

Financial Results for the First Nine 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.

October 30, 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 first six months of FY2020 financial results announcement on July 31, 2020.

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2019	FY2020	Progress
	First nine months	First nine months					
	A	B	B-A	(B-A)/A		C	B/C
Net sales	31,320	30,172	(1,148)	(3.7)	42,998	41,000	73.6
Operating income	662	3,553	2,891	436.5	1,430	4,200	84.6
Ordinary income	839	3,753	2,913	346.9	1,691	4,500	83.4
Net income	26,466	2,508	(23,958)	(90.5)	27,367	3,100	80.9
(Reference)							
R&D expenses	2,588	457	(2,131)	(82.3)	2,956	710	64.4
Earnings per share (EPS)	(¥) 942.93	89.34	(853.59)		974.98	110.40	
Return on equity (ROE)	(%) 26.5	2.2	(24.3)		27.3		
Ratio of ordinary income to total assets	(%) 0.7	2.8	2.1		1.4		
Ratio of operating income to net sales	(%) 2.1	11.8	9.7		3.3		
Return on assets (ROA)	(%) 21.1	1.9	(19.2)		22.5		

② Financial Conditions

(Millions of Yen)	December 31,	September 30,	Change	Change (%)
	2019	2020		
	A	B	B-A	(B-A)/A
Total assets	139,943	124,438	(15,505)	(11.1)
Total equity	113,125	114,180	1,054	0.9
Equity ratio	(%) 80.8	91.7	10.9	
Book value per share (BPS)	(¥) 4,029.30	4,065.51	36.21	

③ Capital Expenditures

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2019	FY2020
	First nine months	First nine months				
	A	B	B-A	(B-A)/A		
Capital expenditures	178	252	73	41.3	330	628
PP&E	107	160	53	49.7	203	353
Intangible assets	71	91	20	28.6	126	275

④ Depreciation/Amortization

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2019	FY2020
	First nine months	First nine months				
	A	B	B-A	(B-A)/A		
Depreciation and amortization of intangible assets	746	493	(252)	(33.9)	985	591
Amortization of long-term prepaid expenses	365	368	3	0.9	486	495

