

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

<u>I Summary Information</u>	P.1
① Financial Results	P.1
② Financial Conditions	P.1
③ Capital Expenditures	P.1
④ Depreciation/Amortization	P.1
<u>II Financial Results for the First Nine Months of FY2019</u>	P.2
① Statement of Income	P.2
② Sales of Products	P.4
③ Research and Development	P.5
<u>III Financial Forecasts for the FY2019</u>	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.

October 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 first six months of FY2019 financial results announcement on July 31, 2019.

(Millions of Yen)	FY2018 First nine months A	FY2019 First nine months B	Change B-A	Change (%) (B-A)/A	FY2018 Full year	FY2019 revised forecast C	Progress ratio (%) B/C
Net sales	45,543	31,320	(14,223)	(31.2)	62,551	42,700	73.4
Operating income or loss	3,044	662	(2,381)	(78.2)	4,951	700	94.6
Ordinary income or loss	3,134	839	(2,294)	(73.2)	5,080	1,000	84.0
Net income	2,248	26,466	24,218	-	1,164	25,700	103.0
(Reference)							
R&D expenses	3,101	2,588	(513)	(16.5)	4,138	3,000	86.3
Earnings per share (EPS)	(¥) 80.14	942.93	862.79		41.51	915.62	
Return on equity (ROE)	(%) 2.6	26.5	23.9		1.3		
Ratio of ordinary income to total assets	(%) 3.0	0.7	(2.3)		4.9		
Ratio of operating income to net sales	(%) 6.7	2.1	(4.6)		7.9		
Return on assets (ROA)	(%) 2.1	21.1	19.0		1.1		

② Financial Conditions

(Millions of Yen)	December 31, 2018 A	September 30, 2019 B	Change B-A	Change (%) (B-A)/A
Total assets	103,253	147,236	43,982	42.6
Total equity	87,092	112,472	25,379	29.1
Equity ratio	(%) 84.3	76.4	(7.9)	
Book value per share (BPS)	(¥) 3,103.28	4,005.94	902.66	

③ Capital Expenditures

(Millions of Yen)	FY2018 First nine months A	FY2019 First nine months B	Change B-A	Change (%) (B-A)/A	FY2018 Full year	FY2019 revised forecast
Capital expenditures	485	178	(307)	(63.3)	811	442
PP&E	353	107	(246)	(69.6)	660	189
Intangible assets	132	71	(60)	(46.1)	150	253

④ Depreciation/Amortization

(Millions of Yen)	FY2018 First nine months A	FY2019 First nine months B	Change B-A	Change (%) (B-A)/A	FY2018 Full year	FY2019 revised forecast
Depreciation and amortization of intangible assets	769	746	(22)	(3.0)	1,040	1,001
Amortization of long-term prepaid expenses	761	365	(395)	(52.0)	965	480

II Financial Results for the First Nine Months of FY2019

① Statement of Income

(Millions of Yen)	FY2018	FY2019	Change	Change (%)	FY2019 revised forecast	Progress ratio (%)
	First nine months	First nine months				
	A	B	B-A	(B-A)/A	C	B/C
Net sales	45,543	31,320	(14,223)	(31.2)	42,700	73.4
Sales of products	44,921	29,501	(15,420)	(34.3)	40,400	73.0
Sales of products (Except HIV infection)	29,627	29,501	(126)	(0.4)	40,400	73.0
Renal disease and hemodialysis	16,579	13,324	(3,255)	(19.6)	18,160	73.4
Skin disease	6,744	6,757	12	0.2	8,930	75.7
Allergens	2,374	5,056	2,681	112.9	7,360	68.7
Other	3,928	4,362	434	11.1	5,950	73.3
HIV infection	15,293	–	(15,293)	(100.0)	–	–
Other sales	622	1,819	1,197	192.3	2,300	79.1
Cost of sales	23,547	14,845	(8,702)	(37.0)	20,800	71.4
Cost of products sold	23,507	14,751	(8,756)	(37.2)		
Other cost	40	93	53	133.9		
Gross profit	21,996	16,475	(5,520)	(25.1)	21,900	75.2
Selling, general and administrative expenses	18,952	15,812	(3,139)	(16.6)	21,200	74.6
R&D expenses	3,101	2,588	(513)	(16.5)	3,000	86.3
Others	15,850	13,224	(2,625)	(16.6)	18,200	72.7
Operating income	3,044	662	(2,381)	(78.2)	700	94.6
Non-operating income and expenses	90	177	87			
Ordinary income	3,134	839	(2,294)	(73.2)	1,000	84.0
Extraordinary income and loss	(24)	36,332	36,356			
Income before income taxes	3,109	37,172	34,062	–		
Income taxes	861	10,705	9,844			
Net income	2,248	26,466	24,218	–	25,700	103.0

