

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2020

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July 31, 2019

KYORIN Holdings, Inc.

These forecast performance figures are based on information currently available to the Company and may include uncertain factors or risk that affect our future performance. Accordingly, actual business results may materially differ from the forecasted figures due to various factors in the future.



Outline of First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2019

Units: millions of yen	First quarter Jun / 2016	First quarter Jun / 2017	First quarter Jun / 2018	First quarter Jun / 2019	YoY change (%)
Net sales	27,707	26,458	25,131	25,749	+ 2.5%
Operating income	3,244	2,595	1,320	1,575	+ 19.3%
Ordinary income	3,485	2,805	1,596	1,827	+ 14.5%
Net income	2,580	2,393	1,077	1,280	+ 18.9%

Interim term Sep / 2019 (forecast)	YoY change (%)	Year ending Mar / 2020 (forecast)	YoY change (%)
52,100	+ 3.5%	114,100	+ 0.4%
2,300	- 19.4%	9,100	+ 1.4%
2,500	- 21.5%	9,600	+ 1.7%
1,900	- 14.3%	7,100	+ 3.4%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2020

[Net sales] Sales from our main product Flutiform grew, and the new product Beova and the newly released last year product Nasonex nasal spray contributed to grow, so sales of new drugs in Japan remained higher than the year-ago level. Regarding sales of the New drugs in overseas sales increased. While sales from generic drugs decreased from the year-ago, overall revenues in the Ethical Drugs Business increased. Sales from healthcare business remained flat. As a result, overall net sales stood at 25,749 million yen, as up 618 million yen from year on year (up 2.5% from year on year).

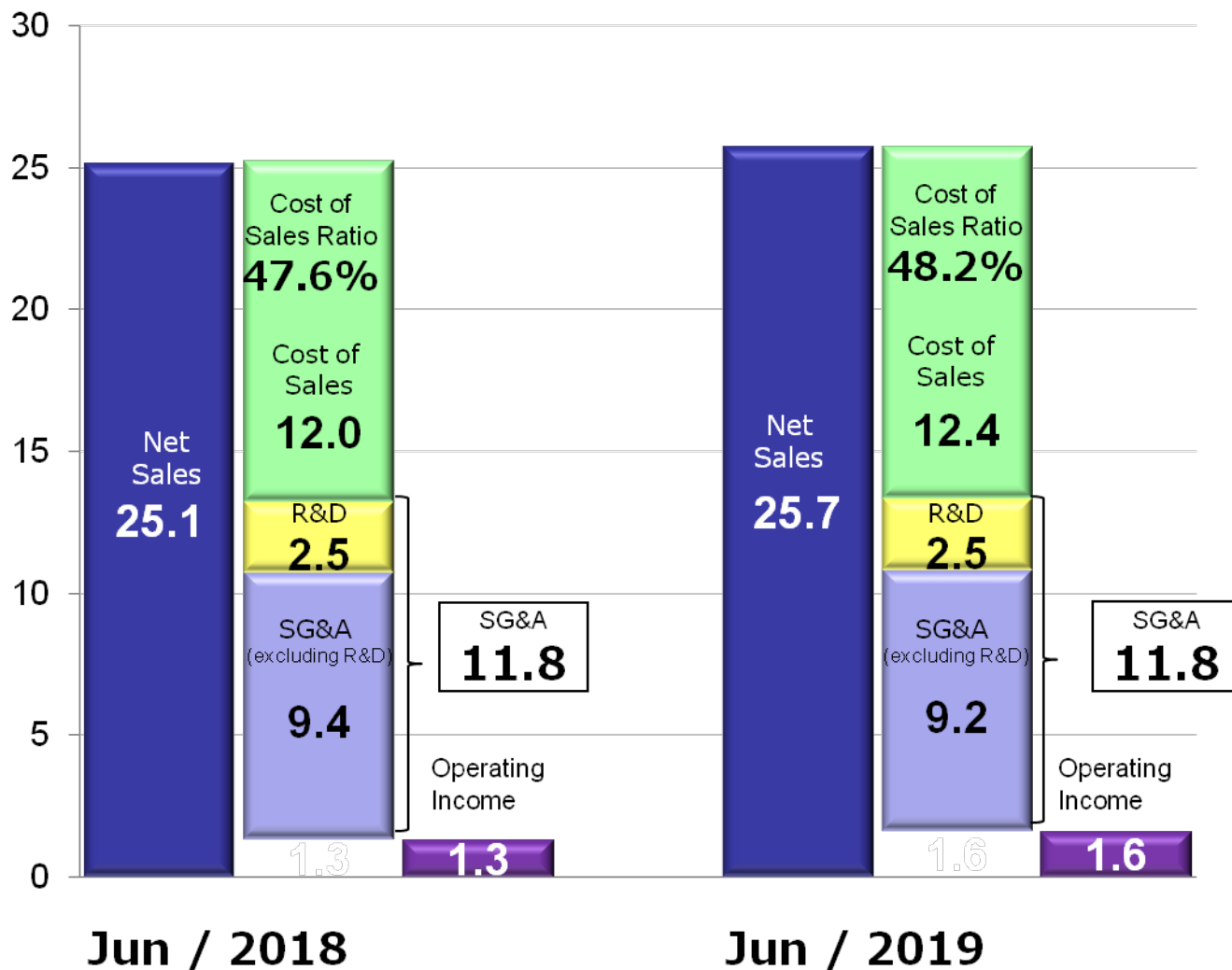
[Profit] Gross profit increased 167 million yen due to the increase of sales of new drugs in Japan and overseas. SG&A declined 87 million yen (of which R&D expense increased 67 million yen). Operating Income was 1,575 million yen, as up 255 million yen from year on year (up 19.3% from year on year), and profit attributable to owners of parent was 1,280 million yen (up 18.9% from year on year).

