

Financial Results for the First Six 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.

July 31, 2020



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

The forecasts for the FY2020 have been changed from the previous forecasts announced at the FY2019 financial results announcement on February 6, 2020.

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 revised forecast	Progress ratio (%)
	First six months	First six months	First six months	First six months					
	A	B	B-A	(B-A)/A			C	B/C	
Net sales	20,684	19,857	(826)	(4.0)			42,998	40,900	48.6
Operating income	290	2,738	2,447	841.3			1,430	3,700	74.0
Ordinary income	402	2,903	2,500	620.9			1,691	4,000	72.6
Net income	26,194	1,800	(24,394)	(93.1)			27,367	2,600	69.3
(Reference)									
R&D expenses	1,834	281	(1,552)	(84.7)			2,956	810	34.7
Earnings per share (EPS)	(¥) 933.34	64.14	(869.20)				974.98	92.60	
Return on equity (ROE)	(%) 26.2	1.6	(24.6)				27.3		
Ratio of ordinary income to total assets	(%) 0.3	2.2	1.9				1.4		
Ratio of operating income to net sales	(%) 1.4	13.8	12.4				3.3		
Return on assets (ROA)	(%) 20.8	1.4	(19.4)				22.5		

② Financial Conditions

(Millions of Yen)	December 31, 2019		June 30, 2020		Change	Change (%)
	A	B	B-A	(B-A)/A		
Total assets	139,943	124,734	(15,208)	(10.9)		
Total equity	113,125	114,112	986	0.9		
Equity ratio	(%) 80.8	91.5	10.7			
Book value per share (BPS)	(¥) 4,029.30	4,063.07	33.77			

③ Statement of Cash Flows

(Millions of Yen)	FY2019		FY2020		Change
	First six months	First six months	First six months	First six months	
	A	B	B-A		
Net cash used in operating activities	48,865	(5,595)	(54,461)		
Net cash used in investing activities	1,705	(649)	(2,354)		
Net cash used in financing activities	(716)	(716)	(0)		
Cash and cash equivalents, end of period	65,508	51,856	(13,651)		

④ Capital Expenditures

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 revised forecast
	First six months	First six months	First six months	First six months				
	A	B	B-A	(B-A)/A				
Capital expenditures	107	211	104	97.4			330	662
PP&E	80	151	71	88.6			203	359
Intangible assets	26	60	33	123.7			126	303

⑤ Depreciation/Amortization

(Millions of Yen)	FY2019		FY2020		Change	Change (%)	FY2019 Full year	FY2020 revised forecast
	First six months	First six months	First six months	First six months				
	A	B	B-A	(B-A)/A				
Depreciation and amortization of intangible assets	497	401	(95)	(19.3)			985	598
Amortization of long-term prepaid expenses	241	240	(0)	(0.3)			486	554