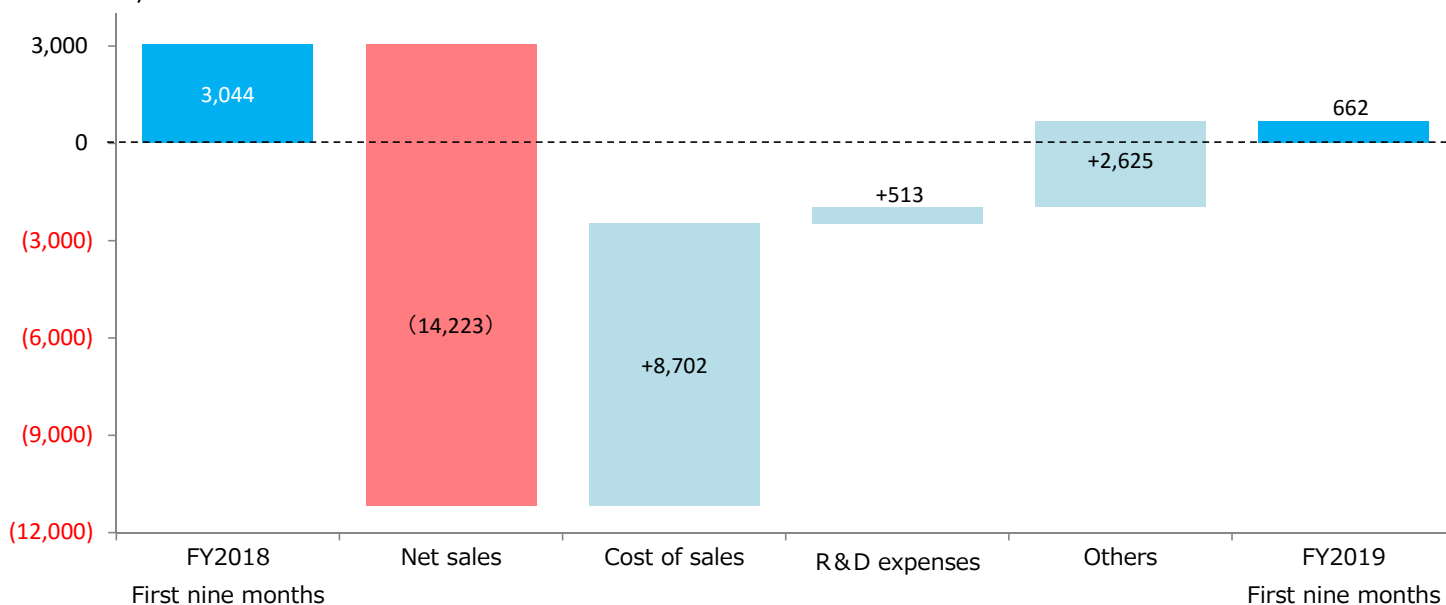
(Reference) Ratio to net sales

(%)	FY2018	FY2019	Change
	First nine months	First nine months	
	A	B	B-A
Cost of sales	51.7	47.4	(4.3)
SG&A	41.6	50.5	8.9
R&D expenses	6.8	8.3	1.5
Operating income	6.7	2.1	(4.6)
Ordinary income	6.9	2.7	(4.2)
Net income	4.9	84.5	79.6

【Factors in increase/decrease compared with the same term of the last fiscal year】

Operating income (¥662 million : Decrease ¥2,381 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
R&D expenses	: Decrease in co-development expenses (JTS-661)
Others	: Decrease with sales promotion expenses and provision of bonuses by business structure reform

Ordinary income (¥839 million : Decrease ¥2,294 million year-on-year)

Special remarks: None

Net income (¥26,466 million : Increase ¥24,218 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

