

Q3 FY 2021 Financial Results

Ended Dec 31, 2021

February 4 , 2022
KYORIN Holdings, Inc.
President Yutaka Ogihara



- **Outline of Consolidated Financial Results**
- **Consolidated Financial Forecast**
- **Status of R&D Pipeline**
- **Renovation of the Group Structure**

Outline of Consolidated Financial Results

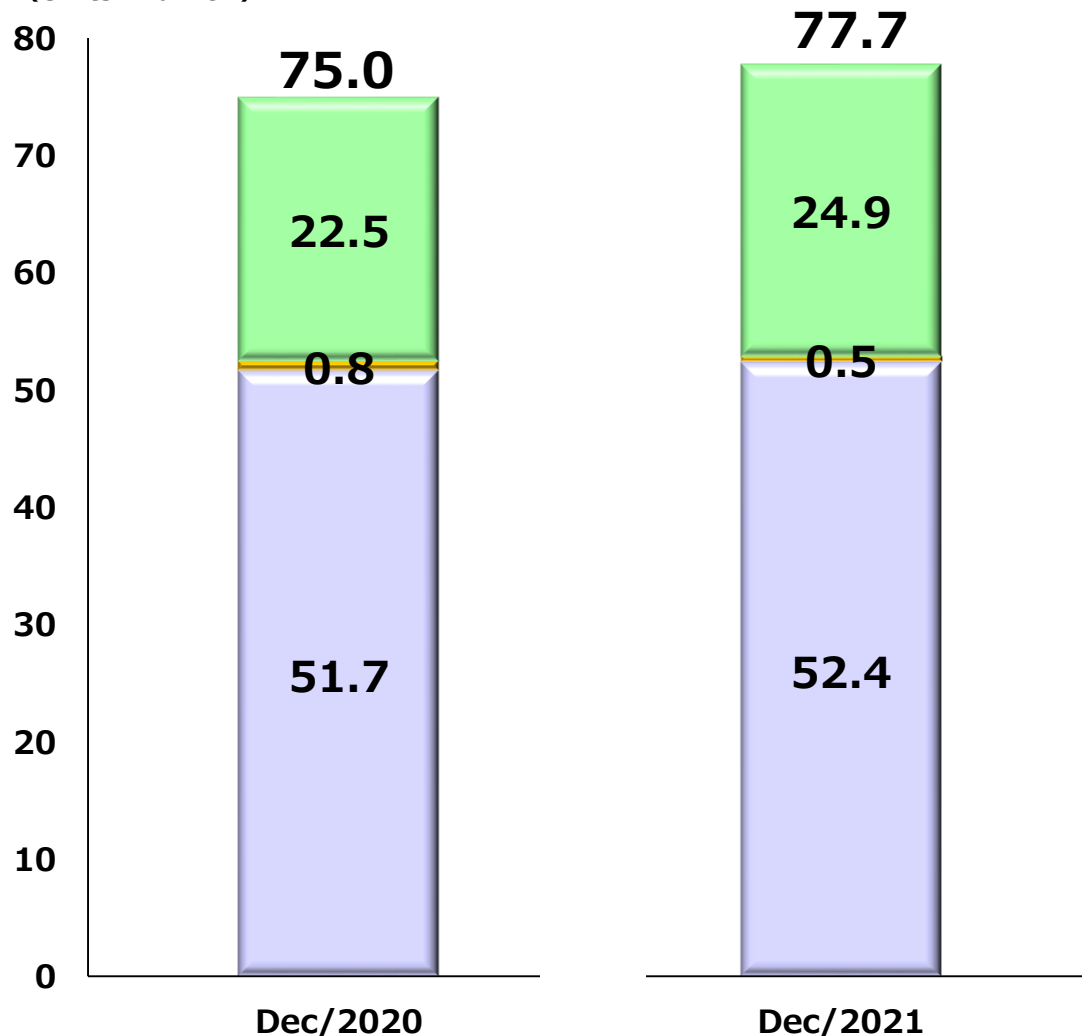
Segment Sales and Breakdown of Gain and Loss

