

# Financial Results for the Fiscal Year 2022, Ended December 31, 2022

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※ This material is prepared based on Japan GAAP.

※ Amounts are rounded down to the nearest million yen.

※ The forecasts presented in this material are forward-looking statements. Reflecting assumptions based on information available on the date of publication, these statements are subject to inherent risks and uncertainties. Accordingly, unforeseen factors may cause actual results to differ materially from the projections contained herein. Torii will not necessarily revise this material regardless of any new information, future events or other results.

February 10, 2023



**TORII PHARMACEUTICAL CO., LTD.**

# I Summary Information

## ① Financial Results

※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of FY2022.

※2 "Accounting Standard for Revenue Recognition" etc. have not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures is reference values.

(Millions of Yen)	FY2021	FY2022	Change	Change	FY2023 Forecast ※1	Change	Change
	A	※1 B	B-A	(%) (B-A)/A			
Net sales	46,987	48,896	1,908	※2 4.1	50,900	2,003	4.1
Operating income	4,656	5,540	884	19.0	4,100	(1,440)	(26.0)
Ordinary income	4,847	5,537	689	14.2	4,400	(1,137)	(20.5)
Net income	3,374	3,944	569	16.9	3,100	(844)	(21.4)
<b>(Reference)</b>							
R&D expenses	832	1,661	828	99.5	3,530	1,868	112.5
Earnings per share (EPS) (¥)	120.13	140.39	20.26		110.33	(30.06)	
Return on equity (ROE) (%)	2.9	3.3	0.4				
Ratio of ordinary income to total assets (%)	3.8	4.2	0.4				
Ratio of operating income to net sales (%)	9.9	11.3	1.4	※2			
Return on assets (ROA) (%)	2.6	3.0	0.4				

## ② Financial Conditions

(Millions of Yen)	December 31, 2021	December 31, 2022	Change	Change
	A	B	B-A	(%) (B-A)/A
Total assets	130,810	133,689	2,878	2.2
Total equity	117,015	119,224	2,209	1.9
Equity ratio (%)	89.5	89.2	(0.3)	
Book value per share (BPS) (¥)	4,165.38	4,243.08	77.70	

## ③ Statement of Cash Flows

(Millions of Yen)	FY2021	FY2022	Change
	A	B	B-A
Net cash provided by operating activities	(156)	2,420	2,576
Net cash used in investing activities	(1,498)	(13,676)	(12,178)
Net cash used in financing activities	(1,546)	(1,698)	(151)
Cash and cash equivalents, end of period	58,374	45,420	(12,954)

## ④ Capital Expenditures

(Millions of Yen)	FY2021	FY2022	Change	Change	FY2023 Forecast	Change	Change
	A	B	B-A	(%) (B-A)/A			
Capital expenditures	822	662	(159)	(19.4)	300	(362)	(54.7)
PP&E	597	504	(93)	(15.6)	180	(324)	(64.3)
Intangible assets	224	158	(66)	(29.6)	120	(38)	(24.1)

## ⑤ Depreciation/Amortization

(Millions of Yen)	FY2021	FY2022	Change	Change	FY2023 Forecast	Change	Change
	A	B	B-A	(%) (B-A)/A			
Depreciation and amortization of intangible assets	413	454	41	10.0	490	35	7.8
Amortization of long-term prepaid expenses	722	767	45	6.2	660	(107)	(14.0)

## II Financial Results for the FY2022

### ① Statement of Income

※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of FY2022.

※2 "Accounting Standard for Revenue Recognition" etc. have not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures is reference values.

(Millions of Yen)	FY2021	FY2022	Change	Change	
	A	※1 B		B-A	(%) (B-A)/A
Net sales	46,987	48,896	1,908	※2	4.1 ※2
Sales of products	46,290	48,563	2,272	※2	4.9 ※2
Renal disease and hemodialysis	13,502	12,013	(1,489)	※2	(11.0) ※2
Skin disease	11,992	12,391	399	※2	3.3 ※2
Allergens	15,971	18,499	2,528	※2	15.8 ※2
Other	4,824	5,658	834	※2	17.3 ※2
Other sales	697	332	(364)	※2	(52.3) ※2
Cost of sales	22,649	25,516	2,867	※2	12.7 ※2
Cost of products sold	22,591	25,437	2,845	※2	12.6 ※2
Other cost	57	79	21		37.7
Gross profit	24,338	23,379	(958)	※2	(3.9) ※2
Selling, general and administrative expenses	19,682	17,839	(1,843)	※2	(9.4) ※2
R&D expenses	832	1,661	828		99.5
Others	18,849	16,177	(2,671)	※2	(14.2) ※2
Operating income	4,656	5,540	884		19.0
Non-operating income and expenses	191	(3)	(194)		
Ordinary income	4,847	5,537	689		14.2
Extraordinary income and loss	(79)	185	265		
Income before income taxes	4,767	5,722	955		20.0
Income taxes	1,392	1,778	385		
Net income	3,374	3,944	569		16.9