Consolidated Financial Results for the Fiscal Year Ending March 31, 2020(forecast)

The results forecast for the first half and full year announced on 13th May, 2019 remain unchanged as of this moment. (Progress compared with the forecast for the first half: net sales: 49.4%; operating income: 68.5%)

Highlights of Business Performance

(Units: ¥ billion)



Highlight

- Net Sales increased ¥0.6bln
- Cost of sales ratio increased 0.6%
 - Product mix, ect.
- Gross Profit increased ¥0.2bln
- SG&A expenses remained flat
 - R&D expense remained flat.
 - SG&A(excluding R&D) decreased
- Operating Income increased ¥0.3bln

Consolidated Financial Results

for the first Quarter ending March 31, 2020

Year on Year

(¥ billion)	Jun/2018	Jun/2019	Change
Net Sales	25.1	25.7	+0.6
Ethical drugs Business	23.7	24.4	+0.7
◆ Sales of new ethical drugs	16.2	17.1	+0.9
● Japan	16.1	16.7	+0.6
● Overseas	0.1	0.4	+0.3
◆ Generic drugs	7.5	7.3	-0.2
Healthcare Business	1.4	1.3	-0.1
Operating Income	1.3	1.6	+0.3
Ordinary Income	1.6	1.8	+0.2
Net Income	1.1	1.3	+0.2

