

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2022

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August 3, 2021

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, 2022

Units: millions of yen	First quarter Jun / 2018	First quarter Jun / 2019	First quarter Jun / 2020	First quarter Jun / 2021	YoY change (%)	Interim term Sep / 2021 (forecast)	YoY change (%)	Year ending Mar / 2022 (forecast)	YoY change (%)
Net sales	25,131	25,749	24,689	24,695	n/a	47,300	n/a	102,600	n/a
Operating income	1,320	1,575	2,014	-756	—	-800	—	3,300	-43.0%
Ordinary income	1,596	1,827	2,265	-491	—	-600	—	3,800	-41.1%
Net income	1,077	1,280	1,609	-462	—	-300	—	2,700	-56.0%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2022

[Net sales] Due to the impact of NHI drug price revisions and the expansion of the new coronavirus infection etc., the respiratory and otolaryngology markets, which are our priority areas, remained sluggish. Although sales of main products “Desalex” and “Lasvic” increased, sales of New ethical drugs, etc. (Japan) decreased due to a decrease in long-listed products and royalty income and service income. On the other hand, Generic drugs increased, and overall sales were 24,695 million yen.

[Profit] Gross profit decreased due to an increase in the cost ratio caused by drug price revisions. In addition, due to the recording of an upfront payment for the introduction of a drug for treating chronic cough, SG&A expenses increased, resulting in an operating loss of 756 million yen.

Consolidated Financial Results for the Fiscal Year Ending March 31, 2022(forecast)

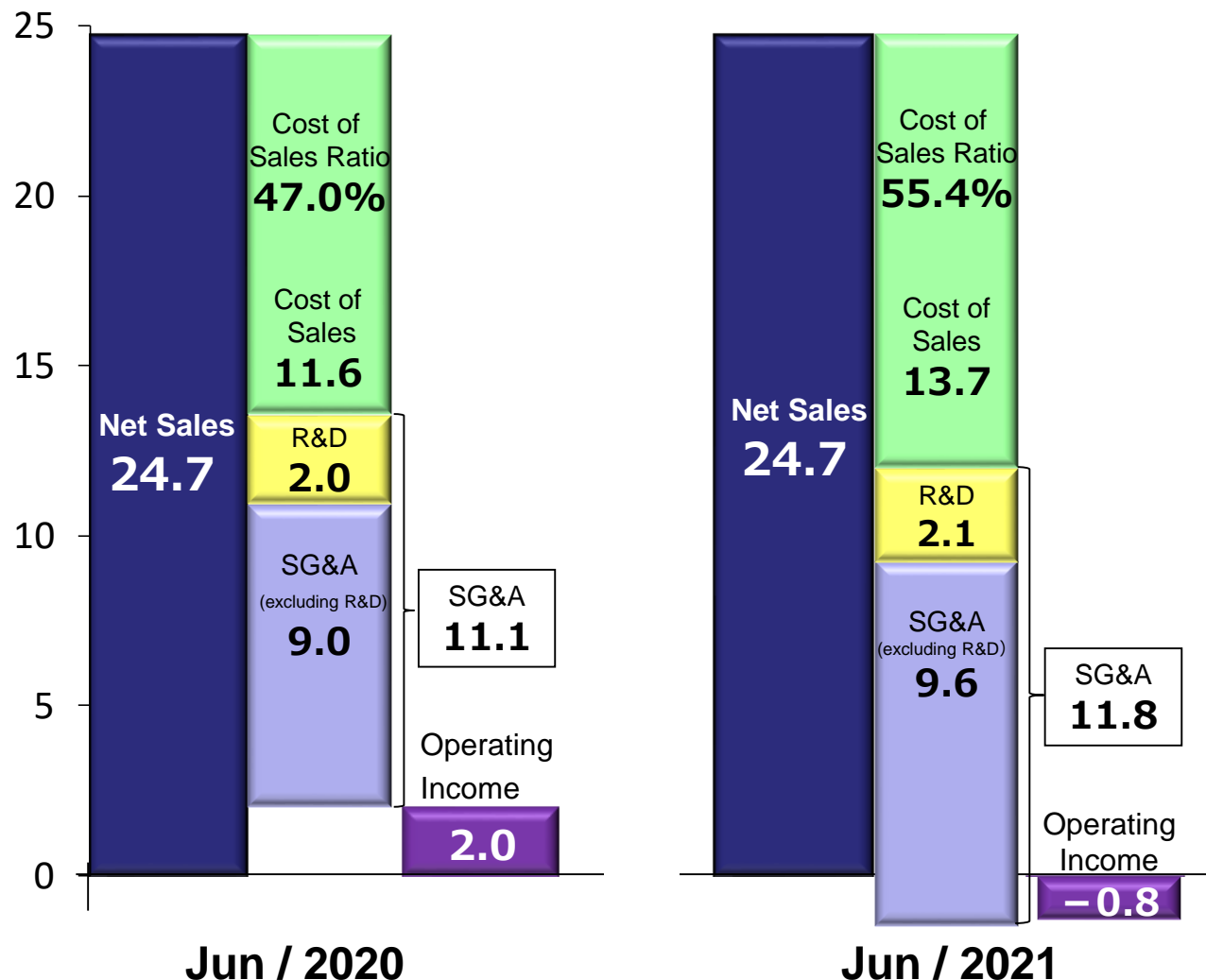
The forecast for the first half and full year announced on May 11, 2021 remain unchanged at this moment.
 (Net sales progress compared with the forecast for the first half : 52,2%)

There is no change to the dividend forecast announced on May 11, 2021 (Annual dividend of 52 yen per share).

