

Financial Results for the Fiscal Year 2018, Ended December 31, 2018

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- ※ This material is prepared based on Japan GAAP.
- ※ Amounts are rounded down to the nearest million yen.

February 6, 2019

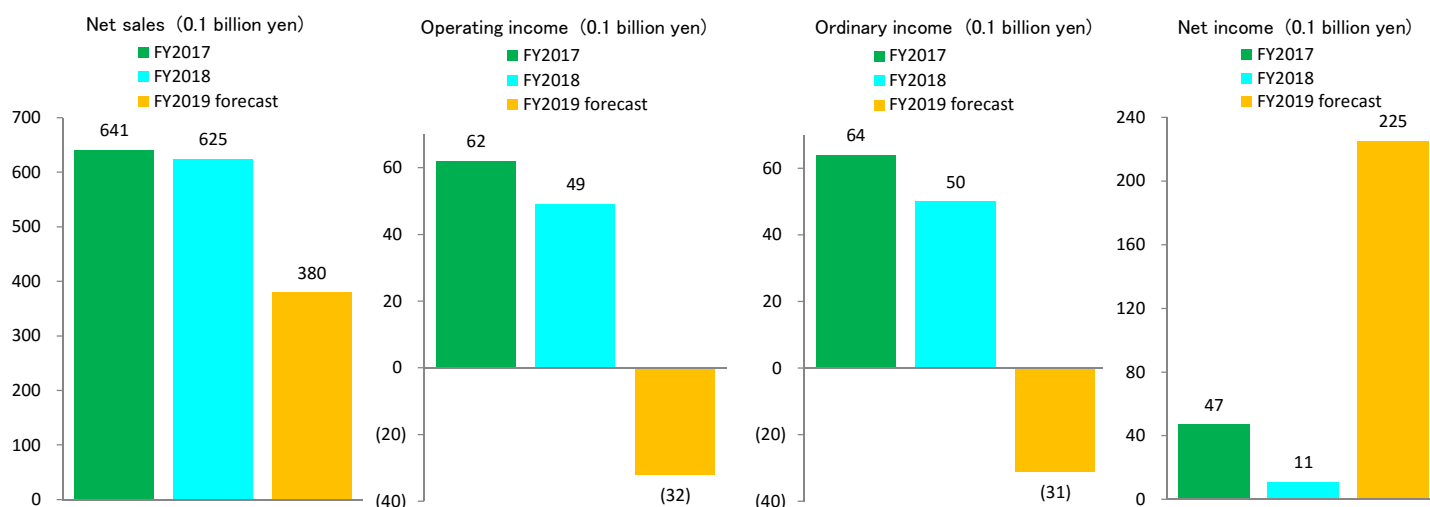


TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

(Millions of Yen)	FY2017	FY2018	Change	Change (%)	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A	C	C-B	(C-B)/B
Net sales	64,135	62,551	(1,583)	(2.5)	38,000	(24,551)	(39.2)
Operating income	6,281	4,951	(1,329)	(21.2)	(3,200)	(8,151)	-
Ordinary income	6,403	5,080	(1,322)	(20.7)	(3,100)	(8,180)	-
Net income	4,718	1,164	(3,553)	(75.3)	22,500	21,335	-
(Reference)							
R&D expenses	4,608	4,138	(470)	(10.2)	3,300	(838)	(20.3)
Earnings per share (EPS) (¥)	168.22	41.51	(126.71)		801.82	760.31	
Return on equity (ROE) (%)	5.5	1.3	(4.2)				
Ratio of ordinary income to total assets (%)	6.3	4.9	(1.4)				
Ratio of operating income to net sales (%)	9.8	7.9	(1.9)				
Return on assets (ROA) (%)	4.6	1.1	(3.5)				



② Financial Conditions

(Millions of Yen)	December 31,		Change	Change (%)
	2017	2018		
	A	B	B-A	(B-A)/A
Total assets	104,741	103,546	(1,195)	(1.1)
Total equity	87,119	87,092	(26)	(0.0)
Equity ratio (%)	83.2	84.1	0.9	
Book value per share (BPS) (¥)	3,105.68	3,103.28	(2.40)	