II Financial Results for the First Six Months of FY2020

① Statement of Income

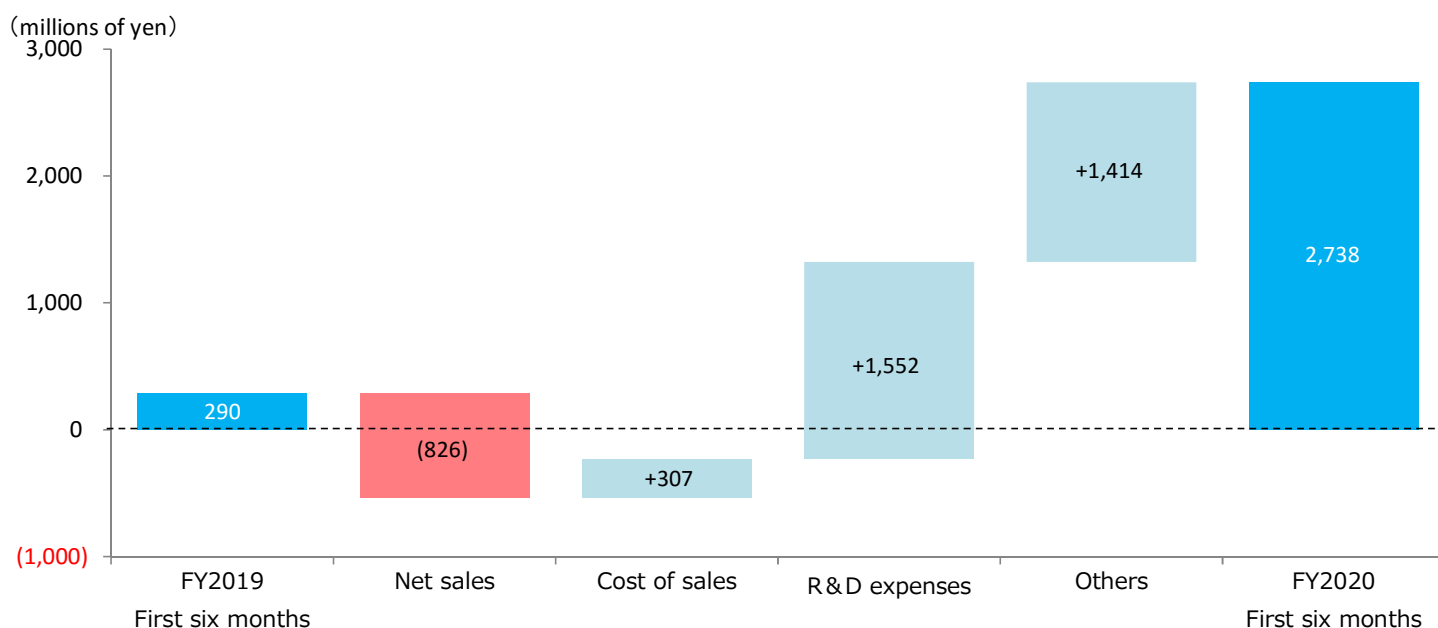
<i>(Millions of Yen)</i>	FY2019	FY2020	Change	Change (%)	FY2020 revised forecast	Progress ratio (%)
	First six months	First six months				
	A	B	B-A	(B-A)/A	C	B/C
Net sales	20,684	19,857	(826)	(4.0)	40,900	48.6
Sales of products	19,280	19,453	173	0.9	40,300	48.3
Renal disease and hemodialysis	8,965	7,217	(1,747)	(19.5)	14,790	48.8
Skin disease	4,562	4,483	(79)	(1.7)	9,500	47.2
Allergens	2,942	5,001	2,058	70.0	10,900	45.9
Other	2,809	2,751	(58)	(2.1)	5,110	53.8
Other sales	1,404	404	(1,000)	(71.2)	600	67.3
Cost of sales	9,784	9,477	(307)	(3.1)	19,300	49.1
Cost of products sold	9,705	9,449	(255)	(2.6)		
Other cost	79	27	(51)	(65.0)		
Gross profit	10,900	10,380	(519)	(4.8)	21,600	48.1
Selling, general and administrative expenses	10,609	7,642	(2,967)	(28.0)	17,900	42.7
R&D expenses	1,834	281	(1,552)	(84.7)	810	34.7
Others	8,775	7,360	(1,414)	(16.1)	17,090	43.1
Operating income	290	2,738	2,447	841.3	3,700	74.0
Non-operating income and expenses	111	164	52			
Ordinary income	402	2,903	2,500	620.9	4,000	72.6
Extraordinary income and loss	36,387	(774)	(37,162)			
Income before income taxes	36,790	2,128	(34,661)	(94.2)		
Income taxes	10,595	327	(10,267)			
Net income	26,194	1,800	(24,394)	(93.1)	2,600	69.3

(Reference) Ratio to net sales

<i>(%)</i>	FY2019	FY2020	Change
	First six months	First six months	
	A	B	B-A
Cost of sales	47.3	47.7	0.4
SG&A	51.3	38.5	(12.8)
R&D expenses	8.9	1.4	(7.5)
Operating income	1.4	13.8	12.4
Ordinary income	1.9	14.6	12.7
Net income	126.6	9.1	(117.5)

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

Operating income (¥2,738 million : Increase ¥2,447 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 (JTT-751, JTE-052)
Others	: Decrease with business structure reform in last fiscal year(personnel optimization)

Ordinary income (¥2,903 million : Increase ¥2,500 million year-on-year)

Special remarks: None

Net income (¥1,800 million : Decrease ¥24,394 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) ¥ 4,224 million

FY2020: Business structure reform expenses(Estimated loss on the plant transfer)