■ Net Sales	¥ 25.7bin	(+0.6)	
◆ Ethical drugs business	¥ 24.4bin	(+0.7)	
● Sales of new ethical drugs	¥ 16.7bin	(+0.6)	
	18.6 (1Q)	19.6 (1Q)	
• Flutiform	3.0	⇒ 3.5	(+0.5)
• Desalex	1.5	⇒ 0	(-1.5)
• Kipres	3.3	⇒ 3.0	(-0.3)
• Nasonex	0	⇒ 1.7	(+1.7)
• Uritos	1.7	⇒ 1.6	(-0.1)
• Beova	0	⇒ 0.2	(+0.2)
• Pentasa	3.5	⇒ 3.5	(0)
• Mucodyne	1.7	⇒ 1.5	(-0.2)
● Sales of new ethical drugs in Overseas	¥ 0.4bin	(+0.3)	
● Sales of Generic drugs	¥ 7.3bin	(-0.2)	
	* Decrease of MONTELKAST AG sales, etc.		
◆ Healthcare Business	¥ 1.3bin	(-0.1)	
■ Operating Income	¥ 1.6bin	(+0.3)	
◆ Operating Income margin increased 0.8 percentage points to 6.1%			
● Cost of Sales Ratio : increased 0.6 percentage points (47.6%⇒48.2%)			
	* Product mix, etc.		
● R&D Ratio : remained flat (9.8%⇒9.8%)			
	R&D expenses ¥2.5bln⇒¥2.5bln		
● SG&A Ratio (excluding R&D expenses) : decreased 1.5 percentage points			
	* ¥9.4bln⇒¥9.2bln ¥-0.2bln		
		(37.3%⇒35.8%)	
	* Decrease of selling costs		
■ Net Income	¥ 1.3bin	(+0.2)	

Main Product Sales Update

Product		Interim term		Full term		First quarter (April 1 to June 30)				
		Sep/2018	Sep/2019 (forecast)	Mar/2019	Mar/2020 (forecast)	Jun/2018	Jun/2019	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
Sales of new ethical drugs (Japan)	Flutiform (Combination drug for asthma treatment)	6.1	6.6	13.1	14.0	3.0	3.5	+ 16.0%	53.0%	25.0%
	DESALEX (Antiallergic Agent)	2.8	—※	3.7	8.0	1.5	0	—	—	—
	KIPRES for adult (Leukotriene Receptor Antagonist)	2.9	2.2	6.2	4.5	1.6	1.4	− 13.4%	61.6%	30.1%
	for children (Leukotriene Receptor Antagonist)	3.3	2.7	7.6	6.1	1.7	1.6	− 4.5%	60.4%	26.7%
	NASONEX (Spray type allergic rhinitis remedy)	1.3	3.1	12.8	6.2	0	1.7	—	53.8%	26.9%
	URITOS(Kyorin) (Therapeutic agent for overactive bladder)	3.5	3.1	6.6	6.0	1.7	1.6	− 5.8%	51.7%	26.7%
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	0	0.7	0.7	2.5	0	0.2	—	34.7%	9.7%
	PENTASA (Ulcerative colitis and Crohn's disease treatment)	7.1	6.3	13.5	12.0	3.5	3.5	+ 1.3%	55.9%	29.4%
MUCODYNE (Mucoregulant)	3.1	2.7	6.8	6.0	1.7	1.5	− 6.9%	57.0%	25.6%	
Generic Drugs	MONTELUKAST Tablets “KM” (Leukotriene Receptor Antagonist)	5.3	5.5	11.9	11.6	3.3	3.0	− 9.3%	54.1%	25.7%
Over-the- counter drugs	Milton (Disinfectant)	1.1	1.2	2.2	2.3	0.6	0.5	− 7.2%	43.2%	22.6%

※It is not reached decision of resumption supply of Desalex and the sales forecast for interim term is not disclosed.

