

Financial Results

Ended March 2024


May 13 , 2024

KYORIN Pharmaceutical Co., Ltd.

Representative Director, President and CEO

Yutaka Ogihara





Outline of Consolidated Financial Results



Trends of Mainstay Products, Generic Product



Consolidated Financial Forecast



Status of R&D Pipeline



Initiatives toward Realization of Vision110 –Stage1–



Outline of Consolidated Financial Results

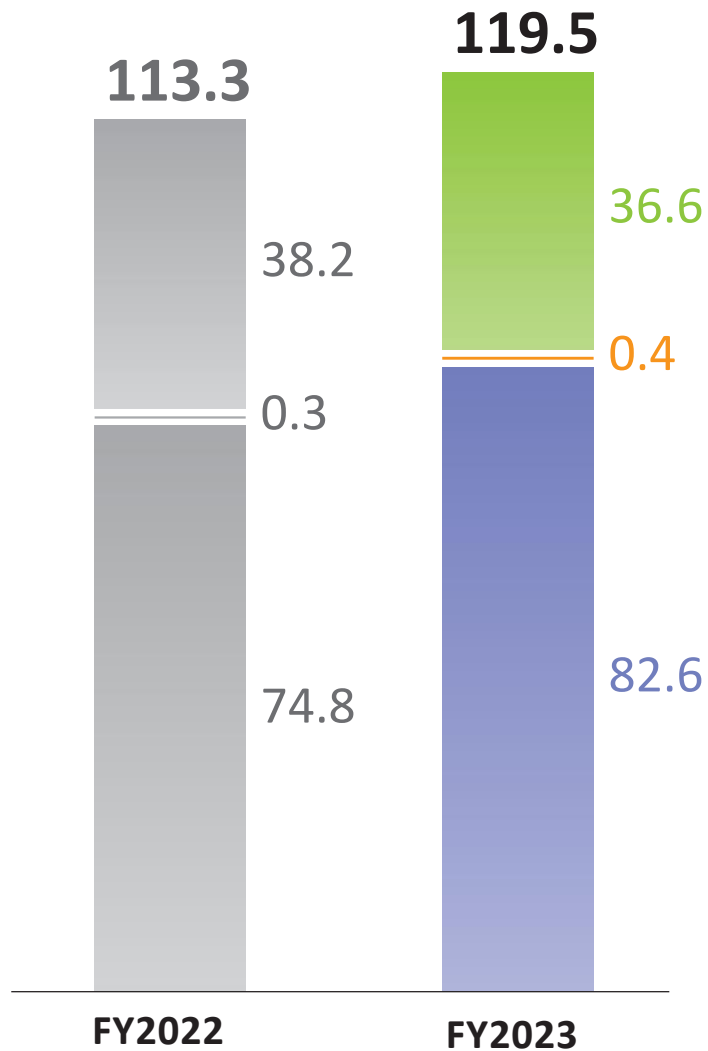
Breakdown of Gain and Loss for FY2023



(Units: JPY billions)

	FY2022	FY2023	Year-on-year		Vs forecast (announced on May 11, 2023)
			Change	Change (%)	Change
Net Sales	113.3	119.5	+6.2	+5.5	+3.3
New drugs, etc. (Japan)	74.8	82.6	+7.8	+10.4	+3.5
New drugs (Overseas)	0.3	0.4	+0.1	+25.1	0
Generic drugs	38.2	36.6	-1.6	-4.3	0
Cost of sales	63.1	68.1	+5.0	+8.0	—
SG&A (R&D)	45.0 (10.9)	45.4 (8.0)	+0.4 (-2.9)	+0.8 (-26.5)	— (-1.6)
Operating profit	5.1	6.0	+0.9	+17.4	0
Ordinary profit	5.8	6.6	+0.8	+13.3	+0.1
Profit attributable to owners of parent	4.7	5.3	+0.6	+12.7	+0.4

(Units: JPY billions)



[Net Sales +6.2]

New drugs, etc. (Japan)

+7.8

Factor of increase

- New drugs grew (Beova, Lasvic, Flutiform etc.)
- Increase in sales long-listed products (Kipres, Mucodyne)

New drugs (Overseas)

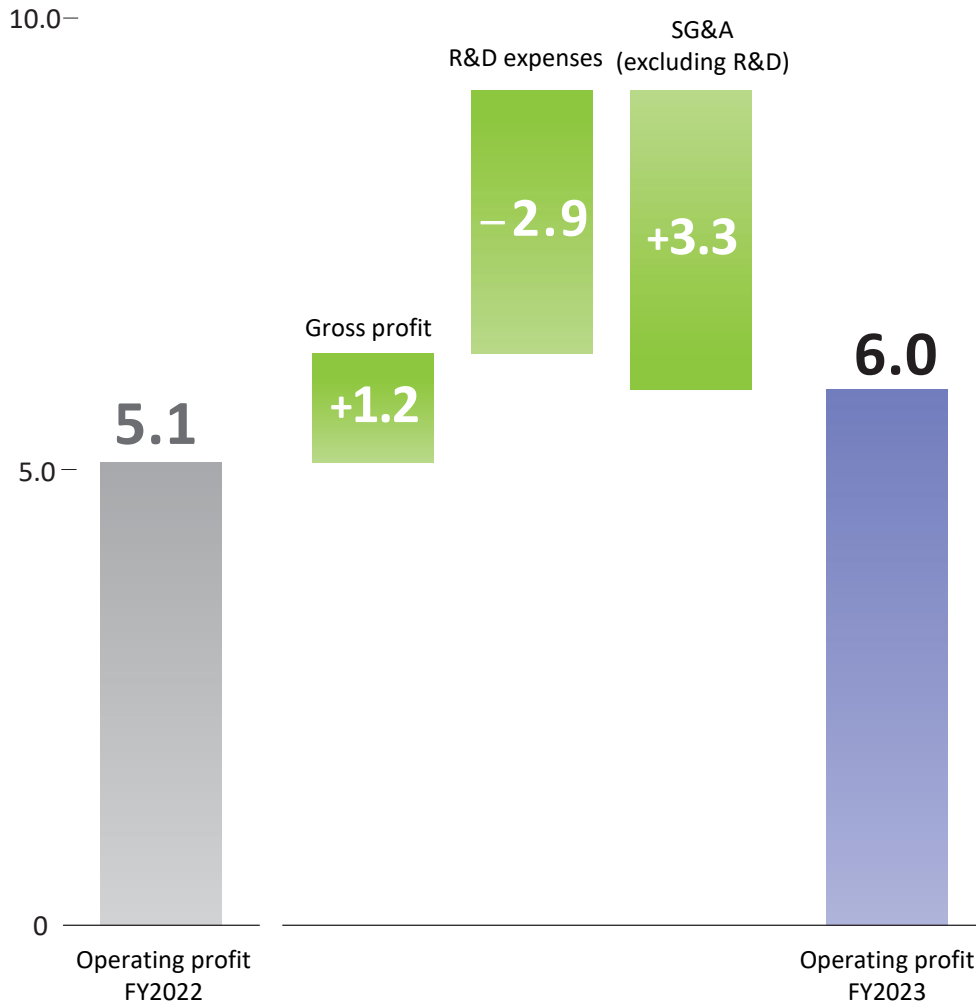
-0.1

Generic drugs

+1.6

- Items launched in FY2023 contribute to sales
- Decrease sales in AG products
- Decrease sales in supplies to other companies

(Units: JPY billions)



[Operating Profit + 0.9]



- Net Sales + 6.2
- Cost of sales ratio + 1.3 %pt

Factor of Decrease | Increase in sales of new drugs (Beova, Lasvic etc)
Increase in ratio of new drugs

Factor of Increase | Impact of NHI drug price revisions (Kyorin Pharmaceutical: 7% range)
Loss on disposal in generic drugs
Effect of exchange rate



10.9 (FY2022) ⇒ 8.0 (FY2023)

Upfront payment recorded in FY2023
Decline of expenses regarding of ActivX



34.1 (FY2022) ⇒ 37.4 (FY2023)

Increase in selling expenses, personnel expenses, depreciation expenses and license fees etc.