¥ 765 million

② Sales of Products

<i>(Millions of Yen)</i>	FY2019 First six months A	FY2020 First six months B	Change B-A	Change (%) (B-A)/A
Sales of Products	19,280	19,453	173	0.9
[Renal disease and hemodialysis]				
Riona Agent for hyperphosphatemia	3,190	3,136	(54)	(1.7)
REMITCH Oral anti-pruritus agent	4,334	3,123	(1,210)	(27.9)
KAYEXALATE ※1 Agent for hyperkalemia	948	849	(98)	(10.4)
Others	492	108	(383)	(77.9)
Total	8,965	7,217	(1,747)	(19.5)
[Skin disease]				
ANTEBATE ※1 Topical corticosteroid	2,750	2,588	(162)	(5.9)
LOCOID ※1 Topical corticosteroid	858	842	(16)	(1.9)
ZEFNART Topical antifungal agent	678	638	(39)	(5.8)
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	–	176	176	–
Others	274	237	(36)	(13.4)
Total	4,562	4,483	(79)	(1.7)
[Allergens]				
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	952	2,678	1,726	181.2
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	1,089	2,079	990	90.9
Others	900	242	(657)	(73.0)
Total	2,942	5,001	2,058	70.0
[Other]				
BIO-THREE Viable bacterial preparations	1,343	1,392	49	3.7
Others	1,466	1,358	(107)	(7.3)
Total	2,809	2,751	(58)	(2.1)

※1 In-house products

※2 Launched in June 2020

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2019 First six months A	FY2020 First six months B	Change B-A	Change (%) (B-A)/A
Sales of in-house products	8,768	10,413	1,644	18.8
Ratio of in-house product sales (%)	45.5	53.5	8.0	–

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	
Renal disease and hemodialysis								
JTT-751 [Riona® Tablets]	Iron-deficiency anemia	Oral				Application	<ul style="list-style-type: none"> •Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan •Co-development with JT(Additional indication) •Riona filed by JT has been approved as a treatment of hyperphosphatemia in January 2014, and is being promoted and distributed by Torii. •sNDA filing by JT in May, 2020 	
JTZ-951	Anemia associated with chronic kidney disease	Oral				Application	<ul style="list-style-type: none"> •JT's original compound •Licensing agreement signed with JT for development and commercialization •NDA filing by JT in November, 2019 	
Skin disease								
JTE-052 [CORRECTIM Ointment]	Atopic dermatitis in children	Topical				Application	<ul style="list-style-type: none"> •JT's original compound •Licensing agreement signed with JT for development and commercialization •NDA filing by JT in May, 2020 	
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 	

Updates since the previous announcement on April 30, 2020 :

- JTT-751[Riona® Tablets] sNDA filing for Iron Deficiency Anemia by JT on May 15, 2020.
- JTE-052 Ointment NDA filing for the Treatment of Pediatric Atopic Dermatitis by JT on May 29, 2020.

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/

III Financial Forecasts for the FY2020

The forecasts for the FY2020 have been changed from the previous forecasts announced at the FY2019 financial results announcement on February 6, 2020.

① Statement of Income

(Millions of Yen)	FY2020	FY2020	Change	FY2019	Change	Change (%)
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Net sales	41,600	40,900	(700)	42,998	(2,098)	(4.9)
Sales of products	40,980	40,300	(680)	40,641	(341)	(0.8)
Renal disease and hemodialysis	14,870	14,790	(80)	18,005	(3,215)	(17.9)
Skin disease	9,290	9,500	210	9,049	450	5.0
Allergens	11,050	10,900	(150)	7,627	3,272	42.9
Other	5,770	5,110	(660)	5,959	(849)	(14.3)
Other sales	620	600	(20)	2,356	(1,756)	(74.5)
Cost of sales	20,000	19,300	(700)	20,702	(1,402)	(6.8)
Gross profit	21,600	21,600	–	22,295	(695)	(3.1)
SG&A	18,600	17,900	(700)	20,864	(2,964)	(14.2)
R&D expenses	1,000	810	(190)	2,956	(2,146)	(72.6)
Others	17,600	17,090	(510)	17,907	(817)	(4.6)
Operating income	3,000	3,700	700	1,430	2,269	158.6
Ordinary income	3,300	4,000	700	1,691	2,308	136.4
Net income	2,100	2,600	500	27,367	(24,767)	(90.5)