II Financial Results for the First Nine Months of FY2020

① Statement of Income

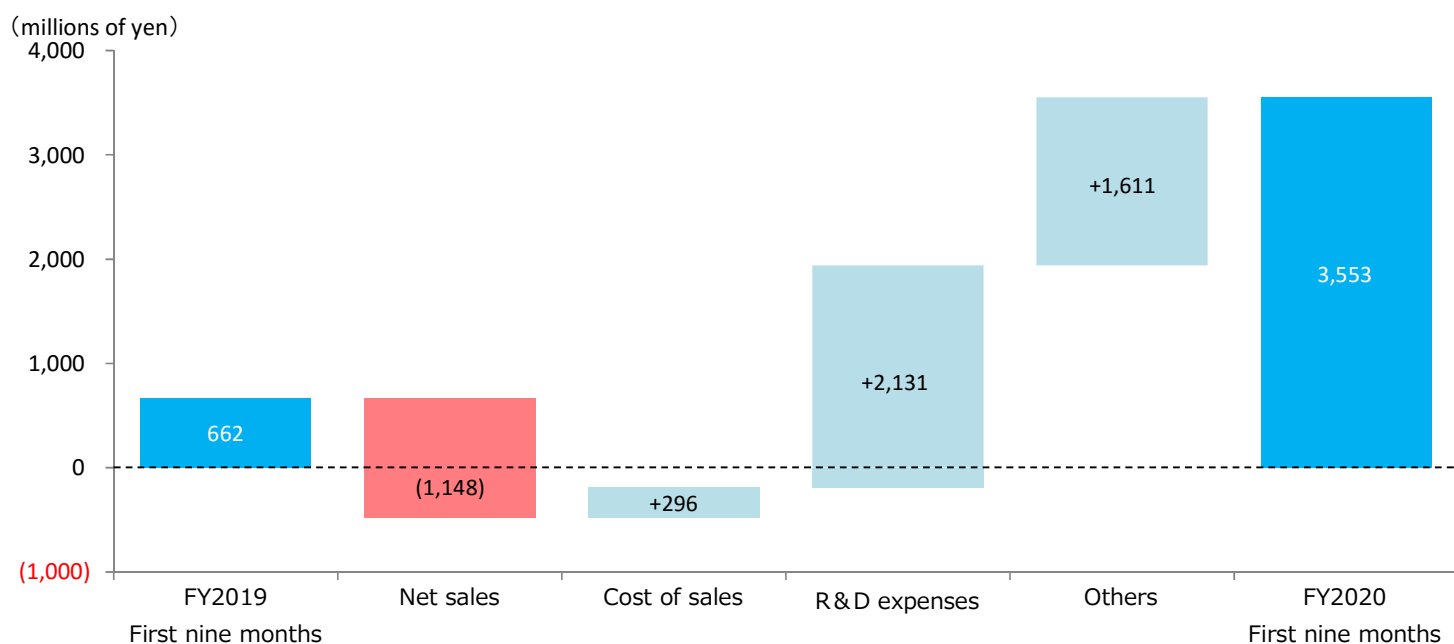
(Millions of Yen)	FY2019	FY2020	Change B-A	Change (%) (B-A)/A	FY2020 revised forecast C	Progress ratio (%) B/C
	First nine months	First nine months				
	A	B				
Net sales	31,320	30,172	(1,148)	(3.7)	41,000	73.6
Sales of products	29,501	29,640	139	0.5	40,400	73.4
Renal disease and hemodialysis	13,324	10,850	(2,473)	(18.6)	14,550	74.6
Skin disease	6,757	7,085	328	4.9	9,680	73.2
Allergens	5,056	7,842	2,785	55.1	11,170	70.2
Other	4,362	3,861	(501)	(11.5)	5,000	77.2
Other sales	1,819	532	(1,287)	(70.8)	600	88.7
Cost of sales	14,845	14,548	(296)	(2.0)	19,700	73.9
Cost of products sold	14,751	14,507	(244)	(1.7)		
Other cost	93	41	(52)	(55.7)		
Gross profit	16,475	15,623	(851)	(5.2)	21,300	73.3
Selling, general and administrative expenses	15,812	12,069	(3,743)	(23.7)	17,100	70.6
R&D expenses	2,588	457	(2,131)	(82.3)	710	64.4
Others	13,224	11,612	(1,611)	(12.2)	16,390	70.9
Operating income	662	3,553	2,891	436.5	4,200	84.6
Non-operating income and expenses	177	199	22			
Ordinary income	839	3,753	2,913	346.9	4,500	83.4
Extraordinary income and loss	36,332	(758)	(37,090)			
Income before income taxes	37,172	2,995	(34,176)	(91.9)		
Income taxes	10,705	486	(10,218)			
Net income	26,466	2,508	(23,958)	(90.5)	3,100	80.9

(Reference) Ratio to net sales

(%)	FY2019	FY2020	Change B-A
	First nine months	First nine months	
	A	B	
Cost of sales	47.4	48.2	0.8
SG&A	50.5	40.0	(10.5)
R&D expenses	8.3	1.5	(6.8)
Operating income	2.1	11.8	9.7
Ordinary income	2.7	12.4	9.7
Net income	84.5	8.3	(76.2)

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

Operating income (¥3,553 million : Increase ¥2,891 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) and increase in IT expenses for information provision activities to the proper use of pharmaceutical products

Ordinary income (¥3,753 million : Increase ¥2,913 million year-on-year)

Special remarks: None

Net income (¥2,508 million : Decrease ¥23,958 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)	¥	4,279 million
FY2020: Business structure reform expenses(Loss on the plant transfer)	¥	748 million

② Sales of Products

<i>(Millions of Yen)</i>	FY2019	FY2020	Change	Change (%)
	First nine months	First nine months		
	A	B		
Sales of Products	29,501	29,640	139	0.5
[Renal disease and hemodialysis]				
Riona	4,845	4,770	(74)	(1.5)
Agent for hyperphosphatemia				
REMITCH	6,447	4,698	(1,749)	(27.1)
Oral anti-pruritus agent				
KAYEXALATE ※1	1,406	1,272	(134)	(9.6)
Agent for hyperkalemia				
Others	624	108	(515)	(82.6)
Total	13,324	10,850	(2,473)	(18.6)
[Skin disease]				
ANTEBATE ※1	4,039	3,857	(182)	(4.5)
Topical corticosteroid				
LOCOID ※1	1,224	1,225	1	0.1
Topical corticosteroid				
ZEFNART	1,104	1,015	(89)	(8.1)
Topical antifungal agent				
CORECTIM ※2	–	641	641	–
Topical Janus kinase (JAK) inhibitor				
Others	388	346	(42)	(10.9)
Total	6,757	7,085	328	4.9
[Allergens]				
CEDARCURE ※1	2,180	4,261	2,081	95.5
Japanese cedar pollinosis (Allergen Immunotherapy)				
MITICURE ※1	1,816	3,249	1,433	78.9
House dust mite allergy (Allergen Immunotherapy)				
Others	1,058	330	(728)	(68.8)
Total	5,056	7,842	2,785	55.1
[Other]				
BIO-THREE	2,064	2,146	82	4.0
Viable bacterial preparations				
Others	2,298	1,715	(583)	(25.4)
Total	4,362	3,861	(501)	(11.5)

