

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

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August 2, 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 Consolidated Financial Results for Fiscal 2022



(¥ in millions)	FY2019 1Q (Apr-Jun)	FY2020 1Q (Apr-Jun)	FY2021 1Q (Apr-Jun)	FY2022 1Q (Apr-Jun)	Change (%)	Interim term FY2022 (Forecast)	Change (%)	Full term FY2022 (Forecast)	Change (%)
Net sales	25,749	24,689	24,695	24,619	-0.3	49,600	+1.0	112,000	+6.1
Operating profit	1,575	2,014	-756	489	-	700	-	5,500	+9.8
Ordinary profit	1,827	2,265	-491	779	-	1,000	+249.8	6,000	+7.7
Profit attributable to owner of parent	1,280	1,609	-462	1,183	-	700	+475.2	4,500	+14.4

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[Net sales] Sales of new ethical drugs decreased from year on year due to the impact of NIH drug price revision (KYORIN pharmaceutical: 8% range), though main products such as “Desalex” and “Beova” etc. increased. On the other hand, sales of generic drugs increased, resulting in net sales of 24,619 million yen.

[Profit] Despite gross profit remain flat, a decline in SG&A expenses (include of R&D expenses) due to the absence of upfront payment in FY2021 lead to operating profit of 489 million yen. Gain on insurance related to storage products damaged from a fire at Nishinohon delivery center was posted in value to extraordinary income of 879 million yen, and profit attributable to owner parent for this quarter was 1,183 million yen.

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

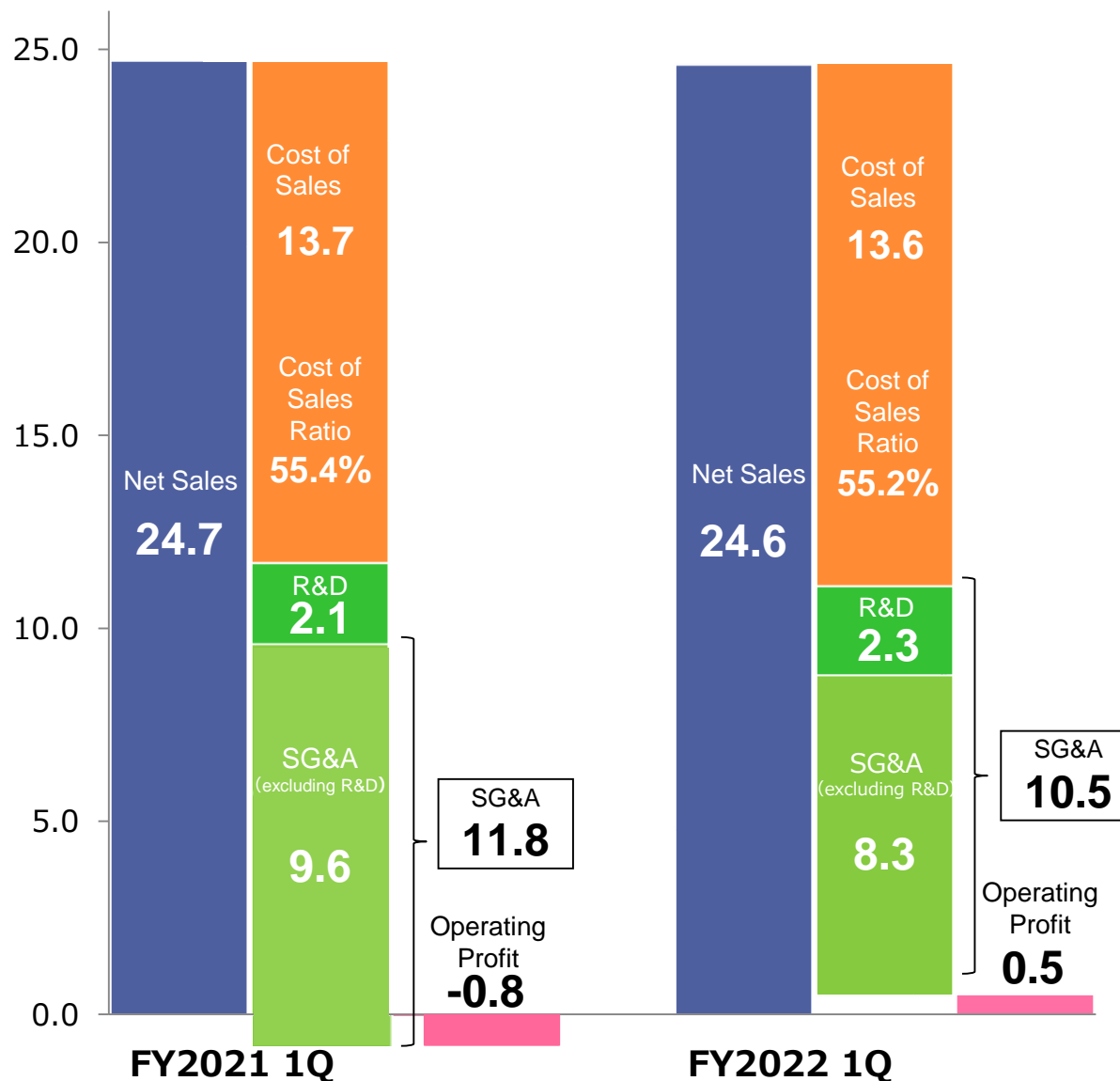
The forecast for the first half and full year announced on May 11, 2022 remain unchanged at this moment.