(Units: ¥billion)	Dec/20	Dec/21	Change	Change (%)	Progress to Full Term Forecast (%)
Sales	75.0	77.7	n/a	n/a	75.7
New ethical drugs, etc. (Japan)	51.7	52.4	n/a	n/a	76.3
New ethical drugs (Overseas)	0.8	0.5	n/a	n/a	61.7
Generic drugs	22.5	24.9	n/a	n/a	75.1
Cost of Sales	36.2	41.5	n/a	n/a	–
SG&A (R&D)	34.7 (7.6)	33.3 (6.6)	n/a (–1.1)	n/a (–13.6)	– (71.4)
Operating Income	4.1	2.9	–1.2	–28.9	88.7
Ordinary Income	4.7	3.5	–1.2	–24.5	92.5
Net Income	4.5	2.5	–2.0	–44.9	92.0

* From the beginning of the current term, "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 third quarter and the Year on Year change rate (%) are not shown. There is no impact on operating income, ordinary income, and net income.

Highlights of Business Performance : Net sales

(Units: ¥billion)



New ethical drugs, etc.(Japan) Increased

- New drugs (Beova,Desalex,Lasvic) grew
- Sales of long-listed products (Pentasa, Mucodyne etc.) increased

New ethical drugs (Overseas) Decreased

Generic drugs Increased

- Sales increase in 3 AG products (Kipres AG, etc.)
- New generic drugs(June & Dec) contributed to sales

