

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2021

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August 3, 2020

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.



Overview of First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2021

Units: millions of yen	First quarter Jun / 2017	First quarter Jun / 2018	First quarter Jun / 2019	First quarter Jun / 2020	YoY change (%)	Interim term Sep / 2020 (forecast)	YoY change (%)	Year ending Mar / 2021 (forecast)	YoY change (%)
Net sales	26,458	25,131	25,749	24,689	-4.1%	52,800	+9.3%	115,500	+5.0%
Operating income	2,595	1,320	1,575	2,014	+27.8%	2,400	+206.2%	9,700	+29.3%
Ordinary income	2,805	1,596	1,827	2,265	+24.0%	2,600	+141.6%	10,200	+24.8%
Net income	2,393	1,077	1,280	1,609	+25.7%	1,900	+127.8%	7,600	+23.6%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2021

[Net sales] In new ethical drugs, etc.(Japan), sales was 17,010 million yen which remained lower than a year ago level due to the decrease of sales of long-listed drugs from NHI drug price revisions and patient's suppressive behavior to go to a medical institution and the delay in market penetration of new products by voluntary restriction on MR activities in COVID-19 coronavirus outbreak, despite the growth of the mainstay product Beova and Desalex. On the other hand, sales from generic drugs increased from the year-ago. As a result, overall net sales stood at 24,689 million yen, as down 1,060 million yen from year on year (down 4.1% from year on year).

[Profit] Gross profit declined 232 million yen year on year due to a fall in sales. Meanwhile, owing to cost reduction, and voluntary restriction on MR activities (by COVID-19 coronavirus outbreak), SG&A decreased 671 million yen year on year (of which R&D expense decreased 475 million yen), as a result Operating Income was 2,014 million yen, as up 438 million yen from year on year (up 27.8% from year on year), and profit attributable to owners of parent was 1,609 million yen (up 25.7% from year on year).

Consolidated Financial Results for the Fiscal Year Ending March 31, 2021(forecast)

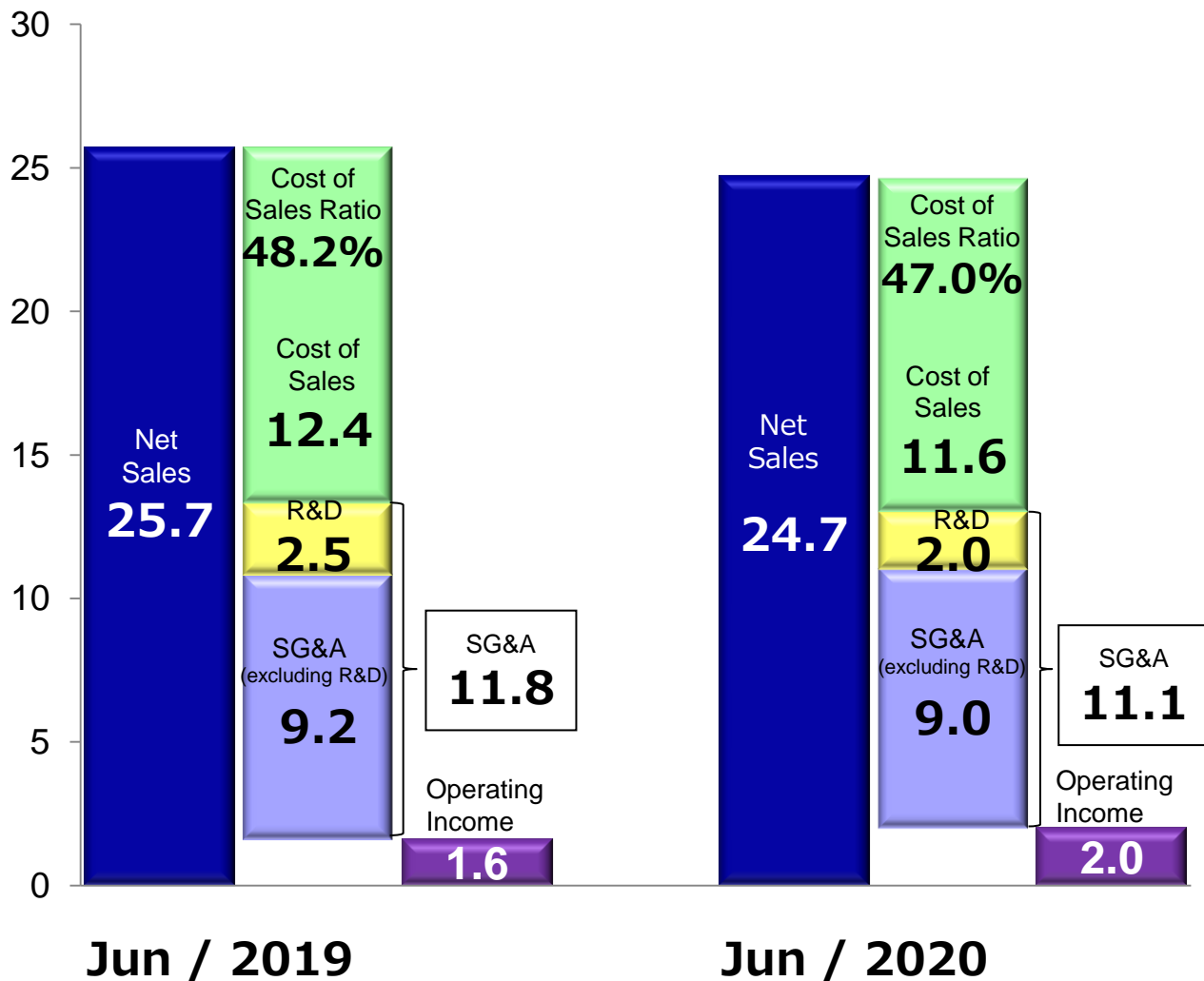
The forecast for the first half and full year announced on May 12, 2020 remain unchanged at this moment.
 (Progress compared with the forecast for the first half: net sales: 46.8%; operating income: 83.9%)

