

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

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February 4, 2022
KYORIN Holdings, Inc.



■ Disclaimer

This material contains performance forecasts, goals and plans, and other forward-looking statements related to the Group.

These statements are based on the judgment of the Group's assumptions and outlooks based on the information and forecasts available at the time of preparation of this material, and contain known or unknown risks and uncertainties. Therefore, due to various factors that may occur, the actual performance, progress / success / failure of the development and other insights may differ significantly from the description. It also contains information about medicines (including those under development), but the description is not for the purpose of advertising or medical advice.

Overview of Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2022



Units: millions of yen	Dec / 2018	Dec / 2019	Dec / 2020	Dec / 2021	% Y/Y	March / 2022 (Forecast)	% Y/Y
Net sales	82,017	78,614	74,955	77,717	n/a	102,600	n/a
Operating income	6,794	5,271	4,114	2,926	-28.9	3,300	-43.0
Ordinary income	7,124	5,836	4,656	3,515	-24.5	3,800	-41.1
Net income	5,112	4,374	4,504	2,483	-44.9	2,700	-56.0

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[Net sales] Although the respiratory and otolaryngology markets, which are our priority areas, remained sluggish due to the impact of NHI drug price revisions and the spread of the new coronavirus infection etc., sales of New ethical drugs increased by efficient promotion, and sales of main long-listed products increased due to product supply insecurity for quality problem of some generics drug companies, then sales of New ethical drugs, etc. (Japan) were higher than the previous year. In addition, Generic drugs increased, and overall sales were 77,717 million yen.

[Profit] Despite an increase of sales, gross profit decreased to 36,240 million yen (38,798 million yen in same period a year ago) due to an increase in the cost ratio. Although an upfront payment for a drug for treating chronic cough was posted, SG&A expenses (including R & D expenses) was 33,313 million yen, down from year on year (34,684 million yen in same period a year ago) due to cost reduction, etc.. As a result, Operating income was 2,926 million yen, Ordinary income was 3,515 million yen, Net income was 2,483 million yen.

Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2022

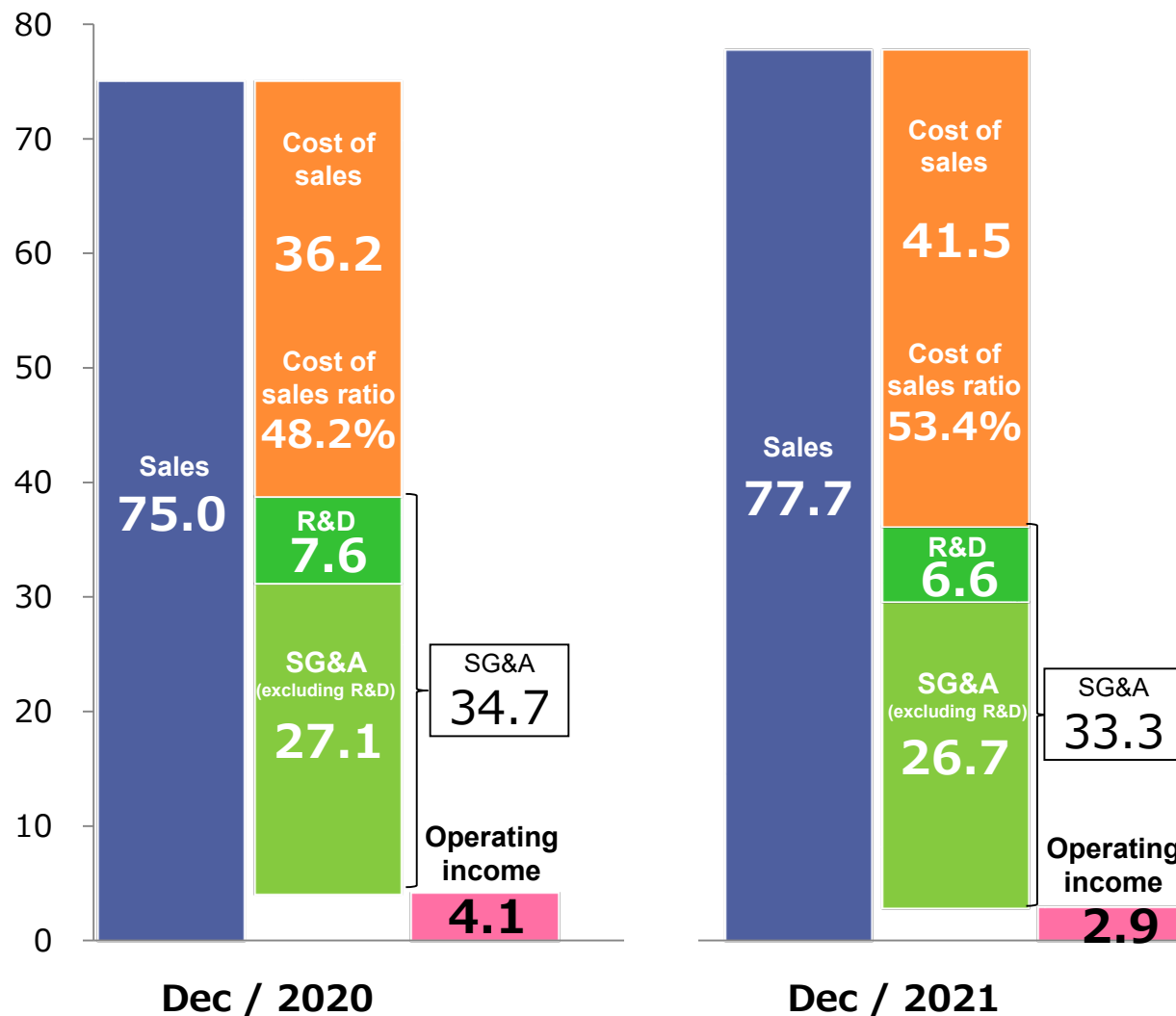
The forecast for the full year announced on May 11, 2021 remain unchanged at this moment.

