

Financial Results for the Fiscal Year 2020, Ended December 31, 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.

February 4, 2021



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A	C	C-B	(C-B)/B
Net sales	42,998	41,700	(1,297)	(3.0)	45,700	3,999	9.6
Operating income	1,430	4,738	3,307	231.2	3,800	(938)	(19.8)
Ordinary income	1,691	4,971	3,279	193.8	4,100	(871)	(17.5)
Net income	27,367	3,495	(23,872)	(87.2)	2,700	(795)	(22.8)
(Reference)							
R&D expenses	2,956	596	(2,360)	(79.8)	980	383	64.3
Earnings per share (EPS)	(¥) 974.98	124.47	(850.51)		96.14	(28.33)	
Return on equity (ROE)	(%) 27.3	3.1	(24.2)				
Ratio of ordinary income to total assets	(%) 1.4	3.7	2.3				
Ratio of operating income to net sales	(%) 3.3	11.4	8.1				
Return on assets (ROA)	(%) 22.5	2.6	(19.9)				

② Financial Conditions

(Millions of Yen)	December 31, 2019	December 31, 2020	Change	Change (%)
	A	B	B-A	(B-A)/A
Total assets	139,943	126,026	(13,917)	(9.9)
Total equity	113,125	115,091	1,965	1.7
Equity ratio	(%) 80.8	91.3	10.5	
Book value per share (BPS)	(¥) 4,029.30	4,097.55	68.25	

③ Statement of Cash Flows

(Millions of Yen)	FY2019	FY2020	Change
	A	B	B-A
Net cash used in operating activities	42,499	(3,443)	(45,942)
Net cash provided by investing activities	2,099	7,625	5,526
Net cash used in financing activities	(1,433)	(1,425)	8
Cash and cash equivalents, end of period	58,819	61,576	2,756

④ Capital Expenditures

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A	C	C-B	(C-B)/B
Capital expenditures	330	392	61	18.7	1,227	834	212.9
PP&E	203	277	73	36.0	861	583	210.6
Intangible assets	126	114	(11)	(9.2)	366	251	218.4

⑤ Depreciation/Amortization

(Millions of Yen)	FY2019	FY2020	Change	Change (%)	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A	C	C-B	(C-B)/B
Depreciation and amortization of intangible assets	985	582	(403)	(40.9)	422	(160)	(27.5)
Amortization of long-term prepaid expenses	486	496	10	2.2	656	159	32.1

II Financial Results for the FY2020

① Statement of Income

<i>(Millions of Yen)</i>	FY2019	FY2020	Change	Change
	A	B	B-A	(%) (B-A)/A
Net sales	42,998	41,700	(1,297)	(3.0)
Sales of products	40,641	41,053	411	1.0
Renal disease and hemodialysis	18,005	14,773	(3,231)	(17.9)
Skin disease	9,049	9,918	868	9.6
Allergens	7,627	11,332	3,705	48.6
Other	5,959	5,029	(930)	(15.6)
Other sales	2,356	647	(1,709)	(72.5)
Cost of sales	20,702	19,962	(740)	(3.6)
Cost of products sold	20,588	19,898	(689)	(3.3)
Other cost	114	63	(50)	(44.2)
Gross profit	22,295	21,737	(557)	(2.5)
Selling, general and administrative expenses	20,864	16,999	(3,865)	(18.5)
R&D expenses	2,956	596	(2,360)	(79.8)
Others	17,907	16,403	(1,504)	(8.4)
Operating income	1,430	4,738	3,307	231.2
Non-operating income and expenses	261	233	(27)	
Ordinary income	1,691	4,971	3,279	193.8
Extraordinary income and loss	36,008	(746)	(36,755)	
Income before income taxes	37,700	4,225	(33,475)	(88.8)
Income taxes	10,333	729	(9,603)	
Net income	27,367	3,495	(23,872)	(87.2)