Financial summary

Consolidated Financial Results

for the first Quarter ending March 31, 2020

(Units: ¥million)	Interim term		Full term		First quarter (April 1 to June 30)					
	Sep/2018	Sep/2019 (forecast)	Mar/2019	Mar/2020 (forecast)	Jun/2018	Jun/2019	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	50,360	52,100	113,620	114,100	25,131	25,749	+618	+2.5%	49.4%	22.6%
Ethical drugs business	47,581	49,100	107,859	108,000	23,735	24,408	+673	+2.8%	49.7%	22.6%
◆Sales of new ethical drugs	34,028	33,800	78,525	75,800	16,204	17,104	+900	+5.6%	50.6%	22.6%
●Japan	34,424	33,400	77,694	74,400	16,057	16,727	+670	+4.2%	50.1%	22.5%
●Overseas	604	400	830	1,300	146	376	+230	+157.3%	94.0%	28.9%
◆Generic drugs	13,552	15,300	29,334	32,200	7,531	7,304	-227	-3.0%	47.7%	22.7%
Healthcare business	2,779	2,900	5,761	6,100	1,396	1,341	-55	-3.9%	46.2%	22.0%
Operating income	2,852	2,300	8,972	9,100	1,320	1,575	+255	+19.3%	68.5%	17.3%
Ordinary income	3,183	2,500	9,438	9,600	1,596	1,827	+231	+14.5%	73.1%	19.0%
Net income	2,217	1,900	6,869	7,100	1,077	1,280	+203	+18.9%	67.4%	18.0%

Main R&D Activities -1 (as of July 31 2019)

Ph III ~ Application submitted

※Changes from the previous announcement (May 13 2019)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Application (4/2017)		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	-Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) -has a powerful antimicrobial activity against anaerobic bacteria	
Preparing for Application		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	- Expectation of high clinical effects with excellent tissue penetration -High degree of safety expected since safety hurdles cleared prior to clinical trials	
Preparing for Application		KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off-labeled drugs with high medical needs "Dimethyl sulfoxide(DMSO)"	
※ Application		KRP-108P	Anti-asthmatic	(U.K.) Vectura	Expand the indication of Flutiform to pediatric patients	

•MK-7264, a drug for chronic coughing: MSD is working on Phase III development. Concluded a memorandum of understanding for sales collaboration.

Main R&D Activities -1 (as of July 31 2019)

POC Project (Ph I ~ Ph II)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Ph II (8/2018)		KRP-N118 (SK-1404)	Nocturia Due to Nocturnal Polyuria	SANWA KAGAKU KENKYUSHO CO., LTD.	A vasopressin V2 receptor agonist that promotes the reabsorption of water by the collecting duct of the kidney to reduce the amount of urine (antidiuretic action). With its high efficacy and safety, the drug is expected to be a therapeutic agent for nocturia due to nocturnal polyuria.	•License agreement with SANWA KAGAKU KENKYUSHO CO., LTD, (3/2018)
Ph II (6/2018)		Ad-SGE-REIC	malignant pleural mesothelioma	Okayama University	A gene-therapy product using a novel tumor suppressor gene of reduced expression in immortalized cells/ Dickkopf-3 (REIC/Dkk-3), which was discovered by researchers from Okayama University, as a therapeutic gene. It is expected to have direct effect on primary tumor lesions and indirect effect on metastatic tumor lesions as a gene-therapy product that simultaneously induces tumor cell-selective apoptosis and the activation of antitumor immunity respectively.	Adopted to Next generation Technology Transfer Program (NexTEP) (6/2014) [US] Momotaro-Gene prostate cancer(Ph I / II) [JP] Okayama University liver cancer(Ph I / I b)

Licensing development

Stage/ Overseas	Compound/ Code	Licensee / Collaborative research	Therapy area/Action	Origin	Features	Comments
Ph I	FPR-2 agonist program	BMS	Non- disclosure	In-house	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action.	License agreement with BMS (12/2015)
Ph I	KRP-203	Implementing licensing activities	GvHD		Sphingosine-1-Phosphate Receptor Agonist	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons,kyorin receive the return of development rights.

Reference

Segment information for the first Quarter Ending March 31, 2020

Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
total	25.7	+0.6	1.6	+0.3
Ethical drugs business	24.4	+0.7	1.5	+0.2
◆Sales of new ethical drugs	17.1	+0.9		
●Japan	16.7	+0.6		
●Overseas	0.4	+0.3		
◆Generic drugs	7.3	-0.2		
Healthcare business	1.3	-0.1	0.1	+0.1
Amount of adjustment	0	0	0.1	0