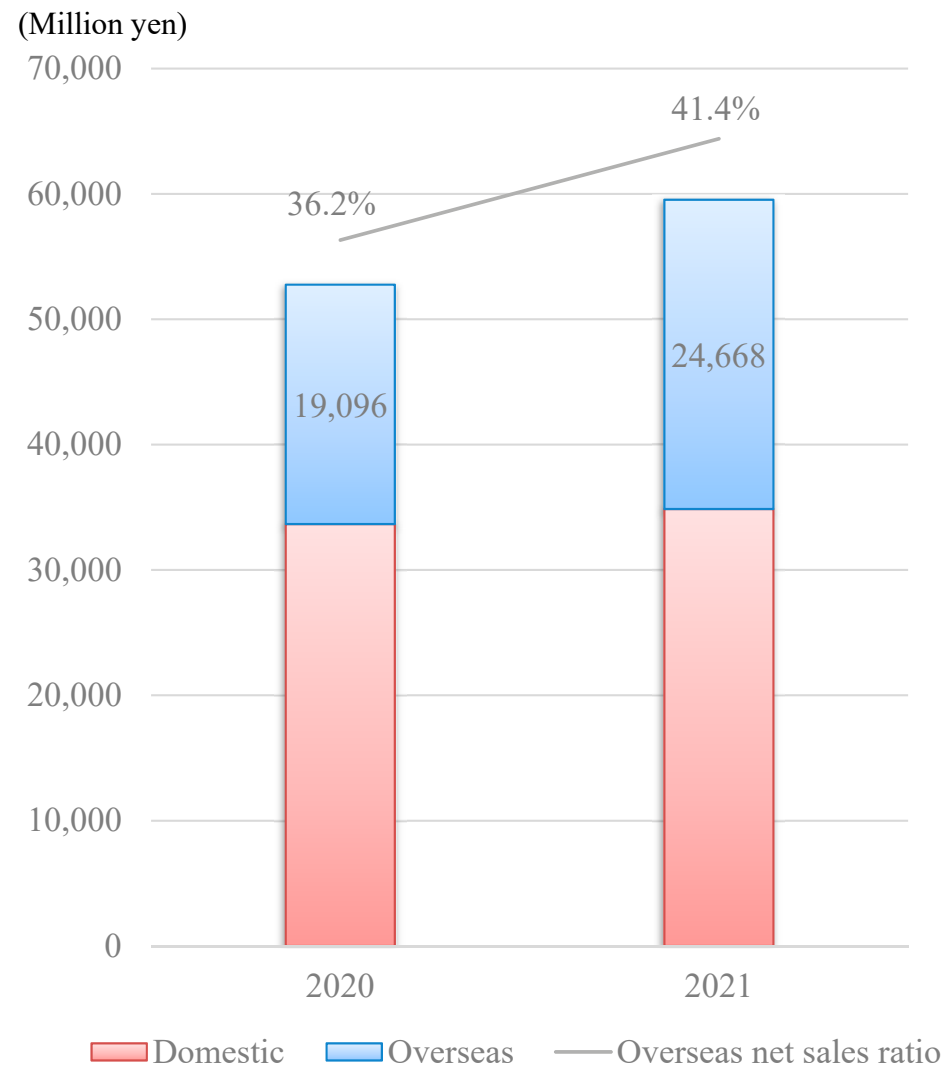
		Fiscal Year 2020	Fiscal Year 2021	
(Unit: Million yen)		Results	Results	Year-on-Year Growth
Consumer Healthcare Business		22,648	22,370	-1.2%
	Hepalyse Range	6,615	7,770	17.5%
	Pharmaceuticals	3,653	4,345	18.9%
	Soft Drinks Dietary Supplements	2,961	3,425	15.7%
	Chondroitin Range	5,383	5,135	-4.6%
	WithOne Range	1,445	1,359	-5.9%
	Others	9,204	8,104	-12.0%

## Factors Causing Changes from Previous Year

		Year-on-Year Comparison	Factors Causing Change
Hepalyse Range	Pharmaceuticals	+18.9%	(+) Growth during whole year by promoting product features using keywords such as “Fatigue recovery” “Metabolism improvement/promotion”
	Soft Drinks Dietary Supplements	+15.7%	(+) Due to the impact of COVID-19 (4th and 5th waves), the first half was the same level as the previous year, but in the second half, growth gradually increased as the pandemic situation improved, resulting in growth from the previous fiscal year for the whole year
Chondroitin Range		-4.6%	(-) Unable to attract new customers due to competing products resulting in a decrease
WithOne Range		-5.9%	(-) Unable to attract new customers due to competing products resulting in a decrease
Others		-12.0%	(-) Decrease in sales due to drop in demand for disinfectants, etc.

