

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

October 31, 2022



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

The forecasts for the FY2022 have been changed from the previous forecasts announced at the first six months of FY2022 financial results announcement on July 29, 2022.

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

※2 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the first three months of FY2022, the forecasts for the FY2022 have already been incorporated the change.

(Millions of Yen)	FY2021	FY2022	Change	Change (%)	FY2021	FY2022	Progress ratio (%)
	First nine months	First nine months			Full year	Revised forecast※2	
	A	B	B-A	(B-A)/A		C	B/C
Net sales	33,437	35,315	1,877 ※1	5.6 ※1	46,987	49,200	71.8
Operating income	3,153	4,066	912	28.9	4,656	6,000	67.8
Ordinary income	3,257	3,918	660	20.3	4,847	6,000	65.3
Net income	2,238	2,856	618	27.6	3,374	4,300	66.4
(Reference)							
R&D expenses	511	1,089	577	112.8	832	1,580	68.9
Earnings per share (EPS)	(¥) 79.68	101.66	21.98		120.13	153.05	
Return on equity (ROE)	(%) 1.9	2.4	0.5		2.9		
Ratio of ordinary income to total assets	(%) 2.6	3.0	0.4		3.8		
Ratio of operating income to net sales	(%) 9.4	11.5	2.1 ※1		9.9		
Return on assets (ROA)	(%) 1.8	2.2	0.4		2.6		

② Financial Conditions

(Millions of Yen)	December 31,	September 30,	Change	Change (%)
	2021	2022		
	A	B	B-A	(B-A)/A
Total assets	130,810	129,677	(1,133)	(0.9)
Total equity	117,015	118,269	1,254	1.1
Equity ratio	(%) 89.5	91.2	1.7	
Book value per share (BPS)	(¥) 4,165.38	4,209.07	43.69	

③ Capital Expenditures

(Millions of Yen)	FY2021	FY2022	Change	Change (%)	FY2021	FY2022
	First nine months	First nine months			Full year	Revised forecast
	A	B	B-A	(B-A)/A		
Capital expenditures	453	612	159	35.1	822	770
PP&E	247	452	204	82.5	597	520
Intangible assets	205	159	(45)	(22.2)	224	250

④ Depreciation/Amortization

(Millions of Yen)	FY2021	FY2022	Change	Change (%)	FY2021	FY2022
	First nine months	First nine months			Full year	Revised forecast
	A	B	B-A	(B-A)/A		
Depreciation and amortization of intangible assets	306	342	36	11.9	413	420
Amortization of long-term prepaid expenses	523	592	68	13.1	722	770

II Financial Results for the First Nine Months of FY2022

① Statement of Income

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

※2 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the first three months of FY2022, the forecasts for the FY2022 have already been incorporated the change.

(Millions of Yen)	FY2021	FY2022	Change	Change		FY2022	Progress ratio (%)
	First nine months	First nine months		(%)	Revised forecast※2		
	A	B	B-A	(B-A)/A	C	B/C	
Net sales	33,437	35,315	1,877	※1 5.6	※1 49,200	71.8	
Sales of products	32,833	35,055	2,221	※1 6.8	※1 48,890	71.7	
Renal disease and hemodialysis	9,874	8,756	(1,118)	※1 (11.3)	※1 11,930	73.4	
Skin disease	8,536	9,107	571	※1 6.7	※1 12,890	70.7	
Allergens	10,968	13,077	2,108	※1 19.2	※1 18,370	71.2	
Other	3,454	4,113	658	※1 19.1	※1 5,700	72.2	
Other sales	603	260	(343)	※1 (56.9)	※1 310	84.0	
Cost of sales	16,190	18,394	2,204	※1 13.6	※1 25,300	72.7	
Cost of products sold	16,146	18,355	2,208	※1 13.7	※1		
Other cost	43	39	(4)	(10.5)			
Gross profit	17,246	16,920	(326)	※1 (1.9)	※1 23,900	70.8	
Selling, general and administrative expenses	14,092	12,854	(1,238)	※1 (8.8)	※1 17,900	71.8	
R&D expenses	511	1,089	577	112.8	1,580	68.9	
Others	13,581	11,765	(1,815)	※1 (13.4)	※1 16,320	72.1	
Operating income	3,153	4,066	912	28.9	6,000	67.8	
Non-operating income and expenses	103	(147)	(251)				
Ordinary income	3,257	3,918	660	20.3	6,000	65.3	
Extraordinary income and loss	(65)	187	253				
Income before income taxes	3,191	4,105	913	28.6			
Income taxes	953	1,249	295				
Net income	2,238	2,856	618	27.6	4,300	66.4	

