

# Financial Results for the First Three Months of Fiscal Year Ending December 2020

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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.

April 30, 2020



**TORII PHARMACEUTICAL CO., LTD.**

# I Summary Information

## ① Financial Results

The forecasts for the FY2020 have not been changed from the previous forecasts announced at the FY2020 financial results announcement on February 6, 2020.

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 Full year forecast	Progress ratio (%)
	First three months	A	First three months	B					
Net sales	9,161		9,571		410	4.5	42,998	41,600	23.0
Operating income or loss	(709)		1,252		1,962	-	1,430	3,000	41.8
Ordinary income or loss	(656)		1,317		1,973	-	1,691	3,300	39.9
Net income	28,522		862		(27,659)	(97.0)	27,367	2,100	41.1
<b>(Reference)</b>									
R&D expenses	986		57		(929)	(94.2)	2,956	1,000	5.7
Earnings per share (EPS)	(¥)	1,016.43	30.74		(985.69)		974.98	74.80	
Return on equity (ROE)	(%)	28.2	0.8		(27.4)		27.3		
Ratio of ordinary income to total assets	(%)	(0.5)	1.0		1.5		1.4		
Ratio of operating income to net sales	(%)	(7.7)	13.1		20.8		3.3		
Return on assets (ROA)	(%)	22.6	0.7		(21.9)		22.5		

## ② Financial Conditions

(Millions of Yen)	December 31, 2019		March 31, 2020		Change	Change (%)
	A	B	B-A	(B-A)/A		
Total assets	139,943		123,967		(15,976)	(11.4)
Total equity	113,125		113,138		12	0.0
Equity ratio	(%)	80.8	91.3		10.5	
Book value per share (BPS)	(¥)	4,029.30	4,029.75		0.45	

## ③ Capital Expenditures

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 Full year forecast
	First three months	A	First three months	B				
Capital expenditures	33		41		7	21.5	330	804
PP&E	19		4		(14)	(74.9)	203	541
Intangible assets	14		36		22	155.2	126	263

## ④ Depreciation/Amortization

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 Full year forecast
	First three months	A	First three months	B				
Depreciation and amortization of intangible assets	250		202		(48)	(19.3)	985	882
Amortization of long-term prepaid expenses	121		119		(1)	(1.5)	486	552

## II Financial Results for the First Three Months of FY2020

### ① Statement of Income

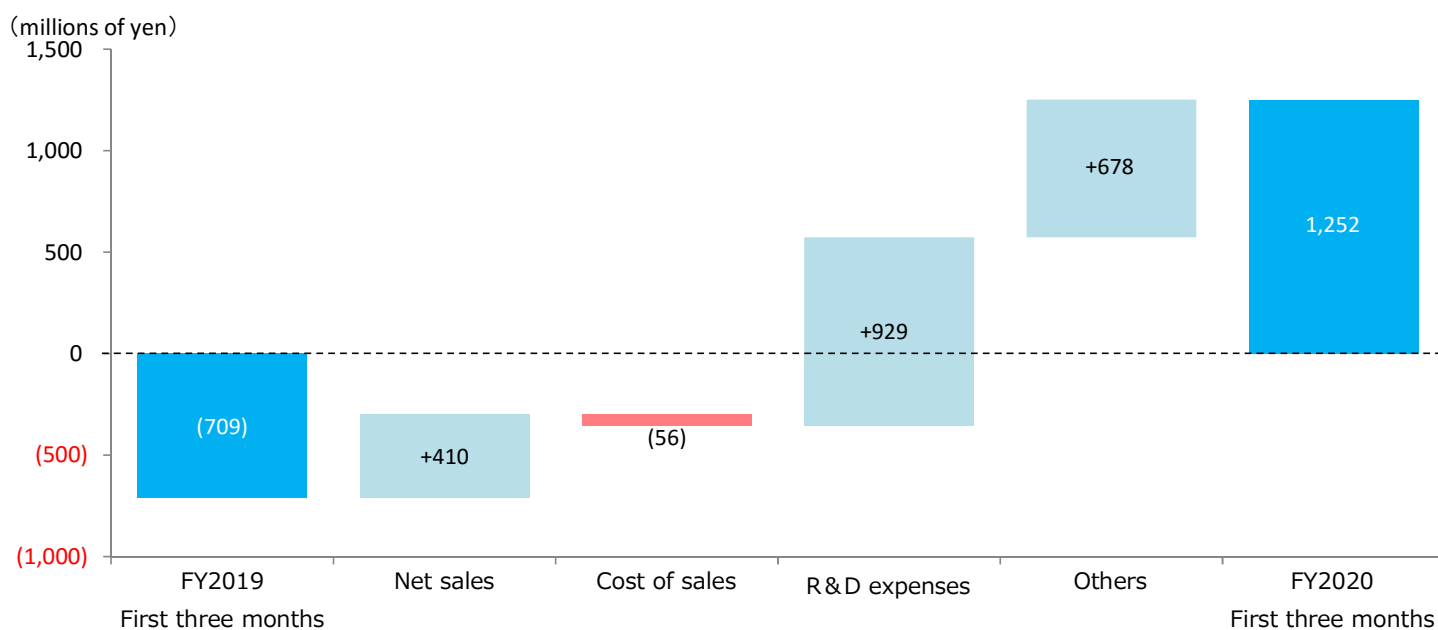
<i>(Millions of Yen)</i>	FY2019 First three months A	FY2020 First three months B	Change B-A	Change (%) (B-A)/A	FY2020 Full year forecast C	Progress ratio (%) B/C
Net sales	9,161	9,571	410	4.5	41,600	23.0
Sales of products	8,702	9,405	702	8.1	40,980	23.0
Renal disease and hemodialysis	4,113	3,478	(635)	(15.4)	14,870	23.4
Skin disease	2,039	1,987	(52)	(2.6)	9,290	21.4
Allergens	1,293	2,582	1,288	99.6	11,050	23.4
Other	1,255	1,357	102	8.2	5,770	23.5
Other sales	458	166	(291)	(63.7)	620	26.9
Cost of sales	4,392	4,449	56	1.3	20,000	22.2
Cost of products sold	4,379	4,435	56	1.3		
Other cost	13	13	0	4.5		
Gross profit	4,768	5,122	353	7.4	21,600	23.7
Selling, general and administrative expenses	5,477	3,869	(1,608)	(29.4)	18,600	20.8
R&D expenses	986	57	(929)	(94.2)	1,000	5.7
Others	4,490	3,811	(678)	(15.1)	17,600	21.7
Operating income	(709)	1,252	1,962	—	3,000	41.8
Non-operating income and expenses	52	64	11			
Ordinary income	(656)	1,317	1,973	—	3,300	39.9
Extraordinary income and loss	40,603	(8)	(40,612)			
Income before income taxes	39,947	1,308	(38,638)	(96.7)		
Income taxes	11,424	445	(10,979)			
Net income	28,522	862	(27,659)	(97.0)	2,100	41.1