II Financial Results for the FY2018

① Statement of Income

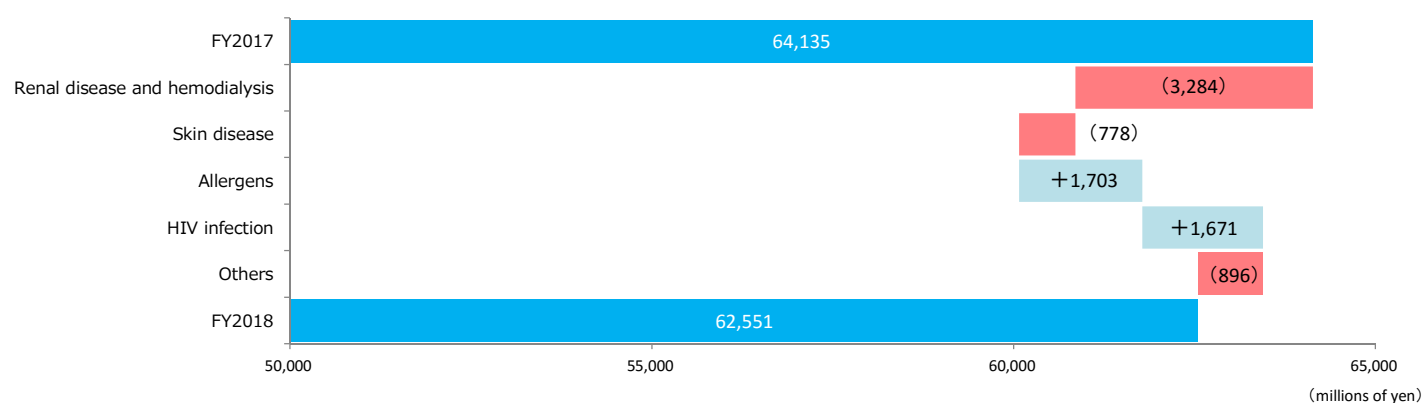
<i>(Millions of Yen)</i>	FY2017	FY2018	Change	Change
	A	B	B-A	(%) (B-A)/A
Net sales	64,135	62,551	(1,583)	(2.5)
Sales of products	62,935	61,835	(1,100)	(1.7)
Renal disease and hemodialysis	25,276	21,991	(3,284)	(13.0)
Skin disease	9,905	9,126	(778)	(7.9)
Allergens	2,099	3,803	1,703	81.2
HIV infection	19,777	21,448	1,671	8.5
Other	5,877	5,464	(412)	(7.0)
Other sales	1,199	716	(483)	(40.3)
Cost of sales	31,293	31,844	550	1.8
Cost of products sold	31,225	31,781	556	1.8
Other cost	68	63	(5)	(8.0)
Gross profit	32,841	30,707	(2,134)	(6.5)
Selling, general and administrative expenses	26,559	25,755	(804)	(3.0)
R&D expenses	4,608	4,138	(470)	(10.2)
Others	21,950	21,616	(333)	(1.5)
Operating income	6,281	4,951	(1,329)	(21.2)
Non-operating income	133	136	2	—
Non-operating expenses	12	7	(4)	—
Ordinary income	6,403	5,080	(1,322)	(20.7)
Extraordinary loss	29	2,049	2,020	—
Income before income taxes	6,373	3,030	(3,343)	(52.5)
Income taxes	1,655	1,865	210	—
Net income	4,718	1,164	(3,553)	(75.3)

(Reference) Ratio to net sales

<i>(%)</i>	FY2017	FY2018	Change
	A	B	B-A
Cost of sales	48.8	50.9	2.1
SG&A	41.4	41.2	(0.2)
R&D expenses	7.2	6.6	(0.6)
Operating income	9.8	7.9	(1.9)
Ordinary income	10.0	8.1	(1.9)
Net income	7.4	1.9	(5.5)

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

Net Sales (¥62,551 million : Decrease ¥1,583 million year-on-year)