(Progress compared with the forecast for the fiscal year ending March 31, 2022: net sales: 75.7%; operating income: 88.7%)

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

*From the beginning of the current term for the fiscal year ending March 31, 2022, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar 31,2020) etc. have been applied, and the revenue recognition standards for the previous Third quarter is different from the current Third quarter, the amount of increase / decrease compared to the current Third quarter and the YoY change rate (%) are not shown. There is no impact on operating income, ordinary income, and net income, from the application of the "Accounting Standard for Revenue Recognition".

(Units : ¥ billion)



Net sales increased

Cost of sales ratio increased

<Reason of decrease>

- Sales of New drugs increased

<Reasons of increase>

- Impact of NHI drug price revisions (Kyorin Pharmaceutical : 6% range)
- Sales of Generic drugs increased
- Loss on retirement of inventories, etc. increased

Gross profit decreased

SG&A cost decreased

- Cost of R&D decreased
Upfront payment for AKP-009 in FY2020
- SG&A (excluding R&D) decreased
Upfront payment for Lyfnua Tablets 45mg
Cost reduction

Operating income decreased

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



(Year on Year)

(Units : ¥ billion)	Dec / 2020	Dec / 2021	Change
Net Sales	75.0	77.7	n/a
New ethical drugs, etc. (Japan)	51.7	52.4	n/a
New ethical drugs (Overseas)	0.8	0.5	n/a
Generic drugs	22.5	24.9	n/a
Operating Income	4.1	2.9	-1.2
Ordinary Income	4.7	3.5	-1.2
Net Income	4.5	2.5	-2.0

*The impact of the application of the "Accounting Standard for Revenue Recognition" was sales decreased by 816 million yen and SG&A expenses decreased by 816 million yen, and there is no impact on operating income, ordinary income, and net income.

■ Net sales	¥ 77.7bln	(n/a)
● New ethical drugs, etc. (Japan)	¥ 52.4bln	(n/a)
	21.3 (3Q)	22.3 (3Q)
• Flutiform	10.2 ⇒	9.8 (-0.4)
• Desalex	3.1 ⇒	4.3 (+1.2)
• Beova	5.5 ⇒	6.5 (+1.0)
• Lasvic	0.6 ⇒	1.4 (+0.8)
• Pentasa	9.8 ⇒	10.9 (+1.1)
• Uritos	2.0 ⇒	1.0 (-1.0)
• Nasonex	1.2 ⇒	1.3 (+0.1)
• Kipres	5.9 ⇒	6.1 (+0.2)
• Mucodyne	2.5 ⇒	2.9 (+0.4)
● New ethical drugs (Overseas)	¥ 0.5bln	(n/a)
	Sales of transfer of intellectual property and APIs in FY2020	
● Generic drugs	¥ 24.9bln	(n/a)
	Sales increase in 3 AG products (Kipres AG, etc.) New generic drugs in June and December contributed to sales	
■ Operating income	¥ 2.9bln	(-1.2)
● Cost of Sales ratio : 53.4% (3Q FY2020: 48.2%)	[Reason of decrease] Increase in sales of New drugs [Reason of increase] NHI drug price revisions, Increase in sales of Generic drugs Increase in loss on retirement of inventories, etc.	
● R&D : ¥ 6.6bln (3Q FY2020 : ¥ 7.6bln)	Upfront payment for AKP-009 in FY2020	
● SG&A (excluding R&D expenses) : ¥ 26.7bln (3Q FY2020 : ¥ 27.1bln)	Decrease in sales and labor costs, Increase in patents royalty (Upfront payment for Lyfnua Tablets 45mg)	
■ Net Income	¥ 2.5bln	(-2.0)

