

# Financial Results for the First Nine Months of Fiscal Year Ending December 2023

<u>I Summary Information</u>	<u>P. 1</u>
① Financial Results	P. 1
② Financial Conditions	P. 1
③ Capital Expenditures	P. 1
④ Depreciation/Amortization	P. 1
<u>II Financial Results for the First Nine Months of FY2023</u>	<u>P. 2</u>
① Statement of Income	P. 2
② Sales of Products	P. 4
③ Research and Development	P. 5
<u>III Financial Forecasts for the FY2023</u>	<u>P. 6</u>
① Statement of Income	P. 6
② Sales of Products	P. 8

※ 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.

October 31, 2023



**TORII PHARMACEUTICAL CO., LTD.**

## I Summary Information

The forecasts for the FY2023 have been changed from the previous forecasts announced at the first six months of FY2023 financial results announcement on July 31, 2023.

※ R&D expenses fluctuate significantly due to aggressive business investments for medium-/long-term growth. For this reason, Torii sets operating income before deduction of R&D expenses as a numerical income indicator in the medium-term management plan.

### ① Financial Results

(Millions of Yen)	FY2022 First nine months A	FY2023 First nine months B	Change B-A	Change (%) (B-A)/A	FY2022 Full year	FY2023 Revised forecast C	Progress ratio (%) B/C
Net sales	35,315	39,132	3,817	10.8	48,896	54,000	72.5
Operating income	4,066	3,211	(855)	(21.0)	5,540	4,500	71.4
Ordinary income	3,918	3,315	(602)	(15.4)	5,537	4,700	70.5
Net income	2,856	2,368	(487)	(17.1)	3,944	3,400	69.7
<b>(Reference)</b>							
R&D expenses	1,089	2,811	1,722	158.1	1,661	3,600	78.1
Operating income before deduction of R&D expenses	※ 5,155	6,022	867	16.8	7,201	8,100	74.4
Earnings per share (EPS)	(¥) 101.66	84.27	(17.39)		140.39	120.99	
Return on equity (ROE)	(%) 2.4	2.0	(0.4)		3.3		
Ratio of ordinary income to total assets	(%) 3.0	2.5	(0.5)		4.2		
Ratio of operating income to net sales	(%) 11.5	8.2	(3.3)		11.3		
Return on assets (ROA)	(%) 2.2	1.8	(0.4)		3.0		

### ② Financial Conditions

(Millions of Yen)	December 31, 2022 A	September 30, 2023 B	Change B-A	Change (%) (B-A)/A
Total assets	133,689	132,181	(1,507)	(1.1)
Total equity	119,224	118,595	(629)	(0.5)
Equity ratio	(%) 89.2	89.7	0.5	
Book value per share (BPS)	(¥) 4,243.08	4,219.67	(23.41)	

### ③ Capital Expenditures

(Millions of Yen)	FY2022 First nine months A	FY2023 First nine months B	Change B-A	Change (%) (B-A)/A	FY2022 Full year	FY2023 Revised forecast
Capital expenditures	612	147	(464)	(75.9)	662	250
PP&E	452	118	(333)	(73.8)	504	180
Intangible assets	159	28	(131)	(82.1)	158	70

### ④ Depreciation/Amortization

(Millions of Yen)	FY2022 First nine months A	FY2023 First nine months B	Change B-A	Change (%) (B-A)/A	FY2022 Full year	FY2023 Revised forecast
Depreciation and amortization of intangible assets	342	338	(3)	(1.1)	454	460
Amortization of long-term prepaid expenses	592	502	(89)	(15.2)	767	670

## II Financial Results for the First Nine Months of FY2023

The forecasts for the FY2023 have been changed from the previous forecasts announced at the first six months of FY2023 financial results announcement on July 31, 2023.

※ R&D expenses fluctuate significantly due to aggressive business investments for medium-/long-term growth. For this reason, Torii sets operating income before deduction of R&D expenses as a numerical income indicator in the medium-term management plan.

