

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

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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, 2019



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

The forecasts for the FY2019 have 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 Full year	FY2019 revised forecast	Progress ratio (%)
	First six months	First six months	Change	Change (%)					
	A	B	B-A	(B-A)/A			C	B/C	
Net sales	30,551	20,684	(9,866)	(32.3)			62,551	40,800	50.7
Operating income or loss	2,109	290	(1,818)	(86.2)			4,951	(700)	-
Ordinary income or loss	2,162	402	(1,759)	(81.4)			5,080	(400)	-
Net income	1,548	26,194	24,645	-			1,164	24,700	106.1
(Reference)									
R&D expenses	2,054	1,834	(220)	(10.7)			4,138	3,200	57.3
Earnings per share (EPS)	(¥)	55.22	933.34	878.12			41.51	880.07	
Return on equity (ROE)	(%)	1.8	26.2	24.4			1.3		
Ratio of ordinary income to total assets	(%)	2.1	0.3	(1.8)			4.9		
Ratio of operating income to net sales	(%)	6.9	1.4	(5.5)			7.9		
Return on assets (ROA)	(%)	1.5	20.8	19.3			1.1		

② Financial Conditions

(Millions of Yen)	December 31,		June 30,		Change	Change (%)
	2018	2019	Change	Change (%)		
	A	B	B-A	(B-A)/A		
Total assets	103,253	148,583	45,329	43.9		
Total equity	87,092	112,852	25,759	29.6		
Equity ratio	(%)	84.3	75.9	(8.4)		
Book value per share (BPS)	(¥)	3,103.28	4,019.48	916.20		

③ Statement of Cash Flows

(Millions of Yen)	FY2018		FY2019		Change
	First six months	First six months	Change	Change (%)	
	A	B	B-A	(B-A)/A	
Net cash provided by operating activities	3,077	48,865	45,787		
Net cash provided by investing activities	(13,254)	1,705	14,959		
Net cash used in financing activities	(716)	(716)	(0)		
Cash and cash equivalents, end of period	25,003	65,508	40,504		

④ Capital Expenditures

(Millions of Yen)	FY2018		FY2019		Change	Change (%)	FY2018 Full year	FY2019 revised forecast
	First six months	First six months	Change	Change (%)				
	A	B	B-A	(B-A)/A				
Capital expenditures	372	107	(265)	(71.3)			811	476
PP&E	282	80	(201)	(71.6)			660	185
Intangible assets	90	26	(63)	(70.4)			150	291

⑤ Depreciation/Amortization

(Millions of Yen)	FY2018		FY2019		Change	Change (%)	FY2018 Full year	FY2019 revised forecast
	First six months	First six months	Change	Change (%)				
	A	B	B-A	(B-A)/A				
Depreciation and amortization of intangible assets	506	497	(8)	(1.7)			1,040	1,004
Amortization of long-term prepaid expenses	535	241	(294)	(54.9)			965	479