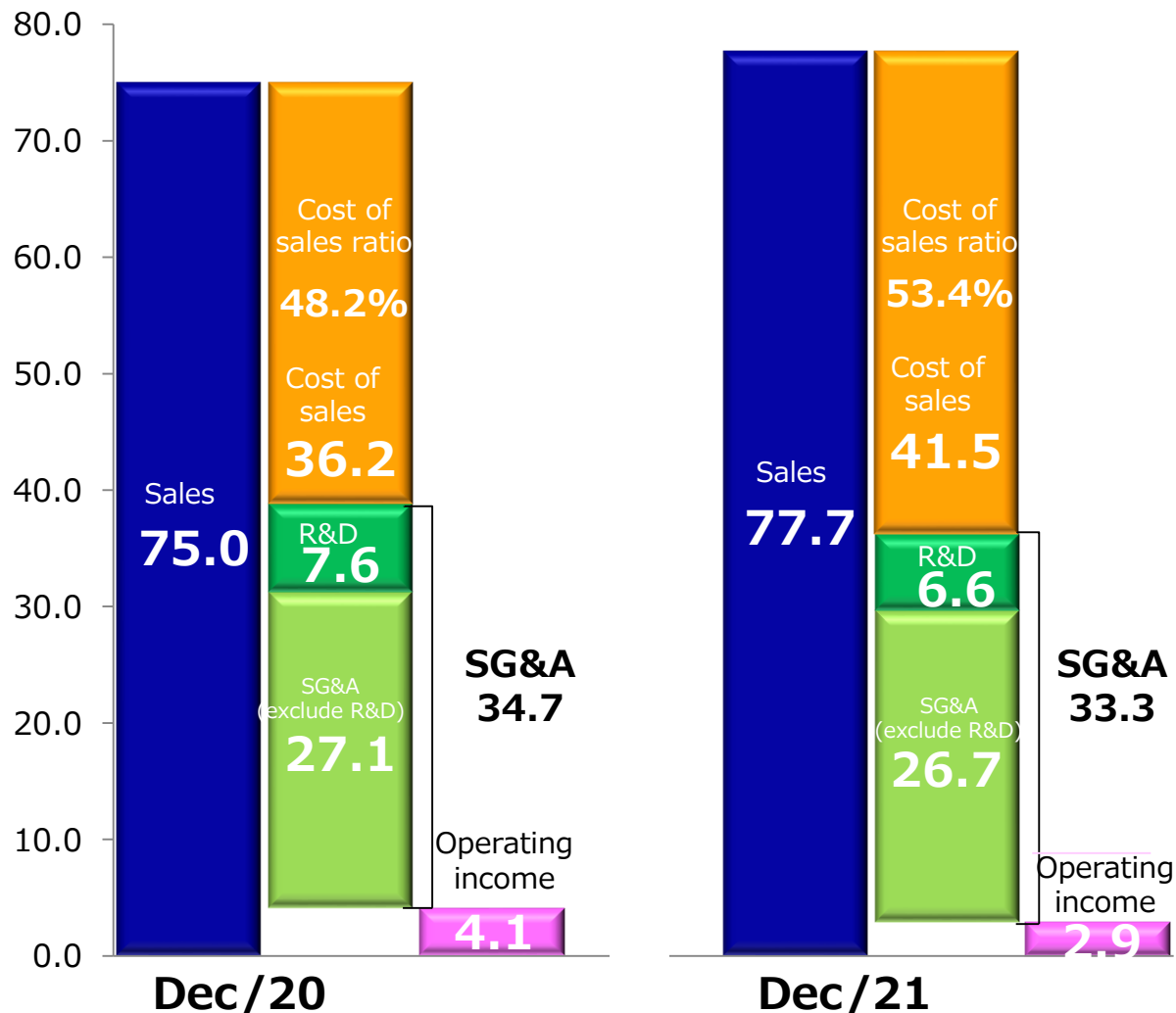
Main Product Sales Update

(Units : ¥billion)

		Dec/20	Dec/21	Change	Change (%)	FY2021 (Forecast)	Progress to Full Term Forecast(%)
New ethical drugs, etc. (Japan)	Flutiform (Combination drug for asthma treatment)	10.2	9.8	-0.4	-4.6	13.9	70.0
	Desalex (Antiallergic Agent)	3.1	4.3	+1.2	+38.3	7.2	59.8
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	5.5	6.5	+1.0	+16.8	8.6	74.7
	Lasvic (New quinolone synthetic antibacterial agent)	0.6	1.4	+0.8	+149.6	2.8	49.5
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.8	10.9	+1.1	+11.6	11.7	92.9
	Uritos (Kyorin) (Overactive bladder)	2.0	1.0	-1.0	-47.9	1.0	101.8
	Nasonex (Spray type allergic rhinitis remedy)	1.2	1.3	+0.1	+3.6	1.8	68.9
	Kipres (Leukotriene Receptor Antagonist)	5.9	6.1	+0.2	+4.2	6.9	87.8
	Mucodyne (Mucoregulant)	2.5	2.9	+0.4	+12.5	2.9	96.4
	Milton (Disinfectant)	1.7	1.6	-0.1	-5.6	2.2	70.7
	Rubysta (Disinfectant)	1.6	1.5	-0.1	-2.2	2.1	70.6
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	7.3	8.5	+1.2	+16.7	9.2	91.7
	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	1.7	1.9	+0.2	+11.6	3.5	53.4
	Imidafenacin tablets & OD "KYORIN" (Overactive bladder)	0.5	0.6	+0.1	+8.9	0.7	75.0

Highlights of Business Performance : Operating Income

(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 revision (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 cost decreased
Upfront payment for AKP-009 in FY20
- SG&A(excluding R&D) decreased
Upfront payment for Lyfnua Tablets
Cost reduction

Operating income decreased

Consolidated Financial Forecast

Consolidated Financial Forecast in FY2021

(Units : ¥billion)	FY2020	FY2021 (Forecast)	Y/Y	
			Change	Change(%)
Net sales	102.9	102.6	n/a	n/a
New ethical drugs, etc.(Japan)	69.7	68.6	n/a	n/a
New ethical drugs (Overseas)	1.0	0.8	n/a	n/a
Generic drugs	32.2	33.1	n/a	n/a
Cost of Sales	51.3	—	—	—
SG&A (R&D)	45.8 (9.7)	— (9.2)	— (-0.5)	— (-5.2)
Operating Income	5.8	3.3	-2.5	-43.0
Ordinary Income	6.4	3.8	-2.6	-41.1
Net Income	6.1	2.7	-3.4	-56.0

※The results forecasts for the full year and sales forecast for main products announced on May 11, 2021 remain unchanged

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Impact of fire at West Japan Distribution Center



Situation of Fire of West Japan Delivery Center of KYORIN Pharmaceutical

Date and time of Fire : AM8:50, November 29, 2021 (Extinguished PM5:00, December 4)

Place : Hitachi Transport System West Japan Co., Ltd. Maishima office (Osaka-City)

Damage situation and impact on business performance

Due to the inventory storage status of KYORIN Pharmaceutical and KYORIN Rimedio products, there was no significant impact on product supply

※Products to West Japan area are shipped from East Japan Delivery Center (Kazo-City, Saitama Pre.)