### ① Statement of Income

(Millions of Yen)	FY2022		FY2023		Change B-A	Change (%) (B-A)/A	FY2023 Revised forecast C	Progress ratio (%) B/C
	First nine months	First nine months						
	A	B						
Net sales	35,315	39,132	3,817	10.8		54,000	72.5	
Sales of products	35,055	38,904	3,849	11.0		53,700	72.4	
Renal disease and hemodialysis	8,756	8,602	(154)	(1.8)		11,970	71.9	
Skin disease	9,107	10,347	1,239	13.6		13,980	74.0	
Allergens	13,077	15,290	2,212	16.9		21,440	71.3	
Other	4,113	4,665	552	13.4		6,310	73.9	
Other sales	260	227	(32)	(12.5)		300	75.9	
Cost of sales	18,394	21,098	2,703	14.7		29,300	72.0	
Cost of products sold	18,355	21,057	2,702	14.7				
Other cost	39	40	0	2.4				
Gross profit	16,920	18,034	1,114	6.6		24,700	73.0	
Selling, general and administrative expenses	12,854	14,823	1,969	15.3		20,200	73.4	
R&D expenses	1,089	2,811	1,722	158.1		3,600	78.1	
Others	11,765	12,012	246	2.1		16,600	72.4	
Operating income	4,066	3,211	(855)	(21.0)		4,500	71.4	
Operating income before deduction of R&D expenses	※ 5,155	6,022	867	16.8		8,100	74.4	
Non-operating income and expenses	(147)	104	252					
Ordinary income	3,918	3,315	(602)	(15.4)		4,700	70.5	
Extraordinary income and loss	187	(2)	(189)					
Income before income taxes	4,105	3,312	(792)	(19.3)				
Income taxes	1,249	944	(304)					
Net income	2,856	2,368	(487)	(17.1)		3,400	69.7	

### (Reference) Ratio to net sales

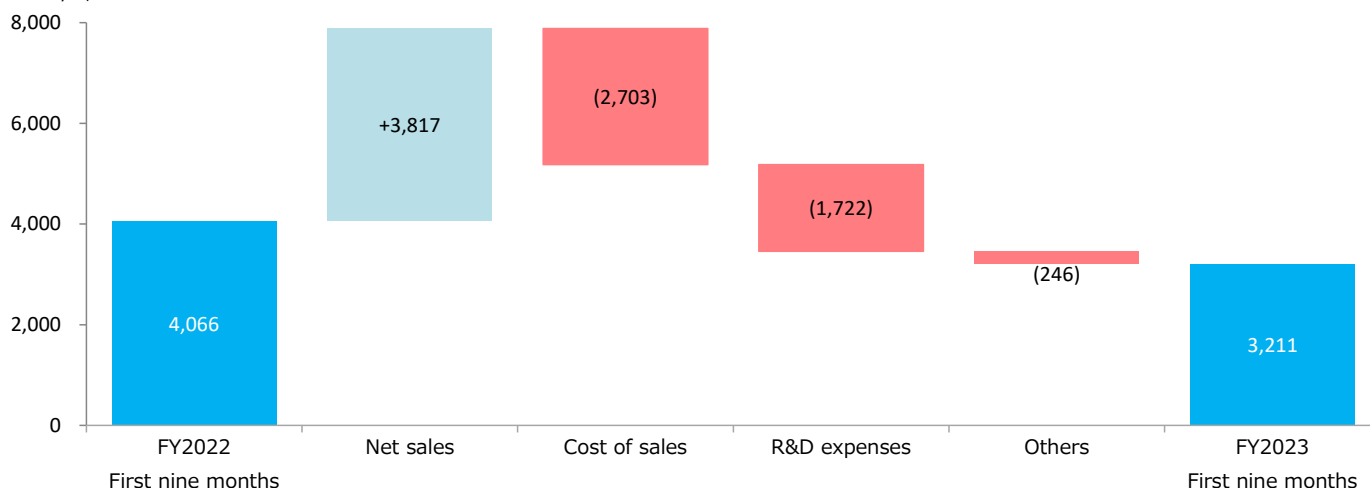
(%)	FY2022		FY2023		Change B-A
	First nine months	First nine months			
	A	B			
Cost of sales	52.1	53.9	1.8		
SG&A	36.4	37.9	1.5		
R&D expenses	3.1	7.2	4.1		
Operating income	11.5	8.2	(3.3)		
Operating income before deduction of R&D expenses	※ 14.6	15.4	0.8		
Ordinary income	11.1	8.5	(2.6)		
Net income	8.1	6.1	(2.0)		

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

**Operating income (¥3,211 million : Decrease ¥855 million year-on-year)**

✓ Increased sales and decreased profits due to increased R&D expenses and cost of sales, despite increased sales of Allergens and CORECTIM

(Millions of yen)