II Financial Results for the First Six Months of FY2019

① Statement of Income

<i>(Millions of Yen)</i>	FY2018	FY2019	Change	Change (%)	FY2019 revised forecast	Progress ratio
	First six months	First six months				
	A	B	B-A	(B-A)/A	C	(%) B/C
Net sales	30,551	20,684	(9,866)	(32.3)	40,800	50.7
Sales of products	30,033	19,280	(10,752)	(35.8)	38,560	50.0
Sales of products (Except HIV infection)	20,072	19,280	(791)	(3.9)	38,560	50.0
Renal disease and hemodialysis	11,665	8,965	(2,700)	(23.1)	18,060	49.6
Skin disease	4,519	4,562	42	0.9	8,420	54.2
Allergens	1,348	2,942	1,594	118.3	6,320	46.6
Other	2,538	2,809	271	10.7	5,760	48.8
HIV infection	9,961	–	(9,961)	(100.0)	–	–
Other sales	518	1,404	886	171.1	2,240	62.7
Cost of sales	15,836	9,784	(6,051)	(38.2)	19,800	49.4
Cost of products sold	15,809	9,705	(6,104)	(38.6)		
Other cost	26	79	52	198.5		
Gross profit	14,715	10,900	(3,814)	(25.9)	21,000	51.9
Selling, general and administrative expenses	12,605	10,609	(1,996)	(15.8)	21,700	48.9
R&D expenses	2,054	1,834	(220)	(10.7)	3,200	57.3
Others	10,550	8,775	(1,775)	(16.8)	18,500	47.4
Operating income or loss	2,109	290	(1,818)	(86.2)	(700)	–
Non-operating income and expenses	52	111	59			
Ordinary income or loss	2,162	402	(1,759)	(81.4)	(400)	–
Extraordinary income and loss	(28)	36,387	36,416			
Income before income taxes	2,133	36,790	34,657	–		
Income taxes	584	10,595	10,011			
Net income	1,548	26,194	24,645	–	24,700	106.1

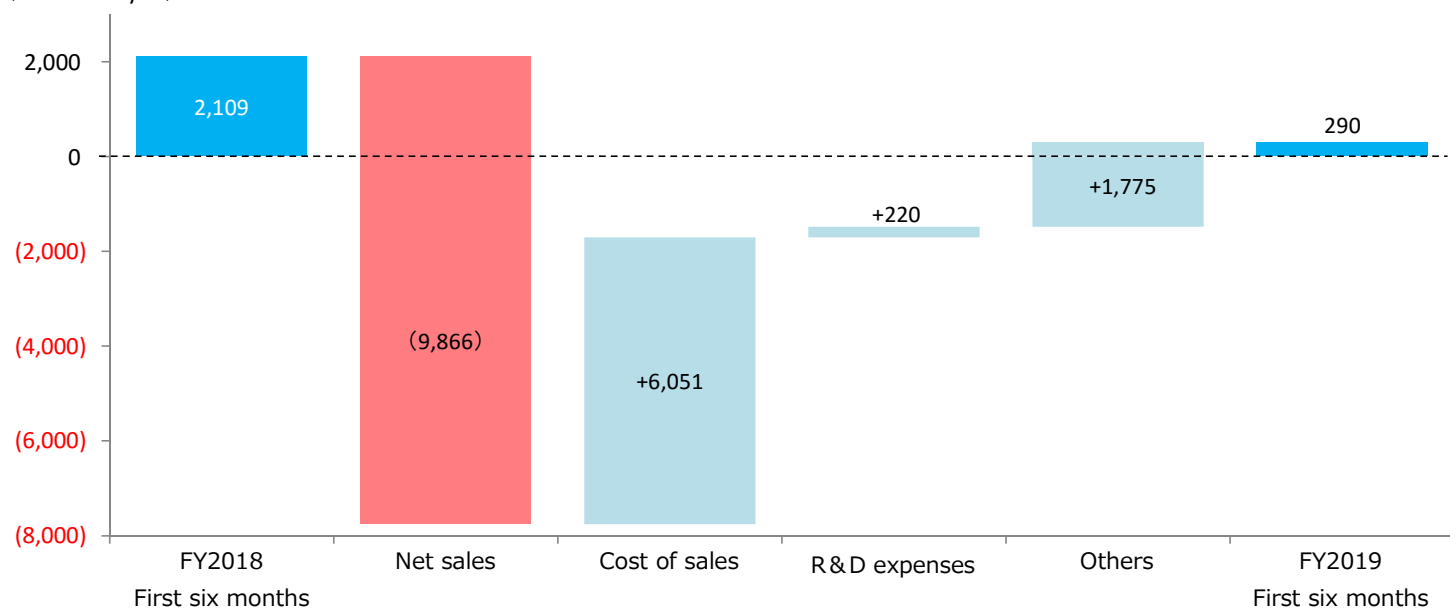
(Reference) Ratio to net sales

<i>(%)</i>	FY2018	FY2019	Change
	First six months	First six months	
	A	B	B-A
Cost of sales	51.8	47.3	(4.5)
SG&A	41.3	51.3	10.0
R&D expenses	6.7	8.9	2.2
Operating income	6.9	1.4	(5.5)
Ordinary income	7.1	1.9	(5.2)
Net income	5.1	126.6	121.5