※1 In-house products

※2 Launched in June 2020

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2019	FY2020	Change	Change (%)
	First nine months	First nine months		
	A	B		
Sales of in-house products	13,595	15,539	1,943	14.3
Ratio of in-house product sales (%)	46.1	52.4	6.3	–

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 [ENAROY® Tablets]	Anemia associated with chronic kidney disease	Oral					Approval	<ul style="list-style-type: none"> •JT's original compound •Licensing agreement signed with JT for development and commercialization •NDA approval obtained by JT in September, 2020
Skin disease								
JTE-052 [CORECTIM® 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
	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
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 July 31, 2020 :

- Manufacturing and marketing approval of JTZ-951(ENAROY® Tablets) for the Treatment of Anemia Associated with CKD by JT on September 25, 2020.
- JTE-052(CORECTIM® Ointment) for the indication of atopic dermatitis in infant has entered into the clinical stage(Phase III) in Japan.

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 August 2020, Torii signed an option agreement with Verrica Pharmaceuticals Inc. for an exclusive option right to acquire an exclusive license to develop and commercialize of Verrica's skin disease treatment drug VP-102 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/

III Financial Forecasts for the FY2020

The forecasts for the FY2020 have been changed from the previous forecasts announced at the first six months of FY2020 financial results announcement on July 31, 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	40,900	41,000	100	42,998	(1,998)	(4.6)
Sales of products	40,300	40,400	100	40,641	(241)	(0.6)
Renal disease and hemodialysis	14,790	14,550	(240)	18,005	(3,455)	(19.2)
Skin disease	9,500	9,680	180	9,049	630	7.0
Allergens	10,900	11,170	270	7,627	3,542	46.4
Other	5,110	5,000	(110)	5,959	(959)	(16.1)
Other sales	600	600	–	2,356	(1,756)	(74.5)
Cost of sales	19,300	19,700	400	20,702	(1,002)	(4.8)
Gross profit	21,600	21,300	(300)	22,295	(995)	(4.5)
SG&A	17,900	17,100	(800)	20,864	(3,764)	(18.0)
R&D expenses	810	710	(100)	2,956	(2,246)	(76.0)
Others	17,090	16,390	(700)	17,907	(1,517)	(8.5)
Operating income	3,700	4,200	500	1,430	2,769	193.6
Ordinary income	4,000	4,500	500	1,691	2,808	166.0
Net income	2,600	3,100	500	27,367	(24,267)	(88.7)