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

Net sales	Renal disease and hemodialysis	: <b>Decrease ¥0.1 billion in sales</b>	REMITCH Decrease ¥0.6 billion (impact of generic drugs and drug price revisions), KAYEXALATE decrease ¥0.1 billion (drug price revisions), Riona Increase ¥0.3 billion, ENAROY Increase ¥0.2 billion (increase in sales quantity)
	Skin disease	: <b>Increase ¥1.2 billion in sales</b>	CORECTIM Increase ¥1.4 billion, ANTEBATE Increase ¥0.2 billion (increase in sales quantity), ZEFNART Decrease ¥0.1 billion (decrease in sales quantity)
	Allergens	: <b>Increase ¥2.2 billion in sales</b>	CEDARCURE Increase ¥1.2 billion, MITICURE Increase ¥1.0 billion (increase in sales quantity)
	Other	: <b>Increase ¥0.5 billion in sales</b>	BIO-THREE Increase ¥0.4 billion, ORLADEYO Increase ¥0.1 billion (increase in sales quantity)
Cost of sales		: Increase in sales quantity Increase in purchasing 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 Increase in expenses for operating activities Payment of one-time special allowance to employees (inflation allowance) Decrease in contract MR	

**Ordinary income (¥3,315 million : Decrease ¥602 million year-on-year)**

Non-operating income : Increase in interest on securities due to increase in marketable securities and investment securities +¥101 million

(FY2022) Non-operating expenses : Cancellation penalty of a manufacturing contract ¥140 million

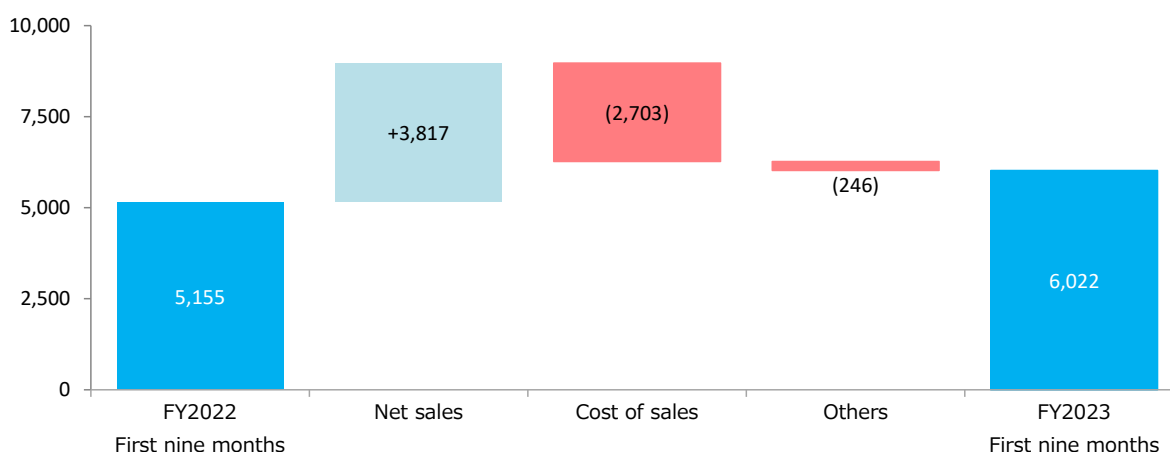
**Net income (¥2,368 million : Decrease ¥487 million year-on-year)**

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

**(Reference)**

**Operating income before deduction of R&D expenses (¥6,022 million : Increase ¥867 million year-on-year)**

(Millions of yen)



## ② Sales of Products

(Millions of Yen)	FY2022		FY2023		Change B-A	Change (%) (B-A)/A
	First nine months		First nine months			
	A		B			
Sales of Products	35,055		38,904		3,849	11.0
<b>[Renal disease and hemodialysis]</b>						
Riona Agent for hyperphosphatemia, Iron-deficiency anemia	5,037		5,403		366	7.3
REMITCH Oral anti-pruritus agent	2,613		2,011		(602)	(23.1)
KAYEXALATE ※ Agent for hyperkalemia	914		780		(133)	(14.6)
Others	191		406		215	112.7
Total	8,756		8,602		(154)	(1.8)
<b>[Skin disease]</b>						
CORECTIM Topical Janus kinase (JAK) inhibitor	3,945		5,392		1,447	36.7
ANTEBATE ※ Topical corticosteroid	2,959		3,201		242	8.2
LOCOID ※ Topical corticosteroid	1,103		1,065		(38)	(3.5)
ZEFNART Topical antifungal agent	863		687		(175)	(20.3)
Others	236		(0)		(237)	—
Total	9,107		10,347		1,239	13.6
<b>[Allergens]</b>						
CEDARCURE ※ Japanese cedar pollinosis (Allergen Immunotherapy)	6,757		7,963		1,205	17.8
MITICURE ※ House dust mite allergy (Allergen Immunotherapy)	6,171		7,189		1,017	16.5
Others	147		137		(10)	(6.9)
Total	13,077		15,290		2,212	16.9
<b>[Other]</b>						
BIO-THREE Viable bacterial preparations	2,423		2,881		457	18.9
ORLADEYO Plasma kallikrein inhibitor	959		1,107		147	15.4
Others	730		677		(53)	(7.3)
Total	4,113		4,665		552	13.4

