

# Financial Results for the First Three Months of Fiscal Year Ending December 2021

I Summary Information	P.1
① Financial Results	P.1
② Financial Conditions	P.1
③ Capital Expenditures	P.1
④ Depreciation/Amortization	P.1
II Financial Results for the First Three Months of FY2021	P.2
① Statement of Income	P.2
② Sales of Products	P.4
③ Research and Development	P.5
III Financial Forecasts for the FY2021	P.6
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.

April 28, 2021



**TORII PHARMACEUTICAL CO., LTD.**

# I Summary Information

## ① Financial Results

The forecasts for the FY2021 have not been changed from the previous forecasts announced at the FY2020 financial results announcement on February 4, 2021.

(Millions of Yen)	FY2020 First three months A	FY2021 First three months B	Change B-A	Change (%) (B-A)/A	FY2020 Full year	FY2021 Full year forecast C	Progress ratio (%) B/C
Net sales	9,571	9,899	328	3.4	41,700	45,700	21.7
Operating income	1,252	689	(562)	(44.9)	4,738	3,800	18.2
Ordinary income	1,317	650	(667)	(50.6)	4,971	4,100	15.9
Net income	862	436	(426)	(49.5)	3,495	2,700	16.2
<b>(Reference)</b>							
R&D expenses	57	108	51	89.6	596	980	11.1
Earnings per share (EPS)	(¥) 30.74	15.53	(15.21)		124.47	96.14	
Return on equity (ROE)	(%) 0.8	0.4	(0.4)		3.1		
Ratio of ordinary income to total assets	(%) 1.0	0.5	(0.5)		3.7		
Ratio of operating income to net sales	(%) 13.1	7.0	(6.1)		11.4		
Return on assets (ROA)	(%) 0.7	0.3	(0.4)		2.6		

## ② Financial Conditions

(Millions of Yen)	December 31, 2020 A	March 31, 2021 B	Change B-A	Change (%) (B-A)/A
Total assets	126,026	127,285	1,258	1.0
Total equity	115,091	114,827	(263)	(0.2)
Equity ratio	(%) 91.3	90.2	(1.1)	
Book value per share (BPS)	(¥) 4,097.55	4,088.15	(9.40)	

## ③ Capital Expenditures

(Millions of Yen)	FY2020 First three months A	FY2021 First three months B	Change B-A	Change (%) (B-A)/A	FY2020 Full year	FY2021 Full year forecast C
Capital expenditures	41	140	98	240.1	392	1,227
PP&E	4	77	72	-	277	861
Intangible assets	36	62	26	73.1	114	366

## ④ Depreciation/Amortization

(Millions of Yen)	FY2020 First three months A	FY2021 First three months B	Change B-A	Change (%) (B-A)/A	FY2020 Full year	FY2021 Full year forecast C
Depreciation and amortization of intangible assets	202	108	(94)	(46.5)	582	422
Amortization of long-term prepaid expenses	119	129	10	8.6	496	656

## II Financial Results for the First Three Months of FY2021

### ① Statement of Income

(Millions of Yen)	FY2020	FY2021	Change	Change (%)	FY2021	Progress ratio (%)
	First three months	First three months			Full year forecast	
	A	B	B-A	(B-A)/A	C	B/C
Net sales	9,571	9,899	328	3.4	45,700	21.7
Sales of products	9,405	9,712	307	3.3	45,240	21.5
Renal disease and hemodialysis	3,478	3,039	(438)	(12.6)	14,580	20.8
Skin disease	1,987	2,444	457	23.0	12,680	19.3
Allergens	2,582	3,213	631	24.5	13,510	23.8
Other	1,357	1,015	(342)	(25.2)	4,470	22.7
Other sales	166	186	20	12.3	460	40.6
Cost of sales	4,449	4,795	345	7.8	22,200	21.6
Cost of products sold	4,435	4,781	345	7.8		
Other cost	13	13	0	0.2		
Gross profit	5,122	5,104	(17)	(0.3)	23,500	21.7
Selling, general and administrative expenses	3,869	4,414	545	14.1	19,700	22.4
R&D expenses	57	108	51	89.6	980	11.1
Others	3,811	4,305	493	13.0	18,720	23.0
Operating income	1,252	689	(562)	(44.9)	3,800	18.2
Non-operating income and expenses	64	(39)	(104)			
Ordinary income	1,317	650	(667)	(50.6)	4,100	15.9
Extraordinary income and loss	(8)	(0)	8			
Income before income taxes	1,308	649	(658)	(50.4)		
Income taxes	445	213	(232)			
Net income	862	436	(426)	(49.5)	2,700	16.2