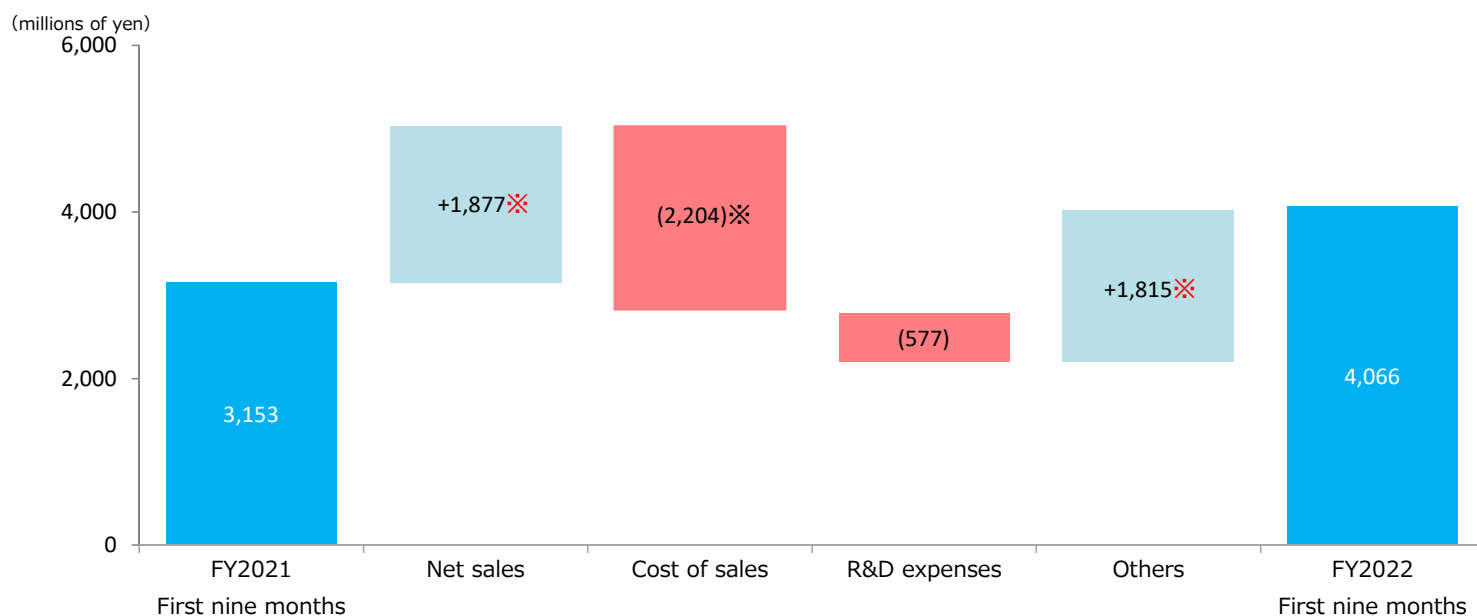
(Reference) Ratio to net sales

(%)	FY2021	FY2022	Change
	First nine months	First nine months	
	A	B	※1 B-A
Cost of sales	48.4	52.1	3.7
SG&A	42.2	36.4	(5.8)
R&D expenses	1.5	3.1	1.6
Operating income	9.4	11.5	2.1
Ordinary income	9.7	11.1	1.4
Net income	6.7	8.1	1.4

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

Operating income (¥4,066 million : Increase ¥912 million year-on-year)

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



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

Major factors in increase/decrease

Net sales	: Increase in sales quantity (CORECTIM, MITICURE, CEDARCURE) Decrease due to application of "Accounting Standard for Revenue Recognition" Decrease in the drug price revisions Decrease in sales quantity (REMITCH)
Cost of sales	: Increase in sales quantity Increase due to application of "Accounting Standard for Revenue Recognition"
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 (¥3,918 million : Increase ¥660 million year-on-year)

(FY2022) Non-operating expenses : Cancellation penalty of a manufacturing contract ¥140 million
Non-operating expenses : Increase in foreign exchange losses on trade payables etc. due to yen depreciation +¥96 million

Net income (¥2,856 million : Increase ¥618 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 first three months of FY2022. The standard is different from the revenue recognition in the results for the first nine months of the FY2021. Increase (Decrease) in products is not listed.

※2 The accounting standard has not been applied to the results for the first nine months of FY2021 retroactively. Increase (Decrease) in figures from the first nine months of FY2021 is a reference value.

