

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2023

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February 6, 2023
KYORIN Holdings, Inc.



■ Disclaimer

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

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Overview of Third Quarter Consolidated Financial Results for FY2022

(¥ in millions)	FY2019 3Q (Apr-Dec)	FY2020 3Q (Apr-Dec)	FY2021 3Q (Apr-Dec)	FY2022 3Q (Apr-Dec)	Change (%)	Full term FY2022 (Forecast)	Change (%)
Net sales	78,614	74,955	77,717	80,707	+3.8	112,000	+6.1
Operating profit	5,271	4,114	2,926	4,702	+60.7	5,500	+9.8
Ordinary profit	5,836	4,656	3,515	5,336	+51.8	6,000	+7.7
Profit attributable to owner of parent	4,374	4,504	2,483	4,377	+76.3	4,500	+14.4

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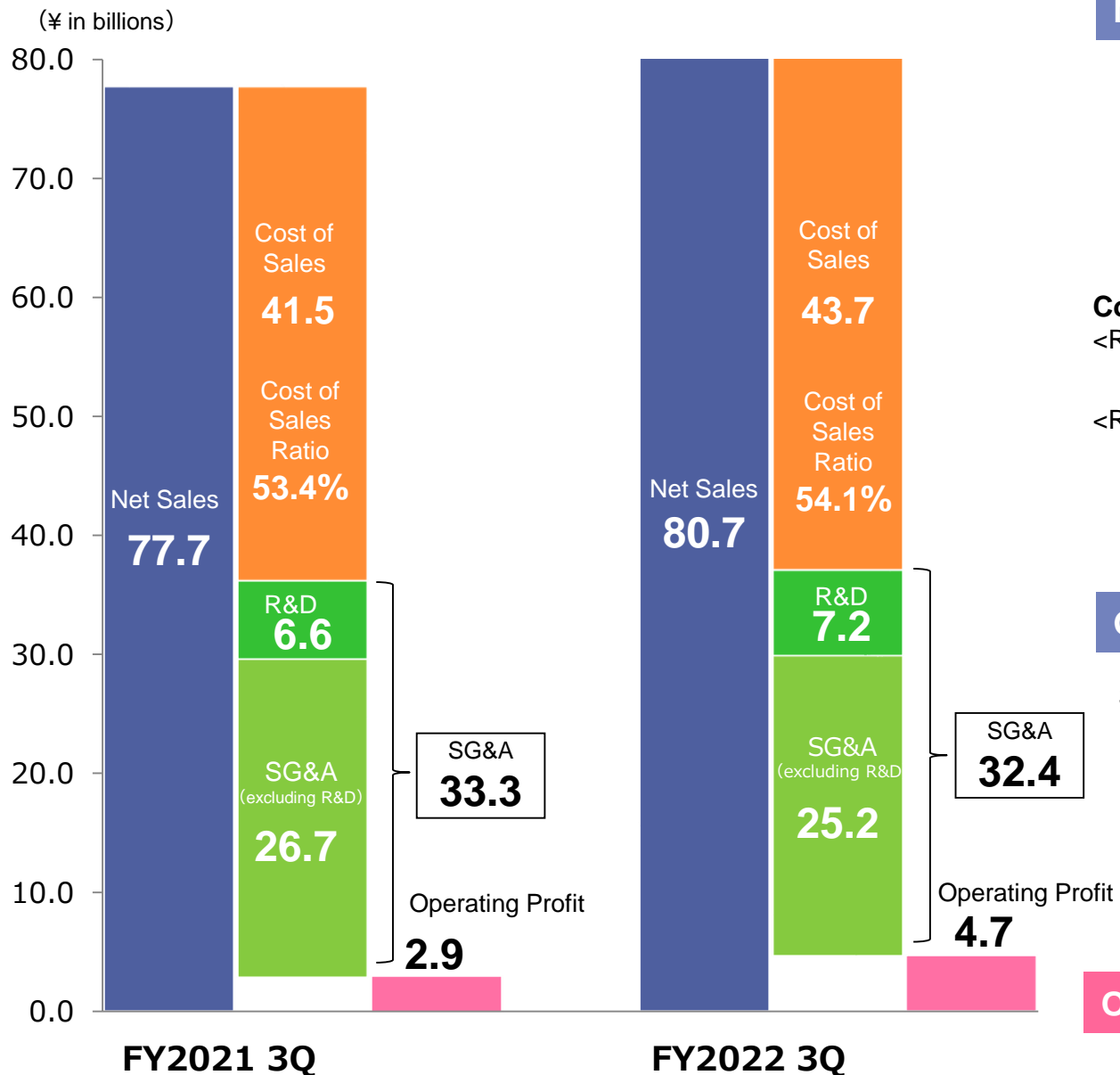
[Net sales] Sales of new ethical drugs etc. (Japan) increased from year on year by the effort to spread of the product, while the impact of the NIH drug price revision (KYORIN pharmaceutical: 8% range) and Covid-19. And also sales of generic drugs increased. As a result, net sales were 80,707 million yen (an increase of 2,989 million yen year on year)