Highlights of Business Performance (3/3) : Vs Forecast



(Units: JPY billions)

	FY2022	FY2023	Year-on-year		Vs forecast (announced on May 11, 2023)
			Change	Change (%)	Change
Net Sales	113.3	119.5	+6.2	+5.5	+3.3
New drugs, etc. (Japan)	74.8	82.6	+7.8	+10.4	+3.5
New drugs (Overseas)	0.3	0.4	+0.1	+25.1	0
Generic drugs	38.2	36.6	-1.6	-4.3	0
Cost of sales	63.1	68.1	+5.0	+8.0	—
SG&A (R&D)	45.0 (10.9)	45.4 (8.0)	+0.4 (-2.9)	+0.8 (-26.5)	— (-1.6)
Operating profit	5.1	6.0	+0.9	+17.4	0
Ordinary profit	5.8	6.6	+0.8	+13.3	+0.1
Profit attributable to owners of parent	4.7	5.3	+0.6	+12.7	+0.4

Difference from the Forecast (Announced on May 11, 2023)]

Net sales: Net sales exceed the forecast due to increase in sales of new drugs (Lasvic, Flutiform), long-listed products (Kipres, Mucodyne) and AG.

Operating profit: Cost of sales ratio was increased and SG&A expenses (R&D expenses) were lower than the forecast. As a result, operating profit was in line.

R&D: -1.6 billion (Forecast 9.6 billion)

Extraordinary profit: 1,404 mil, gain on sale of investment securities etc.

Extraordinary loss: 987 mil, expenses regarding voluntary retirement program, etc.




Mainstay Product Sales Update



(Units: JPY billions)

		FY2022	FY2023	Year-on-year		vs Forecast (announced on May 11, 2023) Change
				Change	Change (%)	
New drugs, etc. (Japan)	Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	12.9	18.1	+ 5.2	+ 40.3	- 0.8
	Lasvic (New quinolone synthetic antibacterial agent)	2.5	4.9	+ 2.4	+ 99.5	+ 1.7
	Lyfnua (Selective P2X3 receptor antagonist / chronic cough)	0.2	0.8	+ 0.6	+ 323.9	- 0.5
	Desalex (Antiallergic Agent)	8.5	8.9	+ 0.4	+ 3.7	0
	Flutiform (Combination drug for asthma treatment)	12.0	12.9	+ 0.9	+ 7.1	+ 1.5
	Pentasa (Ulcerative colitis and Crohn’s disease treatment)	12.8	12.3	- 0.5	- 4.0	+ 0.5
	Kipres (Leukotriene Receptor Antagonist)	6.6	7.0	+ 0.4	+ 5.9	+ 1.7
	Mucodyne (Mucoregulator)	3.5	4.2	+ 0.7	+ 20.6	+ 1.2
	Nasonex (Spray type allergic rhinitis remedy)	2.5	2.0	- 0.5	- 20.1	+ 0.8
	Uritos (KYORIN) (Therapeutic agent for overactive bladder)	0.7	0.5	- 0.2	- 26.4	+ 0.3
	Milton (Disinfectant)	2.0	1.9	- 0.1	- 6.7	0
	Rubysta (Disinfectant)	2.1	1.5	- 0.6	- 25.8	- 0.6
Generic drugs	Montelukast tablets “KM” (Leukotriene Receptor Antagonist)	13.3	12.3	+ 1.0	- 7.7	+ 1.3
	Mometasone Nasal 50mg “KYORIN” (Spray type allergic rhinitis remedy)	4.7	4.5	- 0.2	- 2.7	+ 1.1
	Imidafenacin tablets & OD “KYORIN” (Therapeutic agent for overactive bladder)	0.7	0.6	- 0.1	- 14.0	+ 0.2



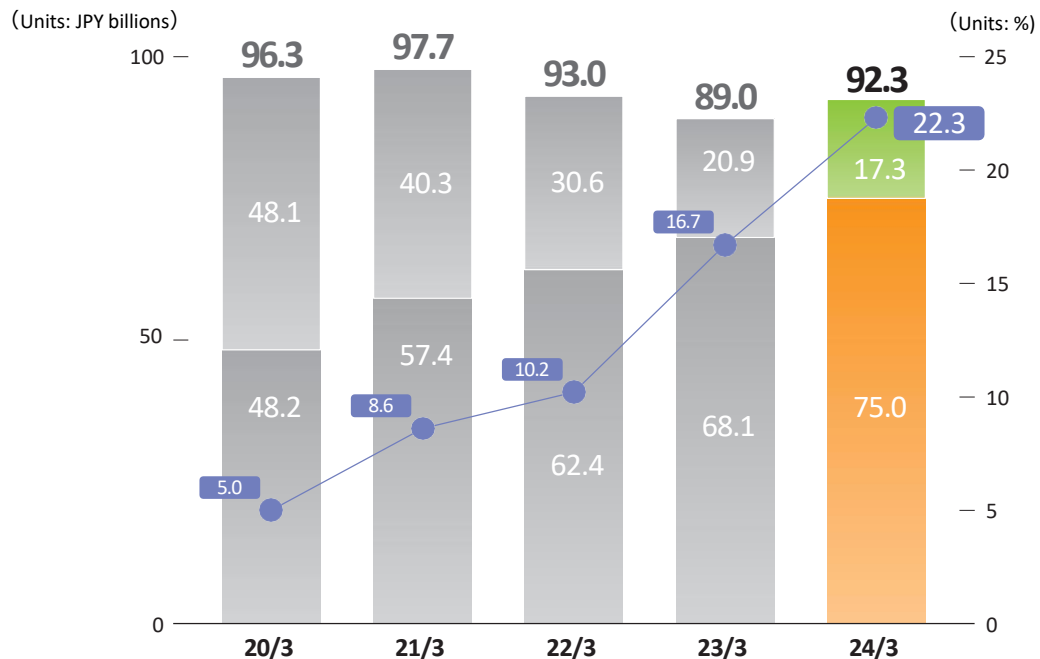
Trends of Mainstay Products and Generic Drugs

[Mainstay products] Beova (Therapeutic agent for OAB)