### (Reference) Ratio to net sales

<i>(%)</i>	FY2019 First three months A	FY2020 First three months B	Change B-A
Cost of sales	48.0	46.5	(1.5)
SG&A	59.7	40.4	(19.3)
R&D expenses	10.8	0.6	(10.2)
Operating income	(7.7)	13.1	20.8
Ordinary income	(7.2)	13.8	21.0
Net income	311.3	9.0	(302.3)

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

**Operating income (¥1,252 million : Increase ¥1,962 million year-on-year)**



**Major factors in increase/decrease**

Net sales	: Increase with the expansion of the products of Allergens Decrease with the drug price revisions and the six anti-HIV drugs distribution fee income ※For sales of products, please refer to the next page
R&D expenses	: Decrease with business structure reform in last fiscal year(organizational reform) and co-development expenses (JTE-052)
Others	: Decrease with business structure reform in last fiscal year(personnel optimization)

**Ordinary income (¥1,317 million : Increase ¥1,973 million year-on-year)**

Special remarks: None

**Net income (¥862 million : Decrease ¥27,659 million year-on-year)**

FY2019: Income from the termination of the exclusive rights to market the six anti-HIV drugs in Japan  
¥ 40,614 million

## ② Sales of Products

<i>(Millions of Yen)</i>	FY2019 First three months A	FY2020 First three months B	Change B-A	Change (%) (B-A)/A
Sales of Products	8,702	9,405	702	8.1
[Renal disease and hemodialysis]				
REMITCH	1,910	1,515	(395)	(20.7)
Oral anti-pruritus agent				
Riona	1,422	1,451	28	2.0
Agent for hyperphosphatemia				
KAYEXALATE ※	439	402	(36)	(8.4)
Agent for hyperkalemia				
Others	340	108	(231)	(68.0)
Total	4,113	3,478	(635)	(15.4)
[Skin disease]				
ANTEBATE ※	1,260	1,224	(35)	(2.8)
Topical corticosteroid				
LOCOID ※	397	395	(2)	(0.7)
Topical corticosteroid				
ZEFNART	256	258	2	0.8
Topical antifungal agent				
Others	125	108	(16)	(13.5)
Total	2,039	1,987	(52)	(2.6)
[Allergens]				
CEDARCURE ※	247	1,343	1,095	441.9
Japanese cedar pollinosis (Allergen Immunotherapy)				
MITICURE ※	476	1,104	627	131.7
House dust mite allergy (Allergen Immunotherapy)				
Others	569	134	(434)	(76.3)
Total	1,293	2,582	1,288	99.6
[Other]				
BIO-THREE	626	673	46	7.5
Viable bacterial preparations				
Others	628	684	55	8.8
Total	1,255	1,357	102	8.2