※ In-house products

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

(Millions of Yen)	FY2022		FY2023		Change B-A	Change (%) (B-A)/A
	First nine months		First nine months			
	A		B			
Sales of in-house products	18,598		20,845		2,246	12.1
Ratio of in-house product sales (%)	53.1		53.6		0.5	—

### 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				Application	<ul style="list-style-type: none"> <li>Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for exclusive development and commercialization in the skin disease area in Japan</li> <li>License agreement signed with JT for joint development and commercialization in Japan</li> <li>NDA filing by JT in September, 2023</li> </ul>	
	Proriasis vulgaris	Topical				Application	<ul style="list-style-type: none"> <li>Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for exclusive development and commercialization in the skin disease area in Japan</li> <li>License agreement signed with JT for joint development and commercialization in Japan</li> <li>NDA filing by JT in September, 2023</li> </ul>	
	Atopic dermatitis in children	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 exclusive development and commercialization in the skin disease area in Japan</li> <li>License agreement signed with JT for joint development and commercialization in Japan</li> </ul>	
TO-208	Molluscum contagiosum	Topical			Phase III		<ul style="list-style-type: none"> <li>License 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>License 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 July 31, 2023 :

- JTE-061 for the indication of atopic dermatitis in children has entered into the clinical stage(Phase III) in Japan in August 2023.(previous announcement : Development stage(Phase II J))
- JTE-061 NDA filing for the indication of Atopic dermatitis and Proriasis Vulgaris by JT in September 2023.(previous announcement : Development stage(Phase III J))

#### Additional Information

- In January 2023, Torii entered into a licence agreement with Nogra Pharma Limited(Nogra) for an exclusive licence in Japan to develop and commercialize NAC-GED-0507,a treatment drug for acne vulgaris developed by Nogra.

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 company's website.

[https://www.it.com/investors/results/S information/pharmaceuticals/index.html](https://www.it.com/investors/results/S%20information/pharmaceuticals/index.html)

### III Financial Forecasts for the FY2023

The forecasts for the FY2023 have been changed from the previous forecasts announced at the first six months of FY2023 financial results announcement on July 31, 2023.

✖ R&D expenses fluctuate significantly due to aggressive business investments for medium-/long-term growth. For this reason, Torii sets operating income before deduction of R&D expenses as a numerical income indicator in the medium-term management plan.

#### ① Statement of Income

(Millions of Yen)	FY2023	FY2023	Change	FY2022	Change	Change
	Previous forecast	Revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Net sales	52,700	54,000	1,300	48,896	5,103	10.4
Sales of products	52,400	53,700	1,300	48,563	5,136	10.6
Renal disease and hemodialysis	11,170	11,970	800	12,013	(43)	(0.4)
Skin disease	13,540	13,980	440	12,391	1,588	12.8
Allergens	21,500	21,440	(60)	18,499	2,940	15.9
Other	6,190	6,310	120	5,658	651	11.5
Other sales	300	300	—	332	(32)	(9.9)
Cost of sales	28,300	29,300	1,000	25,516	3,783	14.8
Gross profit	24,400	24,700	300	23,379	1,320	5.6
SG&A	20,300	20,200	(100)	17,839	2,360	13.2
R&D expenses	3,530	3,600	70	1,661	1,938	116.7
Others	16,770	16,600	(170)	16,177	422	2.6
Operating income	4,100	4,500	400	5,540	(1,040)	(18.8)
Operating income before deduction of R&D expenses	✖ 7,630	8,100	470	7,201	898	12.5
Ordinary income	4,400	4,700	300	5,537	(837)	(15.1)
Net income	3,100	3,400	300	3,944	(544)	(13.8)