② Sales of Products

<i>(Millions of Yen)</i>	FY2018	FY2019	Change	Change (%)
	First nine months	First nine months		
	A	B		
Sales of Products	44,921	29,501	(15,420)	(34.3)
Sales of products(Except HIV infection)	29,627	29,501	(126)	(0.4)
[Renal disease and hemodialysis]				
REMITCH	9,043	6,447	(2,596)	(28.7)
Oral anti-pruritus agent				
Riona	4,754	4,845	90	1.9
Agent for hyperphosphatemia				
KAYEXALATE ※	1,430	1,406	(23)	(1.6)
Agent for hyperkalemia				
Others	1,350	624	(726)	(53.8)
Total	16,579	13,324	(3,255)	(19.6)
[Skin disease]				
ANTEBATE ※	4,057	4,039	(17)	(0.4)
Topical corticosteroid				
LOCOID ※	1,133	1,224	90	8.0
Topical corticosteroid				
ZEFNART	1,117	1,104	(12)	(1.1)
Topical antifungal agent				
Others	436	388	(47)	(10.9)
Total	6,744	6,757	12	0.2
[Allergens]				
CEDARCURE ※	142	2,180	2,038	—
Japanese cedar pollinosis (Allergen Immunotherapy)				
MITICURE ※	741	1,816	1,075	145.1
House dust mite allergy (Allergen Immunotherapy)				
CEDARTOLEN ※	1,260	840	(420)	(33.3)
Japanese cedar pollinosis (Allergen Immunotherapy)				
Others	231	218	(12)	(5.3)
Total	2,374	5,056	2,681	112.9
[Other]				
BIO-THREE	1,923	2,064	140	7.3
Viable bacterial preparations				
Others	2,004	2,298	294	14.7
Total	3,928	4,362	434	11.1
HIV infection	15,293	—	(15,293)	(100.0)

※ In-house products

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2018	FY2019	Change	Change (%)
	First nine months	First nine months		
	A	B		
Sales of in-house products	11,176	13,595	2,418	21.6
Ratio of in-house product sales (%)	24.9	46.1	21.2	—

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 July 31, 2019 :
None

(Reference)

In July 2019, Torii Pharmaceutical Co., Ltd. (Torii) and Japan Tobacco Inc. (JT) announced the top-line results of the pivotal Phase 3 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 3 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 first six months of FY2019 financial results announcement on July 31, 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	40,800	42,700	1,900	62,551	(19,851)	(31.7)
Sales of products	38,560	40,400	1,840	61,835	(21,435)	(34.7)
Sales of products (Except HIV infection)	38,560	40,400	1,840	40,386	13	0.0
Renal disease and hemodialysis	18,060	18,160	100	21,991	(3,831)	(17.4)
Skin disease	8,420	8,930	510	9,126	(196)	(2.2)
Allergens	6,320	7,360	1,040	3,803	3,556	93.5
Other	5,760	5,950	190	5,464	485	8.9
HIV infection	–	–	–	21,448	(21,448)	(100.0)
Other sales	2,240	2,300	60	716	1,583	221.1
Cost of sales	19,800	20,800	1,000	31,844	(11,044)	(34.7)
Gross profit	21,000	21,900	900	30,707	(8,807)	(28.7)
SG&A	21,700	21,200	(500)	25,755	(4,555)	(17.7)
R&D expenses	3,200	3,000	(200)	4,138	(1,138)	(27.5)
Others	18,500	18,200	(300)	21,616	(3,416)	(15.8)
Operating income or loss	(700)	700	1,400	4,951	(4,251)	(85.9)
Ordinary income or loss	(400)	1,000	1,400	5,080	(4,080)	(80.3)
Net income	24,700	25,700	1,000	1,164	24,535	–