(Millions of Yen)	FY2021		FY2022		Change	Change (%)
	First nine months		First nine months		※1	※1
	A	B	B-A	(B-A)/A		
Sales of Products	32,833	35,055	2,221	※2	6.8	※2
[Renal disease and hemodialysis]						
Riona	4,941	5,037	-		-	
Agent for hyperphosphatemia, Iron-deficiency anemia						
REMITCH	3,780	2,613	-		-	
Oral anti-pruritus agent						
KAYEXALATE ※3	1,134	914	-		-	
Agent for hyperkalemia						
Others	18	191	-		-	
Total	9,874	8,756	(1,118)	※2	(11.3)	※2
[Skin disease]						
CORECTIM	2,669	3,945	-		-	
Topical Janus kinase (JAK) inhibitor						
ANTEBATE ※3	3,546	2,959	-		-	
Topical corticosteroid						
LOCOID ※3	1,254	1,103	-		-	
Topical corticosteroid						
ZEFNART	768	863	-		-	
Topical antifungal agent						
Others	297	236	-		-	
Total	8,536	9,107	571	※2	6.7	※2
[Allergens]						
CEDARCURE ※3	5,687	6,757	-		-	
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※3	5,085	6,171	-		-	
House dust mite allergy (Allergen Immunotherapy)						
Others	196	147	-		-	
Total	10,968	13,077	2,108	※2	19.2	※2
[Other]						
BIO-THREE	2,308	2,423	-		-	
Viable bacterial preparations						
ORLADEYO ※4	221	959	-		-	
Plasma kallikrein inhibitor						
Others	923	730	-		-	
Total	3,454	4,113	658	※2	19.1	※2

※3 In-house products

※4 Launched in April 2021

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2021		FY2022		Change	Change (%)
	First nine months		First nine months		※1	※1
	A	B	B-A	(B-A)/A		
Sales of in-house products	17,515	18,598	-		-	
Ratio of in-house product sale: (%)	53.3	53.1	-		-	

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	
Skin disease								
JTE-052 「CORECTIM® Ointment」	Atopic dermatitis in infant	Topical			Phase III			<ul style="list-style-type: none"> • JT's original compound • Licensing agreement signed with JT for development and commercialization
JTE-061	Atopic dermatitis	Topical			Phase III			<ul style="list-style-type: none"> • 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 • Licensing agreement signed with JT for development and commercialization
	Proriasis Vulgaris	Topical			Phase III			<ul style="list-style-type: none"> • 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 • Licensing agreement signed with JT for development and commercialization
	Atopic dermatitis in children	Topical		Phase II				<ul style="list-style-type: none"> • 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 • Licensing agreement signed with JT for development and commercialization
TO-208	Molluscum contagiosum	Topical			Phase III			<ul style="list-style-type: none"> • Licensing agreement signed with Verrica Pharmaceuticals Inc. for exclusive development and commercialization in Japan • In-house • Verrica Pharmaceuticals Inc., the development code: VP-102
Allergens								
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"> • Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan • In-house ※Examining the future development policy

Update since the previous announcement on July 29, 2022 :

None

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/

III Financial Forecasts for the FY2022

The forecasts for the FY2022 have been changed from the previous forecasts announced at the first six months of FY2022 financial results announcement on July 29, 2022.

① Statement of Income

※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the first three months of FY2022, the forecasts for the FY2022 have already been incorporated the change.

※2 The accounting standard has not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures from FY2021 is a reference value.

(Millions of Yen)	FY2022 Previous forecast※1 A	FY2022 Revised forecast※1 B	Change B-A	FY2021 C	Change B-C	Change (%) (B-C)/C	
Net sales	49,800	49,200	(600)	46,987	2,212	※2	4.7 ※2
Sales of products	49,520	48,890	(630)	46,290	2,599	※2	5.6 ※2
Renal disease and hemodialysis	12,250	11,930	(320)	13,502	(1,572)	※2	(11.6) ※2
Skin disease	12,590	12,890	300	11,992	897	※2	7.5 ※2
Allergens	19,510	18,370	(1,140)	15,971	2,398	※2	15.0 ※2
Other	5,170	5,700	530	4,824	875	※2	18.1 ※2
Other sales	280	310	30	697	(387)	※2	(55.6) ※2
Cost of sales	25,600	25,300	(300)	22,649	2,650	※2	11.7 ※2
Gross profit	24,200	23,900	(300)	24,338	(438)	※2	(1.8) ※2
SG&A	18,000	17,900	(100)	19,682	(1,782)	※2	(9.1) ※2
R&D expenses	1,580	1,580	—	832	747		89.8
Others	16,420	16,320	(100)	18,849	(2,529)	※2	(13.4) ※2
Operating income	6,200	6,000	(200)	4,656	1,343		28.9
Ordinary income	6,100	6,000	(100)	4,847	1,152		23.8
Net income	4,400	4,300	(100)	3,374	925		27.4

