

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

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February 4, 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 Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2021

(¥ million)	Dec/2017	Dec/2018	Dec/2019	Dec/2020	Y to Y change (%)	Mar/2021 (forecast)	Y to Y change (%)
Net Sales	82,923	82,017	78,614	74,955	-4.7%	108,000	-1.8%
Operating Income	7,805	6,794	5,271	4,114	-21.9%	7,800	+4.0%
Ordinary Income	8,246	7,124	5,836	4,656	-20.2%	8,400	+2.7%
Net Income	6,119	5,112	4,374	4,504	+3.0%	7,200	+17.1%

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

[Net Sales] Although the main products "Desalex" and "Beova" grew, the main product market shrank due to the impact of drug price revisions and patient's suppressive behavior to medical consultation caused by the spread of new coronavirus infections. Also MR activity restraint led the delay in market penetration of New drug groups, as the result New ethical drugs etc. (Japan) was lower than the previous year. On the other hand, although Mometasone (AG) and Imidafenacin (AG) grew and sales of Generic drugs increased, New ethical drugs (overseas) fell below the previous year's level, and overall sales decreased by 3,658 million yen year-on-year (4.7% in the same period of the previous year) to 74,955 million yen.

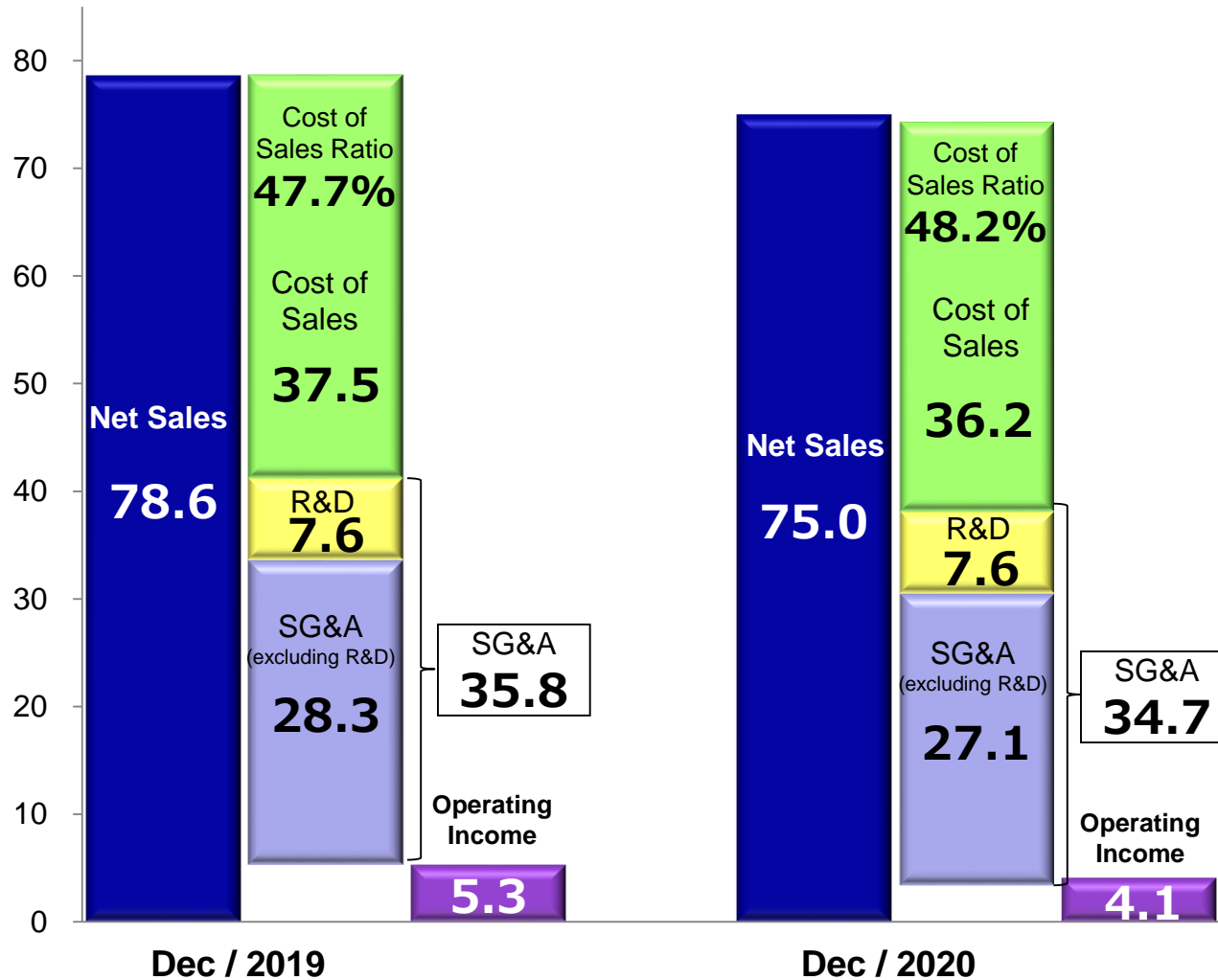
[Profit] Gross profit decreased by 2,314 million yen year-on-year due to a decrease in sales. On the other hand, selling, general and administrative expenses decreased by 1,157 million yen (including R & D expenses increased by 18 million yen) from the same period of the previous year due to cost reduction efforts and voluntary restriction on MR activities, etc., and operating income was 4,114 million yen. Profit decreased by 1,156 million yen year-on-year (down 21.9%). Net income attributable to owners of the parent was 4,504 million yen (up 3.0%) due to the recording of extraordinary income.