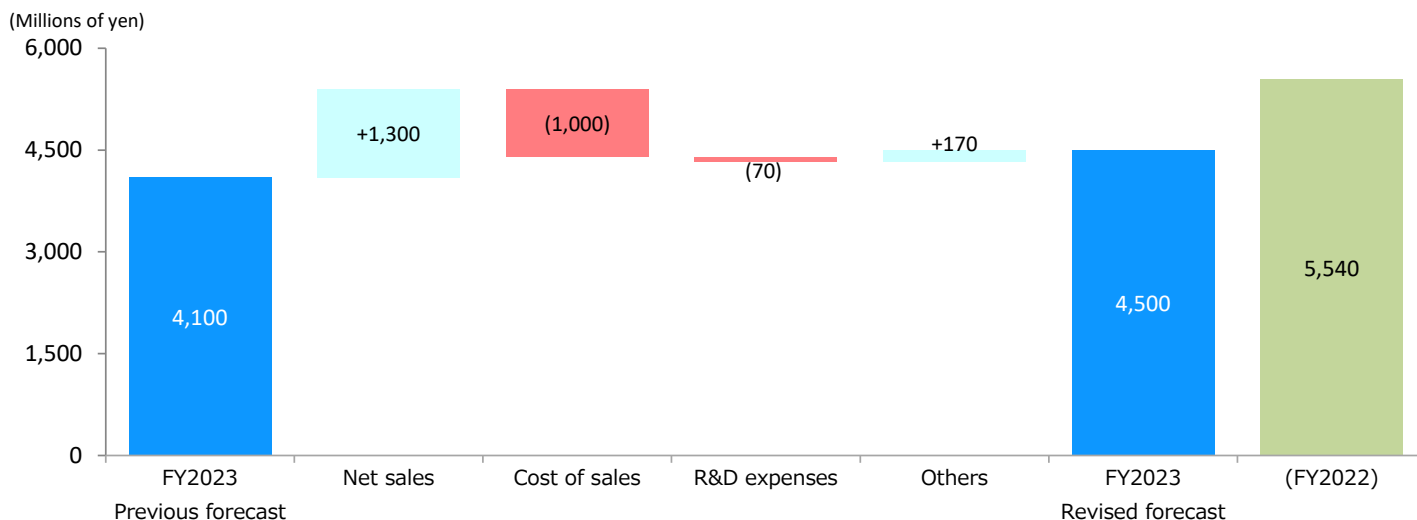
#### (Reference) Ratio to net sales

(%)	FY2023	FY2023	Change	FY2022	Change
	Previous forecast	Revised forecast			
	A	B	B-A	C	B-C
Cost of sales	53.7	54.3	0.6	52.2	2.1
SG&A	38.5	37.4	(1.1)	36.5	0.9
R&D expenses	6.7	6.7	0.0	3.4	3.3
Operating income	7.8	8.3	0.5	11.3	(3.0)
Operating income before deduction of R&D expenses	✖ 14.5	15.0	0.5	14.7	0.3
Ordinary income	8.3	8.7	0.4	11.3	(2.6)
Net income	5.9	6.3	0.4	8.1	(1.8)

**[Factors in increase/decrease compared with the previous forecast for the FY2023]**

**Operating income (¥4,500 million : Increase ¥400 million)**

✓ Despite an increase in the cost of sales, operating income are revised upward due to sales of Riona and ANTEBATE exceeding previous forecasts.



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

Net sales	Renal disease and hemodialysis	: Increase ¥0.8 billion in sales	Riona Increase ¥ 0.6 billion (increase in sales quantity)
	Skin disease	: Increase ¥0.4 billion in sales	ANTEBATE Increase ¥0.4 billion (increase in sales quantity)
	Allergens	: Decrease ¥0.0 billion in sales	
	Other	: Increase ¥0.1 billion in sales	BIO-THREE Increase ¥0.1 billion (increase in sales quantity)
Cost of sales		: Increase in sales quantity	
		: Increase due to the effect of foreign exchange rates	
		: Increase in purchasing unit price	
Others		: Decrease in sales promotion expenses	