(Reference) Ratio to net sales

(%)	FY2022 Previous forecast※1 A	FY2022 Revised forecast※1 B	Change B-A	FY2021 C	Change ※2 B-C
Cost of sales	51.4	51.4	0.0	48.2	3.2
SG&A	36.2	36.4	0.2	41.9	(5.5)
R&D expenses	3.2	3.2	0.0	1.8	1.4
Operating income	12.4	12.2	(0.2)	9.9	2.3
Ordinary income	12.2	12.2	0.0	10.3	1.9
Net income	8.8	8.7	(0.1)	7.2	1.5

[Factors in increase/decrease compared with the previous forecast for the FY2022]

Operating Income (¥6,000 million : Decrease ¥200 million)

✓ Downward revision due to decreases in net sales of CEDARCURE and MITICURE, despite increases in net sales of ORLADEYO and CORECTIM



※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the first three months of FY2022, the forecasts for the FY2022 have already been incorporated the change.

※2 The accounting standard has not been applied to the results for the FY2021 retroactively.

Major factors in increase/decrease

Net sales	: Decrease in sales quantity (CEDARCURE, MITICURE) Increase in sales quantity (ORLADEYO, CORECTIM)
Cost of sales	: Decrease in sales quantity
Others	: Decrease in sales-linked expenses

Ordinary income (¥6,000 million : Decrease ¥100 million)

Special remarks: None

Net income (¥4,300 million : Decrease ¥100 million)

Special remarks: None

② Sales of Products

※1 "Accounting Standard for Revenue Recognition" etc. have been applied from the beginning of the first three months of FY2022, the forecasts for the FY2022 have already been incorporated the change.

The standard is different from the revenue recognition in the results for the FY2021. Increase (Decrease) in products is not listed.

※2 The accounting standard has not been applied to the results for the FY2021 retroactively. Increase (Decrease) in figures from FY2021 is a reference value.

(Millions of Yen)	FY2022 Previous forecast※1 A	FY2022 Revised forecast※1 B	Change B-A	FY2021 C	Change ※1 B-C	Change (%) ※1 (B-C)/C
Sales of Products	49,520	48,890	(630)	46,290	2,599	※2 5.6
[Renal disease and hemodialysis]						
Riona	7,100	6,900	(200)	6,863	-	-
Agent for hyperphosphatemia, Iron-deficiency anemia						
REMITCH	3,670	3,510	(160)	5,058	-	-
Oral anti-pruritus agent						
KAYEXALATE ※3	1,250	1,250	-	1,525	-	-
Agent for hyperkalemia						
Others	230	270	40	55	-	-
Total	12,250	11,930	(320)	13,502	(1,572)※2	(11.6) ※2
[Skin disease]						
CORECTIM	5,380	5,880	500	4,025	-	-
Topical Janus kinase (JAK) inhibitor						
ANTEBATE ※3	4,170	4,040	(130)	4,825	-	-
Topical corticosteroid						
LOCOID ※3	1,560	1,510	(50)	1,698	-	-
Topical corticosteroid						
ZEFNART	1,150	1,140	(10)	1,043	-	-
Topical antifungal agent						
Others	330	320	(10)	398	-	-
Total	12,590	12,890	300	11,992	897 ※2	7.5 ※2
[Allergens]						
CEDARCURE ※3	10,050	9,380	(670)	8,325	-	-
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※3	9,280	8,810	(470)	7,386	-	-
House dust mite allergy (Allergen Immunotherapy)						
Others	180	180	-	258	-	-
Total	19,510	18,370	(1,140)	15,971	2,398 ※2	15.0 ※2
[Other]						
BIO-THREE	3,230	3,230	-	3,213	-	-
Viable bacterial preparations						
ORLADEYO ※4	960	1,490	530	399	-	-
Plasma kallikrein inhibitor						
Others	980	980	-	1,211	-	-
Total	5,170	5,700	530	4,824	875 ※2	18.1 ※2

※3 In-house products

※4 Launched in April 2021

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2022 Previous forecast※1 A	FY2022 Revised forecast※1 B	Change B-A	FY2021 C	Change ※1 B-C	Change (%) ※1 (B-C)/C
Sales of in-house products	27,210	25,900	(1,310)	24,843	-	-
Ratio of in-house product sales (%)	54.9	53.0	(1.9)	53.7	-	-