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

The forecasts for the full year announced on November 5, 2020 remain unchanged.
 (Progress compared with the forecast for the fiscal year ending March 31, 2021: net sales: 69.4%; operating income: 52.8%)
 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 ¥3.6billion year on year

➤ Cost of sales ratio increased 0.5%
 ・NHI drug price revisions
 ・Generic drugs ratio increased

■ Gross Profit decreased ¥2.3billion year on year

➤ SG&A expenses decreased ¥1.1billion year on year
 ・R & D expenses remained flat
 ・SG&A(excluding R&D) decreased ¥1.2billion

■ Operating Income decreased
 ¥1.2billion year on year

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

(unit : ¥ billion)

(Year on Year)

(¥ billion)	Dec/ 2019	Dec/ 2020	Change
Net Sales	78.6	75.0	- 3.6
New ethical drugs, etc. (Japan)	55.4	51.7	- 3.7
New ethical drugs (Overseas)	1.2	0.8	- 0.4
Generic drugs	22.0	22.5	+ 0.5

Operating Income	5.3	4.1	- 1.2
Ordinary Income	5.8	4.7	- 1.1
Net Income	4.4	4.5	+ 0.1

※ 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)" and "Generic drugs".

■ Net Sales **¥75.0bln (-3.6)**

● Sales of new ethical drugs in Japan **¥51.7bln (-3.7)**

(billion)	20.3 (3Q)	⇒	21.3 (3Q)	
• Flutiform	10.8	⇒	10.2	(-0.6)
• Desalex	0.8	⇒	3.1	(+2.3)
• Beova	2.2	⇒	5.5	(+3.3)
• Lasvic	0.6	⇒	0.6	(0)
• Pentasa	10.3	⇒	9.8	(-0.5)
• Uritos	4.6	⇒	2.0	(-2.6)
• Nasonex	3.8	⇒	1.2	(-2.6)
• Kipres	8.6	⇒	5.9	(-2.7)
• Mucodyne	4.5	⇒	2.5	(-2.0)

● Sales of new ethical drugs in Overseas **¥0.8bln (-0.4)**

Decreased the sales of Gatifloxacin

● Sales of Generic drugs **¥22.5bln (+0.5)**

Sales increase by Nazonex AG, and Uritos AG(launched in June),supplement products in 2020 contributed

■ Operating Income **¥4.1bln (-1.2)**

◆ Operating Income margin decreased 1.2 percentage points to 5.5%

● Cost of Sales Ratio : 47.7%⇒48.2% Increased 0.5 percentage points

[Increase] NHI drug price revisions, Increase of sales of Generic products etc.
[Decrease]Product mix, Efforts to reduce costs(Raw material costs, etc.)

● R&D Ratio : 9.6%⇒10.1% increased 0.5 percentage points

* ¥7.6bln⇒¥7.6bln

● SG&A Ratio (excluding R&D) : 35.9%⇒36.1% (+0.2%)

* Decrease of ¥1.2bln (¥28.3bln⇒¥27.1bln) Decrease of selling and general expenses

■ Net Income **¥4.5bln (+0.1)**

Debt exemption gain due to the partial exemption of repayment obligation for long-term debt from JST, and gain on sale of fixed assets were recorded as extraordinary profit.