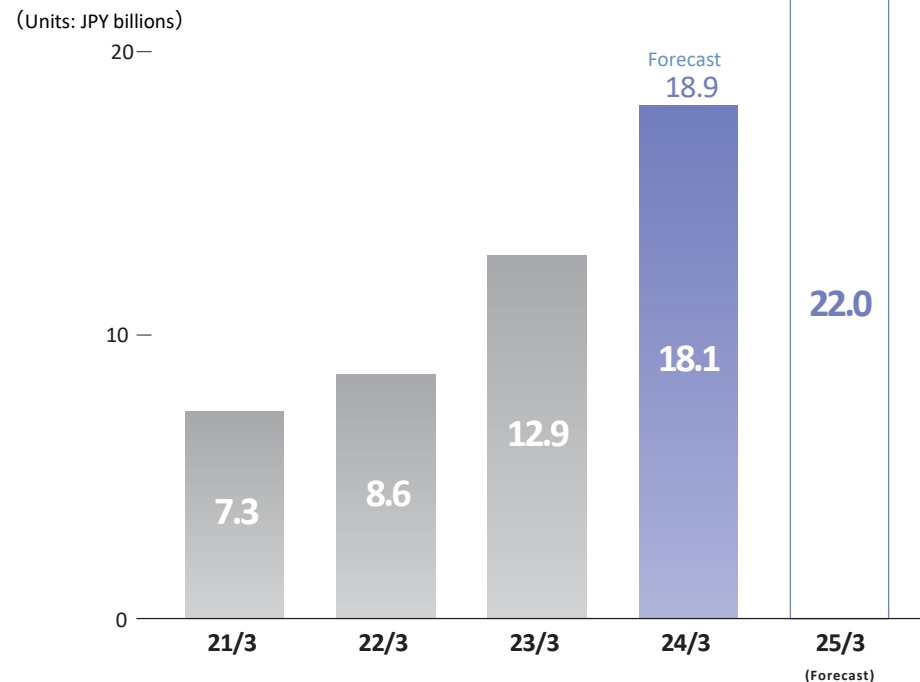
OAB market

■ β3 receptor antagonist
 ■ Anticholinergic agents
 ● Beova (KYORIN) share



Copyright © 2024 IQVIA. Calculated based on JPM 2020/3 MAT-2024/3 MAT. Reprinted with permission

Sales



Market

OAB market: +3.8%*
 Market expansion of β3 adrenergic receptor

Medium to long-term market outlook

The number of OAB patients tend to increase
 Market is forecast to remain flat due to NHI drug price revision and launch generic drug
 Market expansion for β3 adrenergic receptor.

*Copyright © 2024 IQVIA. Calculated based on JPM 2023/3 MAT, 2024/3 MAT Reprinted with permission

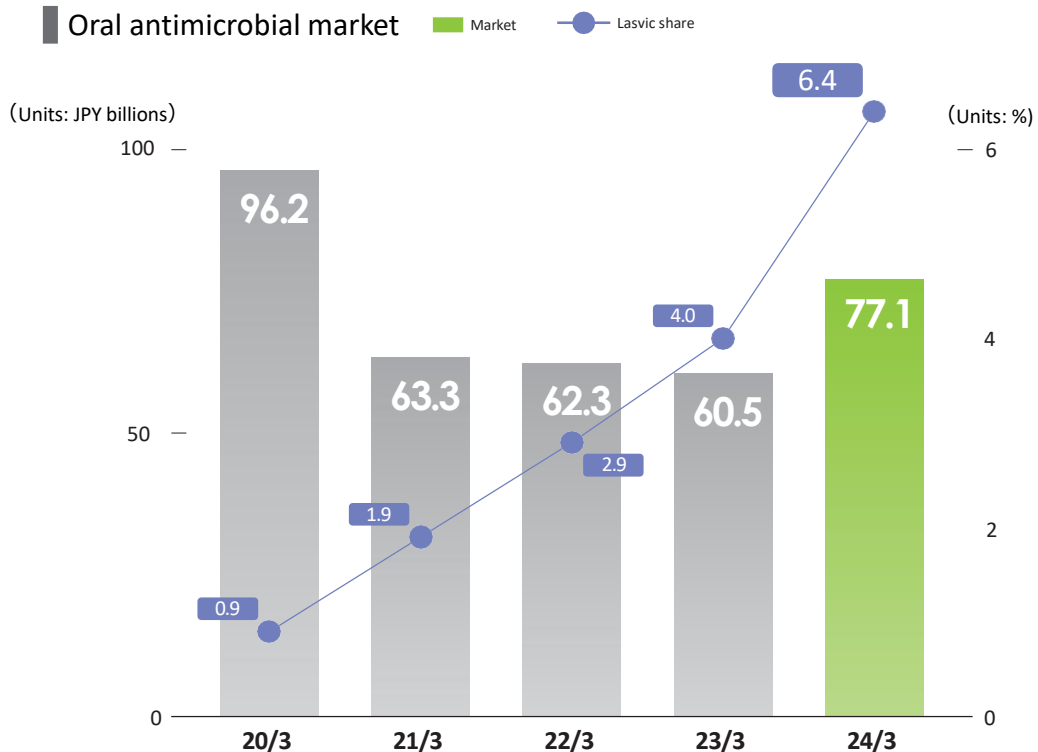
Result in FY2023

No.1 market share in OAB market (as Beova)
 No.1 share of OAB patients and rate of new patients acquisition (as Beova)
 [NHI drug price revision: Beova -4.6% (Apr 2023)]

[Mainstay products] Lasvic (New quinolone synthetic antibacterial agent)

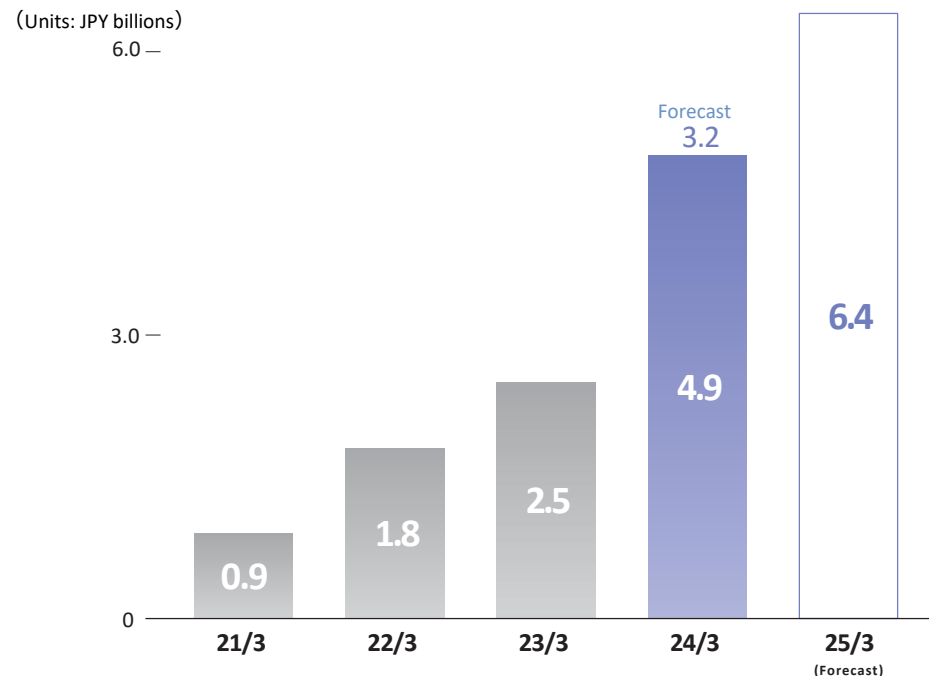


Oral antimicrobial market



Copyright © 2024 IQVIA. Calculated based on JPM 2020/3 MAT-2024/3 MAT. Reprinted with permission