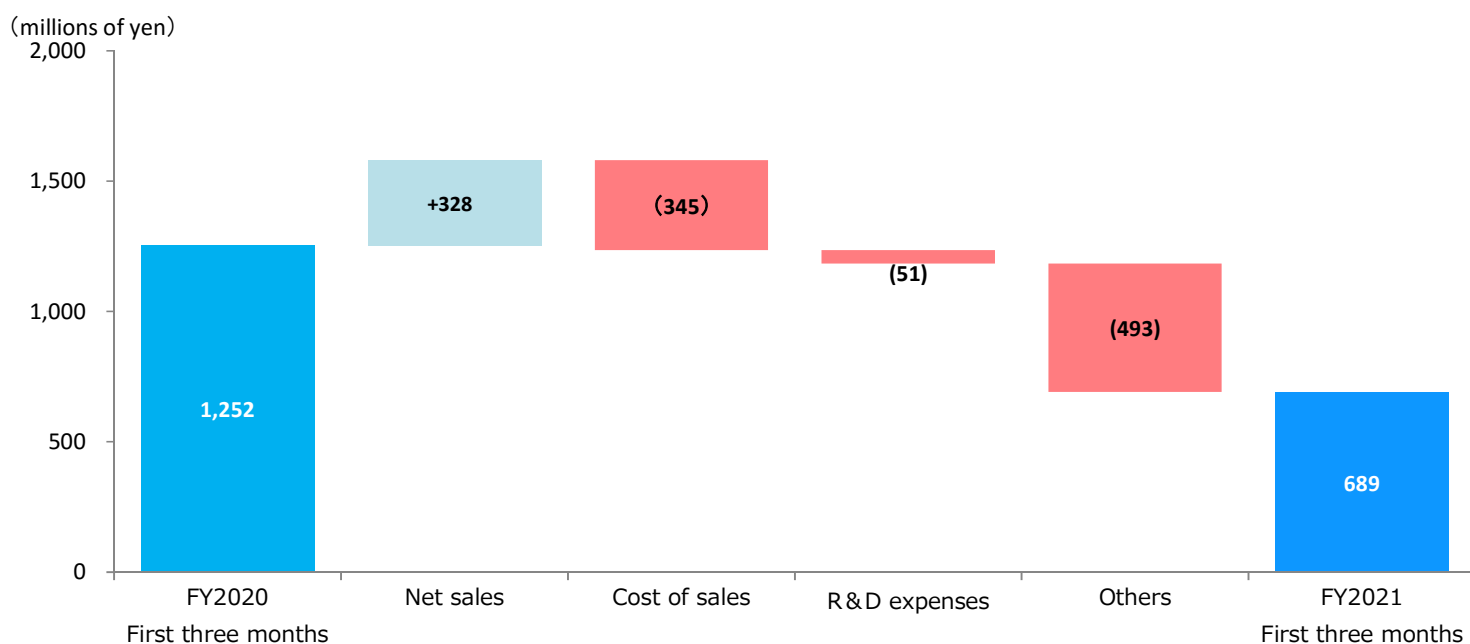
### (Reference) Ratio to net sales

(%)	FY2020	FY2021	Change
	First three months	First three months	
	A	B	B-A
Cost of sales	46.5	48.4	1.9
SG&A	40.4	44.6	4.2
R&D expenses	0.6	1.1	0.5
Operating income	13.1	7.0	(6.1)
Ordinary income	13.8	6.6	(7.2)
Net income	9.0	4.4	(4.6)