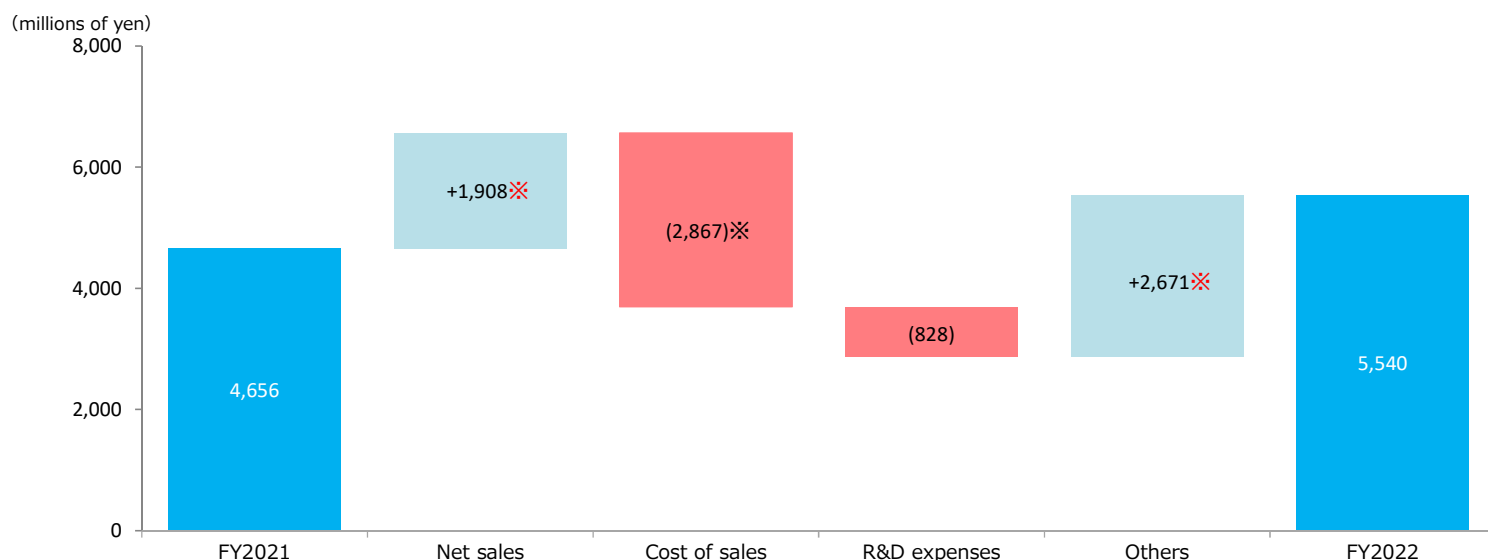
(Reference) Ratio to net sales

(%)	FY2021	FY2022	Change
	A	※1 B	※2 B-A
Cost of sales	48.2	52.2	4.0
SG&A	41.9	36.5	(5.4)
R&D expenses	1.8	3.4	1.6
Operating income	9.9	11.3	1.4
Ordinary income	10.3	11.3	1.0
Net income	7.2	8.1	0.9

**[Factors in increase/decrease compared with the same term of the last fiscal year]**

**Operating income (¥5,540 million : Increase ¥884 million year-on-year)**

✓ Sales and profits increase with increase in net sales of Allergens and CORECTIM



※ "Accounting Standard for Revenue Recognition" etc. have not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures is reference values.