The Company have been paying full attention for the future trend of business performance by the delay of market penetration of new products and mainstay products with continuation or spread of the COVID-19.

There is no change to the dividend forecast announced on May 12, 2020 (annual dividend of 75 yen per share).

Highlights of Business Performance

(Units: ¥ billion)



➢ **Net Sales decreased ¥1.0bn year on year**

➢ **Cost of sales ratio decreased 1.2%**
 •Improvement of product mix, etc.

■ **Gross Profit decreased ¥0.2bn year on year**

➢ **SG&A expenses decreased ¥0.7bn year on year**
 •R&D expenses decreased ¥0.5bn
 •SG&A(excluding R&D) decreased ¥0.2bn

■ **Operating Income increased ¥0.4bn year on year**

Consolidated Financial Results

for the first Quarter ending March 31, 2021

Year on Year

(¥ billion)	Jun/2019	Jun/2020	Change
Net Sales	25.7	24.7	- 1.0
New ethical drugs, etc. (Japan)	18.1	17.0	- 1.1
New ethical drugs (Overseas)	0.4	0.2	- 0.2
Generic drugs	7.3	7.5	+ 0.2

Operating Income	1.6	2.0	+ 0.4
Ordinary Income	1.8	2.3	+ 0.5
Net Income	1.3	1.6	+ 0.3

■ **Net Sales** **¥ 24.7bln** **(- 1.0)**

● **New Ethical drugs, etc. (Japan)** **¥ 17.0bln** **(- 1.1)**

	19.6 (1Q)		20.6 (1Q)	
• Flutiform	3.5	⇒	3.1	(- 0.4)
• Desalex	0	⇒	0.9	(+ 0.9)
• Beova	0.2	⇒	1.9	(+ 1.7)
• Lasvic	-	⇒	0.1	(+ 0.1)
• Pentasa	3.5	⇒	3.2	(- 0.3)
• Uritos	1.6	⇒	1.2	(- 0.4)
• Nasonex	1.7	⇒	0.3	(- 1.4)
• Kipres	3.0	⇒	1.8	(- 1.2)
• Mucodyne	1.5	⇒	0.7	(- 0.8)

● **New Ethical drugs business (Overseas)** **¥ 0.2bln** **(- 0.2)**

● **Generic drugs** **¥ 7.5bln** **(+ 0.2)**

Increase of Nasonex AG sales, and Uritos AG and products released in June

■ **Operating Income** **¥ 2.0bln** **(+ 0.4)**

◆ **Operating Income margin increased 2.1 percentage points to 8.2%**

● **Cost of Sales Ratio : decreased 1.2 percentage points (48.2%⇒47.0%)**

[Decrease] Improvement of product mix

[Increase] Impact of NHI price revision, increase of sales for Generic drugs

● **R&D Ratio : decreased 1.5 percentage points (9.8%⇒8.3%)**

• R & D expenses decreased ¥0.5billion (¥2.5bln ⇒¥2.0bln)

Decrease in development project (Late-stage pipeline)

● **SG&A Ratio(excluding R&D expenses) : increased 0.8 percentage points**

(35.8%⇒36.6%)

• SG&A(excluding R&D) decreased ¥0.2billion (¥9.2bln⇒¥9.0bln) decrease in selling costs, etc.

■ **Net Income** **¥ 1.6bln** **(+ 0.3)**

※ The classification of reporting segment ("Prescription drugs business" and "Healthcare business") was consolidated to a single segment from the first quarter consolidated financial results for the fiscal year ending March 31, 2021. Along with this, the classification of sales was changed to combine the existing "New ethical drugs (Japan)" and "healthcare business" to "New ethical drugs, etc. (Japan)". There is no change in "New ethical drugs (overseas)" or "Generic drugs".