**Ordinary income (¥4,700 million : Increase ¥300 million)**

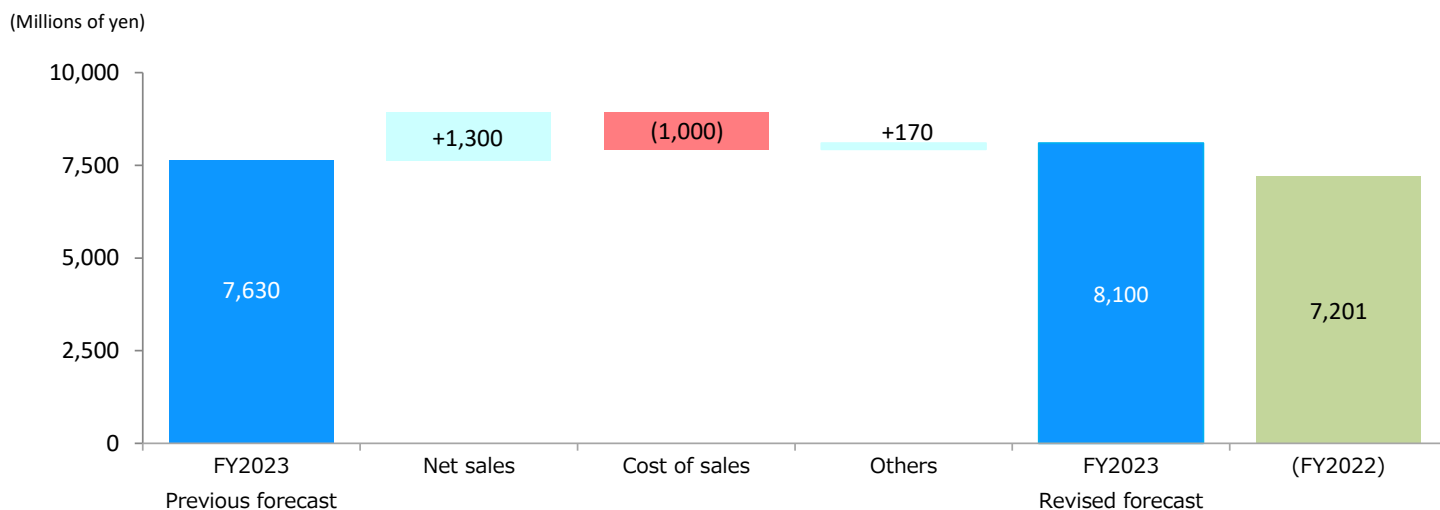
Non-operating expenses : Increase in foreign exchange losses on trade payables etc. due to yen depreciation. +125 million

**Net income (¥3,400 million : Increase ¥300 million)**

None

**(Reference)**

**Operating income before deduction of R&D expenses (¥8,100 million : Increase 470 million)**





## ② Sales of Products

(Millions of Yen)	FY2023	FY2023	Change	FY2022	Change	Change(%)
	Previous forecast	Revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of Products	52,400	53,700	1,300	48,563	5,136	10.6
[Renal disease and hemodialysis]						
Riona	6,920	7,610	690	6,939	670	9.7
Agent for hyperphosphatemia, Iron-deficiency anemia						
REMITCH	2,670	2,730	60	3,536	(806)	(22.8)
Oral anti-pruritus agent						
KAYEXALATE ※	1,040	1,050	10	1,230	(180)	(14.7)
Agent for hyperkalemia						
Others	540	580	40	306	273	89.3
Total	11,170	11,970	800	12,013	(43)	(0.4)
[Skin disease]						
CORECTIM	7,160	7,230	70	5,469	1,760	32.2
Topical Janus kinase (JAK) inhibitor						
ANTEBATE ※	3,940	4,370	430	3,995	374	9.4
Topical corticosteroid						
LOCOID ※	1,400	1,420	20	1,476	(56)	(3.8)
Topical corticosteroid						
ZEFNART	1,040	960	(80)	1,091	(131)	(12.1)
Topical antifungal agent						
Others	—	—	—	358	(358)	(100.0)
Total	13,540	13,980	440	12,391	1,588	12.8
[Allergens]						
CEDARCURE ※	11,230	11,170	(60)	9,608	1,561	16.3
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※	10,070	10,090	20	8,694	1,395	16.0
House dust mite allergy (Allergen Immunotherapy)						
Others	200	180	(20)	196	(16)	(8.6)
Total	21,500	21,440	(60)	18,499	2,940	15.9
[Other]						
BIO-THREE	3,800	3,900	100	3,361	538	16.0
Viable bacterial preparations						
ORLADEYO	1,500	1,500	—	1,313	186	14.2
Plasma kallikrein inhibitor						
Others	890	910	20	983	(73)	(7.5)
Total	6,190	6,310	120	5,658	651	11.5

※ In-house products

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

(Millions of Yen)	FY2023	FY2023	Change	FY2022	Change	Change(%)
	Previous forecast	Revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of in-house products	28,600	29,000	400	25,933	3,066	11.8
Ratio of in-house product sales (%)	54.6	54.0	(0.6)	53.4	0.6	—