Major factors in increase/decrease	
Net sales	: Increase in sales quantity (CORECTIM, MITICURE, CEDARCURE, ORLADEYO) Decrease due to application of "Accounting Standard for Revenue Recognition" Decrease in the drug price revisions
Cost of sales	: Increase in sales quantity Decrease in sales quantity (REMITCH, ANTEBATE)
R&D expense	: Increase in sales quantity Increase due to application of "Accounting Standard for Revenue Recognition" Increase due to the effect of foreign exchange rates
R&D expense	: Increase in clinical study expenses (TO-208) Increase in expenses for improvement of the product quality in Allergens
Others	: Decrease due to application of "Accounting Standard for Revenue Recognition" Increase in sales-linked expenses

**Ordinary income (¥5,537 million : Increase ¥689 million year-on-year)**

(FY2022) Non-operating expenses : Cancellation penalty of a manufacturing contract ¥141 million  
Non-operating expenses : Increase in foreign exchange losses on trade payables etc. due to yen depreciation +¥72 million

**Net income (¥3,944 million : Increase ¥569 million year-on-year)**

(FY2022) Extraordinary income : Gain on sales of investment securities due to reduction of policy shareholdings ¥187 million

## ② Sales of Products

※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the current fiscal year. The standard is different from the revenue recognition in the results for the FY2021. Increase (Decrease) in products is not listed.

※2 "Accounting Standard for Revenue Recognition" etc. have not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures is reference values.

(Millions of Yen)	FY2021	FY2022	Change	Change (%)
	A	※1 B	※1 B-A	※1 (B-A)/A
Sales of Products	46,290	48,563	2,272	※2 4.9
[Renal disease and hemodialysis]				
Riona	6,863	6,939	—	—
Agent for hyperphosphatemia, Iron-deficiency anemia				
REMITCH	5,058	3,536	—	—
Oral anti-pruritus agent				
KAYEXALATE ※3	1,525	1,230	—	—
Agent for hyperkalemia				
Others	55	306	—	—
Total	13,502	12,013	(1,489)	※2 (11.0)
[Skin disease]				
CORECTIM	4,025	5,469	—	—
Topical Janus kinase (JAK) inhibitor				
ANTEBATE ※3	4,825	3,995	—	—
Topical corticosteroid				
LOCOID ※3	1,698	1,476	—	—
Topical corticosteroid				
ZEFNART	1,043	1,091	—	—
Topical antifungal agent				
Others	398	358	—	—
Total	11,992	12,391	399	※2 3.3
[Allergens]				
CEDARCURE ※3	8,325	9,608	—	—
Japanese cedar pollinosis (Allergen Immunotherapy)				
MITICURE ※3	7,386	8,694	—	—
House dust mite allergy (Allergen Immunotherapy)				
Others	258	196	—	—
Total	15,971	18,499	2,528	※2 15.8
[Other]				
BIO-THREE	3,213	3,361	—	—
Viable bacterial preparations				
ORLADEYO ※4	399	1,313	—	—
Plasma kallikrein inhibitor				
Others	1,211	983	—	—
Total	4,824	5,658	834	※2 17.3

※3 In-house products

※4 Launched in April 2021

### (References) Sales and ratio of in-house products

(Millions of Yen)	FY2021	FY2022	Change	Change (%)
	A	※1 B	※1 B-A	※1 (B-A)/A
Sales of in-house products	24,843	25,933	—	—
Ratio of in-house product sales (%)	53.7	53.4	—	—

### ③ Research and Development

Development code 「Product Name」	Indication	Formulation/ Route of administration	Development stage (domestic)					Remarks
			Phase I	Phase II	Phase III	Application	Approval	
<b>Skin disease</b>								
JTE-061	Atopic dermatitis	Topical			Phase III			<ul style="list-style-type: none"> <li>Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for an exclusive license to develop and commercialize skin diseases in Japan</li> <li>Licensing agreement signed with JT for development and commercialization</li> </ul>
	Proriasis Vulgaris	Topical			Phase III			<ul style="list-style-type: none"> <li>Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for an exclusive license to develop and commercialize skin diseases in Japan</li> <li>Licensing agreement signed with JT for development and commercialization</li> </ul>
	Atopic dermatitis in children	Topical		Phase II				<ul style="list-style-type: none"> <li>Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for an exclusive license to develop and commercialize skin diseases in Japan</li> <li>Licensing agreement signed with JT for development and commercialization</li> </ul>
TO-208	Molluscum contagiosum	Topical			Phase III			<ul style="list-style-type: none"> <li>Licensing agreement signed with Verrica Pharmaceuticals Inc. for exclusive development and commercialization in Japan</li> <li>In-house</li> <li>Verrica Pharmaceuticals Inc., the development code: VP-102</li> </ul>
<b>Allergens</b>								
TO-203 「MITICURE® House Dust Mite Sublingual Tablets」	House dust mite induced allergic asthma (Allergen Immunotherapy)	Sublingual tablet			Phase II / III (Study completed) ※			<ul style="list-style-type: none"> <li>Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan</li> <li>In-house</li> <li>※Examining the future development policy</li> </ul>