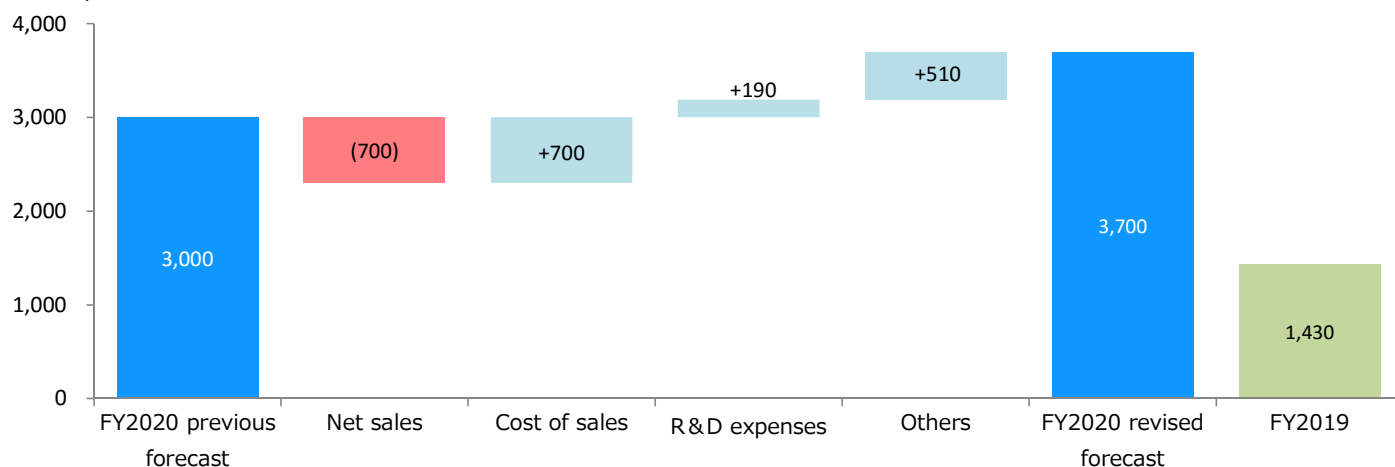
(Reference) Ratio to net sales

(%)	FY2020	FY2020	Change	FY2019	Change
	previous forecast	revised forecast			
	A	B	B-A	C	B-C
Cost of sales	48.1	47.2	(0.9)	48.1	(0.9)
SG&A	44.7	43.8	(0.9)	48.6	(4.8)
R&D expenses	2.4	2.0	(0.4)	6.9	(4.9)
Operating income	7.2	9.0	1.8	3.3	5.7
Ordinary income	7.9	9.8	1.9	3.9	5.9
Net income	5.0	6.4	1.4	63.6	(57.2)

[Factors in increase/decrease compared with the previous forecast for the FY2020]

Operating income (¥3,700 million : Increase ¥700 million)

(millions of yen)



Major factors in increase/decrease

Net sales	: Decrease in contract manufacturing sales due to the plant transfer ※For sales of products, please refer to the next page
Cost of sales	: Decrease in net sales
R&D expenses	: Decrease in co-development expenses (JTE-052)
Others	: Decrease with measures to prevent the spread of the new coronavirus (MRs refrain from visiting medical institutions)

Ordinary income (¥4,000 million : Increase ¥700 million)

Special remarks: None

Net income (¥2,600 million : Increase ¥500 million)

FY2020: Business structure reform expenses (Estimated loss on the plant transfer)	¥	765 million
Decrease in income taxes (Inclusion in deductible expenses of Impairment Losses)	¥	700 million

② Sales of Products

(Millions of Yen)	FY2020	FY2020	Change	FY2019	Change	Change (%)
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of Products	40,980	40,300	(680)	40,641	(341)	(0.8)
[Renal disease and hemodialysis]						
Riona Agent for hyperphosphatemia	6,620	6,700	80	6,630	69	1.0
REMITCH Oral anti-pruritus agent	6,350	6,270	(80)	8,693	(2,423)	(27.9)
KAYEXALATE ※1 Agent for hyperkalemia	1,810	1,700	(110)	1,907	(207)	(10.9)
Others	90	120	30	773	(653)	(84.5)
Total	14,870	14,790	(80)	18,005	(3,215)	(17.9)
[Skin disease]						
ANTEBATE ※1 Topical corticosteroid	4,920	5,080	160	5,439	(359)	(6.6)
LOCOID ※1 Topical corticosteroid	1,490	1,560	70	1,630	(70)	(4.3)
ZEFNART Topical antifungal agent	1,360	1,380	20	1,454	(74)	(5.1)
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	1,070	1,000	(70)	–	1,000	–
Others	450	480	30	524	(44)	(8.5)
Total	9,290	9,500	210	9,049	450	5.0
[Allergens]						
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	6,340	5,920	(420)	3,654	2,265	62.0
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	4,150	4,460	310	2,749	1,710	62.2
Others	560	520	(40)	1,223	(703)	(57.5)
Total	11,050	10,900	(150)	7,627	3,272	42.9
[Other]						
BIO-THREE Viable bacterial preparations	2,990	3,040	50	2,843	196	6.9
Others	2,780	2,070	(710)	3,115	(1,045)	(33.6)
Total	5,770	5,110	(660)	5,959	(849)	(14.3)

※1 In-house products

※2 launched in June 2020

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2020	FY2020	Change	FY2019	Change	Change (%)
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of in-house products	21,600	20,820	(780)	19,068	1,751	9.2
Ratio of in-house product sales (%)	52.7	51.7	(1.0)	46.9	4.8	–