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

**Operating income (¥689 million : Decrease ¥562 million year-on-year)**

✓ Although sales of CORECTIM and Allergens increase, profits decrease by expenses for the launch of new products



**Major factors in increase/decrease**

Net sales	Renal disease and hemodialysis	: <b>Decrease in sales</b>	REMITCH Decrease ¥0.2billion (Impact of the drug price revisions and generic drugs)
	Skin disease	: <b>Increase in sales</b>	CORECTIM Increase ¥0.6billion (Launched in June 2020)
	Allergens	: <b>Increase in sales</b>	MITICURE Increase ¥0.3billion, CEDARCURE Increase ¥0.3billion (Increase in sales volume)
	Other sales	: <b>Decrease in sales</b>	(FY2020) Decrease in contract manufacturing sales
Cost of sales			Increase in net sales (FY2020) Gain on reversal of expected loss for raw material waste
Others		: Increase in sales-linked expenses	Increase in expenses due to the launch of new products, etc.

**Ordinary income (¥650 million : Decrease ¥667 million year-on-year)**

Special remarks: None

**Net income (¥436 million : Decrease ¥426 million year-on-year)**

Special remarks: None

## ② Sales of Products

<i>(Millions of Yen)</i>	FY2020	FY2021	Change	Change (%)
	First three months	First three months		
	A	B	B-A	(B-A)/A
<b>Sales of Products</b>	<b>9,405</b>	<b>9,712</b>	<b>307</b>	<b>3.3</b>
<b>[Renal disease and hemodialysis]</b>				
Riona Agent for hyperphosphatemia, Iron-deficiency anemia	1,451	1,430	(20)	(1.4)
REMITCH Oral anti-pruritus agent	1,515	1,239	(276)	(18.2)
KAYEXALATE ※1 Agent for hyperkalemia	402	368	(34)	(8.5)
Others	108	1	(107)	(98.9)
<b>Total</b>	<b>3,478</b>	<b>3,039</b>	<b>(438)</b>	<b>(12.6)</b>
<b>[Skin disease]</b>				
ANTEBATE ※1 Topical corticosteroid	1,224	1,164	(59)	(4.9)
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	–	612	612	–
LOCOID ※1 Topical corticosteroid	395	421	25	6.6
ZEFNART Topical antifungal agent	258	153	(105)	(40.9)
Others	108	93	(15)	(13.9)
<b>Total</b>	<b>1,987</b>	<b>2,444</b>	<b>457</b>	<b>23.0</b>
<b>[Allergens]</b>				
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	1,343	1,662	319	23.8
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	1,104	1,474	370	33.6
Others	134	76	(58)	(43.3)
<b>Total</b>	<b>2,582</b>	<b>3,213</b>	<b>631</b>	<b>24.5</b>
<b>[Other]</b>				
BIO-THREE Viable bacterial preparations	673	691	18	2.7
Others	684	323	(360)	(52.7)
<b>Total</b>	<b>1,357</b>	<b>1,015</b>	<b>(342)</b>	<b>(25.2)</b>

※1 In-house products

※2 Launched in June 2020

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

<i>(Millions of Yen)</i>	FY2020	FY2021	Change	Change (%)
	First three months	First three months		
	A	B	B-A	(B-A)/A
<b>Sales of in-house products</b>	<b>5,168</b>	<b>5,363</b>	<b>195</b>	<b>3.8</b>
<b>Ratio of in-house product sales (%)</b>	<b>55.0</b>	<b>55.2</b>	<b>0.2</b>	<b>–</b>

### 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					Approval	<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> <li>·sNDA approval obtained by JT in March,2021</li> </ul>
<b>Skin disease</b>								
JTE-052 [CORECTIM® Ointment]	Atopic dermatitis in children	Topical					Approval	<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</li> <li>·Manufacturing and marketing approval obtained by JT in March,2021</li> </ul>
	Atopic dermatitis in infant	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 4, 2021 :

- Additional approval of JTT-751[Riona® Tablets] sNDA for Iron Deficiency Anemia by JT on March 23, 2021.
- Manufacturing and marketing approval of JTE-052(CORECTIM®Ointment) for Atopic dermatitis in children by JT on March 23, 2021.