Update since the previous announcement on October 31, 2022 :

- In January 2023, revised the package insert based on the results of Phase III clinical study of JTE-052「CORECTIM® Ointment」(atopic dermatitis in infant) by JT.  
(Previous announcement: Development stage Phase III)

#### Additional Information

- In January 2023, Torii has entered into a License Agreement with Nogra Pharma Limited (Nogra) with respect to the exclusive development and commercialization of Nogra's skin disease treatment drug NAC-GED-0507 for the treatment of acne in Japan.

Torii and its parent company, JT (specifically, the pharmaceutical division of the company) each leverage their own pharmaceutical product and service strengths. Torii is primarily responsible for manufacturing and marketing functions, while the parent company is responsible for research and development functions. For the clinical research and development of JT, please refer to the following posted on the company's website.

[https://www.jt.com/investors/results/S\\_information/pharmaceuticals/index.html](https://www.jt.com/investors/results/S_information/pharmaceuticals/index.html)

### III Financial Forecasts for the FY2023

#### ① Statement of Income

<i>(Millions of Yen)</i>	FY2022	FY2023 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Net sales	48,896	50,900	2,003	4.1
Sales of products	48,563	50,600	2,036	4.2
Renal disease and hemodialysis	12,013	10,850	(1,163)	(9.7)
Skin disease	12,391	13,130	738	6.0
Allergens	18,499	20,360	1,860	10.1
Other	5,658	6,260	601	10.6
Other sales	332	300	(32)	(9.9)
Cost of sales	25,516	26,800	1,283	5.0
Gross profit	23,379	24,100	720	3.1
SG&A	17,839	20,000	2,160	12.1
R&D expenses	1,661	3,530	1,868	112.5
Others	16,177	16,470	292	1.8
Operating income	5,540	4,100	(1,440)	(26.0)
Ordinary income	5,537	4,400	(1,137)	(20.5)
Net income	3,944	3,100	(844)	(21.4)

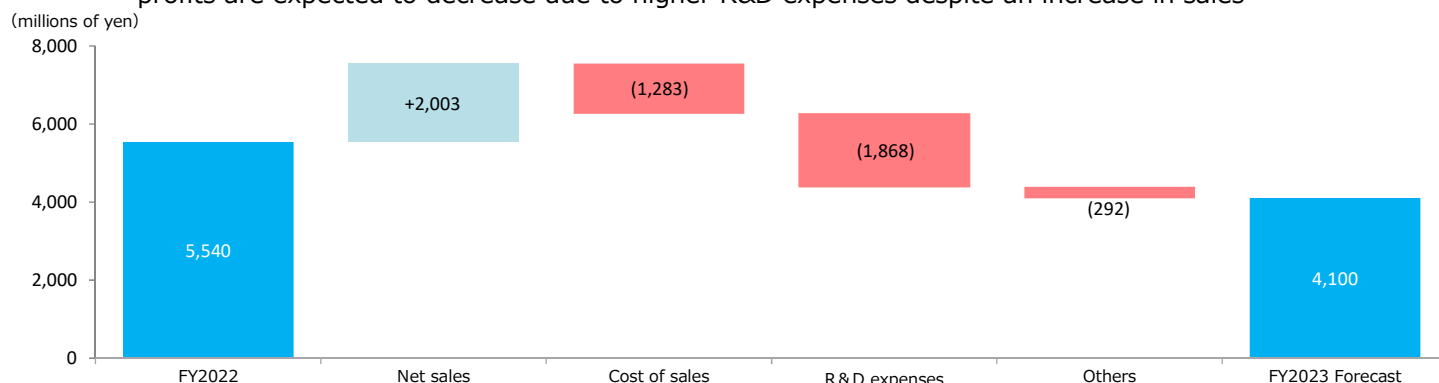
(Reference) Ratio to net sales

<i>(%)</i>	FY2022	FY2023 forecast	Change
	A	B	B-A
Cost of sales	52.2	52.7	0.5
SG&A	36.5	39.2	2.7
R&D expenses	3.4	6.9	3.5
Operating income	11.3	8.1	(3.2)
Ordinary income	11.3	8.6	(2.7)
Net income	8.1	6.1	(2.0)

