

Financial Results for the First Three Months of Fiscal Year Ending December 2019

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 FY2019	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 FY2019	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 25, 2019



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

The forecasts for the FY2019 have not been changed from the previous forecasts announced at the FY2018 financial results announcement on February 6, 2019.

(Millions of Yen)	FY2018	FY2019	Change	Change (%)	FY2018	FY2019	Progress
	First three months	First three months					
	A	B	B-A	(B-A)/A		C	B/C
Net sales	13,930	9,161	(4,769)	(34.2)	62,551	38,000	24.1
Operating income or loss	769	(709)	(1,478)	-	4,951	(3,200)	22.2
Ordinary income or loss	790	(656)	(1,446)	-	5,080	(3,100)	21.2
Net income	569	28,522	27,953	-	1,164	22,500	126.8
(Reference)							
R&D expenses	1,016	986	(29)	(2.9)	4,138	3,300	29.9
Earnings per share (EPS)	(¥) 20.29	1,016.43	996.14		41.51	801.82	
Return on equity (ROE)	(%) 0.7	28.2	27.5		1.3		
Ratio of ordinary income to total assets	(%) 0.8	(0.5)	(1.3)		4.9		
Ratio of operating income to net sales	(%) 5.5	(7.7)	(13.2)		7.9		
Return on assets (ROA)	(%) 0.5	22.6	22.1		1.1		

② Financial Conditions

(Millions of Yen)	December 31,	March 31,	Change	Change (%)
	2018	2019		
	A	B	B-A	(B-A)/A
Total assets	103,253	148,785	45,532	44.1
Total equity	87,092	115,177	28,084	32.2
Equity ratio	(%) 84.3	77.4	(6.9)	
Book value per share (BPS)	(¥) 3,103.28	4,104.13	1,000.85	

③ Capital Expenditures

(Millions of Yen)	FY2018	FY2019	Change	Change (%)	FY2018	FY2019
	First three months	First three months				
	A	B	B-A	(B-A)/A		
Capital expenditures	165	33	(131)	(79.5)	811	502
PP&E	99	19	(80)	(80.2)	660	292
Intangible assets	65	14	(51)	(78.3)	150	210

④ Depreciation/Amortization

(Millions of Yen)	FY2018	FY2019	Change	Change (%)	FY2018	FY2019
	First three months	First three months				
	A	B	B-A	(B-A)/A		
Depreciation and amortization of intangible assets	249	250	1	0.4	1,040	1,020
Amortization of long-term prepaid expenses	268	121	(147)	(54.9)	965	476