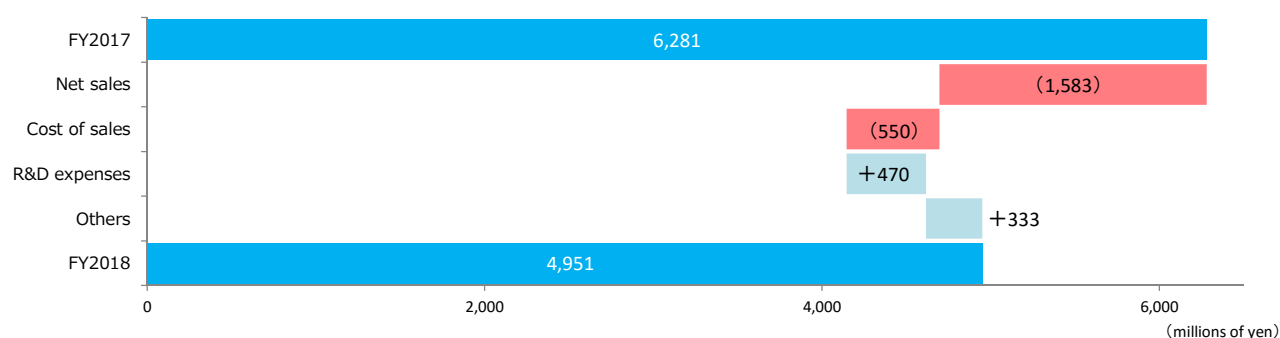


Major factors in increase/decrease

Sales of products	: Decrease with the drug price revision implemented on April 1, 2018 and generic drugs Increase with increase in sales quantity			
Renal disease and hemodialysis	REMICH	Decrease ¥ 2,240 million	FUTHAN	Decrease ¥ 909 million
	URINORM	Decrease ¥ 332 million	Riona	Increase ¥ 357 million
Skin disease	ANTEBATE	Decrease ¥ 745 million		
Allergens	MITICURE	Increase ¥ 785 million	CEDARTOLEN	Increase ¥ 563 million
	CEDARCURE	Increase ¥ 405 million		
HIV infection	Descovy	Increase ¥ 3,249 million	Genvoya	Increase ¥ 1,043 million
	Truvada	Decrease ¥ 2,504 million		
Others	Commission income	Decrease ¥ 447 million		

※ For details, please refer to "② Sales of Products" on page 4.

Operating income (¥4,951 million : Decrease ¥1,329 million year-on-year)



Major factors in increase/decrease

Cost of sales	: Increase with disposal of excess cedar pollen inventory	
R&D expenses	: Decrease in clinical study expenses (TO-206, TO-203 House dust mite induced allergic rhinitis in children) and co-development expenses (JTE-052) Increase in co-development expenses (JTS-661, JTT-751)	
Others	: Decrease in administrative expenses	

Ordinary income (¥5,080 million : Decrease ¥1,322 million year-on-year)

Special remarks: None

Net income (¥1,164 million : Decrease ¥3,553 million year-on-year)

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

② Sales of Products

(Millions of Yen)	FY2017	FY2018	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	62,935	61,835	(1,100)	(1.7)
Descovy Antiviral agent for HIV [HIV infection]	9,218	12,467	3,249	35.3
REMITCH Oral anti-pruritus agent [Renal disease and hemodialysis]	13,838	11,598	(2,240)	(16.2)
Genvoya Antiviral agent for HIV [HIV infection]	6,325	7,369	1,043	16.5
Riona Agent for hyperphosphatemia [Renal disease and hemodialysis]	6,245	6,603	357	5.7
ANTEBATE ※ Topical corticosteroid [Skin disease]	6,282	5,536	(745)	(11.9)
BIO-THREE Viable bacterial preparations [Other]	2,545	2,682	136	5.4
KAYEXALATE ※ Agent for hyperkalemia [Renal disease and hemodialysis]	2,123	1,963	(159)	(7.5)
CEDARTOLEN ※ Japanese cedar pollinosis (Allergen Immunotherapy) [Allergens]	1,295	1,859	563	43.5
LOCOID ※ Topical corticosteroid [Skin disease]	1,411	1,541	129	9.2
ZEFNART Topical antifungal agent [Skin disease]	1,483	1,454	(28)	(2.0)
Truvada Antiviral agent for HIV [HIV infection]	3,941	1,436	(2,504)	(63.5)
MITICURE ※ House dust mite allergy (Allergen Immunotherapy) [Allergens]	461	1,247	785	170.4
FUTHAN ※ Protease inhibitor [Renal disease and hemodialysis]	2,047	1,138	(909)	(44.4)
Magsent Tocolysis in threatened premature labor Eclampsia-suppressing and treatment [Other]	1,115	967	(147)	(13.3)
URINORM ※ Uricosuric agent [Renal disease and hemodialysis]	1,020	688	(332)	(32.6)
Others	3,579	3,280	(298)	(8.3)

※ In-house products

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2017	FY2018	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	16,323	15,855	(467)	(2.9)
Ratio of in-house product sales (%)	25.9	25.6	(0.3)	-