**[Factors in increase/decrease compared with the FY2022]**

**Operating Income (¥4,100 million : Decrease ¥1,440 million year-on-year)**

✓ Although net sales of Allergens and CORECTIM are expected to increase, profits are expected to decrease due to higher R&D expenses despite an increase in sales



**Major factors in increase/decrease (Rounded down to the nearest 0.1 billion yen)**

Net sales	Renal disease and hemodialysis	: <b>Decrease</b> <b>¥1.1 billion in sales</b>	REMITCH Decrease ¥0.9 billion (Impact of generic drugs and drug price revisions)
	Skin disease	: <b>Increase</b> <b>¥0.7 billion in sales</b>	CORECTIM Increase ¥1.3 billion (Increase in sales quantity)
	Allergens	: <b>Increase</b> <b>¥1.8 billion in sales</b>	MITICURE Increase ¥1.1 billion, CEDARCURE Increase ¥0.7 billion (Increase in sales quantity)
	Other	: <b>Increase</b> <b>¥0.6 billion in sales</b>	ORLADEYO Increase ¥0.5 billion (Increase in sales quantity)
	Cost of sales	: Increase in sales quantity Increase in outsourcing contractor unit price Increase due to the effect of foreign exchange rates	
R&D expenses	: Increase due to upfront licensing fees for license agreement with Nogra Pharma Limited Increase in clinical study expenses (TO-208)		
Others	: Increase in sales-linked expenses One-time expenses for mobile communication equipment renewal, etc. Decrease in contract MR		

**Ordinary income (¥4,400 million : Decrease ¥1,137 million year-on-year)**

(FY2022)	Non-operating expenses : Cancellation penalty of a manufacturing contract	¥141 million
(FY2022)	Non-operating expenses : Foreign exchange losses on trade payables etc. due to yen depreciation	¥132 million

**Net income (¥3,100 million : Decrease ¥844 million year-on-year)**

(FY2022)	Extraordinary income : Gain on sales of investment securities due to reduction of policy shareholdings	¥187 million
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## ② Sales of Products

(Millions of Yen)	FY2022	FY2023 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	48,563	50,600	2,036	4.2
[Renal disease and hemodialysis]				
Riona	6,939	6,630	(309)	(4.5)
Agent for hyperphosphatemia, Iron-deficiency anemia				
REMITCH	3,536	2,630	(906)	(25.6)
Oral anti-pruritus agent				
KAYEXALATE ※	1,230	1,030	(200)	(16.3)
Agent for hyperkalemia				
Others	306	560	253	82.7
Total	12,013	10,850	(1,163)	(9.7)
[Skin disease]				
CORECTIM	5,469	6,850	1,380	25.2
Topical Janus kinase (JAK) inhibitor				
ANTEBATE ※	3,995	3,900	(95)	(2.4)
Topical corticosteroid				
LOCOID ※	1,476	1,350	(126)	(8.6)
Topical corticosteroid				
ZEFNART	1,091	1,030	(61)	(5.6)
Topical antifungal agent				
Others	358	–	(358)	(100.0)
Total	12,391	13,130	738	6.0
[Allergens]				
CEDARCURE ※	9,608	10,390	781	8.1
Japanese cedar pollinosis (Allergen Immunotherapy)				
MITICURE ※	8,694	9,800	1,105	12.7
House dust mite allergy (Allergen Immunotherapy)				
Others	196	170	(26)	(13.6)
Total	18,499	20,360	1,860	10.1
[Other]				
BIO-THREE	3,361	3,510	148	4.4
Viable bacterial preparations				
ORLADEYO	1,313	1,880	566	43.1
Plasma kallikrein inhibitor				
Others	983	870	(113)	(11.5)
Total	5,658	6,260	601	10.6

※ In-house products

### (References) Sales and ratio of in-house products

(Millions of Yen)	FY2022	FY2023 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	25,933	27,300	1,366	5.3
Ratio of in-house product sales (%)	53.4	54.0	0.6	–