II Financial Results for the First Three Months of FY2019

① Statement of Income

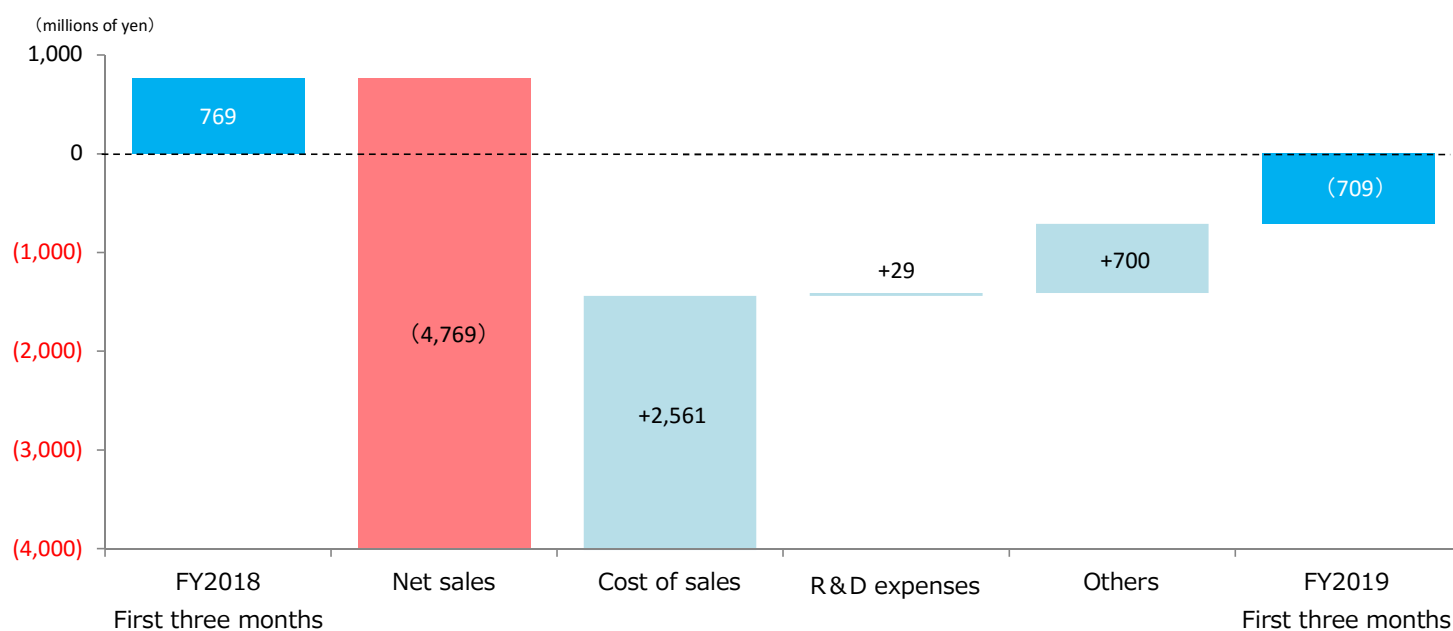
(Millions of Yen)	FY2018	FY2019	Change	Change (%)	FY2019 Full year forecast	Progress ratio (%)
	First three months	First three months				
	A	B				
Net sales	13,930	9,161	(4,769)	(34.2)	38,000	24.1
Sales of products	13,550	8,702	(4,848)	(35.8)	36,170	24.1
Sales of products (Except HIV infection)	9,092	8,702	(390)	(4.3)	36,170	24.1
Renal disease and hemodialysis	5,279	4,113	(1,166)	(22.1)	16,270	25.3
Skin disease	2,018	2,039	21	1.1	8,420	24.2
Allergens	631	1,293	662	105.0	5,670	22.8
Other	1,163	1,255	91	7.9	5,810	21.6
HIV infection	4,457	–	(4,457)	(100.0)	–	–
Other sales	380	458	78	20.6	1,830	25.1
Cost of sales	6,954	4,392	(2,561)	(36.8)	19,400	22.6
Cost of products sold	6,941	4,379	(2,561)	(36.9)		
Other cost	13	13	0	1.8		
Gross profit	6,976	4,768	(2,208)	(31.7)	18,600	25.6
Selling, general and administrative expenses	6,206	5,477	(729)	(11.8)	21,800	25.1
R&D expenses	1,016	986	(29)	(2.9)	3,300	29.9
Others	5,190	4,490	(700)	(13.5)	18,500	24.3
Operating income or loss	769	(709)	(1,478)	–	(3,200)	22.2
Non-operating income and expenses	20	52	32	–		
Ordinary income or loss	790	(656)	(1,446)	–	(3,100)	21.2
Extraordinary income and loss	(0)	40,603	40,604	–		
Income before income taxes	789	39,947	39,157	–		
Income taxes	220	11,424	11,204	–		
Net income	569	28,522	27,953	–	22,500	126.8

(Reference) Ratio to net sales

(%)	FY2018	FY2019	Change
	First three months	First three months	
	A	B	
Cost of sales	49.9	48.0	(1.9)
SG&A	44.6	59.7	15.1
R&D expenses	7.3	10.8	3.5
Operating income or loss	5.5	(7.7)	(13.2)
Ordinary income or loss	5.7	(7.2)	(12.9)
Net income	4.1	311.3	307.2

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

Operating loss (¥709 million : Decrease ¥1,478 million year-on-year)



Major factors in increase/decrease

Net sales	: Decrease with the termination of the exclusive rights to market the six anti-HIV drugs in Japan and generic drugs(REMITCH) Increase with the expansion of the products of Allergens ※For sales of products, please refer to the next page
Cost of sales	: Decrease in net sales
Others	: Decrease in sales promotion expenses

Ordinary loss (¥656 million : Decrease ¥1,446 million year-on-year)

Special remarks: None

Net income (¥28,522 million : Increase ¥27,953 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