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

Operating income (¥290 million : Decrease ¥1,818 million year-on-year)

(millions of yen)



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 and the six anti-HIV drugs distribution fee income ※For sales of products, please refer to the next page
Cost of sales	: Decrease in net sales
Others	: Decrease with sales promotion expenses and provision of bonuses by business structure reform

Ordinary income (¥402 million : Decrease ¥1,759 million year-on-year)

Special remarks: None

Net income (¥26,194 million : Increase ¥24,645 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

② Sales of Products

<i>(Millions of Yen)</i>	FY2018		FY2019		Change B-A	Change (%) (B-A)/A
	First six months		First six months			
	A		B			
Sales of Products	30,033		19,280		(10,752)	(35.8)
Sales of products(Except HIV infection)	20,072		19,280		(791)	(3.9)
[Renal disease and hemodialysis]						
REMITCH	6,687		4,334		(2,352)	(35.2)
Oral anti-pruritus agent						
Riona	3,092		3,190		97	3.2
Agent for hyperphosphatemia						
KAYEXALATE ※	946		948		1	0.1
Agent for hyperkalemia						
Others	939		492		(446)	(47.5)
Total	11,665		8,965		(2,700)	(23.1)
[Skin disease]						
ANTEBATE ※	2,753		2,750		(2)	(0.1)
Topical corticosteroid						
LOCOID ※	780		858		78	10.0
Topical corticosteroid						
ZEFNART	680		678		(2)	(0.3)
Topical antifungal agent						
Others	304		274		(30)	(10.0)
Total	4,519		4,562		42	0.9
[Allergens]						
MITICURE ※	386		1,089		703	181.9
House dust mite allergy (Allergen Immunotherapy)						
CEDARCURE ※	17		952		935	—
Japanese cedar pollinosis (Allergen Immunotherapy)						
CEDARTOLEN ※	780		752		(28)	(3.6)
Japanese cedar pollinosis (Allergen Immunotherapy)						
Others	164		148		(15)	(9.6)
Total	1,348		2,942		1,594	118.3
[Other]						
BIO-THREE	1,252		1,343		90	7.3
Viable bacterial preparations						
Others	1,286		1,466		180	14.0
Total	2,538		2,809		271	10.7
HIV infection	9,961		—		(9,961)	(100.0)

※ In-house products

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2018		FY2019		Change B-A	Change (%) (B-A)/A
	First six months		First six months			
	A		B			
Sales of in-house products	7,315		8,768		1,453	19.9
Ratio of in-house product sales (%)	24.4		45.5		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

Updates since the previous announcement on April 25, 2019 :
None

(Reference)

In July 2019, Torii and JT announced the top-line results of the pivotal Phase III comparative study in adult patients with iron deficiency anemia (IDA) in Japan for Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate, development code: JTT-751, hereinafter Riona®). The top-line results show that the study met the primary endpoint by establishing non-inferiority of Riona® compared with a control drug in the changes. Furthermore, Riona® showed a favorable tolerability profile on safety within the treatment period. Regarding the safety endpoint, the incidence rates of nausea / vomiting (adverse events) were 13.0% / 3.2% (Riona®) and 32.7% / 15.2% (control drug), respectively.

And in July 2019, Torii and JT announced the top-line results of two pivotal Phase III comparative studies in anemic patients with non-dialysis dependent chronic kidney disease (NDD-CKD) (MBA4-4 study) or hemodialysis dependent CKD (HDD-CKD) on erythropoiesis stimulating agent (ESA) therapy (MBA4-5 study) for JTZ-951 (generic name: enarodustat), an hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor. The top-line results show that the differences achieved the non-inferiority criterion and both studies met the primary endpoints. Furthermore, the favorable tolerability profile on safety of JTZ-951 was obtained during the studies.