#### 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.)
- In march 2021, Torii signed a license agreement with Verrica Pharmaceuticals Inc. for the exclusive development and commercialization of Verrica' s skin disease treatment drug VP 102 for the treatment of molluscum contagiosum and common warts in Japan.

#### (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 FY2021

The forecasts for the FY2021 have not been changed from the previous forecasts announced at the FY2020 financial results announcement on February 4,2021.

#### ① Statement of Income

<i>(Millions of Yen)</i>	FY2020	FY2021 forecast	Change	Change (%)
	<i>A</i>	<i>B</i>	<i>B-A</i>	<i>(B-A)/A</i>
Net sales	41,700	45,700	3,999	9.6
Sales of products	41,053	45,240	4,186	10.2
Renal disease and hemodialysis	14,773	14,580	(193)	(1.3)
Skin disease	9,918	12,680	2,761	27.8
Allergens	11,332	13,510	2,177	19.2
Other	5,029	4,470	(559)	(11.1)
Other sales	647	460	(187)	(28.9)
Cost of sales	19,962	22,200	2,237	11.2
Gross profit	21,737	23,500	1,762	8.1
SG&A	16,999	19,700	2,700	15.9
R&D expenses	596	980	383	64.3
Others	16,403	18,720	2,316	14.1
Operating income	4,738	3,800	(938)	(19.8)
Ordinary income	4,971	4,100	(871)	(17.5)
Net income	3,495	2,700	(795)	(22.8)

(Reference) Ratio to net sales

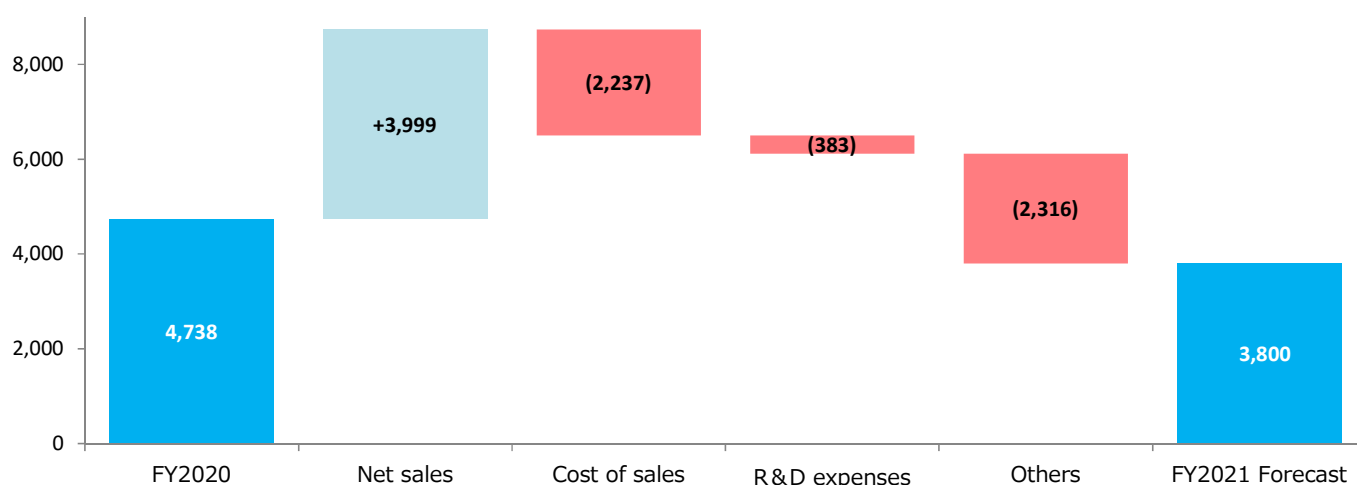
<i>(%)</i>	FY2020	FY2021 forecast	Change
	<i>A</i>	<i>B</i>	<i>B-A</i>
Cost of sales	47.9	48.6	0.7
SG&A	40.7	43.1	2.4
R&D expenses	1.4	2.1	0.7
Operating income	11.4	8.3	(3.1)
Ordinary income	11.9	9.0	(2.9)
Net income	8.4	5.9	(2.5)