③ Balance Sheet

<i>(Millions of Yen)</i>	December 31, 2017 A	December 31, 2018 B	Change B-A	Change (%) (B-A)/A	Component ratio (%) (December 31, 2018)
Current assets	83,980	80,240	(3,739)	(4.5)	77.5
Cash and deposits	6,458	3,484	(2,973)		
Deposits in the cash management system	9,836	9,169	(666)		
Notes and accounts receivable-trade	29,123	27,137	(1,985)		
Short-term investment securities	24,957	28,606	3,648		
Inventories	10,126	8,315	(1,811)		
Others	3,478	3,527	48		
Noncurrent assets	20,761	23,305	2,544	12.3	22.5
Property, plant and equipment	5,540	3,431	(2,108)		
Intangible assets	817	669	(147)		
Investments and other assets	14,403	19,204	4,800		
Investment securities	7,478	13,770	6,292		
Long-term prepaid expenses	5,748	4,793	(954)		
Others	1,176	639	(536)		
Total assets	104,741	103,546	(1,195)	(1.1)	100.0
Current liabilities	15,868	14,274	(1,593)	(10.0)	13.8
Accounts payable-trade	8,242	6,657	(1,585)		
Income taxes payable	1,396	852	(544)		
Accrued employees' bonuses	684	675	(8)		
Others	5,544	6,089	545		
Long-term liabilities	1,753	2,178	424	24.2	2.1
Total liabilities	17,622	16,453	(1,168)	(6.6)	15.9
Shareholders' equity	86,364	86,217	(146)	(0.2)	83.3
Unrealized gain on available-for-sale securities	745	864	118	16.0	0.8
Subscription rights to shares	9	11	1	14.3	0.0
Total equity	87,119	87,092	(26)	(0.0)	84.1
Total liabilities and equity	104,741	103,546	(1,195)	(1.1)	100.0

Major factors in increase/decrease

(Current assets)	
Notes and accounts receivable-trade	: Decrease with decrease in sales
Short-term investment securities	: Increase with acquisition of debt securities and trust beneficiary rights
Inventories	: Decrease with redemption of money trust
(Noncurrent assets)	
Property, plant and equipment	: Decrease with inventories of products
Investment securities	: Decrease with impairment loss as business structure reform expenses
(Current liabilities)	
Accounts payable-trade	: Increase with acquisition of debt securities and investment trust
Accounts payable-trade	: Decrease with decrease in purchasing products

④ Statement of Cash Flows

(Millions of Yen)	FY2017	FY2018	Change
	A	B	B-A
Income before income taxes	6,373	3,030	(3,343)
Depreciation and amortization of intangible assets	1,174	1,040	(133)
Business structure reform expenses (Impairment loss)	–	2,021	2,021
Decrease (Increase) in trade notes and accounts receivable-trade	(2,562)	1,985	4,548
Decrease in inventories	480	1,811	1,330
Decrease (Increase) in trade notes and accounts payable-trade	1,544	(1,585)	(3,130)
Increase in accounts payable-other	486	365	(120)
Decrease in long-term prepaid expenses	737	954	216
Income taxes paid	(1,263)	(1,855)	(592)
Other-net	(621)	490	1,112
Net cash provided by operating activities	6,349	8,259	1,910
Purchases of property, plant and equipment	(529)	(528)	0
Purchases of intangible assets	(260)	(147)	112
Other-net	(6,803)	(26,392)	(19,588)
Net cash used in investing activities	(7,593)	(27,068)	(19,475)
Net cash used in financing activities	(1,546)	(1,432)	113
Net Decrease in cash and cash equivalents	(2,789)	(20,241)	(17,451)
Cash and cash equivalents, beginning of period	38,685	35,895	(2,789)
Cash and cash equivalents, end of period	35,895	15,654	(20,241)

(※) Cash and cash equivalents consist of cash on hand and in banks without time deposits with maturities more than three months, deposits in the cash management system and marketable securities of which the period from the date of acquisition to the date of redemption is not more than three months.

Major factors in increase/decrease		
(Operating activities)		
Decrease (Increase) in trade notes and accounts receivable-trade	: FY2018	Decrease with decrease in sales
Decrease in inventories	: FY2018	Decrease in products
Decrease (Increase) in trade notes and accounts payable-trade	: FY2018	Decrease with decrease in purchasing products
(Investing activities)		
Other-net	: FY2018	Acquisition of short-term investment securities and investment securities

⑤ Capital Expenditures

(Millions of Yen)	FY2017	FY2018	Change	Change
	A	B	B-A	(%) (B-A)/A
Capital expenditures	931	811	(120)	(12.9)
PP&E	714	660	(53)	(7.5)
Intangible assets	217	150	(67)	(30.8)

Descriptions of capital expenditures

PP&E	: Investment mainly in manufacturing facilities aiming to maintain and improve productivity
Intangible assets	: Investment in software aiming to streamline operations

⑥ Depreciation/Amortization

(Millions of Yen)	FY2017	FY2018	Change	Change
	A	B	B-A	(%) (B-A)/A
Depreciation and amortization of intangible assets	1,174	1,040	(133)	(11.4)
Amortization of long-term prepaid expenses	1,061	965	(95)	(9.0)

⑦ 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 October 31, 2018

•JTE-052 NDA filing for the indication of Atopic dermatitis by JT in January, 2019

(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.