* From the beginning of the first quarter, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar 31,2020) etc. have been applied, and the revenue recognition standards for the previous first quarter is different from the current first quarter, the amount of increase / decrease compared to the current first quarter and the YoY change rate (%) are not shown. The impact of the application of the "Accounting Standard for Revenue Recognition" was sales decreased by 256 million yen and SG&A expenses decreased by 256 million yen, and there is no impact on operating loss, ordinary loss, and net loss.

Highlights of Business Performance

(Units : ¥ billion)



■ Net Sales remains flat

- Sales of New ethical drugs, etc.(Japan) decreased
 - Sales of main products grew
- Sales of Generic drugs increased

■ Gross Profit decreased

- 1Q FY2021: 11.0 ¥ billion
 (1Q FY2020 : 13.1 ¥ billion)
- Cost of Sales Ratio increased
 - Impact of NHI drug price revisions (Kyorin Pharmaceutical : 6% level)
 - Sales of Generic drugs increased
 - Loss on retirement of inventories, etc. increased

■ SG&A expenses increased

- Cost of R&D remains flat
- Upfront payment for the introduction of Gefapixant citrate
- Labor expenses decrease

Consolidated Financial Results

for the first Quarter ending March 31, 2022

Year on Year

(¥ billion)	1Q FY2020	1Q FY2021	Change
Net Sales	24.7	24.7	n/a
New ethical drugs, etc. (Japan)	17.0	16.8	n/a
New ethical drugs (Overseas)	0.2	0.2	n/a
Generic drugs	7.5	7.7	n/a

Operating Income	2.0	-0.8	-2.8
Ordinary Income	2.3	-0.5	-2.8
Net Income	1.6	-0.5	-2.1

* From the beginning of the first quarter, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar.31,2020) etc. have been applied, and the revenue recognition standards for the previous first quarter is different from the current first quarter, the amount of increase / decrease compared to the first quarter and the Year on Year change rate (%) are not shown. There is no impact on operating loss, ordinary loss, and net loss.

■ **Net Sales** **¥ 24.7bln** **(n/a)**

● **New Ethical drugs, etc. (Japan)** **¥ 16.8bln** **(n/a)**

	20.6 (1Q)		21.6 (1Q)	
• Flutiform	3.1	⇒	3.2	(+0.1)
• Desalex	0.9	⇒	1.3	(+0.4)
• Beova	1.9	⇒	2.1	(+0.2)
• Lasvic	0.1	⇒	0.4	(+0.3)
• Pentasa	3.2	⇒	3.6	(+0.4)
• Uritos	1.2	⇒	0.4	(-0.8)
• Nasonex	0.3	⇒	0.4	(+0.1)
• Kipres	1.8	⇒	1.8	(0)
• Mucodyne	0.7	⇒	0.8	(+0.1)

● **New Ethical drugs business (Overseas)** **¥ 0.2bln** **(n/a)**

● **Generic drugs** **¥ 7.7bln** **(n/a)**

Increase of Montelukast AG, Mometasone AG and products released in June

■ **Operating Income** **¥ -0.8bln** **(-2.8)**

● **Cost of Sales Ratio : 1Q FY2021: 55.4% (1Q FY2020: 47.0%)**

[Decrease] Sales increase in New drugs group

[Increase] Impact of NHI price revision, increase of sales for Generic drugs
 Increase of loss on retirement of inventories

● **R&D**

• 1Q FY2021: ¥2.1bln (1Q FY2020: ¥2.0bln)

● **SG&A Ratio(excluding R&D expenses)**

1Q FY2021: ¥9.6bln (1Q FY2020: ¥9.0bln)

• Decrease in labor costs, increase in patents royalty
 (Upfront payment for the introduction of Gefapixant)

■ **Net Income** **¥ -0.5bln** **(-2.1)**

Main Product Sales Update

(Units: ¥ billion)