[Profit] Gross profit was 37,055 million yen (an increase of 814 million yen year on year) due to increase in sales, despite a increase in cost of sales ratio due to the impact of NIH drug price revision etc. On the other hand, decline in SG&A expenses (include of R&D expenses) of 961 million yen (R&D expenses increased 585 million yen) due to the absence of upfront payment in FY2021 lead to operating profit of 4,702 million yen (increased 1,776 million yen, year on year). Extraordinary income of 1,283 million yen regarding a fire at Nishinohon delivery, and extraordinary loss of 689 million yen regarding dissolution of ActivX, subsidiary of KYORIN Pharmaceutical Co., Ltd., caused to profit attributable to owner of parent of 4,377 million yen.

Consolidated Financial Results for the Fiscal Year Ending March 31, 2023 (forecast)

The forecast for full year announced on May 11, 2022 remain unchanged at this moment.
(There is no change to the dividend forecast announced on May 11, 2022 (Annual dividend of 52 yen per share).)

Highlights of Business Performance



Net sales increased (+3.0 bln yen)

- Increase in sales of new ethical drugs etc. (Japan)
 - Main product (Beova, Desalex etc.) grew
 - Decrease in sales of long-listed products and out-licensing product to other company
- Increase in sales of generic drugs

Cost of sales ratio increased (+0.7 point)

<Reason of decrease>

- Increase in sales of main product

<Reasons of increase>

- Impact of NHI drug price revisions (Kyorin Pharmaceutical: 8% range)
- Increase in sales of generic drugs

Gross profit increased (+0.9 bln yen)

SG&A cost decreased (-0.9 bln yen)

- R&D expenses increased (+0.6 bln yen)
Upfront payment, progress in pipeline
- SG&A (excluding R&D) decreased
Decrease in license fees etc.
(Decline of upfront payment posted in FY2021 and payment of royalty)

Operating profit increased (+1.8 bln yen)

Consolidated Financial Results



(Year on Year)

(¥ in billions)	FY2021 3Q (Apr- Dec)	FY2022 3Q (Apr- Dec)	Change
Net sales	77.7	80.7	+3.0
New ethical drugs, etc. (Japan)	52.4	54.1	+1.7
New ethical drugs (Overseas)	0.5	0.5	0
Generic drugs	24.9	26.1	+1.2
Operating profit	2.9	4.7	+1.8
Ordinary profit	3.5	5.3	+1.8
Profit attributable to owner of parent	2.5	4.4	+1.9

■ Net sales **¥80.7 bln (+ 3.0)**

● New ethical drugs, etc. (Japan) **¥54.1 bln (+ 1.7)**

	FY2021 (3Q)		FY2022 (3Q)	
• Flutiform	9.8	⇒	9.1	(-0.7)
• Desalex	4.3	⇒	4.8	(+0.5)
• Beova	6.5	⇒	9.2	(+2.7)
• Lasvic	1.4	⇒	1.8	(+0.4)
• Lyfnua	—	⇒	0.1	(+0.1)
• Pentasa	10.9	⇒	9.9	(-1.0)
• Kipres	6.1	⇒	4.6	(-1.5)
• Mucodyne	2.9	⇒	2.8	(-0.1)
• Nasonex	1.3	⇒	1.1	(-0.2)
• Uritos	1.0	⇒	0.6	(-0.4)

● New ethical drugs (Overseas) **¥0.5 bln (0)**

● Generic drugs **¥26.1 bln (+ 1.2)**

Increase sales in AG products (Kipres AG)
Items launched in FY2022 contribute to sales

■ Operating profit **¥4.7 bln (+ 1.8)**

● Cost of sales ratio : 54.1% (3Q FY2021: 53.4%)

[Reasons of decrease] Increase of sales for new drugs (Beova, Desalex etc.)

[Reasons of increase] NHI drug price revisions, Increase in sales of generic drugs

● R&D : ¥7.2 bln (3Q FY2021: ¥6.6 bln)

Upfront payment (GMAC, Digital Therapeutics), progress in pipeline

● SG&A (excluding R&D expenses) : ¥25.2 bln (3Q FY2021: ¥26.7 bln)

Decrease in license fees etc.