(Progress compared with the forecast for the first half; Net sales 49.6%, Operating profit 70.0%)

There is no change to the dividend forecast announced on May 11, 2022 (Annual dividend of 52 yen per share).

Highlights of Business Performance

(¥ in billions)



Net sales decreased (–¥0.1 bln)

- Decrease in sales of new ethical drugs etc. (Japan)
 - Main product (Beova, Desalex) grew
- Increase in sales of generic drugs

Cost of sales ratio decreased (– 0.2 point)

<Reasons of decrease>

- Increase in sales of new drugs, Cost reduction of Beova
- Decrease of loss on retirement of inventories

<Reasons of increase>

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

Gross profit remained flat

SG&A cost decreased (–¥1.3 bln)

- R&D cost increase (+¥0.2 bln)
 - Upfront payment
- SG&A (excluding R&D) decreased
 - Decrease in license fees (Absence of upfront payment in FY2021)

Operating profit increased (+¥1.3 bln)

Consolidated Financial Results



(Year on Year)

(¥ in billions)	FY2021 1Q (Apr- Jun)	FY2022 1Q (Apr- Jun)	Change
Net sales	24.7	24.6	-0.1
New ethical drugs, etc. (Japan)	16.8	16.4	-0.4
New ethical drugs (Overseas)	0.2	0.1	-0.1
Generic drugs	7.7	8.1	+0.4
Operating profit	-0.8	0.5	+1.3
Ordinary profit	-0.5	0.8	+1.3
Profit attributable to owner of parent	-0.5	1.2	+1.7

■ Net sales	¥24.6 bln	(-0.1)
<ul style="list-style-type: none"> ● New ethical drugs, etc. (Japan) ¥16.4 bln (-0.4) <ul style="list-style-type: none"> 21.6 (1Q) → 22.6 (1Q) • Flutiform 3.2 ⇒ 2.9 (-0.3) • Desalex 1.3 ⇒ 1.6 (+0.3) • Beova 2.1 ⇒ 2.7 (+0.6) • Lasvic 0.4 ⇒ 0.4 (0) • Lyfnua - ⇒ 0.1 (+0.1) • Pentasa 3.6 ⇒ 3.4 (-0.2) • Kipres 1.8 ⇒ 1.5 (-0.3) • Mucodyne 0.8 ⇒ 0.8 (0) • Nasonex 0.4 ⇒ 0.4 (0) • Uritos 0.4 ⇒ 0.2 (-0.2) ● New ethical drugs (Overseas) ¥1.0 bln (-0.1) Decrease in sales of Gatifloxacin ● Generic drugs ¥8.1 bln (+0.4) Sales increase in AG products (Kipres AG, etc.) 		
■ Operating profit	¥0.5 bln	(+1.3)
<ul style="list-style-type: none"> ● Cost of Sales ratio : 55.2% (1Q FY2021: 55.4%) [Reasons of decrease] Increase of sales for new drugs, Cost reduction of Beova, Decrease of loss on retirement of inventories [Reasons of increase] NHI drug price revisions, Increase in sales of generic drugs ● R&D : ¥2.3 bln (1Q FY2021: ¥2.1 bln) Upfront payment ● SG&A (excluding R&D expenses) : ¥8.3 bln (1Q FY2021: ¥9.6 bln) Decrease in license fee (Absence of upfront payment in FY2021), Decrease in labor costs 		
■ Profit attributable to owner of parent	¥ 1.2 bln	(+1.7)
<ul style="list-style-type: none"> ● Extraordinary income: ¥ 0.9 bln Gain on insurance related to storage products damaged from a fire at Nishinohon delivery center 		