## I-4 Overseas Net Sales

◆ Overseas net sales increased significantly by 29.2% compared to the previous year





## **II. Initiatives 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**

**II-6 Introduction of Executive Officer System**

### Domestic Market

- Focus on Acofide, Asacol, and Ferinject

### Overseas Market

- Focus on three main products (Dificlir, Asacol, and Entocort)
- Special focus on Dificlir

## II-1 Ethical Pharmaceuticals Business: Tillotts Pharma



Products are sold in 64 countries around the world

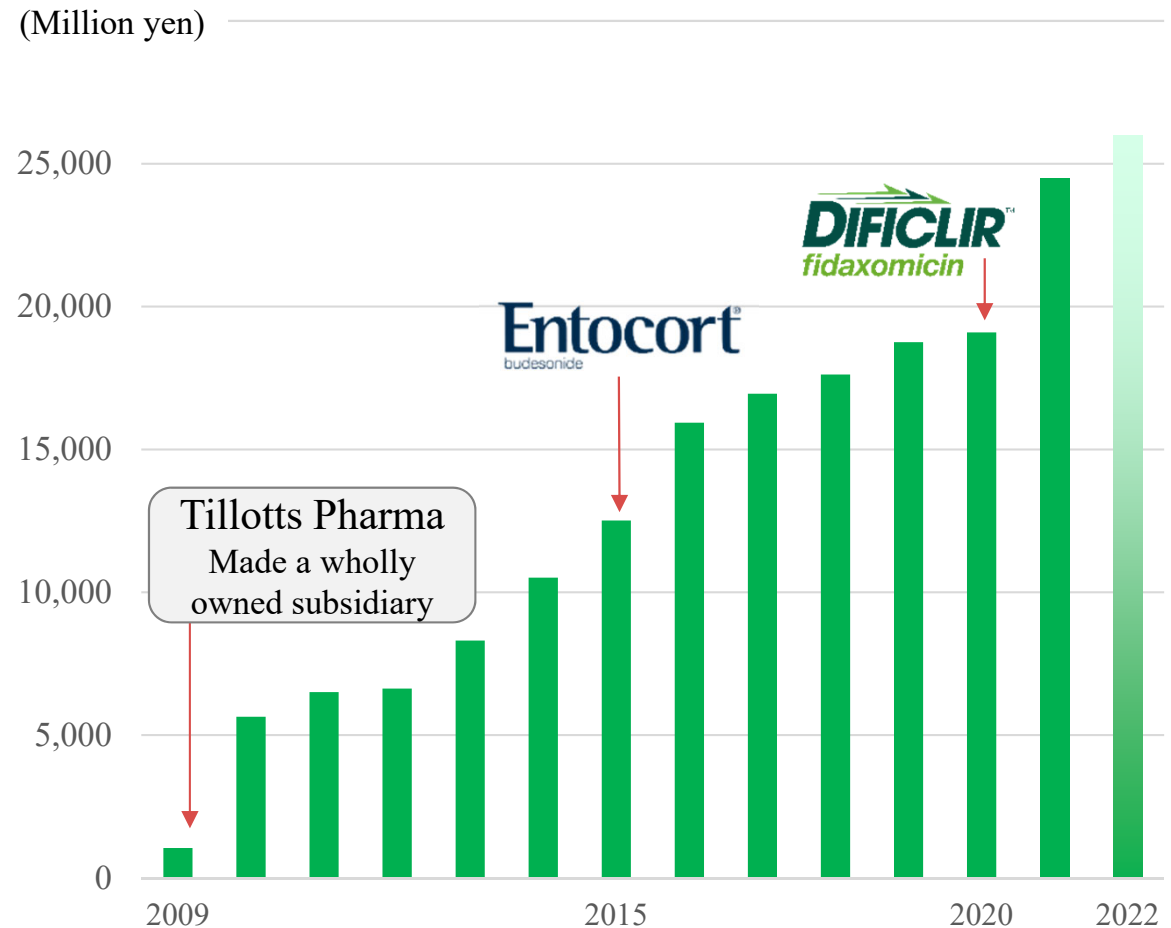
**ASACOL**<sup>TM</sup> **Entocort**<sup>®</sup>  
mesalazine budesonide

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

### 8 Subsidiaries Established

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

Overseas net sales increased significantly after Tillotts was acquired as a consolidated subsidiary