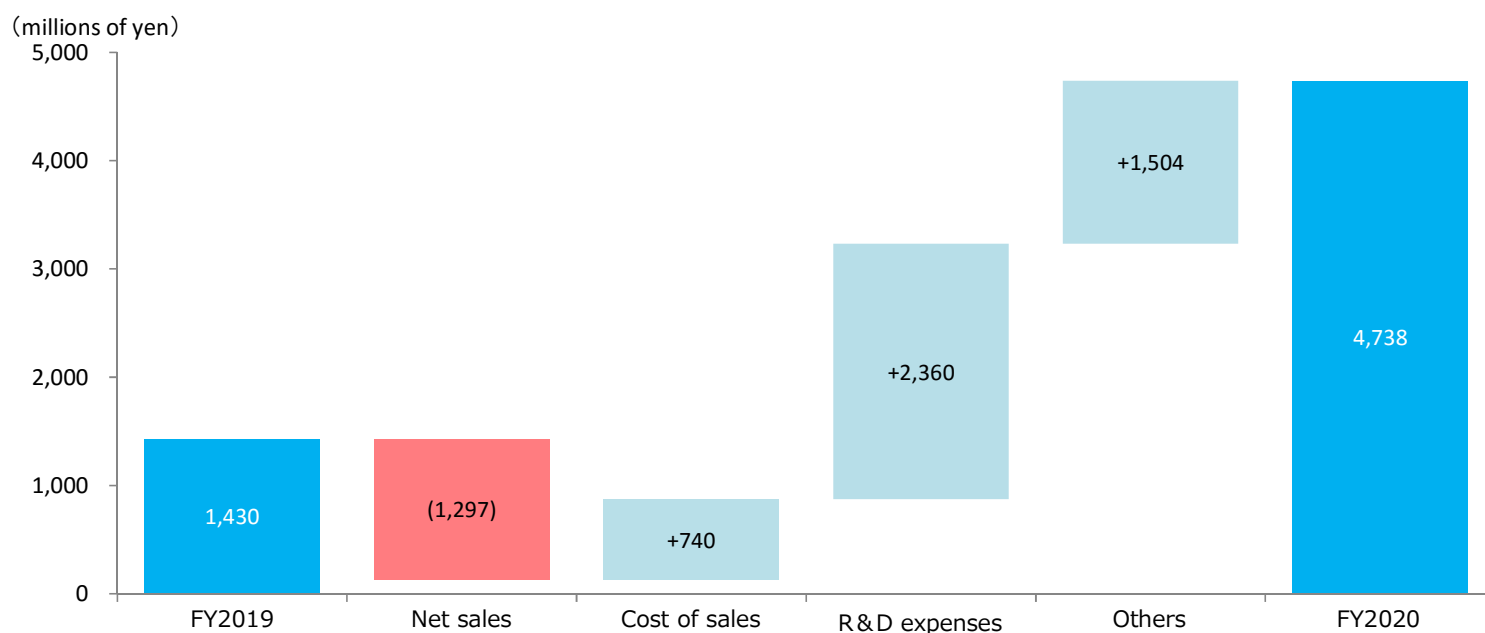
(Reference) Ratio to net sales

<i>(%)</i>	FY2019	FY2020	Change
	A	B	B-A
Cost of sales	48.1	47.9	(0.2)
SG&A	48.6	40.7	(7.9)
R&D expenses	6.9	1.4	(5.5)
Operating income	3.3	11.4	8.1
Ordinary income	3.9	11.9	8.0
Net income	63.6	8.4	(55.2)

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

Operating income (¥4,738 million : Increase ¥3,307 million year-on-year)

✓ Although fee income decreased,
profits increased by the full year effect of business structure reform



Major factors in increase/decrease

Net sales	Renal disease and hemodialysis	: Decrease in sales	REMITCH Decrease ¥2.3 billion(Impact of the drug price revisions and generic drugs)
	Skin disease	: Increase in sales	CORECTIM Increase ¥1.2 billion(Launched in June 2020)
	Allergens	: Increase in sales	CEDARCURE Increase ¥2.4 billion, MITICURE Increase ¥2.0 billion(increase in sales quantity)
	Other sales	: Decrease in sales	(FY2019)The six anti-HIV drugs distribution fee income
Cost of sales		: Decrease with changes in sales mix among the products(increase in the in-house product ratio)	
R&D expenses		: Decrease with business structure reform in last fiscal year(organizational reform) Decrease with co-development expenses (JTT-751, JTE-052)	
Others		: Decrease with business structure reform in last fiscal year(personnel optimization) Decrease with measures to prevent the spread of COVID-19 infection (MRs refrain from visiting medical institutions) Increase in contract MR expenses due to the launch of new products, etc. Increase in IT expenses for information provision activities to the proper use of pharmaceutical products	

Ordinary income (¥4,971 million : Increase ¥3,279 million year-on-year)