(Millions of Yen)	FY2018		FY2019		Change B-A	Change (%) (B-A)/A
	First three months		First three months			
	A		B			
Sales of Products	13,550		8,702		(4,848)	(35.8)
Sales of products(Except HIV infection)	9,092		8,702		(390)	(4.3)
[Renal disease and hemodialysis]						
REMITCH	3,005		1,910		(1,094)	(36.4)
Oral anti-pruritus agent						
Riona	1,359		1,422		62	4.6
Agent for hyperphosphatemia						
KAYEXALATE ※1	434		439		5	1.3
Agent for hyperkalemia						
FUTHAN ※1	314		206		(108)	(34.4)
Protease inhibitor						
Others	165		133		(31)	(19.1)
Total	5,279		4,113		(1,166)	(22.1)
[Skin disease]						
ANTEBATE ※1	1,296		1,260		(36)	(2.8)
Topical corticosteroid						
LOCOID ※1	348		397		48	14.0
Topical corticosteroid						
ZEFNART	241		256		15	6.5
Topical antifungal agent						
Others	131		125		(6)	(5.2)
Total	2,018		2,039		21	1.1
[Allergens]						
CEDARTOLEN ※1	394		489		95	24.2
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※1	151		476		325	214.9
House dust mite allergy (Allergen Immunotherapy)						
CEDARCURE ※1, 2	–		247		247	–
Japanese cedar pollinosis (Allergen Immunotherapy)						
Others	85		79		(5)	(6.8)
Total	631		1,293		662	105.0
[Other]						
BIO-THREE	573		626		53	9.3
Viable bacterial preparations						
Others	589		628		38	6.5
Total	1,163		1,255		91	7.9
HIV infection	4,457		–		(4,457)	(100.0)

※1 In-house products

※2 Launched in June 2018

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2018		FY2019		Change B-A	Change (%) (B-A)/A
	First three months		First three months			
	A		B			
Sales of in-house products	3,433		4,034		600	17.5
Ratio of in-house product sales (%)	25.3		46.4		21.1	–

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	
Renal disease and hemodialysis								
JTT-751 [Riona® Tablets]	Iron-deficiency anemia	Oral			Phase III			<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.
JTZ-951	Anemia associated with chronic kidney disease	Oral			Phase III			<ul style="list-style-type: none"> ·JT's original compound ·Licensing agreement signed with JT for development and commercialization
Skin disease								
JTE-052	Atopic dermatitis	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 January, 2019
	Atopic dermatitis in children	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

(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 FY2019

The forecasts for the FY2019 have not been changed from the previous forecasts announced at the FY2018 financial results announcement on February 6, 2019.

① Statement of Income

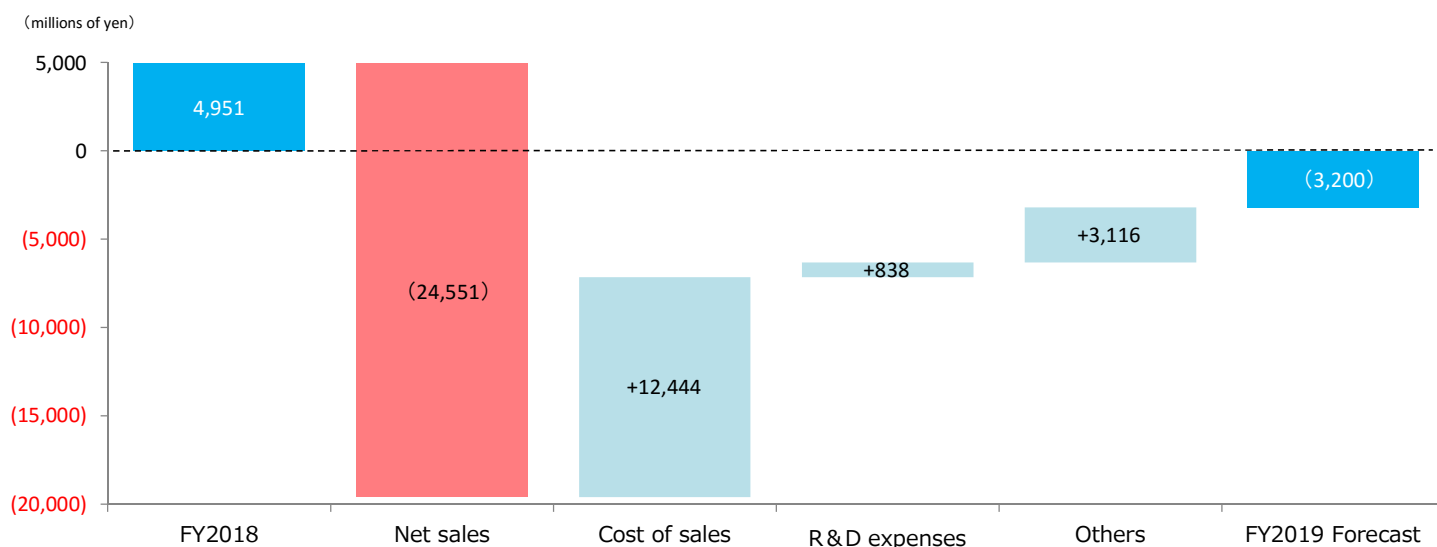
<i>(Millions of Yen)</i>	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Net sales	62,551	38,000	(24,551)	(39.2)
Sales of products	61,835	36,170	(25,665)	(41.5)
Sales of products (Except HIV infection)	40,386	36,170	(4,216)	(10.4)
Renal disease and hemodialysis	21,991	16,270	(5,721)	(26.0)
Skin disease	9,126	8,420	(706)	(7.7)
Allergens	3,803	5,670	1,866	49.1
Other	5,464	5,810	345	6.3
HIV infection	21,448	–	(21,448)	(100.0)
Other sales	716	1,830	1,113	155.5
Cost of sales	31,844	19,400	(12,444)	(39.1)
Gross profit	30,707	18,600	(12,107)	(39.4)
SG&A	25,755	21,800	(3,955)	(15.4)
R&D expenses	4,138	3,300	(838)	(20.3)
Others	21,616	18,500	(3,116)	(14.4)
Operating income or loss	4,951	(3,200)	(8,151)	–
Ordinary income or loss	5,080	(3,100)	(8,180)	–
Net income	1,164	22,500	21,335	–