Main Product Sales Update



(Units : ¥billion)		Sep / 2020	Sep / 2021	Dec / 2020	Dec / 2021	Change	YoY Change (%)	Mar / 2021	Mar / 2022 Forecast	Mar / 2022 Progress (%)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	6.4	6.3	10.2	9.8	-0.4	-4.6	13.3	13.9	70.0
	Desalex (Antiallergic Agent)	1.8	2.6	3.1	4.3	+1.2	+38.3	5.7	7.2	59.8
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	3.8	4.3	5.5	6.5	+1.0	+16.8	7.3	8.6	74.7
	Lasvic (New quinolone synthetic antibacterial agent)	0.2	0.8	0.6	1.4	+0.8	+149.6	0.9	2.8	49.5
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.4	7.1	9.8	10.9	+1.1	+11.6	12.8	11.7	92.9
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	1.6	0.7	2.0	1.0	-1.0	-47.9	2.3	1.0	101.8
	Nasonex (Spray type allergic rhinitis remedy)	0.6	0.7	1.2	1.3	+0.1	+3.6	2.8	1.8	68.9
	Kipres (Leukotriene Receptor Antagonist)	3.5	3.6	5.9	6.1	+0.2	+4.2	8.3	6.9	87.8
	Mucodyne (Mucoregulant)	1.4	1.6	2.5	2.9	+0.4	+12.5	3.3	2.9	96.4
	Milton (Disinfectant)	1.1	1.0	1.7	1.6	-0.1	-5.6	2.1	2.2	70.7
	Rubysta (Disinfectant)	1.0	1.0	1.6	1.5	-0.1	-2.2	2.0	2.1	70.6
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	4.5	5.1	7.3	8.5	+1.2	+16.7	10.8	9.2	91.7
	Mometasone Nasal 50μg "KYORIN" (Spray type allergic rhinitis remedy)	0.9	1.0	1.7	1.9	+0.2	+11.6	3.8	3.5	53.4
	Imidafenacin tablets & OD "KYORIN" (Therapeutic agent for overactive bladder)	0.3	0.4	0.5	0.6	+0.1	+8.9	0.7	0.7	75.0

Consolidated Financial Results for the Third Quarter and full year forecast



(Units : ¥ million)	Sep / 2020	Sep / 2021	Dec / 2020	Dec / 2021	Change	YoY Change (%)	Mar / 2021	Mar / 2022 (Forecast)	Mar / 2022 (Progress)
Net sales	47,735	49,102	74,955	77,717	n/a	n/a	102,904	102,600	75.7
New ethical drugs, etc. (Japan)	32,857	33,279	51,671	52,369	n/a	n/a	69,735	68,600	76.3
New ethical drugs (Overseas)	527	342	755	493	n/a	n/a	996	800	61.7
Generic drugs	14,351	15,481	22,528	24,855	n/a	n/a	32,172	33,100	75.1
Operating Income	1,502	-68	4,114	2,926	-1,188	-28.9	5,786	3,300	88.7
Ordinary Income	1,813	285	4,656	3,515	-1,141	-24.5	6,447	3,800	92.5
Net Income	2,118	121	4,504	2,483	-2,021	-44.9	6,130	2,700	92.0

From the beginning of the first quarter for the Fiscal Year Ending March 31, 2022, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar.31,2020) etc. have been applied, and the Second quarter results, Third quarter results, and the full-year forecast are based on the "Accounting Standard for Revenue Recognition".

Development pipeline

Main R&D Activities -1 (as of February 4, 2022)

Ph III ~ Application submitted

※Changes from the previous announcement (Nov 8, 2021)

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”	
Approval※ (Jan 2022) MSD	—	Lyfnua Tablets 45mg / 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 Ib / IIa (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 February 4, 2022)

Licensing development (License-in)

※Changes from the previous announcement (Nov 8, 2021)

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)

Additional Ph I study at a higher dose started (Sep 2021)

Licensing development (License-out)

Stage	Compound / Code	Licensee	Therapy area / Action	Origin	Features	Comments
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

※FPR-2 agonist program : Deleted from Main R&D Activities
BMS(Licensee) decided to discontinue development of FPR-2 agonist program for strategic reasons