Special remarks: None

Net income (¥3,495 million : Decrease ¥23,872 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)	¥	4,504 million
	Income taxes	¥	10,333 million
FY2020:	Business structure reform expenses(Loss on the plant transfer)	¥	748 million
	Income taxes		
	(Reduct of impairment loss and enterprise tax in last fiscal year, etc.)	¥	729 million

② Sales of Products

(Millions of Yen)	FY2019	FY2020	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	40,641	41,053	411	1.0
[Renal disease and hemodialysis]				
Riona Agent for hyperphosphatemia	6,630	6,507	(123)	(1.9)
REMITCH Oral anti-pruritus agent	8,693	6,365	(2,328)	(26.8)
KAYEXALATE ※1 Agent for hyperkalemia	1,907	1,717	(189)	(9.9)
Others	773	182	(591)	(76.4)
Total	18,005	14,773	(3,231)	(17.9)
[Skin disease]				
ANTEBATE ※1 Topical corticosteroid	5,439	5,241	(198)	(3.6)
LOCOID ※1 Topical corticosteroid	1,630	1,674	43	2.7
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	—	1,291	1,291	—
ZEFNART Topical antifungal agent	1,454	1,241	(212)	(14.6)
Others	524	469	(55)	(10.6)
Total	9,049	9,918	868	9.6
[Allergens]				
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	3,654	6,139	2,484	68.0
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	2,749	4,776	2,027	73.7
Others	1,223	416	(806)	(65.9)
Total	7,627	11,332	3,705	48.6
[Other]				
BIO-THREE Viable bacterial preparations	2,843	2,969	125	4.4
Others	3,115	2,059	(1,056)	(33.9)
Total	5,959	5,029	(930)	(15.6)

※1 In-house products

※2 Launched in June 2020

(References) Sales and ratio of in-house products

(Millions of Yen)	FY2019	FY2020	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	19,068	21,539	2,471	13.0
Ratio of in-house product sales (%)	46.9	52.5	5.6	—

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 	
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 October 30, 2020 :

•JTZ-951(ENAROY® Tablets) for the Treatment of Anemia Associated with CKD was launched on December 8, 2020.(previous announcement : Development stage[Approval])

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 FY2021

① Statement of Income

<i>(Millions of Yen)</i>	FY2020	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Net sales	41,700	45,700	3,999	9.6
Sales of products	41,053	45,240	4,186	10.2
Renal disease and hemodialysis	14,773	14,580	(193)	(1.3)
Skin disease	9,918	12,680	2,761	27.8
Allergens	11,332	13,510	2,177	19.2
Other	5,029	4,470	(559)	(11.1)
Other sales	647	460	(187)	(28.9)
Cost of sales	19,962	22,200	2,237	11.2
Gross profit	21,737	23,500	1,762	8.1
SG&A	16,999	19,700	2,700	15.9
R&D expenses	596	980	383	64.3
Others	16,403	18,720	2,316	14.1
Operating income	4,738	3,800	(938)	(19.8)
Ordinary income	4,971	4,100	(871)	(17.5)
Net income	3,495	2,700	(795)	(22.8)

(Reference) Ratio to net sales

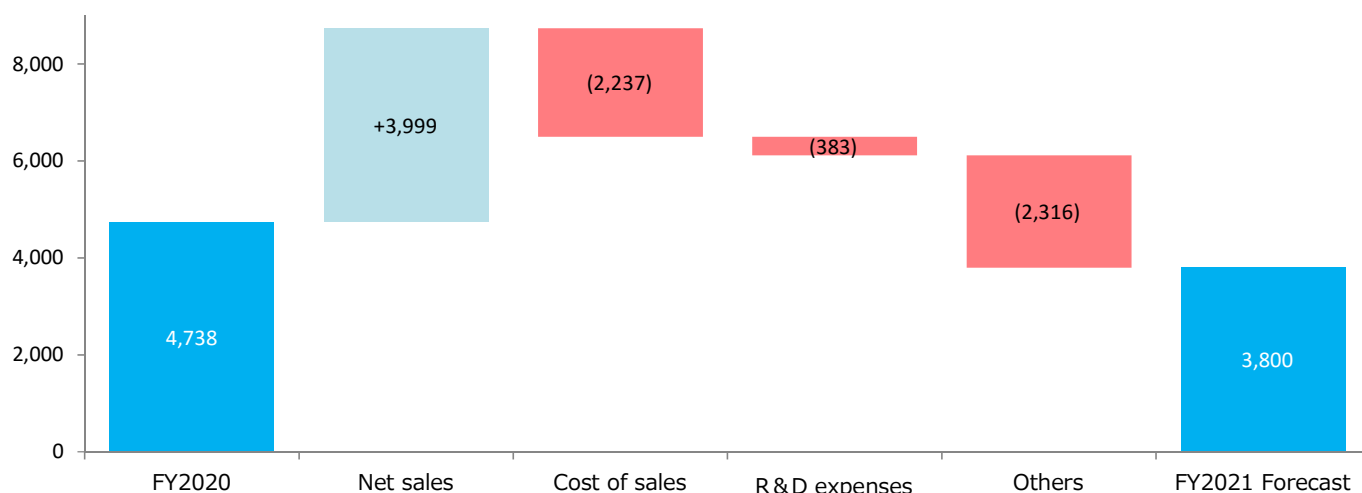
<i>(%)</i>	FY2020	FY2021 forecast	Change
	A	B	B-A
Cost of sales	47.9	48.6	0.7
SG&A	40.7	43.1	2.4
R&D expenses	1.4	2.1	0.7
Operating income	11.4	8.3	(3.1)
Ordinary income	11.9	9.0	(2.9)
Net income	8.4	5.9	(2.5)