(Reference) Ratio to net sales

<i>(%)</i>	FY2018	FY2019 forecast	Change
	A	B	B-A
Cost of sales	50.9	51.1	0.2
SG&A	41.2	57.3	16.1
R&D expenses	6.6	8.7	2.1
Operating income or loss	7.9	(8.4)	(16.3)
Ordinary income or loss	8.1	(8.2)	(16.3)
Net income	1.9	59.2	57.3

[Factors in increase/decrease compared with the FY2018]

Operating loss (¥3,200 million : Decrease ¥8,151 million year-on-year)



Major factors in increase/decrease

Net sales	: Decrease with the termination of the exclusive rights to market the six anti-HIV drugs in Japan and generic drugs(REMITCH) ※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 (JTS-661, JTE-052)
Others	: Decrease in sales promotion expenses and personnel expenses by business structure reform

Ordinary loss (¥3,100 million : Decrease ¥8,180 million year-on-year)

Special remarks: None

Net income (¥22,500 million : Increase ¥21,335 million year-on-year)

FY2018: Business structure reform expenses (Impairment loss)	¥	2,021 million
Reversal of deferred tax assets	¥	467 million
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)	¥	5,200 million

② Sales of Products

<i>(Millions of Yen)</i>	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	61,835	36,170	(25,665)	(41.5)
Sales of products(Except HIV infection)	40,386	36,170	(4,216)	(10.4)
[Renal disease and hemodialysis]				
Riona Agent for hyperphosphatemia	6,603	7,150	546	8.3
REMITCH Oral anti-pruritus agent	11,598	6,450	(5,148)	(44.4)
KAYEXALATE ※1 Agent for hyperkalemia	1,963	1,930	(33)	(1.7)
FUTHAN ※1 Protease inhibitor	1,138	190	(948)	(83.3)
Others	688	550	(138)	(20.1)
Total	21,991	16,270	(5,721)	(26.0)
[Skin disease]				
ANTEBATE ※1 Topical corticosteroid	5,536	4,890	(646)	(11.7)
LOCOID ※1 Topical corticosteroid	1,541	1,570	28	1.8
ZEFNART Topical antifungal agent	1,454	1,450	(4)	(0.3)
Others	593	510	(83)	(14.1)
Total	9,126	8,420	(706)	(7.7)
[Allergens]				
CEDARCURE ※1、2 Japanese cedar pollinosis (Allergen Immunotherapy)	405	2,750	2,344	578.6
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	1,247	1,760	512	41.1
CEDARTOLEN ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	1,859	850	(1,009)	(54.3)
Others	291	310	18	6.4
Total	3,803	5,670	1,866	49.1
[Other]				
BIO-THREE Viable bacterial preparations	2,682	2,840	157	5.9
Others	2,782	2,970	187	6.7
Total	5,464	5,810	345	6.3
HIV infection	21,448	—	(21,448)	(100.0)

※1 In-house products

※2 Launched in June 2018

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	15,855	16,350	494	3.1
Ratio of in-house product sales (%)	25.6	45.2	19.6	—