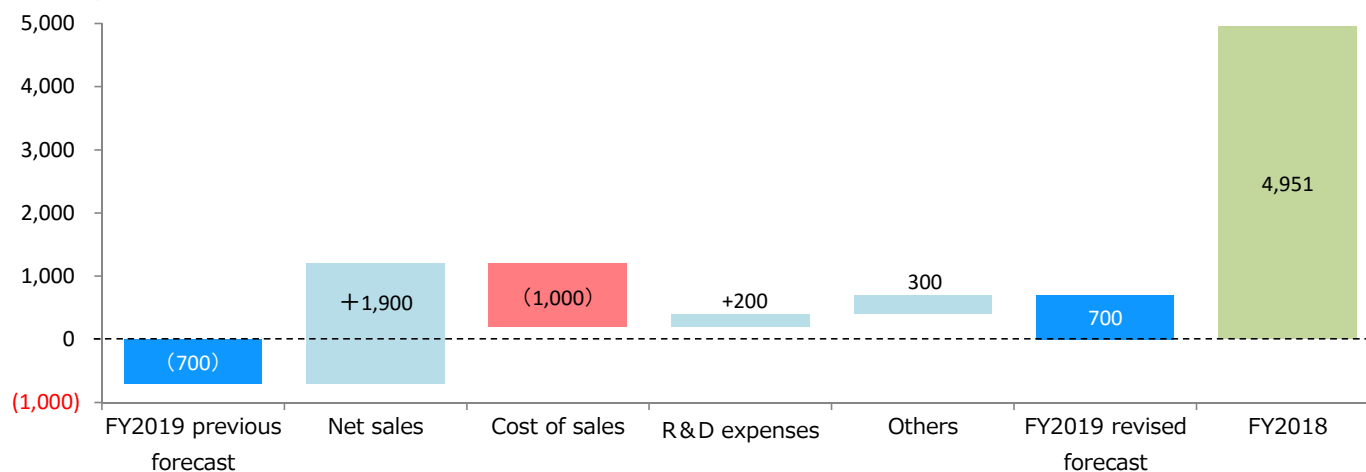
(Reference) Ratio to net sales

(%)	FY2019	FY2019	Change	FY2018	Change
	previous forecast	revised forecast			
	A	B	B-A	C	B-C
Cost of sales	48.5	48.7	0.2	50.9	(2.2)
SG&A	53.2	49.7	(3.5)	41.2	8.5
R&D expenses	7.8	7.0	(0.8)	6.6	0.4
Operating income or loss	(1.7)	1.6	3.3	7.9	(6.3)
Ordinary income or loss	(1.0)	2.3	3.3	8.1	(5.8)
Net income	60.5	60.2	(0.3)	1.9	58.3

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

Operating income (¥ 700 million : Increase ¥ 1,400 million)

(millions of yen)



Major factors in increase/decrease

Net sales : Increase with the expansion of CEDARCURE, MITICURE, and ANTEBATE
 ※For sales of products, please refer to the next page
 Cost of sales : Increase with increase in net sales

Ordinary income (¥ 1,000 million : Increase ¥ 1,400 million)

Special remarks: None

Net income (¥ 25,700 million : Increase ¥ 1,000 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	38,560	40,400	1,840	61,835	(21,435)	(34.7)
Sales of products(Except HIV infection)	38,560	40,400	1,840	40,386	13	0.0
[Renal disease and hemodialysis]						
REMITCH	8,230	8,770	540	11,598	(2,828)	(24.4)
Oral anti-pruritus agent						
Riona	7,150	6,690	(460)	6,603	86	1.3
Agent for hyperphosphatemia						
KAYEXALATE ※	1,930	1,930	–	1,963	(33)	(1.7)
Agent for hyperkalemia						
Others	750	770	20	1,826	(1,056)	(57.8)
Total	18,060	18,160	100	21,991	(3,831)	(17.4)
[Skin disease]						
ANTEBATE ※	4,890	5,350	460	5,536	(186)	(3.4)
Topical corticosteroid						
LOCOID ※	1,570	1,600	30	1,541	58	3.8
Topical corticosteroid						
ZEFNART	1,450	1,440	(10)	1,454	(14)	(1.0)
Topical antifungal agent						
Others	510	540	30	593	(53)	(9.1)
Total	8,420	8,930	510	9,126	(196)	(2.2)
[Allergens]						
CEDARCURE ※	2,420	3,370	950	405	2,964	731.6
Japanese cedar pollinosis (Allergen Immunotherapy)						
MITICURE ※	2,350	2,700	350	1,247	1,452	116.5
House dust mite allergy (Allergen Immunotherapy)						
CEDARTOLEN ※	1,250	990	(260)	1,859	(869)	(46.8)
Japanese cedar pollinosis (Allergen Immunotherapy)						
Others	300	300	–	291	8	3.0
Total	6,320	7,360	1,040	3,803	3,556	93.5
[Other]						
BIO-THREE	2,840	2,840	–	2,682	157	5.9
Viable bacterial preparations						
Others	2,920	3,110	190	2,782	327	11.8
Total	5,760	5,950	190	5,464	485	8.9
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	16,960	18,700	1,740	15,855	2,844	17.9
Ratio of in-house product sales (%)	44.0	46.3	2.3	25.6	20.7	–