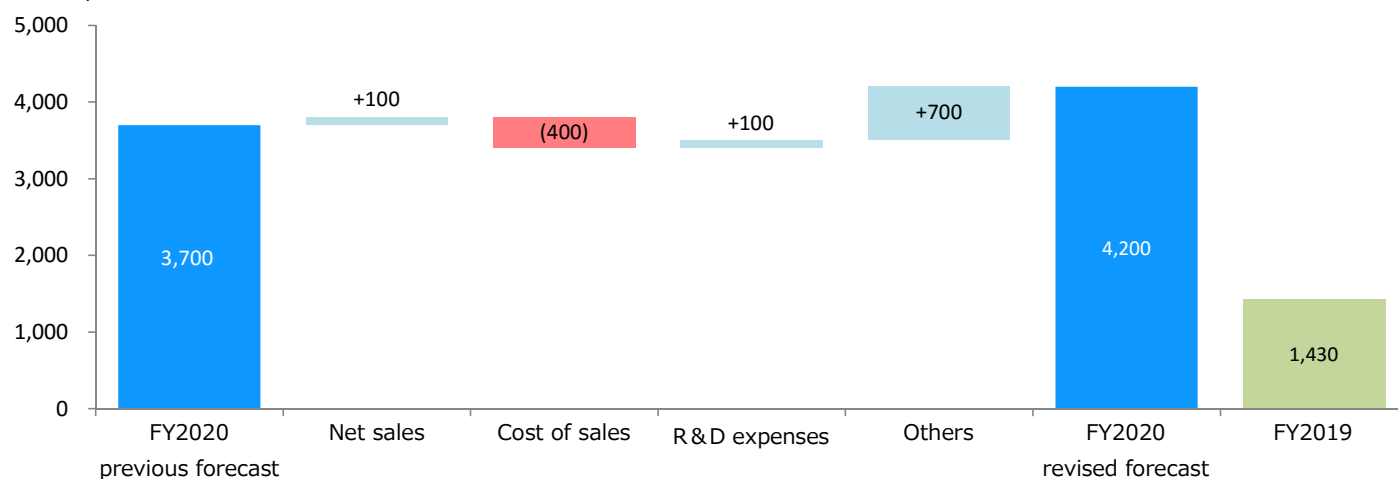
(Reference) Ratio to net sales

(%)	FY2020	FY2020	Change	FY2019	Change
	previous forecast	revised forecast			
	A	B	B-A	C	B-C
Cost of sales	47.2	48.0	0.8	48.1	(0.1)
SG&A	43.8	41.8	(2.0)	48.6	(6.8)
R&D expenses	2.0	1.7	(0.3)	6.9	(5.2)
Operating income	9.0	10.2	1.2	3.3	6.9
Ordinary income	9.8	11.0	1.2	3.9	7.1
Net income	6.4	7.6	1.2	63.6	(56.0)

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

Operating income (¥4,200 million : Increase ¥500 million)

(millions of yen)



Major factors in increase/decrease

Net sales	: Increase with the expansion of CEDARCURE, MITICURE and CORECTIM and decrease in REMITCH ※For sales of products, please refer to the next page
Cost of sales	: Increase in overseas outsourced manufacturing expenses
Others	: Decrease with measures to prevent the spread of COVID-19 infection (MRs refrain from visiting medical institutions)

Ordinary income (¥4,500 million : Increase ¥500 million)

Special remarks: None

Net income (¥3,100 million : Increase ¥500 million)

Special remarks: None

② Sales of Products

<i>(Millions of Yen)</i>	FY2020	FY2020	Change	FY2019	Change	Change (%)
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of Products	40,300	40,400	100	40,641	(241)	(0.6)
[Renal disease and hemodialysis]						
Riona	6,700	6,610	(90)	6,630	(20)	(0.3)
Agent for hyperphosphatemia						
REMITCH	6,270	6,120	(150)	8,693	(2,573)	(29.6)
Oral anti-pruritus agent						
KAYEXALATE ※1	1,700	1,700	–	1,907	(207)	(10.9)
Agent for hyperkalemia						
Others	120	120	–	773	(653)	(84.5)
Total	14,790	14,550	(240)	18,005	(3,455)	(19.2)
[Skin disease]						
ANTEBATE ※1	5,080	5,100	20	5,439	(339)	(6.2)
Topical corticosteroid						
LOCOID ※1	1,560	1,580	20	1,630	(50)	(3.1)
Topical corticosteroid						
ZEFNART	1,380	1,390	10	1,454	(64)	(4.4)
Topical antifungal agent						
CORECTIM ※2	1,000	1,120	120	–	1,120	–
Topical Janus kinase (JAK) inhibitor						
Others	480	490	10	524	(34)	(6.6)
Total	9,500	9,680	180	9,049	630	7.0
[Allergens]						
CEDARCURE ※1	5,920	6,060	140	3,654	2,405	65.8
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※1	4,460	4,660	200	2,749	1,910	69.5
House dust mite allergy (Allergen Immunotherapy)						
Others	520	450	(70)	1,223	(773)	(63.2)
Total	10,900	11,170	270	7,627	3,542	46.4
[Other]						
BIO-THREE	3,040	2,960	(80)	2,843	116	4.1
Viable bacterial preparations						
Others	2,070	2,040	(30)	3,115	(1,075)	(34.5)
Total	5,110	5,000	(110)	5,959	(959)	(16.1)

※1 In-house products

※2 launched in June 2020

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	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	20,820	21,110	290	19,068	2,041	10.7
Ratio of in-house product sales (%)	51.7	52.3	0.6	46.9	5.4	–