※ In-house products

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

<i>(Millions of Yen)</i>	FY2019 First three months A	FY2020 First three months B	Change B-A	Change (%) (B-A)/A
Sales of in-house products	4,034	5,168	1,133	28.1
Ratio of in-house product sales (%)	46.4	55.0	8.6	—

### 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>Renal disease and hemodialysis</b>								
JTT-751 [Riona® Tablets]	Iron-deficiency anemia	Oral			Phase III			<ul style="list-style-type: none"> <li>·Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan</li> <li>·Co-development with JT(Additional indication)</li> <li>·Riona filed by JT has been approved as a treatment of hyperphosphatemia in January 2014, and is being promoted and distributed by Torii.</li> </ul>
JTZ-951	Anemia associated with chronic kidney disease	Oral				Application		<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</li> <li>·NDA filing by JT in November, 2019</li> </ul>
<b>Skin disease</b>								
JTE-052 [CORECTIM Ointment]	Atopic dermatitis in children	Topical			Phase III			<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</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>

Updates since the previous announcement on February 6, 2020 :

·JTE-052(CORECTIM Ointment) for the indication of Atopic dermatitis is expected to be launched on June 24, 2020.(previous announcement : Development stage[Approval])

#### Additional Information

·In January 2020, Torii signed an exclusive license agreement with JT for co development and commercialization of tapinarof, a topical, therapeutic aryl hydrocarbon receptor modulating agent (TAMA), in Japan. JT signed an exclusive license agreement on January 15, 2020, with Dermavant Sciences GmbH for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. (Torii and JT will jointly develop tapinarof.)

(Reference)

·In October 2017, JT announced that the company signed an exclusive license agreement with EirGen Pharma Limited for the development and commercialization in Japan of calcifediol extended-release capsules (marketed by OPKO Health, Inc. in the U.S. under the brand name "RAYALDEE®") for the treatment of secondary hyperparathyroidism (SHPT) in chronic kidney disease, and Torii is expected to commercialize the product once it is approved.

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/](https://www.jt.com/investors/results/S_information/pharmaceuticals/)

### III Financial Forecasts for the FY2020

The forecasts for the FY2020 have not been changed from the previous forecasts announced at the FY2020 financial results announcement on February 6, 2020.

#### ① Statement of Income

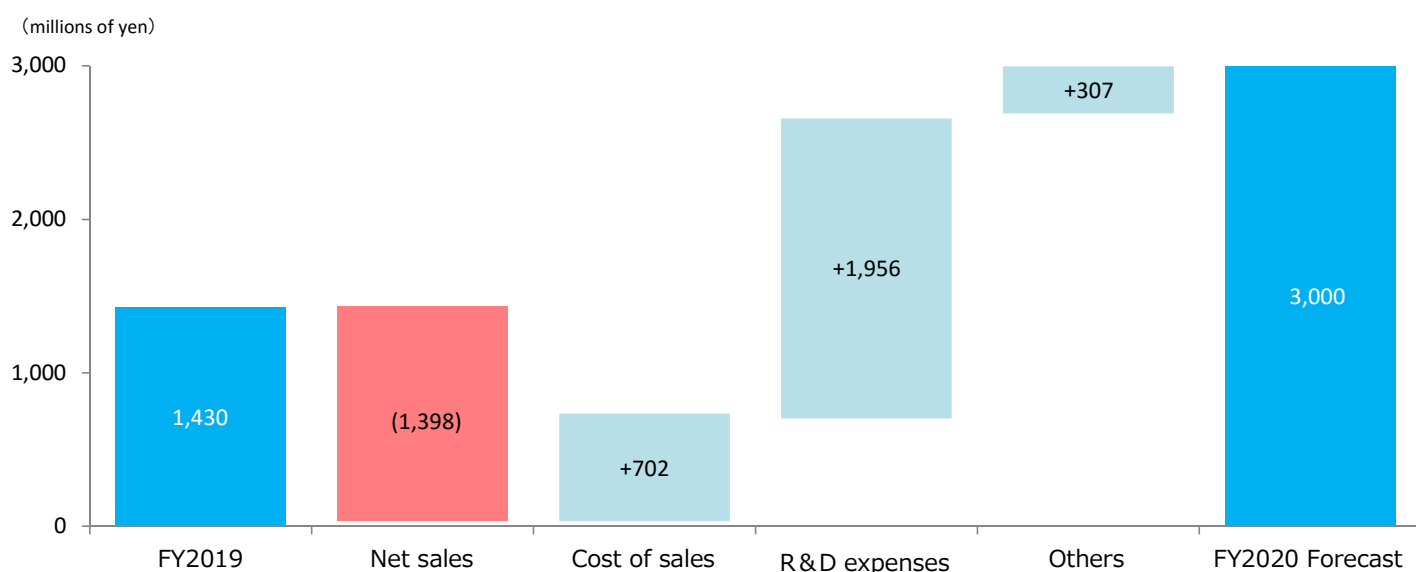
<i>(Millions of Yen)</i>	FY2019	FY2020 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Net sales	42,998	41,600	(1,398)	(3.3)
Sales of products	40,641	40,980	338	0.8
Renal disease and hemodialysis	18,005	14,870	(3,135)	(17.4)
Skin disease	9,049	9,290	240	2.7
Allergens	7,627	11,050	3,422	44.9
Other	5,959	5,770	(189)	(3.2)
Other sales	2,356	620	(1,736)	(73.7)
Cost of sales	20,702	20,000	(702)	(3.4)
Gross profit	22,295	21,600	(695)	(3.1)
SG&A	20,864	18,600	(2,264)	(10.9)
R&D expenses	2,956	1,000	(1,956)	(66.2)
Others	17,907	17,600	(307)	(1.7)
Operating income	1,430	3,000	1,569	109.7
Ordinary income	1,691	3,300	1,608	95.0
Net income	27,367	2,100	(25,267)	(92.3)