## II-1 Ethical Pharmaceuticals Business: Dificlir

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

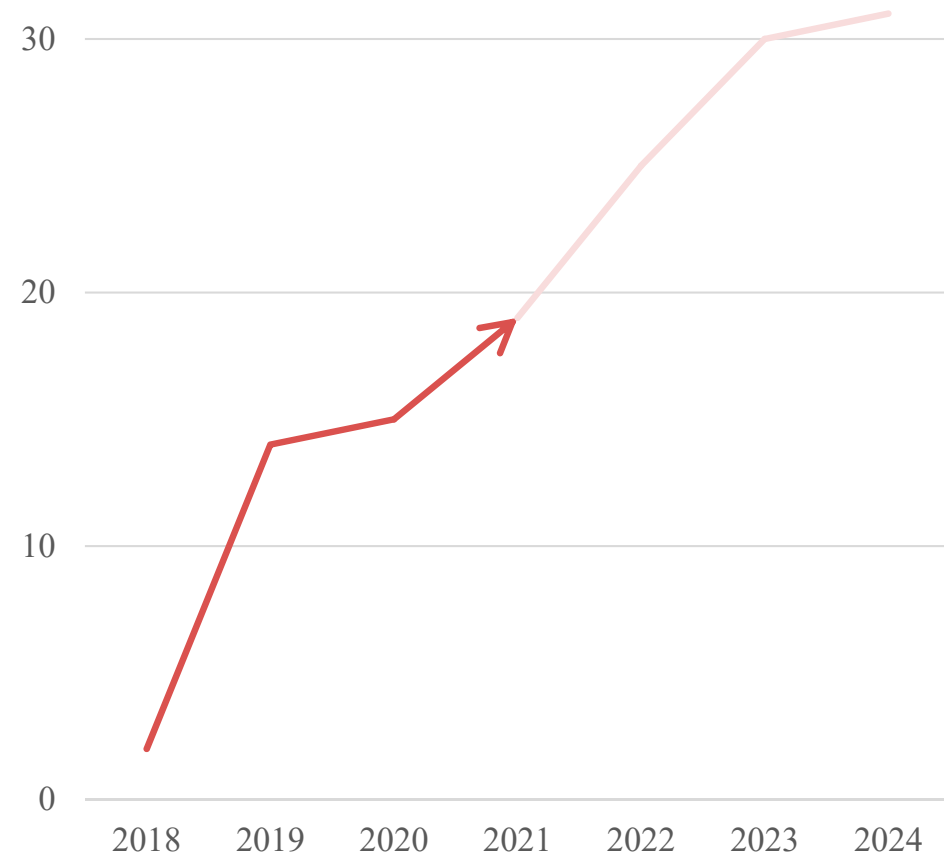
- We believe the recommendations in these guidelines will create a good environment for Dificlir in major European markets including France and the UK
- We will proactively invest sales resources to strengthen access to medical institutions, and expect sales to increase

## II-1 Ethical Pharmaceuticals Business: ASACOL 1600mg Tablet

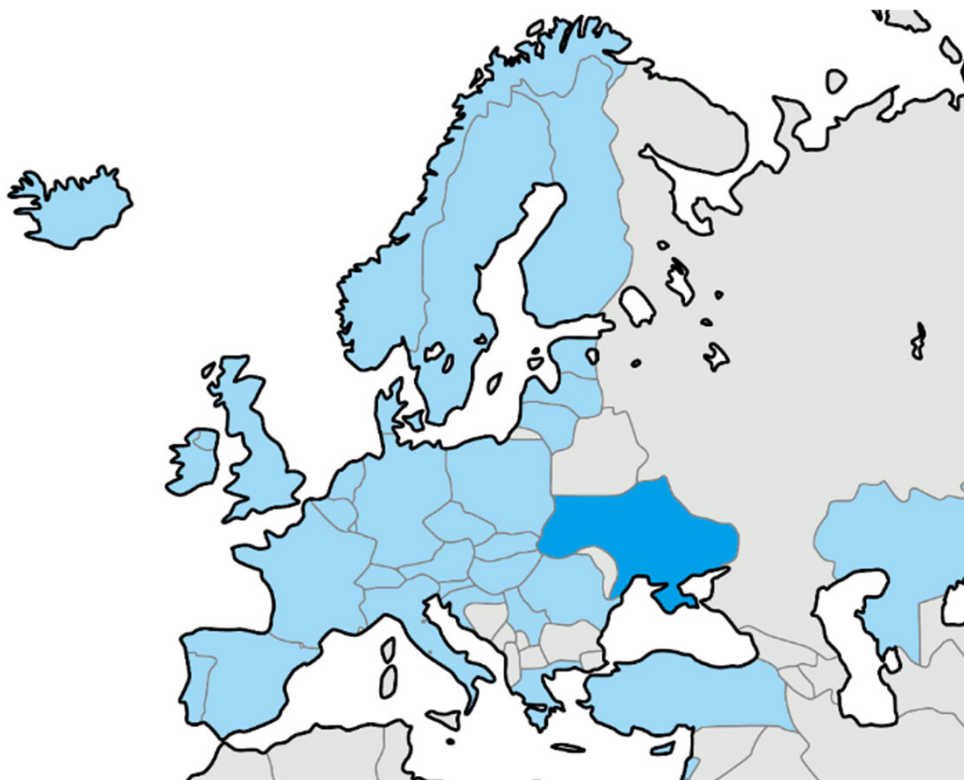
- It is being sold in 19 countries including Germany and France (as of December 2021)
- Sales tripled from the previous fiscal year
- It is being promoted to encourage switching from competing high-dose formulations
- We will continue to expand sales to more countries