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 been changed from the previous forecasts announced at the FY2018 financial results announcement on February 6, 2019.

① Statement of Income

(Millions of Yen)	FY2019	FY2019	Change	FY2018	Change	Change (%)
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Net sales	38,000	40,800	2,800	62,551	(21,751)	(34.8)
Sales of products	36,170	38,560	2,390	61,835	(23,275)	(37.6)
Sales of products (Except HIV infection)	36,170	38,560	2,390	40,386	(1,826)	(4.5)
Renal disease and hemodialysis	16,270	18,060	1,790	21,991	(3,931)	(17.9)
Skin disease	8,420	8,420	–	9,126	(706)	(7.7)
Allergens	5,670	6,320	650	3,803	2,516	66.2
Other	5,810	5,760	(50)	5,464	295	5.4
HIV infection	–	–	–	21,448	(21,448)	(100.0)
Other sales	1,830	2,240	410	716	1,523	212.7
Cost of sales	19,400	19,800	400	31,844	(12,044)	(37.8)
Gross profit	18,600	21,000	2,400	30,707	(9,707)	(31.6)
SG&A	21,800	21,700	(100)	25,755	(4,055)	(15.7)
R&D expenses	3,300	3,200	(100)	4,138	(938)	(22.7)
Others	18,500	18,500	–	21,616	(3,116)	(14.4)
Operating income or loss	(3,200)	(700)	2,500	4,951	(5,651)	–
Ordinary income or loss	(3,100)	(400)	2,700	5,080	(5,480)	–
Net income	22,500	24,700	2,200	1,164	23,535	–