**[Factors in increase/decrease compared with the FY2020]**

**Operating Income (¥3,800 million : Decrease ¥938 million year-on-year)**

✓ Although sales of CORECTIM and Allergens are expected to increase, profits are expected to decrease by expenses for the launch of new products

(millions of yen)



**Major factors in increase/decrease**

Net sales	Renal disease and hemodialysis	: <b>Decrease in sales</b>	REMITCH Decrease ¥1.4 billion(Impact of the drug price revisions and generic drugs), Riona Increase ¥1.4 billion(Increase in sales quantity due to additional indication)
	Skin disease	: <b>Increase in sales</b>	CORECTIM Increase ¥3.4 billion(Launched in June 2020)
	Allergens	: <b>Increase in sales</b>	CEDARCURE Increase ¥1.2 billion, MITICURE Increase ¥1.1 billion(Increase in sales quantity)
Cost of sales		: Increase in net sales	
R&D expenses		: Increase in products improvement expenses	
Others		: Increase in sales-linked expenses Increase in launching new products expenses Temporary expenses to purchase computers	

**Ordinary Income (¥4,100 million : Decrease ¥871 million year-on-year)**

Special remarks: None

**Net income (¥2,700 million : Decrease ¥795 million year-on-year)**

FY2020: Business structure reform expenses(Loss on the plant transfer, etc.)

Income taxes

(Reduct of impairment loss and enterprise tax in last fiscal year, etc.)



## ② Sales of Products

(Millions of Yen)	FY2020		FY2021 forecast		Change	
	A	B	B-A	(B-A)/A		
Sales of Products	41,053	45,240	4,186	10.2		
[Renal disease and hemodialysis]						
Riona Agent for hyperphosphatemia, Iron-deficiency anemia	6,507	7,910	1,402	21.5		
REMITCH Oral anti-pruritus agent	6,365	4,920	(1,445)	(22.7)		
KAYEXALATE ※1 Agent for hyperkalemia	1,717	1,500	(217)	(12.7)		
Others	182	250	67	36.7		
Total	14,773	14,580	(193)	(1.3)		
[Skin disease]						
ANTEBATE ※1 Topical corticosteroid	5,241	4,840	(401)	(7.7)		
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	1,291	4,730	3,438	266.2		
LOCOID ※1 Topical corticosteroid	1,674	1,590	(84)	(5.0)		
ZEFNART Topical antifungal agent	1,241	1,090	(151)	(12.2)		
Others	469	430	(39)	(8.3)		
Total	9,918	12,680	2,761	27.8		
[Allergens]						
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	6,139	7,370	1,230	20.0		
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	4,776	5,890	1,113	23.3		
Others	416	250	(166)	(40.0)		
Total	11,332	13,510	2,177	19.2		
[Other]						
BIO-THREE Viable bacterial preparations	2,969	3,070	100	3.4		
Others	2,059	1,400	(659)	(32.0)		
Total	5,029	4,470	(559)	(11.1)		

※1 In-house products

※2 launched in June 2020

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

(Millions of Yen)	FY2020		FY2021 forecast		Change	
	A	B	B-A	(B-A)/A		
Sales of in-house products	21,539	22,100	560	2.6		
Ratio of in-house product sales (%)	52.5	48.9	(3.6)	—		