III Financial Forecasts for the FY2019

① Statement of Income

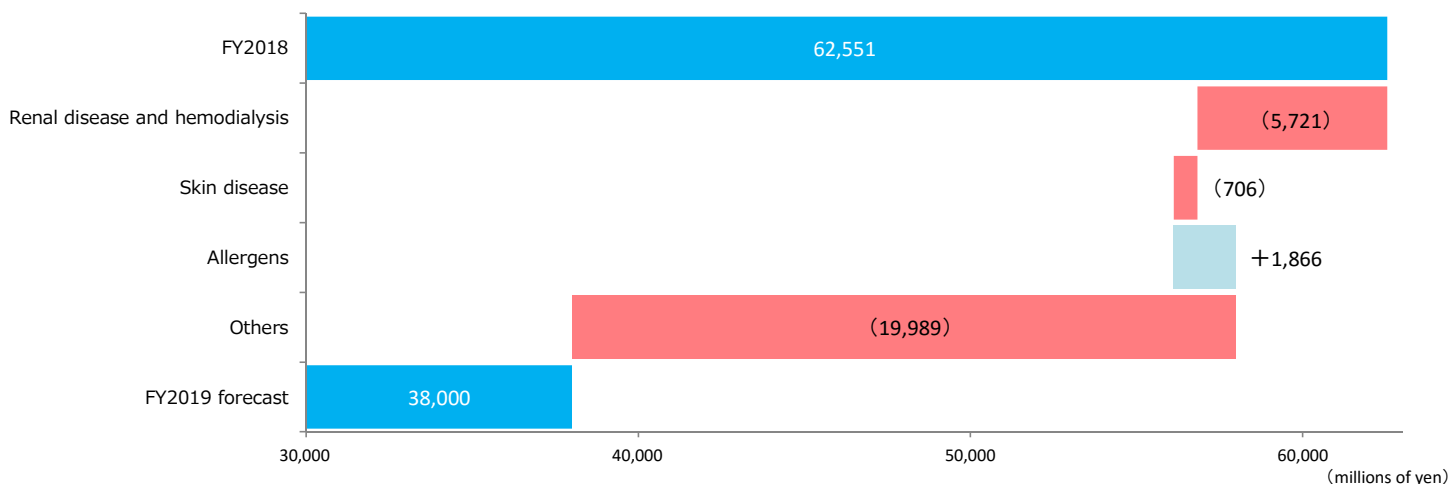
(Millions of Yen)	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Net sales	62,551	38,000	(24,551)	(39.2)
Sales of products	61,835	36,170	(25,665)	(41.5)
Renal disease and hemodialysis	21,991	16,270	(5,721)	(26.0)
Skin disease	9,126	8,420	(706)	(7.7)
Allergens	3,803	5,670	1,866	49.1
Other *	26,913	5,810	(21,103)	(78.4)
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	—
* HIV infection	21,448	—	(21,448)	—

(Reference) Ratio to net sales

(%)	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	7.9	(8.4)	(16.3)
Ordinary income	8.1	(8.2)	(16.3)
Net income	1.9	59.2	57.3

[Factors in increase/decrease compared with the FY2018]

Net sales (¥ 38,000 million : Decrease ¥ 24,551 million year-on-year)