Main Product Sales Update



(¥ in billions)		1Q (Apr-Jun)					Interim term		Full term		
		FY2021 (Actual)	FY2022 (Actual)	Change	Change (%)	Progress to interim (%)	Progress to full term (%)	FY2021 (Actual)	FY2022 (Forecast)	FY2021 (Actual)	FY2022 (Forecast)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	3.2	2.9	-0.3	-10.8	50.2	23.8	6.3	5.6	12.6	12.0
	Desalex (Antiallergic Agent)	1.3	1.6	+0.3	+24.2	55.2	20.3	2.6	2.9	7.1	8.0
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	2.1	2.7	+0.6	+28.1	42.1	19.1	4.3	6.4	8.6	14.1
	Lasvic (New quinolone synthetic antibacterial agent)	0.4	0.4	0	+7.6	34.4	14.7	0.8	1.3	1.8	3.0
	Lyfnua (selective P2X3 receptor antagonist for the treatment of chronic cough)	-	0.1	+0.1	-	23.2	9.0	-	0.2	-	0.5
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	3.6	3.4	-0.2	-6.7	52.5	26.7	7.1	6.3	14.0	12.5
	Kipres (Leukotriene Receptor Antagonist)	1.8	1.5	-0.3	-17.8	52.0	21.7	3.6	2.8	8.4	6.8
	Mucodyne (Mucoregulant)	0.8	0.8	0	-5.6	55.0	26.4	1.6	1.4	3.5	2.9
	Nasonex (Spray type allergic rhinitis remedy)	0.4	0.4	0	-3.3	70.1	20.0	0.7	0.5	2.4	1.8
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	0.4	0.2	-0.2	-44.4	52.1	26.4	0.7	0.3	1.3	0.7
	Milton (Disinfectant)	0.5	0.5	0	-0.2	47.7	24.4	1.0	1.0	2.1	2.0
Rubysta (Disinfectant)	0.5	0.5	0	-4.0	44.0	23.2	1.0	1.0	2.1	2.0	
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	2.6	2.8	+0.2	+8.6	59.5	25.8	5.1	4.6	12.2	10.7
	Mometasone Nasal 50µg "KYORIN" (Spray type allergic rhinitis remedy)	0.5	0.6	+0.1	+26.1	61.9	17.3	1.0	1.0	3.6	3.6
	Imidafenacin tablets & OD "KYORIN" (Therapeutic agent for overactive bladder)	0.2	0.2	0	-8.1	62.3	31.9	0.4	0.2	0.8	0.5

(¥ in millions)	1Q (Apr-Jun)						Interim term		Full term	
	FY2021 (Actual)	FY2022 (Actual)	Change	Change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)	FY2021 (Actual)	FY2022 (Forecast)	FY2021 (Actual)	FY2022 (Forecast)
Net sales	24,695	24,619	-75	-0.3	49.6	22.0	49,102	49,600	105,534	112,000
New ethical drugs, etc. (Japan)	16,820	16,373	-447	-2.7	49.0	22.0	33,279	33,400	69,725	74,500
New ethical drugs (Overseas)	200	142	-57	-28.9	47.5	20.4	342	300	1,033	700
Generic drugs	7,674	8,103	+429	+5.6	51.3	22.1	15,481	15,800	34,775	36,700
Operating profit	-756	489	+1,246	-	70.0	8.9	-68	700	5,007	5,500
Ordinary profit	-491	779	+1,271	-	78.0	13.0	285	1,000	5,569	6,000
Profit attributable to owner of parent	-462	1,183	+1,645	-	169.0	26.3	121	700	3,932	4,500

Development pipeline

Main R&D Activities -1 (as of August 2, 2022)

POC Project (Ph I ~ Ph II)

Stage		Code	Proposed Indication	Origin	Features	Note
Japan	Overseas					
Ph 1 (Jul 2020)	Ph 1b / 2a (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 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 August 2, 2022)

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 2	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)