Main Product Sales Update

(Units: ¥billion)		Sep/ 2019	Sep/ 2020	Dec/ 2019	Dec/ 2020	Change	Change (%)	Mar/2020 (Actual)	Mar/2021 (forecast)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	6.7	6.4	10.8	10.2	-0.6	-5.2%	14.6	14.5
	Desalex (Antiallergic Agent)	0	1.8	0.8	3.1	+2.3	+294.3%	2.6	7.5
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	0.6	3.8	2.2	5.5	+3.3	+151.2%	4.3	7.3
	Lasvic tablets (Oral new quinolone synthetic antibacterial agent)	-	0.2	0.6	0.6	0	+1.7%	1.1	1.7
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.8	6.4	10.3	9.8	-0.5	-5.3%	13.3	12.5
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	3.0	1.6	4.6	2.0	-2.6	-56.9%	5.8	2.2
	Nasonex (Spray type allergic rhinitis remedy)	2.7	0.6	3.8	1.2	-2.6	-67.6%	6.0	2.4
	Kipres for adult (Leukotriene Receptor Antagonist)	2.4	1.7	3.8	2.7	-1.1	-27.6%	5.3	3.8
	for children	3.0	1.8	4.8	3.1	-1.7	-35.3%	6.5	4.3
	Mucodyne (Mucoregulant)	2.8	1.4	4.5	2.5	-2.0	-44.1%	5.8	3.3
	Milton (Disinfectant)	1.1	1.1	1.7	1.7	0	+2.1%	2.4	2.3
Rubysta (Disinfectant)	0.6	1.0	1.0	1.6	+0.6	+54.6%	1.5	2.1	
Generic drugs	Montelukast tablets "KM"	5.4	4.5	8.3	7.3	-1.0	-11.9%	11.5	10.2
	Mometasone Nasal 50mg "KYORIN"	0.4	0.9	1.1	1.7	+0.6	+57.6%	2.8	3.5
	Imidafenacin tablets & OD "KYORIN"	-	0.3	-	0.5	+0.5	-	-	0.8

Development pipeline

Main R&D Activities -1 (as of February 4 2021)

Ph III ~ Application submitted

※Changes from the previous announcement (Nov 5 2020)

Stage		Compound/ Code	Indication	Origin	Features	Comments
Japan	Overseas					
Approval※ (Nov 2020)		Lasvic Intravenous Drip Infusion Kit 150mg/ KRP- AM1977Y	New quinolone antibacterial Injection	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	
Approval※ (Jan 2021)		Zymso Intravesical Solution 50% /KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off-labeled drugs with high medical needs “Dimethyl sulfoxid”	

•MK-7264, a drug for chronic coughing: MSD is working on Phase III development. Concluded a memorandum of understanding for sales collaboration (May 2019).

POC Project (Ph I ~ Ph II)

Stage		Compound/ Code	Proposed Indication	Origin	Features	Comments
Japan	Overseas					
Ph I (Jul 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.	

Main R&D Activities -2 (as of February 4 2021)

Licensing development (License-in)

Stage		Compound/ Code	Proposed Indication	Origin	Features	Comments
Japan	Overseas					
Ph II (Dec /2019) ASKA Pharmac eutical		AKP-009	Benign Prostatic Hyperplasia	ASKA Pharmaceuti cal	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 within Japan (09/2020)

Licensing development (License-out)

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	Priothera	-	In-house	Sphingosine-1-Phosphate Receptor Agonist	Transfer of intellectual property(patents and data required for the development and sale) and APIs (9/2020)
Nonclinical	Compound for Sensorineural Hearing Loss	Otonomy	-	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(8/2020) Kyorin Pharmaceutical reserves a commercialization right of the therapeutic agent in Japan Otonomy's Code: OTO-6XX

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

(Units: ¥Million)	Sep/2019	Sep/2020	Dec/2019	Dec/2020	Change	Change (%)	Mar/2020 (Actual)	Mar/2021 (forecast)
Net sales (total)	48,299	47,735	78,614	74,955	-3,658	-4.7	109,983	108,000
New ethical drugs, etc. (Japan)	33,742	32,857	55,351	51,671	-3,679	-6.6	77,535	73,800
New ethical drugs (Overseas)	390	527	1,224	755	-468	-38.3	1,490	1,100
Generic drugs	14,166	14,351	22,038	22,528	-489	+2.2	30,957	33,000
Operating Income	783	1,502	5,271	4,114	-1,156	-21.9	7,503	7,800
Ordinary Income	1,076	1,813	5,836	4,656	-1,180	-20.2	8,175	8,400
Net Income	834	2,118	4,374	4,504	+130	+3.0	6,149	7,200

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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