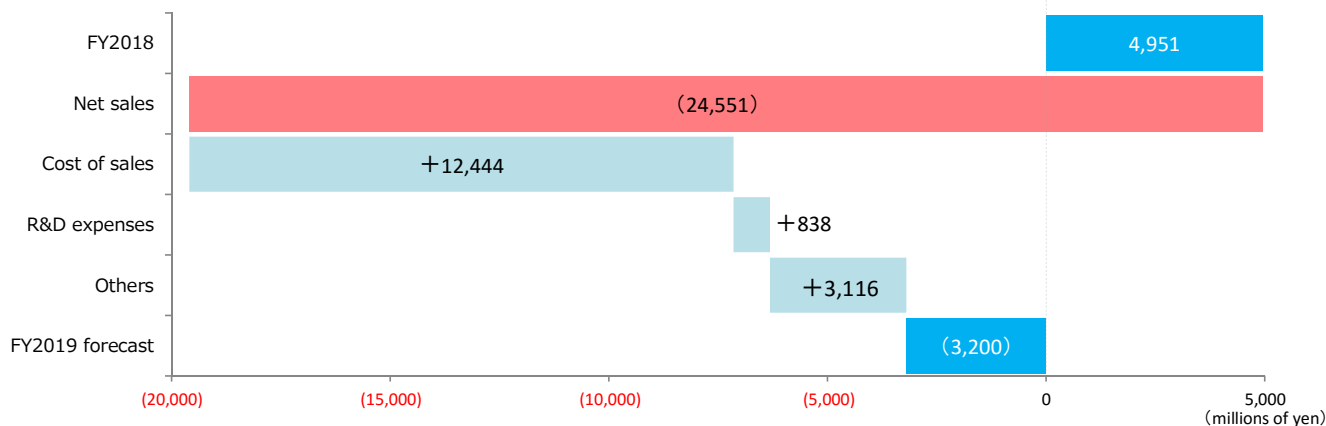


Major factors in increase/decrease

Renal disease and hemodialysis	: REMITCH	Decrease	¥ 5,148 million	FUTHAN	Decrease	¥ 948 million
	: Riona	Increase	¥ 546 million			
Skin disease	: ANTEBATE	Decrease	¥ 646 million			
Allergens	: CEDARCURE	Increase	¥ 2,344 million	MITICURE	Increase	¥ 512 million
	: CEDARTOLEN	Decrease	¥ 1,009 million			
Others	: HIV infection	Decrease	¥ 21,448 million			
	Distribution fee of the six anti-HIV drugs in Japan				Increase	¥ 1,100 million

※ For details, please refer to "② Sales of Products" on page 10.

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



Major factors in increase/decrease

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

※ More information is available at the following website:

https://www.torii.co.jp/en/release/2019/20190206_E1.pdf

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)
Riona Agent for hyperphosphatemia [Renal disease and hemodialysis]	6,603	7,150	546	8.3
REMITCH Oral anti-pruritus agent [Renal disease and hemodialysis]	11,598	6,450	(5,148)	(44.4)
ANTEBATE ※1 Topical corticosteroid [Skin disease]	5,536	4,890	(646)	(11.7)
BIO-THREE Viable bacterial preparations [Other]	2,682	2,840	157	5.9
CEDARCURE ※1, 2 Japanese cedar pollinosis (Allergen Immunotherapy) [Allergens]	405	2,750	2,344	578.6
KAYEXALATE ※1 Agent for hyperkalemia [Renal disease and hemodialysis]	1,963	1,930	(33)	(1.7)
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy) [Allergens]	1,247	1,760	512	41.1
LOCOID ※1 Topical corticosteroid [Skin disease]	1,541	1,570	28	1.8
ZEFNART Topical antifungal agent [Skin disease]	1,454	1,450	(4)	(0.3)
CEDARTOLEN ※1 Japanese cedar pollinosis (Allergen Immunotherapy) [Allergens]	1,859	850	(1,009)	(54.3)
FUTHAN ※1 Protease inhibitor [Renal disease and hemodialysis]	1,138	190	(948)	(83.3)
Others *	25,804	4,340	(21,464)	(83.2)
* HIV infection	21,448	—	(21,448)	—

※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	—

③ Capital Expenditures

<i>(Millions of Yen)</i>	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Capital expenditures	811	502	(309)	(38.1)
PP&E	660	292	(368)	(55.8)
Intangible assets	150	210	59	39.4

Descriptions of capital expenditures	
PP&E	: Investment mainly in manufacturing facilities aiming to maintain and improve productivity
Intangible assets	: Investment in software aiming to streamline operations

④ Depreciation/Amortization

<i>(Millions of Yen)</i>	FY2018	FY2019 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Depreciation and amortization of intangible assets	1,040	1,020	(20)	(2.0)
Amortization of long-term prepaid expenses	965	476	(489)	(50.7)

⑤ Dividends

		FY2018	FY2019 forecast	Change	Change (%)
		A	B	B-A	(B-A)/A
Dividends per share	(¥)	48	48	0	0.0
Dividends payout ratio	(%)	115.6	6.0	(109.6)	—

【Important notes on forward-looking statements】

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.