Sales



Market

Oral antimicrobial market: +27.5%*
Increase to seek treatment after Covid-19 classified to the Category V

Medium to long-term market outlook

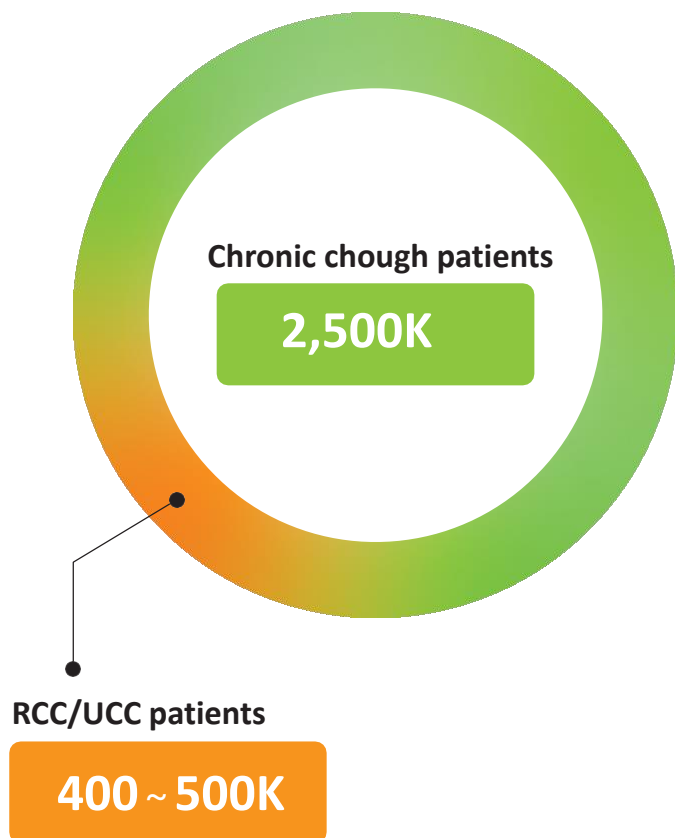
Expect to tend to decrease in oral antimicrobial market due to prevent infection/appropriate use against AMR

*Copyright © 2024 IQVIA. Calculated based on JPM 2023/3 MAT, 2024/3 MAT Reprinted with permission

Result in FY2023

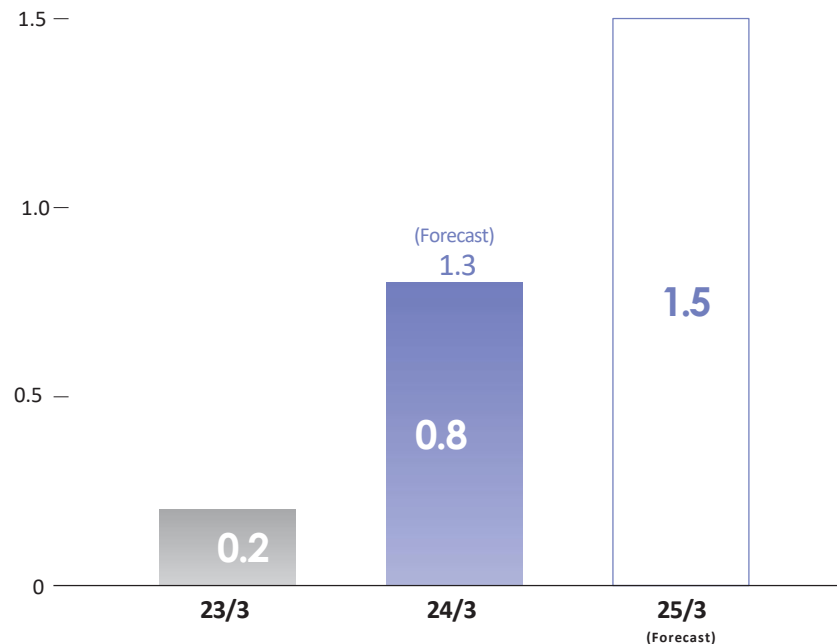
- Listed in guidelines as a recommended drug
- No.1 market share in oral antimicrobial market
[NHI drug price revision: -5.3% (oral), 0% (iv) (Apr 2023)]

The number of estimated patients



Sales

(Units: JPY billions)



Result in FY2023

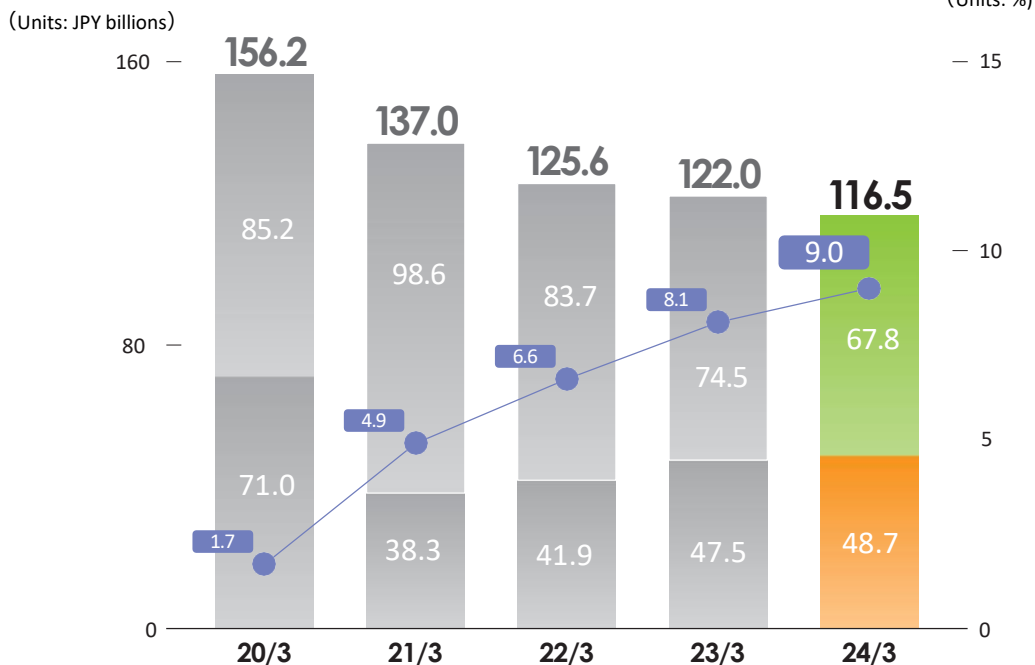
- Number of customers : Target was not achieved
- Period of taking drug was shorter than expected
[NHI drug price revision: 0% (Apr 2023), by cost-effectiveness evaluation: -7.7%]

[Mainstay products] Desalex (Antiallergic Agent)