• Decline of upfront payment posted in FY2021 and payment of royalty

■ Profit attributable to owner of parent **¥4.4 bln (+ 1.9)**

Extraordinary profit: gain on insurance of ¥881 mln,
income of compensation for damages of ¥401 mln,
regarding a fire at Nishinohon delivery center

Extraordinary loss: Impairment losses of ¥105 mln, provision for loss on liquidation of
subsidiaries and associates of ¥583 mln regarding dissolution of ActivX⁴

Main Product Sales Update



(¥ in billions)		2Q (Apr-Sep)		3Q (Apr-Dec)				Full term		
		FY2021 (Actual)	FY2022 (Actual)	FY2021 (Actual)	FY2022 (Actual)	Change	Change (%)	FY2021 (Actual)	FY2022 (Forecast)	Progress to full term forecast (%)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	6.3	5.7	9.8	9.1	-0.7	-7.1	12.6	12.0	75.6
	Desalex (Antiallergic Agent)	2.6	3.0	4.3	4.8	+0.5	+10.4	7.1	8.0	59.7
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	4.3	5.5	6.5	9.2	+2.7	+42.8	8.6	14.1	65.1
	Lasvic (New quinolone synthetic antibacterial agent)	0.8	1.0	1.4	1.8	+0.4	+24.4	1.8	3.0	57.8
	Lyfnua (selective P2X3 receptor antagonist for the treatment of chronic cough)	—	0.1	—	0.1	+0.1	—	—	0.5	25.0
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	7.1	6.5	10.9	9.9	-1.0	-9.0	14.0	12.5	79.1
	Kipres (Leukotriene Receptor Antagonist)	3.6	2.7	6.1	4.6	-1.5	-24.8	8.4	6.8	67.0
	Mucodyne (Mucoregulant)	1.6	1.5	2.9	2.8	-0.1	-3.0	3.5	2.9	93.3
	Nasonex (Spray type allergic rhinitis remedy)	0.7	0.6	1.3	1.1	-0.2	-14.2	2.4	1.8	59.6
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	0.7	0.4	1.0	0.6	-0.4	-45.1	1.3	0.7	74.1
Milton (Disinfectant)	1.0	1.0	1.6	1.6	0	+0.1	2.1	2.0	77.4	
Rubysta (Disinfectant)	1.0	1.1	1.5	1.6	+0.1	+5.6	2.1	2.0	78.9	
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	5.1	5.4	8.5	8.7	+0.2	+2.6	12.2	10.7	81.1
	Mometasone Nasal 50µg "KYORIN" (Spray type allergic rhinitis remedy)	1.0	1.1	1.9	1.9	0	+1.2	3.6	3.6	53.4
	Imidafenacin tablets & OD "KYORIN" (Therapeutic agent for overactive bladder)	0.4	0.4	0.6	0.5	-0.1	-9.0	0.8	0.5	95.4

Financial Result and Forecast



(¥ in millions)	2Q (Apr-Sep)		3Q (Apr-Dec)				Full term		
	FY2021 (Actual)	FY2022 (Actual)	FY2021 (Actual)	FY2022 (Actual)	Change	Change (%)	FY2021 (Actual)	FY2022 (Forecast)	Progress to full term forecast (%)
Net sales	49,102	49,093	77,717	80,707	+2,989	+3.8	105,534	112,000	72.1
New ethical drugs, etc. (Japan)	33,279	32,651	52,369	54,055	+1,686	+3.2	69,725	74,500	72.6
New ethical drugs (Overseas)	342	312	493	532	+39	+7.9	1,033	700	76.1
Generic drugs	15,481	16,128	24,855	26,119	+1,264	+5.1	34,775	36,700	71.2
Operating profit	-68	777	2,926	4,702	+1,776	+60.7	5,007	5,500	85.5
Ordinary profit	285	1,171	3,515	5,336	+1,820	+51.8	5,569	6,000	88.9
Profit attributable to owner of parent	121	1,242	2,483	4,377	+1,894	+76.3	3,932	4,500	97.3

Development pipeline

Main R&D Activities -1 (as of February 6 , 2023)



Ph 3 ~ Launch

Stage		Code	Proposed Indication	Origin	Features	Note
Japan	Overseas					
Ph 3 (Sep 2022)	Ph 3 (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	

POC Project (Ph1 ~ Ph2)

Stage		Code	Proposed Indication	Origin	Features	Note
Japan	Overseas					
Ph 1 (Aug 2022)		KRP-114VP	Overactive bladder	Merck	It selectively acts on β_3 receptors in the bladder and increases bladder capacity by enhancing the bladder-relaxing effect of noradrenaline during the urinary storage phase, resulting in the improvement of incontinence symptoms of urinary urgency, frequent urination and urge urinary incontinence with OAB.	Additional Indication for Beova in pediatric patients
—	Ph 1 (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 6, 2023)

Licensing development (License-in)

Stage		Code	Proposed Indication	Origin	Features	Note
Japan	Over seas					
Ph 2 (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 Ph1 study at a higher dose has been completed (ASKA)

Licensing development (License-out)

Stage	Compound / Code	Licensee	Therapy area / Action	Origin	Features	Note
Ph 1	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)

Date	Origin	Note
Nov 2022	SUSMED	Collaboration research and sales agreement for development of Digital Therapeutics (DTx) in otolaryngology Field Development using KYORIN's knowledge in disease areas and clinical development, and SUSMED's platform, clinical trial management system of DTx and its know-how.