Main Product Sales Update

(Units: ¥ billion)

Product		Interim term		Full term		First quarter (April 1 to June 30)				
		Sep/2019	Sep/2020 (forecast)	Mar/2020	Mar/2021 (forecast)	Jun/2019	Jun/2020	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	6.7	7.0	14.6	15.0	3.5	3.1	-10.0%	44.9%	21.0%
	Desalex (Antiallergic Agent)	0	3.1	2.6	8.8	0	0.9	—	29.3%	10.4%
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	0.6	3.5	4.3	7.0	0.2	1.9	+675.5%	53.8%	26.9%
	Lasvic tablets (Oral new quinolone synthetic antibacterial agent)	—	1.4	1.1	4.1	—	0.1	—	3.1%	1.1%
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.8	5.9	13.3	11.7	3.5	3.2	-8.5%	54.4%	27.5%
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	3.0	1.8	5.8	2.7	1.6	1.2	-23.8%	66.4%	43.8%
	Nasonex (Spray type allergic rhinitis remedy)	2.7	0.6	6.0	2.6	1.7	0.3	-79.6%	49.3%	13.0%
	Kipres for adult (Leukotriene Receptor Antagonist)	2.4	1.8	5.3	4.2	1.4	0.9	-34.4%	47.7%	20.9%
	Kipres for children (Leukotriene Receptor Antagonist)	3.0	2.2	6.5	5.3	1.6	0.9	-45.4%	38.8%	16.5%
	Mycodyne (Mucoregulant)	2.8	2.2	5.8	4.9	1.5	0.7	-52.3%	31.9%	14.9%
Milton (Disinfectant)	1.1	1.1	2.4	2.2	0.5	0.5	-1.2%	46.4%	23.3%	
Generic Drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	5.4	4.7	11.5	10.7	3.0	2.3	-21.2%	49.6%	21.7%
	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	0.4	0.9	2.8	3.5	—	0.4	—	45.9%	12.3%
	Imidafenacin tablets & OD "KYORIN" (Therapeutic agent for overactive bladder)	—	0.4	—	1.0	—	0.2	—	39.4%	16.7%

Consolidated Financial Results for the first Quarter ending March 31, 2021

(Units: ¥million)	Interim term		Full term		First quarter (April 1 to June 30)					
	Sep/2019	Sep/2020 (forecast)	Mar/2020	Mar/2021 (forecast)	Jun/2019	Jun/2020	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	48,299	52,800	109,983	115,500	25,749	24,689	-1,060	-4.1%	46.8%	21.4%
New ethical drugs, etc. (Japan)	33,742	36,800	77,535	79,700	18,068	17,010	-1,058	-5.9%	46.2%	21.3%
New ethical drugs (Overseas)	390	300	1,490	1,000	376	220	-156	-41.5%	73.5%	22.0%
Generic drugs	14,166	15,600	30,957	34,900	7,304	7,458	+154	+2.1%	47.8%	21.4%
Operating income	783	2,400	7,503	9,700	1,575	2,014	+439	+27.8%	83.9%	20.8%
Ordinary income	1,076	2,600	8,175	10,200	1,827	2,265	+438	+24.0%	87.1%	22.2%
Net income	834	1,900	6,149	7,600	1,280	1,609	+328	+25.7%	84.7%	21.2%

※ The classification of reporting segment ("Prescription drugs business" and "Healthcare business") was consolidated to a single segment from the first quarter consolidated financial results for the fiscal year ending March 31, 2021

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Development pipeline

Main R&D Activities -1 (as of August 3 2020)

Ph III ~ Application submitted

※Changes from the previous announcement (May 12, 2020)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Application (10 / 2019)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	A novel quinolone injection developed specifically for the treatment of lower respiratory tract infections 1. Highly distributed in the lung, showing strong antibacterial activity against pathogenic bacteria of respiratory tract infection 2. Effective against both aerobic and anaerobic bacteria, and able to administer once a day 3. Showed effectiveness against aspiration pneumonia, pulmonary suppuration, and lung abscess	
Application (3 / 2020)		KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off-labeled drugs with high medical needs “Dimethyl sulfoxide(DMSO)”	

・MK-7264, a drug for chronic coughing: Merck Phase III (Oversea).
 Concluded a memorandum of understanding for sales collaboration (5 / 2019).

※KRP-108P (additional indication for pediatric use of Flutiform® 50 Aerosol, a combination drug for asthma treatment) : obtained approval in June, 2020

Development pipeline

Main R&D Activities -2 (as of August 3 2020)

POC Project (Ph I ~ Ph II)

※Changes from the previous announcement (May 12, 2020)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Ph I ※ (7/2020)	Ph I b/II a (aTyr pharma)	KRP-R120	Interstitial lung disease : ILD (pulmonary sarcoidosis)	aTyr pharma	It is a fusion protein drug having the action to suppress, by binding to neuropilin-2 (NRP2) receptor, the excessive activation of immune cells, and is a potential first-in-class therapy to treat inflammatory diseases such as pulmonary sarcoidosis.	
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)

Status of Licensed Compound / Program

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.

※KYORIN Pharmaceutical Co., Ltd. signed license agreement with Otonomy, Inc. for the novel candidate compound for sensorineural hearing loss (8/2020)
 The company granted Otonomy a global exclusive license to develop, manufacture and commercialize the therapeutic agent for the treatment of otic disorders such as hearing loss (KYORIN Pharmaceutical Co., Ltd. reserves a commercialization right of the therapeutic agent in Japan).