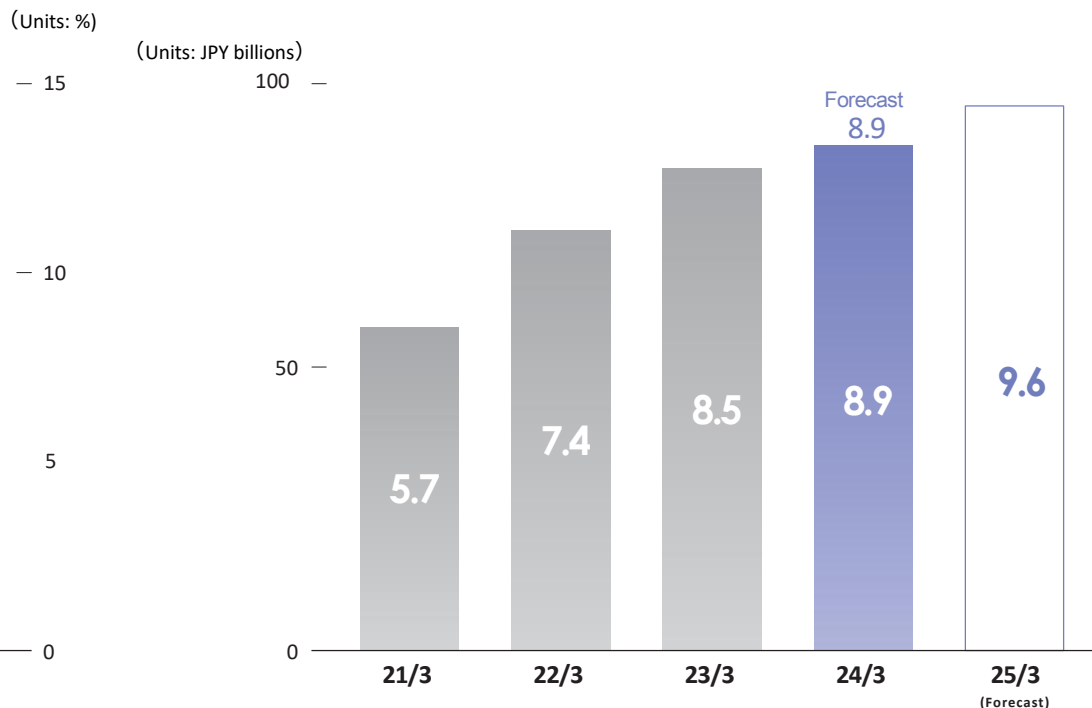
Antihistamine market

■ New drugs
■ Long-listed and generic drugs
● Desalex share



Copyright © 2024 IQVIA. Calculated based on JPM 2020/3 MAT-2024/3 MAT. Reprinted with permission

Sales



Market

Antihistamine Market: -4.5%*

Medium to long-term market outlook

Number of patients tend to increase

Shrinking market due to NHI drug price revision and launch generic drug

Result in FY2023

- Prescription in otolaryngology: No.2
- Focus on acquiring prescriptions in otolaryngology and internal medicine [NHI drug price revision: -9.1% (Apr 2023)]

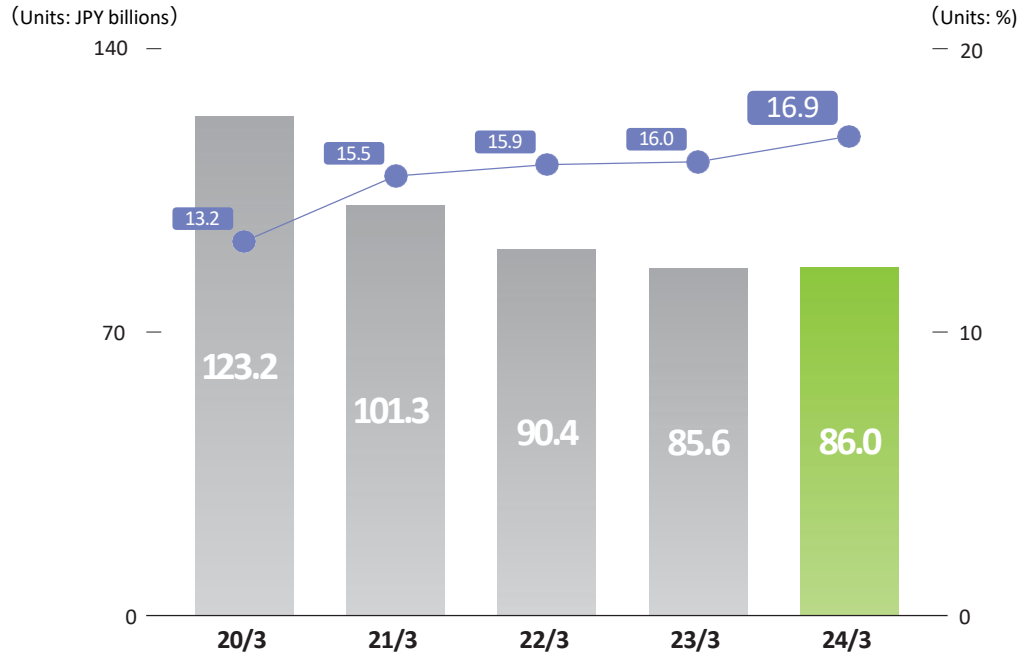
*Copyright © 2024 IQVIA. Calculated based on JPM 2023/3 MAT, 2024/3 MAT Reprinted with permission

[Mainstay products] Flutiform (Anti-asthmatic)



ICS/LABA market

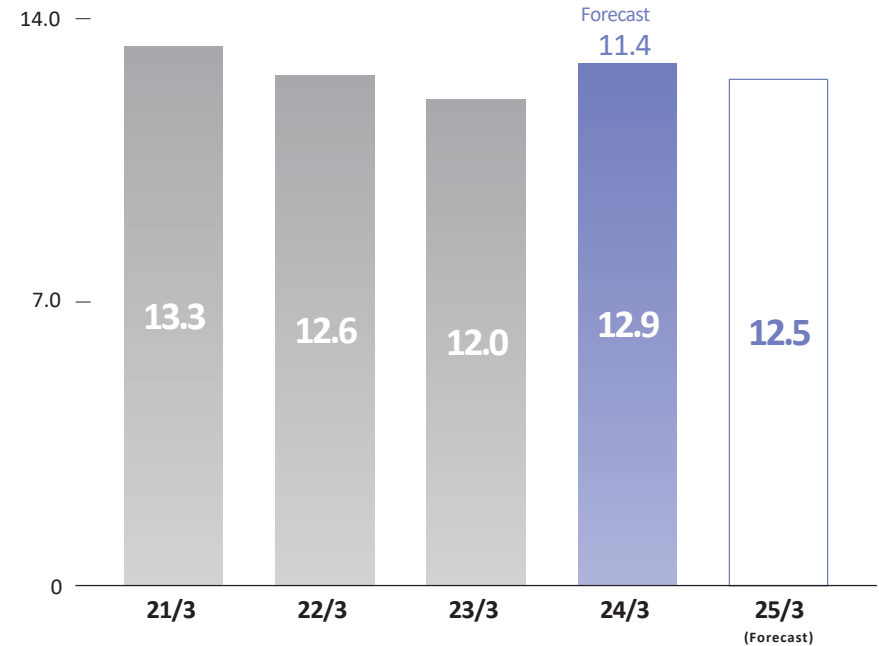
Market Flutiform share



Copyright © 2024 IQVIA. Calculated based on JPM 2020/3 MAT-2024/3 MAT. Reprinted with permission

Sales

(Units: JPY billions)



Market

ICS/LABA market: remain flat
Increase to seek treatment after Covid-19 classified to the Category V

Medium to long-term market outlook

Market remained flat due to impact of NHI drug price revision etc.