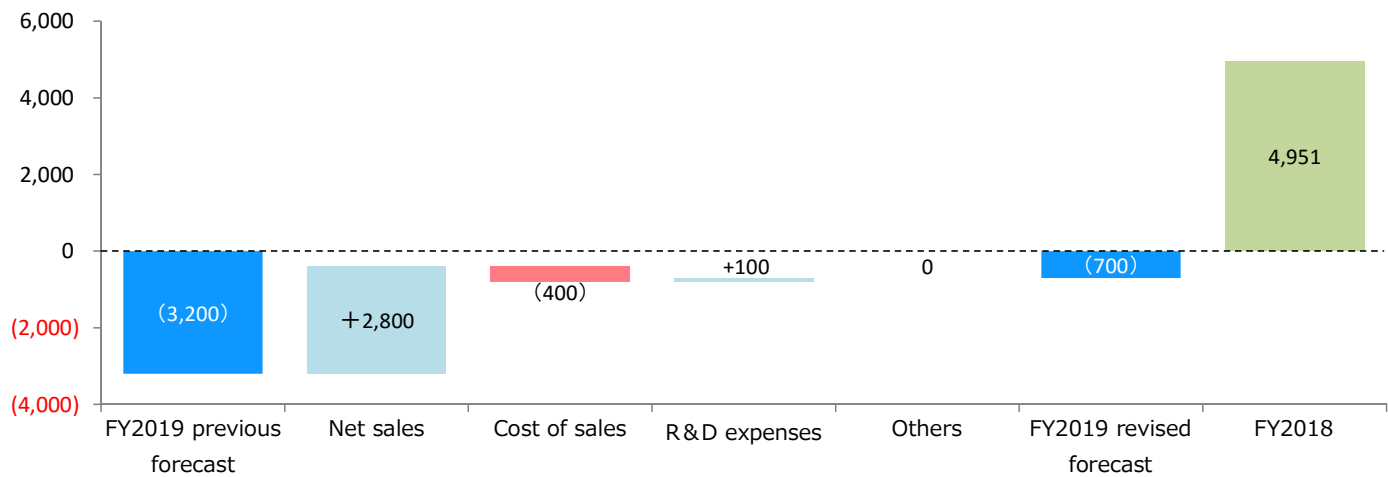
(Reference) Ratio to net sales

(%)	FY2019	FY2019	Change	FY2018	Change
	previous forecast	revised forecast			
	A	B	B-A	C	B-C
Cost of sales	51.1	48.5	(2.6)	50.9	(2.4)
SG&A	57.3	53.2	(4.1)	41.2	12.0
R&D expenses	8.7	7.8	(0.9)	6.6	1.2
Operating income or loss	(8.4)	(1.7)	6.7	7.9	(9.6)
Ordinary income or loss	(8.2)	(1.0)	7.2	8.1	(9.1)
Net income	59.2	60.5	1.3	1.9	58.6

[Factors in increase/decrease compared with the previous forecast for the FY2019]

Operating loss (¥700 million : Decrease ¥2,500 million)

(millions of yen)



Major factors in increase/decrease

Net sales : Increase with the reduced impact of generic drugs of REMITCH and the expansion of MITICURE
 ※For sales of products, please refer to the next page
 Cost of sales : Increase with increase in net sales
 and changes in sales mix

Ordinary loss (¥400 million : Decrease ¥2,700 million)

Special remarks: None

Net income (¥24,700 million : Increase ¥2,200 million)

Special remarks: None

② Sales of Products

(Millions of Yen)	FY2019 previous forecast A	FY2019 revised forecast B	Change B-A	FY2018 C	Change B-C	Change (%) (B-C)/C
Sales of Products	36,170	38,560	2,390	61,835	(23,275)	(37.6)
Sales of products(Except HIV infection)	36,170	38,560	2,390	40,386	(1,826)	(4.5)
[Renal disease and hemodialysis]						
REMITCH	6,450	8,230	1,780	11,598	(3,368)	(29.0)
Oral anti-pruritus agent						
Riona	7,150	7,150	–	6,603	546	8.3
Agent for hyperphosphatemia						
KAYEXALATE ※	1,930	1,930	–	1,963	(33)	(1.7)
Agent for hyperkalemia						
Others	740	750	10	1,826	(1,076)	(58.9)
Total	16,270	18,060	1,790	21,991	(3,931)	(17.9)
[Skin disease]						
ANTEBATE ※	4,890	4,890	–	5,536	(646)	(11.7)
Topical corticosteroid						
LOCOID ※	1,570	1,570	–	1,541	28	1.8
Topical corticosteroid						
ZEFNART	1,450	1,450	–	1,454	(4)	(0.3)
Topical antifungal agent						
Others	510	510	–	593	(83)	(14.1)
Total	8,420	8,420	–	9,126	(706)	(7.7)
[Allergens]						
CEDARCURE ※	2,750	2,420	(330)	405	2,014	497.1
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※	1,760	2,350	590	1,247	1,102	88.4
House dust mite allergy (Allergen Immunotherapy)						
CEDARTOLEN ※	850	1,250	400	1,859	(609)	(32.8)
Japanese cedar pollinosis (Allergen Immunotherapy)						
Others	310	300	(10)	291	8	3.0
Total	5,670	6,320	650	3,803	2,516	66.2
[Other]						
BIO-THREE	2,840	2,840	–	2,682	157	5.9
Viable bacterial preparations						
Others	2,970	2,920	(50)	2,782	137	4.9
Total	5,810	5,760	(50)	5,464	295	5.4
HIV infection	–	–	–	21,448	(21,448)	(100.0)

※ In-house products

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2019 previous forecast A	FY2019 revised forecast B	Change B-A	FY2018 C	Change B-C	Change (%) (B-C)/C
Sales of in-house products	16,350	16,960	610	15,855	1,104	7.0
Ratio of in-house product sales (%)	45.2	44.0	(1.2)	25.6	18.4	–