Impact on business performance

At this time, KYORIN believes that there will not be any impact on the consolidated earnings forecast

Status of R&D Pipeline

Drug R&D Pipeline: Progress



Progress in FY21

※Change from the previous presentation (Nov.8,21)

	Development code	Ph I	Ph II	Ph III	Application	Approval/ Launch
Respiratory	KRP-R120	Completed				
	Ryfdua Tablets 45mg					MSD approved (Jan,2022) ※
Infections	KRP-A218	(Apr,2021)				
Urology	KRP-116D					Launched (Apr,2021)
	AKP-009		ASKA interrupted ※			

※ASKA started an additional Ph I study to confirm the maximum effect at a higher dose

【 Licensed Compound / Program 】

Compound/Code	Licensee	Stage	Features
KRP-203	Priothera	Ph I	<ul style="list-style-type: none"> • Sphingosine-1-Phosphate Receptor Agonist • Target: AML patients undergoing HSCT • Assignment of intellectual properties and drug substances(Sep.2020)
Compound for Sensorineural Hearing Loss	Otonomy	Non-clinical	<ul style="list-style-type: none"> • 「OTO-6XX」 (Otonomy's Development Code) • License Agreement (Aug.2020)

※ BMS decided to discontinue development of FPR2 agonist program from their strategic viewpoint, it was deleted from the list

FPR2 agonist program

Out-licensee

Bristol-Myers Squibb(BMS)

Progress

- Concluded a license agreement related to out-licensing (Dec, 2015)
- BMS announces that it is conducting a Ph1 study in the cardiovascular area (Jan, 2018)
- KYORIN and BMS have given presentations at American Chemical Society National Meeting and European Society of Cardiology Congress (Aug-Sep, 2019)



Though BMS has continued Ph1 study, they decided to discontinue the development of from their development strategy viewpoint and return the development right etc. to KYORIN Pharmaceutical

KYORIN considers activities for searching for a new out-licensee

- Concluded an agreement for exclusive distribution rights in Japan (Apr, 2021)
- MSD received manufacturing and marketing approval (Jan, 2022)

Indication

Refractory chronic cough

Dosage and Administration

Normally for adults, 45 mg of gefapixant is administered orally twice daily

Mode of Action

Reduce sensory nerve activation and, subsequently cough by inhibiting binding of extracellular ATP to P2X3 receptors on found on sensory nerve fibers, predominantly C fibers in the airway

As the world's first selective P2X3 receptor antagonist indicated for refractory chronic cough, KYORIN will penetrate the market soon after launch

- MHLW granted a special approval for emergency to LAGEVRIO (Dec, 2021)
- KYORIN and MSD concluded a co-promotion agreement (Jan, 2022)
- Both companies started co-promotion (Jan 31, 2022)

Indication

SARS-CoV-2 infection

Dosage and Administration

Normally for patients over 18 years old , take molnupiravir 800 mg twice a day for five days

Characteristics

- First oral antiviral drug in Japan indicated for SARS-CoV-2 infection
- It is a ribonucleoside analog that inhibits the replication of SARS-CoV-2 causing COVID-19

**KYORIN will prompt proper use of the drug
and contribute to the treatment of COVID-19**

Renovation of the Group Structure

Background of Renovation of the Group Structure

Mid-term
Management Plan

Kyorin MIC-09
2005-2009

HOPE 100 Long term vision

Stage 1

2010-2015

Stage 2

2016-2019

Stage 3

2020-2023

Corporate Image

Unique and
integrated
healthcare company
centered on drug
discovery operations

Company that supports healthy lifestyles

Business Domain

Expand
Diversification

Business selection
and concentration
(Reduce
Diversification)