*Copyright © 2024 IQVIA. Calculated based on JPM 2023/3 MAT, 2024/3 MAT Reprinted with permission

Result in FY2023

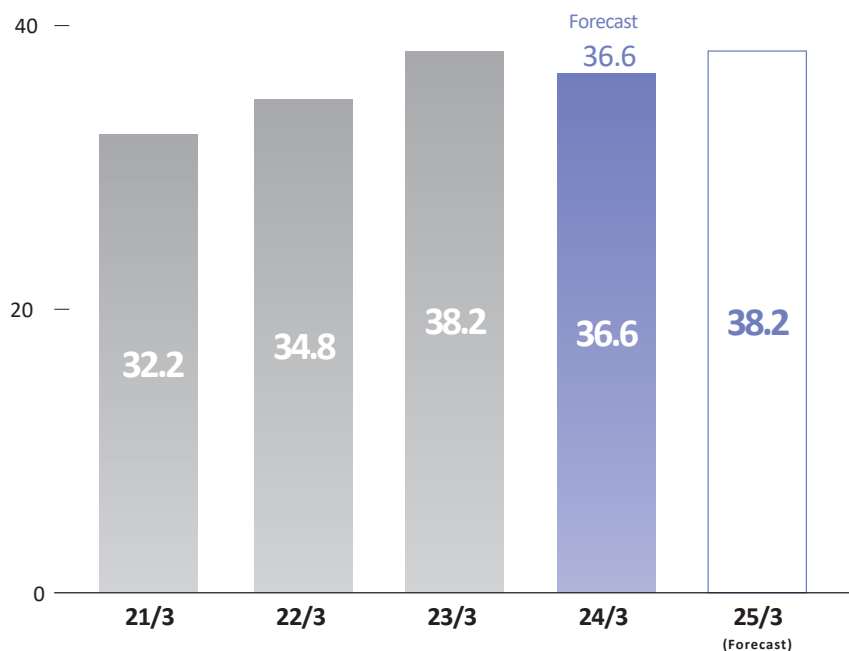
Expansion market share in terms of volume (17.5% FY2022 ⇒ 18.2% FY2023)
Synergy effects with Lyfnua promotion
[NHI drug price revision: -6.1% (Apr 2023)]



Status of Generic Drugs



Sales



Copyright © 2024 IQVIA. Calculated based on JPM 2020/3 MAT-2024/3 MAT. Reprinted with permission

Result in FY2023 (Generic drug)

Sales decreased

New products launched in June 2023

Eplerenone tablets 25mg/50mg/100mg

Fluticasone FR Nasal Solution 27.5µg 56/120 puffs

Azilsartan OD tablets 10mg/20mg/40mg

Effort in FY2024 (Generic drug)

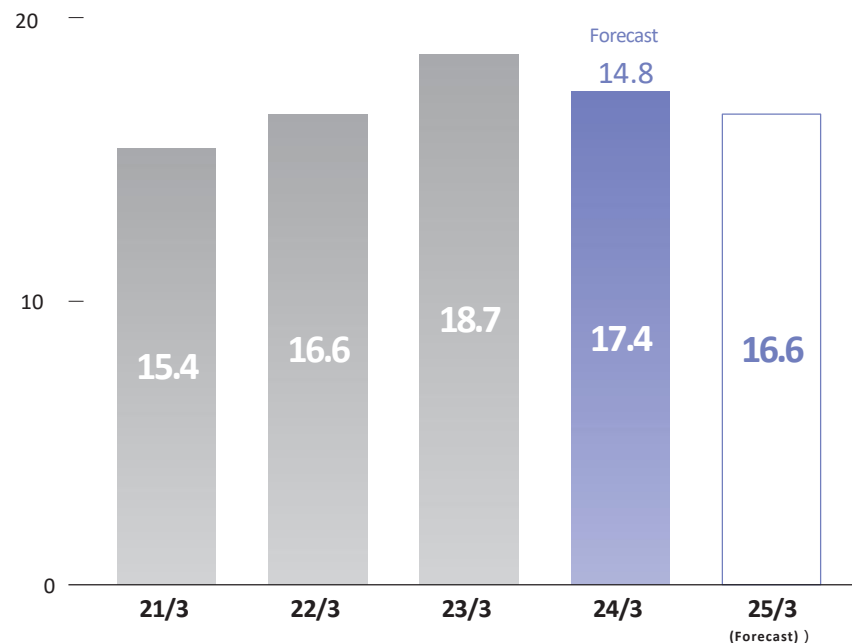
Sales expansion of new products launched in FY2024

Products succession from other companies

Sales increase in supplies to other companies

*Copyright © 2024 IQVIA. Calculated based on JPM 2023/3 MAT, 2024/3 MAT Reprinted with permission

Sales in AG (three products) among with the sales at left



Result in FY2023 (AG)

- Restrictions on Shipment due to impact of restrictions in other company : Mometasone, Montelukast
- Effects of lower volume of airborne pollen than previous year
- Keep market share of 50% in AG



Consolidated Financial Forecast

Consolidated Financial Forecast



	FY2023	FY2024	Year-on-year	
			Change	Change (%)
Net Sales	119.5	123.4	+ 3.9	+ 3.2
New drugs, etc. (Japan)	82.6	84.7	+ 2.1	+ 2.6
New drugs (Overseas)	0.4	0.4	0	+ 3.6
Generic drugs	36.6	38.2	+ 1.6	+ 4.5
Cost of sales	68.1	-	-	-
SG&A (R&D)	45.4 (8.0)	- (8.5)	- (+ 0.5)	- (+ 6.0)
Operating profit	6.0	6.5	+ 0.5	+ 8.1
Ordinary profit	6.6	6.9	+ 0.3	+ 4.5
Profit attributable to owners of parent	5.3	5.0	- 0.3	- 6.1

[Key factors for increase / decrease (Year-on-year)]

Net sales: The sales of new drugs (Beova, Lasvic etc.) and generic drugs are expected to increased.

Operating profit: Gross profit are expected to increased due to sales increased in mainstay products, although cost of sales ratio increase.

SG&A expenses (including R&D) are expected in flat.

Cost of sales ratio: +0.5 %pt

SG&A expenses (excluding R&D): - 1%pt

R&D expenses: +0.5 billion (8.0 to 8.5)

Forecast of Mainstay Products Sales



(Units: JPY billions)

		FY2022	FY2023	Year-on-year	
				Change	Change (%)
New drugs, etc. (Japan)	Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	18.1	22.0	+ 3.9	+ 21.6
	Lasvic (New quinolone synthetic antibacterial agent)	4.9	6.4	+ 1.4	+ 29.8
	Lyfnua (Selective P2X3 receptor antagonist / chronic cough)	0.8	1.5	+ 0.7	+ 86.3
	Desalex (Antiallergic Agent)	8.9	9.6	+ 0.7	+ 8.5
	Flutiform (Combination drug for asthma treatment)	12.9	12.5	- 0.4	- 2.6
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	12.3	11.6	- 0.7	- 5.0
	Kipres (Leukotriene Receptor Antagonist)	7.0	5.3	- 1.7	- 23.5
	Mucodyne (Mucoregulator)	4.2	4.3	+ 0.1	+ 2.6
	Uritos (KYORIN) (Therapeutic agent for overactive bladder)	0.5	0.3	- 0.2	- 34.7
	Milton (Disinfectant)	1.9	1.9	0	+ 2.1
	Rubysta (Disinfectant)	1.5	1.5	0	+ 1.8
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	12.3	11.8	- 0.5	- 3.9
	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	4.5	4.3	- 0.2	- 3.4
	Imidafenacin tablets & OD"KYORIN" (Therapeutic agent for overactive bladder)	0.6	0.5	- 0.1	- 12.5