### Expanding Sales to More Countries, Mainly in Europe

(Number of sales countries)



### European Market Geopolitical Risk



Countries in Europe where Tillotts products are sold

- Tillotts sells products in Europe, mainly in the UK and EU member states
- Impact from the situation in Ukraine
  - Currently no significant impact across Europe
  - No transactions with Russia
  - While the sales outlook in Ukraine is uncertain, since the amount is small, the impact on overall sales would be limited

### Hepalyse Range

- Pharmaceutical Hepalyse range  
Promote recognition of liver hydrolysate as a nutrient tonic
- Hepalyse W range  
Promote tie-up projects with convenience stores and develop sales promotion campaigns through SNS

### Chondroitin Range

- Promote recognition of the effects of chondroitin Sulfate Na
- Strengthen promotion by expanding the promotion target groups

### WithOne Range

- Develop active advertising activities
- Strengthen promotion by expanding the promotion target groups

### IONA Cosmetics Range

- Develop store sales of serialized Spa & Mineral Essence products, and develop promotion of the IONA R series

### Continue to nurture and develop the European Herbal Medicine Range as a new category

2014	Therapeutic medicine for premenstrual syndrome(PMS)	“Prefemin”
2021	Therapeutic medicine for foot swelling due to mild venous insufficiency	“Belfemin”
2022	Therapeutic medicine for irritable bowel syndrome (IBS)	“Colpermin”

Plan for further new product development



Prefemin



Belfemin



Colpermin



### Prefemin: From Pharmacist Intervention Required Medicines to Class I drug



- The reexamination period (8 years) has ended and it has shifted to a Class I drug from April 2022
- We will continue raising awareness and understanding of PMS through Internet media, etc., and focusing on sales development at stores

### Domestic: Ethical Pharmaceuticals Business

- Asacol  
Volume is expected to increase, and drug price revisions will have a major impact
- Acofide  
Further relaxation of patient consultation restraints, spread of gastroscopy, and increase in sales based on aggressive sales resource investment
- Ferinject  
Increase in sales based on aggressive sales resource investment

### Overseas: Ethical Pharmaceuticals Business

- Asacol  
Addition of countries where 1600mg tablets are sold, increase in sales in countries where sold, addition of new pharmaceutical preparations in launch countries, etc.
- Entocort  
Recovery from inventory adjustments in Canada and elsewhere
- Dificlir  
Favorable market environment such as prescriptions being recommended by clinical guidelines

### Consumer Healthcare Business

- Hepalyse range
  - Pharmaceutical Hepalyse range  
Increase in sales by continuing promotion activities that clearly communicate product features
  - Hepalyse W range  
Increase in sales through 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
- European Herbal Medicine range
  - Move Prefemin to a Class I drug
  - Raise awareness of Belfemin and Colpermin by raising awareness of diseases

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

	Fiscal Year Ended March 31, 2022	Fiscal Year Ending March 31, 2023	
	Results	Expectation	Year-on-Year Growth Rate
(Million yen)			
<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 (planned)	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	27,500	11.5%

## 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-206 (Asacol)	Zeria and Tillotts	Ulcerative colitis	China					
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	4 Latin-American countries Chili, Colombia, Peru, and Ecuador					
			Mexico					

### <Investment>

Multiple projects are being considered under the global development system

- Introduction of pharmaceuticals to the gastrointestinal field and areas closely related to existing businesses

Growth strategy including M&A

- Areas that have synergy with existing businesses
- Areas where management resources, etc., can be developed efficiently

### <Others>

- Promoting the introduction of our products overseas

### 1. Purpose

Separating decision-making and supervisory functions related to management from business execution functions will help to clarify the responsibilities and authority for executing business, will enhance management agility, and will further strengthen corporate governance. It will also provide more opportunities for human resources to be promoted and help develop management personnel.

### 2. Overview

- (1) The appointment and dismissal of Executive Officers and determination of their duties shall be done by resolutions of the Board of Directors
- (2) The term of office for Executive Officers shall be one year, and reappointment shall be possible
- (3) Directors may also serve as Executive Officers
- (4) Executive Officers shall carry out their duties according to the basic company policy determined by the Board of Directors

### 3. Date of Executive Officer System Introduction

June 29, 2022

This document includes statements related to future performance. These statements are not a guarantee of future performance and include risks and uncertainties. Please keep in mind that future business results may differ from expectations due to changes in the business environment and other factors. In addition, this document is for informational purposes only and is not intended to solicit transactions.

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