#### (Reference) Ratio to net sales

<i>(%)</i>	FY2019	FY2020 forecast	Change
	A	B	B-A
Cost of sales	48.1	48.1	0.0
SG&A	48.6	44.7	(3.9)
R&D expenses	6.9	2.4	(4.5)
Operating income	3.3	7.2	3.9
Ordinary income	3.9	7.9	4.0
Net income	63.6	5.0	(58.6)

**[Factors in increase/decrease compared with the FY2019]**

**Operating Income ( ¥3,000 million : Increase ¥1,569 million year-on-year)**



**Major factors in increase/decrease**

Net sales	: Decrease with the drug price revisions and the six anti-HIV drugs distribution fee income Increase with the expansion of the products of Allergens ※For sales of products, please refer to the next page
Cost of sales	: Decrease with changes in sales mix among the products(increase in the in-house product ratio)
R&D expenses	: Decrease with business structure reform in last fiscal year(organizational reform) and co-development expenses(JTT-751)
Others	: Decrease with business structure reform in last fiscal year(personnel optimization, cost reductions, etc.)

**Ordinary Income ( ¥3,300 million : increase ¥1,608 million year-on-year)**

Special remarks: None

**Net income ( ¥2,100 million : Decrease ¥25,267 million year-on-year)**

FY2019 Income from the termination of the exclusive rights to market the six anti-HIV drugs in Japan

	¥	40,614 million
Business structure reform expenses (Extra retirement allowance)	¥	4,504 million



## ② Sales of Products

<i>(Millions of Yen)</i>	FY2019	FY2020 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	40,641	40,980	338	0.8
[Renal disease and hemodialysis]				
Riona Agent for hyperphosphatemia	6,630	6,620	(10)	(0.2)
REMITCH Oral anti-pruritus agent	8,693	6,350	(2,343)	(27.0)
KAYEXALATE ※1 Agent for hyperkalemia	1,907	1,810	(97)	(5.1)
Others	773	90	(683)	(88.4)
Total	18,005	14,870	(3,135)	(17.4)
[Skin disease]				
ANTEBATE ※1 Topical corticosteroid	5,439	4,920	(519)	(9.6)
LOCOID ※1 Topical corticosteroid	1,630	1,490	(140)	(8.6)
ZEFNART Topical antifungal agent	1,454	1,360	(94)	(6.5)
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	–	1,070	1,070	–
Others	524	450	(74)	(14.2)
Total	9,049	9,290	240	2.7
[Allergens]				
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	3,654	6,340	2,685	73.5
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	2,749	4,150	1,400	50.9
Others	1,223	560	(663)	(54.2)
Total	7,627	11,050	3,422	44.9
[Other]				
BIO-THREE Viable bacterial preparations	2,843	2,990	146	5.1
Others	3,115	2,780	(335)	(10.8)
Total	5,959	5,770	(189)	(3.2)

※1 In-house products

※2 Expected launch on June 24, 2020

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

<i>(Millions of Yen)</i>	FY2019	FY2020 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	19,068	21,600	2,531	13.3
Ratio of in-house product sales (%)	46.9	52.7	5.8	–