Capital Policy

- Increase capital efficiency through investment for growth and shareholder returns, with a constant awareness of the cost of capital and return on capital, while maintaining a sound financial base
- Maintain stable dividends taking DOE (Dividend on Equity ratio) into account

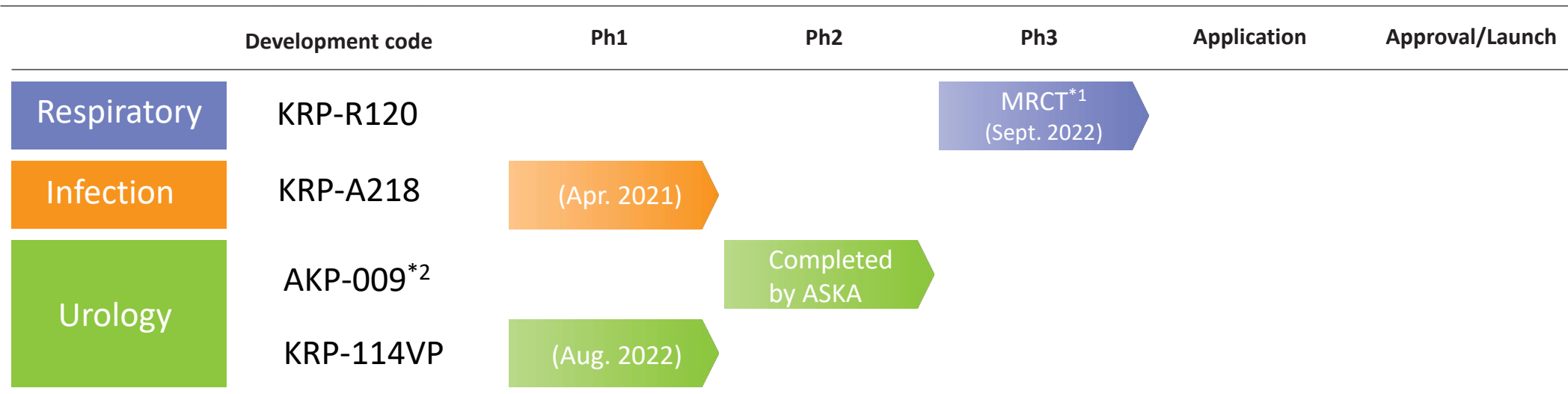
Dividend	FY2021	FY2022	FY2023*	FY2024 (Forecast)
Dividend per share (Yen)	¥75 (Year end ¥45)	¥52 (Year end ¥32)	¥52 (Year end ¥32)	¥52 (Year end ¥32)
Consolidated payout ratio	76.9%	64.0%	56.8%	60.5%

*The year-end dividend of 32 yen have been decided at in the Board Meeting scheduled in May 24, 2024



Status of R&D Pipeline

Clinical trials are making steady progress



*1 MRCT: Multi-Regional Clinical Trials

*2 Ph1 trial is being conducted again (ASKA Pharmaceutical)

Development of GMAC for Fabry disease is terminated

[Licensed Compound]

Compound/Code	Licensee	Stage	Features
KRP-203	Priothera	Ph3	<ul style="list-style-type: none"> ● Sphingosine-1-Phosphate receptor Agonist ● Target: AML patients undergoing HSCT ● Assignment of IP and drug substances (Sep. 2020)

[DTx development]

Compound/Code	Proposed Indication	Features
KRP-DT123	Tinnitus	<ul style="list-style-type: none"> ● Specified clinical trial (Sept 2023)



Initiatives toward Realization of Vision110 –Stage1–

Vision 110

Stage 1

Strengthening drug discovery capability to create high-value new drugs that meet medical needs

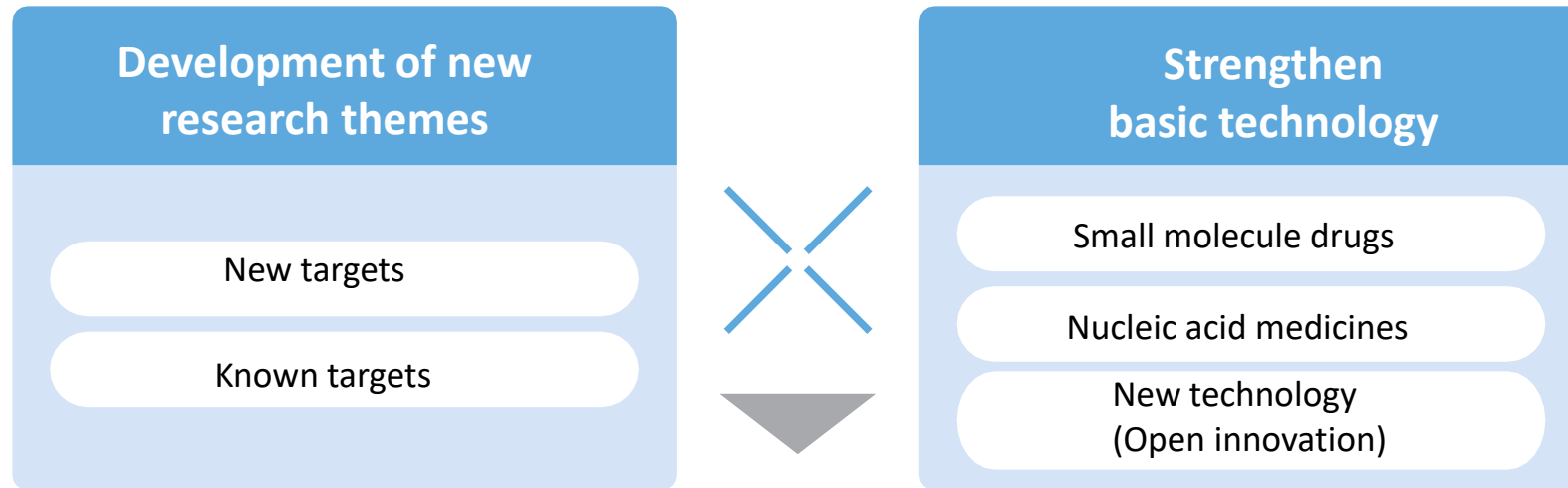
Expansion of development pipeline through in-licensing

Maximization of the ratio of new drugs

Promoting healthcare-related businesses that have synergies with the new drugs business

Building a sustainable corporate foundation

Try for drug innovation through new drug discovery strategies



Drug discovery capability to create high-value new drugs that meet medical needs

FY2023

Result

Focus on 3 research areas that utilize Kyorin's skills and knowledge and meet medical needs, and concentrate management resource