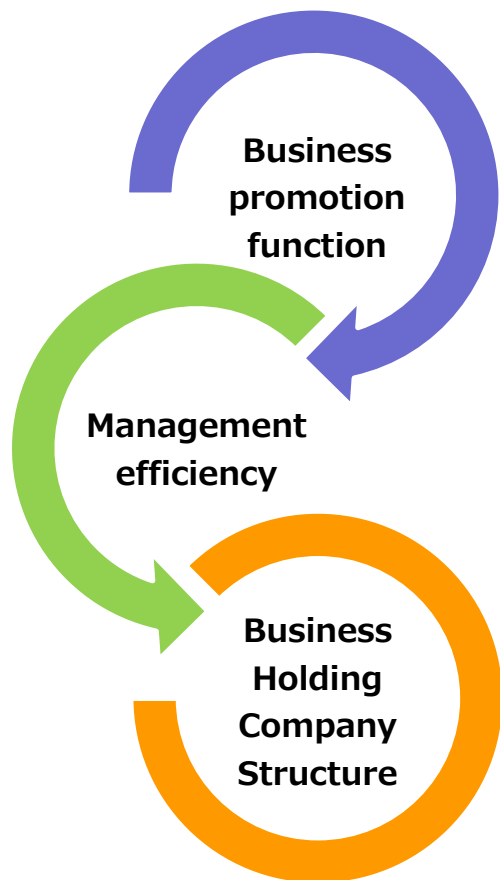
Management
System

Mar 2006
Pure Holding
Company Structure

Apr 2023
Business Holding
Company Structure

Outline of the Group Structure Renovation

To become “a globally recognized company by creating innovative new drugs”



- Strongly promote new drug businesses at the core and develop medical-related businesses
- Increase management efficiency and providing new value to patients and healthcare professionals in collaboration with the new drug business



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- Renovate the group structure in FY 2023, and aim for a further leap toward the next 100 years
-

The Group chart

Merger scheme and date

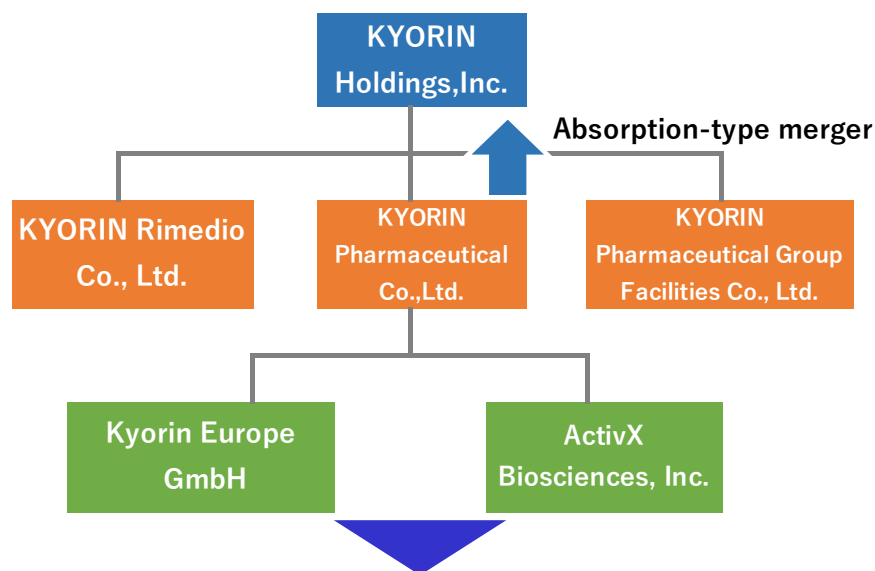
Change Scheme

KYORIN Holdings will absorb KYORIN pharmaceutical and change its trade name to KYORIN pharmaceutical

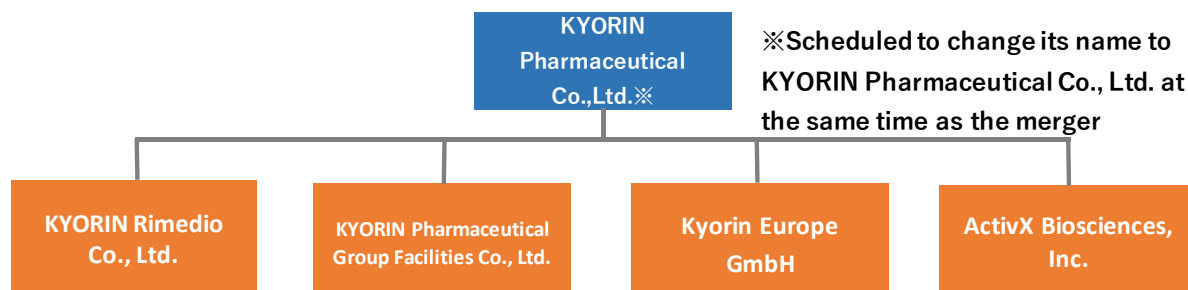
Expected Merger Date

April 1, 2023

[Pure Holding Company Structure]



[Business Holding Company Structure]



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.

Kyorin 