[Factors in increase/decrease compared with the FY2020]

Operating Income (¥3,800 million : Decrease ¥938 million year-on-year)

✓ Although sales of CORECTIM and Allergens are expected to increase, profits are expected to decrease by expenses for the launch of new products

(millions of yen)



Major factors in increase/decrease			
Net sales	Renal disease and hemodialysis	: Decrease in sales	REMITCH Decrease ¥1.4 billion(Impact of the drug price revisions and generic drugs), Riona Increase ¥1.4 billion(Increase in sales quantity due to additional indication)
	Skin disease	: Increase in sales	CORECTIM Increase ¥3.4 billion(Launched in June 2020)
	Allergens	: Increase in sales	CEDARCURE Increase ¥1.2 billion, MITICURE Increase ¥1.1 billion(Increase in sales quantity)
Cost of sales		: Increase in net sales	
R&D expenses		: Increase in products improvement expenses	
Others		: Increase in sales-linked expenses	
		Increase in launching new products expenses	
		Temporary expenses to purchase computers	

Ordinary Income (¥4,100 million : Decrease ¥871 million year-on-year)

Special remarks: None

Net income (¥2,700 million : Decrease ¥795 million year-on-year)

FY2020: Business structure reform expenses(Loss on the plant transfer, etc.)

Income taxes

(Reduct of impairment loss and enterprise tax in last fiscal year, etc.)

② Sales of Products

<i>(Millions of Yen)</i>	FY2020	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of Products	41,053	45,240	4,186	10.2
[Renal disease and hemodialysis]				
Riona Agent for hyperphosphatemia	6,507	7,910	1,402	21.5
REMITCH Oral anti-pruritus agent	6,365	4,920	(1,445)	(22.7)
KAYEXALATE ※1 Agent for hyperkalemia	1,717	1,500	(217)	(12.7)
Others	182	250	67	36.7
Total	14,773	14,580	(193)	(1.3)
[Skin disease]				
ANTEBATE ※1 Topical corticosteroid	5,241	4,840	(401)	(7.7)
CORECTIM ※2 Topical Janus kinase (JAK) inhibitor	1,291	4,730	3,438	266.2
LOCOID ※1 Topical corticosteroid	1,674	1,590	(84)	(5.0)
ZEFNART Topical antifungal agent	1,241	1,090	(151)	(12.2)
Others	469	430	(39)	(8.3)
Total	9,918	12,680	2,761	27.8
[Allergens]				
CEDARCURE ※1 Japanese cedar pollinosis (Allergen Immunotherapy)	6,139	7,370	1,230	20.0
MITICURE ※1 House dust mite allergy (Allergen Immunotherapy)	4,776	5,890	1,113	23.3
Others	416	250	(166)	(40.0)
Total	11,332	13,510	2,177	19.2
[Other]				
BIO-THREE Viable bacterial preparations	2,969	3,070	100	3.4
Others	2,059	1,400	(659)	(32.0)
Total	5,029	4,470	(559)	(11.1)

※1 In-house products

※2 launched in June 2020

(References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2020	FY2021 forecast	Change	Change (%)
	A	B	B-A	(B-A)/A
Sales of in-house products	21,539	22,100	560	2.6
Ratio of in-house product sales (%)	52.5	48.9	(3.6)	—