Product		Interim term		Full term		First quarter (April 1 to June 30)				
		Sep/2020	Sep/2021 (forecast)	Mar/2021	Mar/2022 (forecast)	Jun/2020	Jun/2021	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	6.4	6.6	13.3	13.9	3.1	3.2	+1.8%	48.5%	22.9%
	Desalex (Antiallergic Agent)	1.8	2.8	5.7	7.2	0.9	1.3	+44.5%	47.0%	18.1%
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	3.8	4.1	7.3	8.6	1.9	2.1	+12.1%	50.6%	24.4%
	Lasvic tablets (Oral new quinolone synthetic antibacterial agent)	0.2	1.1	0.9	2.8	0.1	0.4	+814.9%	36.1%	14.6%
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.4	6.0	12.8	11.7	3.2	3.6	+11.5%	59.6%	30.5%
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	1.6	0.5	2.3	1.0	1.2	0.4	-70.2%	72.7%	35.8%
	Nasonex (Spray type allergic rhinitis remedy)	0.6	0.5	2.8	1.8	0.3	0.4	+10.6%	67.7%	20.5%
	Kipres (Leukotriene Receptor Antagonist)	3.5	3.0	8.3	6.9	1.8	1.8	+1.6%	58.4%	26.0%
	Mycodyne (Mucoregulant)	1.4	1.2	3.3	2.9	0.7	0.8	+13.2%	66.6%	28.1%
	Milton (Disinfectant)	1.1	1.1	2.1	2.2	0.5	0.5	-1.3%	45.9%	22.3%
	Rubysta (Disinfectant)	1.0	1.0	2.0	2.1	0.6	0.5	-12.4%	48.3%	22.8%
Generic Drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	4.5	4.0	10.8	9.2	2.3	2.6	+8.9%	63.1%	27.6%
	Mometasone Nasal 50μg "KYORIN" (Spray type allergic rhinitis remedy)	0.9	1.0	3.8	3.5	0.4	0.5	+13.2%	48.5%	13.9%
	Imidafenacin tablets & OD "KYORIN" (Therapeutic agent for overactive bladder)	0.3	0.4	0.7	0.7	0.2	0.2	+10.3%	49.0%	24.9%

Consolidated Financial Results and Forecast for the first Quarter ending March 31, 2022

(Units: ¥million)	Interim term		Full term		First quarter (April 1 to June 30)					
	Sep/2020	Sep/2021 (forecast)	Mar/2021	Mar/2022 (forecast)	Jun/2020	Jun/2021	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	47,735	47,300	102,904	102,600	24,689	24,695	n/a	n/a	52.2%	24.1%
New ethical drugs, etc. (Japan)	32,857	31,900	69,735	68,600	17,010	16,820	n/a	n/a	52.7%	24.5%
New ethical drugs (Overseas)	527	500	996	800	220	200	n/a	n/a	40.0%	25.0%
Generic drugs	14,351	14,800	32,172	33,100	7,458	7,674	n/a	n/a	51.9%	23.2%
Operating income	1,502	-800	5,786	3,300	2,014	-756	-2,771	-	-	-
Ordinary income	1,813	-600	6,447	3,800	2,265	-491	-2,756	-	-	-
Net income	2,118	-300	6,130	2,700	1,609	-462	-2,071	-	-	-

From the beginning of the first quarter, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar.31,2020) etc. have been applied, and the first quarter results, second quarter forecast, and the full-year forecast are based on the "Accounting Standard for Revenue Recognition".

Development pipeline

Main R&D Activities -1 (as of August 3 2021)

Ph III ~ Application submitted

Stage		Compound / Code	Indication	Origin	Features	Comments
Japan	Overseas					
Launch (Apr 2021)	—	Zymso Intravesical Solution 50% /KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off-labeled drugs with high medical needs “Dimethyl sulfoxid”	
Application (Feb 2021) MSD	—	Gefapixant citrate(INN)	Chronic coughing (planned)	Merck	Selective P2X3 receptor antagonist expected as the treatment of refractory chronic cough (RCC) or unexplained chronic cough (UCC)	Distribution agreement in Japan with MSD (Apr 2021)

POC Project (Ph I ~ Ph II)

Stage		Code	Proposed Indication	Origin	Features	Comments
Japan	Overseas					
Ph I (Jul 2020)	Ph I b/ II a (aTyr pharma,USA)	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 I (Apr 2021, England)	KRP-A218	Rhinovirus infection at risk of potentially severe	In-house	It is antiviral drug that suppresses viral growth by targeting host molecules	

Development pipeline

Main R&D Activities -2 (as of August 3 2021)

Licensing development (License-in)

Stage		Code	Proposed Indication	Origin	Features	Comments
Japan	Overseas					
Ph II (Dec 2019) ASKA Pharmaceutical	—	AKP-009	Benign Prostatic Hyperplasia	ASKA Pharmaceutical	Novel androgen receptor modulator mode of action with the potential to exhibit prostatic shrinkage and to improve urinary function as a novel therapeutic agent for Benign Prostatic Hyperplasia	ASKA Pharmaceutical granted KYORIN Pharmaceutical the joint development and commercialization rights for AKP-009 in Japan (Sep 2020)

Licensing development (License-out)

Stage	Compound / Code	Licensee	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 (Dec 2015)
Ph I	KRP-203	Priothera	—	In-house	Sphingosine-1-Phosphate Receptor Agonist	Transfer of intellectual property(patents and data required for the development and sale) and APIs (Sep 2020)
Nonclinical	Compound for Sensorineural Hearing Loss	Otonomy	Sensorineural Hearing Loss	In-house	Candidate compound for sensorineural hearing loss	Grant a global exclusive license to develop, manufacture and commercialize the therapeutic agent for the treatment of otic disorders such as hearing loss (Aug 2020) Kyorin Pharmaceutical reserves a commercialization right of the therapeutic agent in Japan Otonomy's Code: OTO-6XX