Research areas

Fibrosis

Pain

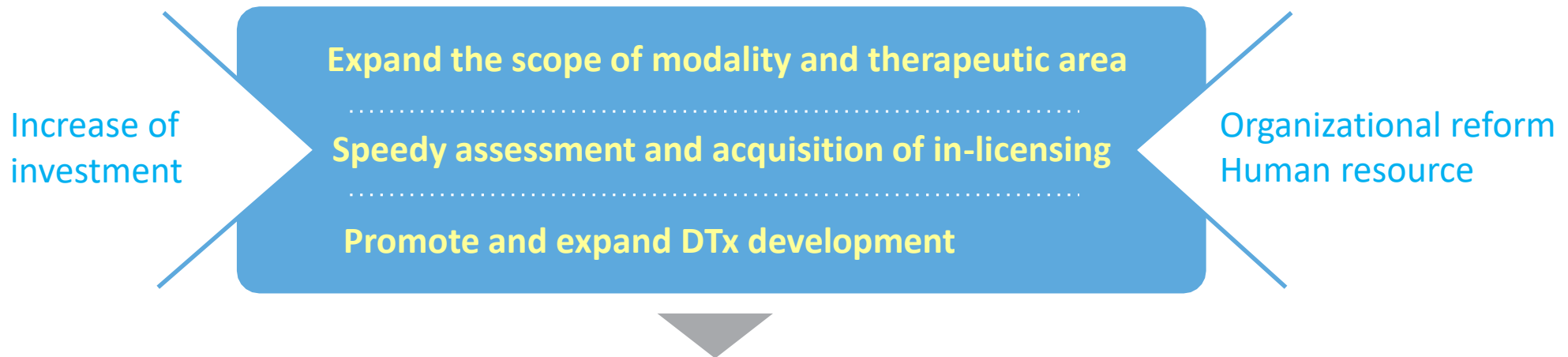
Autoimmune disorder

FY2024

Initiatives

Strive to enrich the drug discovery pipeline by promotion of in-house research activities and utilized external technology

Strengthen the foundation of new drug business by enhancement of in-licensing and alliance function and expansion of development pipeline



Stage 1 Target | **At least 6 in-licensing items**

2023年度

結果

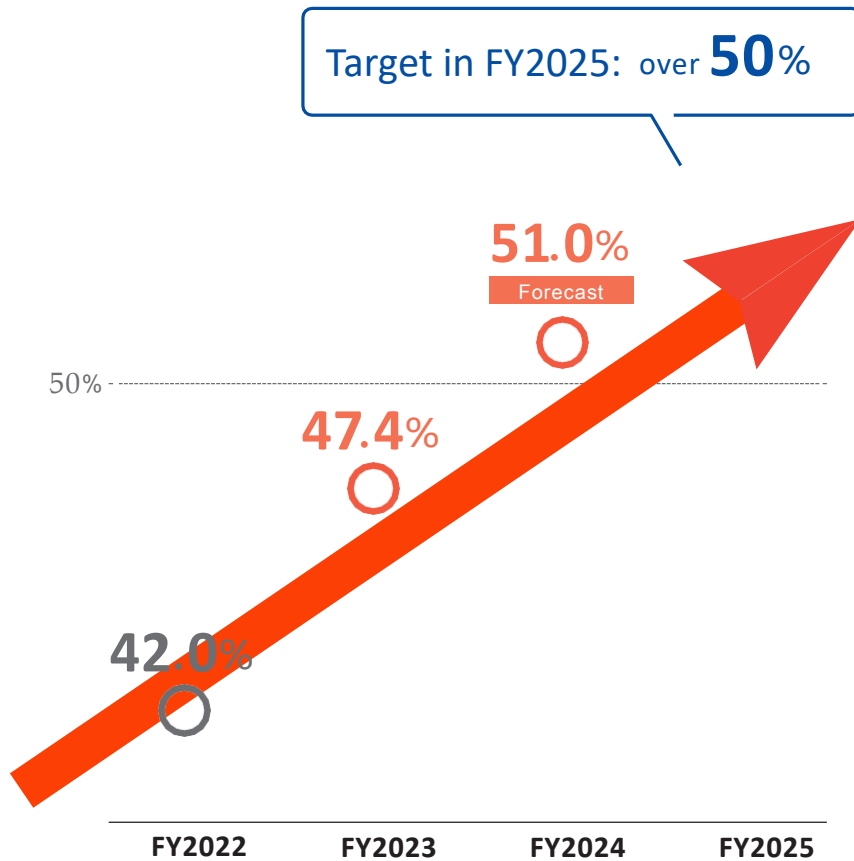
Human resources	Double (vs FY2022)	Number of evaluation item	Tree times (vs FY2022)	In-licensed	0 item
-----------------	-----------------------	---------------------------	---------------------------	-------------	--------

2024年度

取り組み

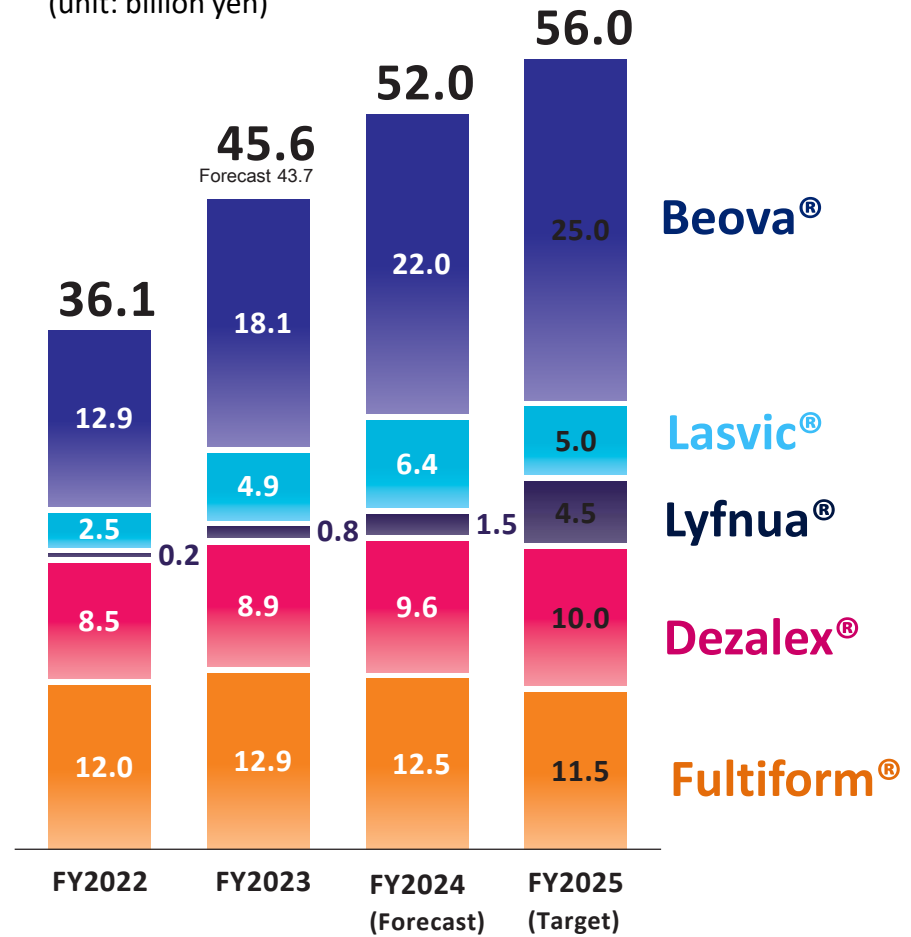
Strive to acquire in-licensed products expected to make early contribution to business performance

Ratio of new drugs



Sales

(unit: billion yen)



Beova®

Status

- **No.1* in OAB market**
- **No.1 of OAB patients' share**
(FY2023: 34%*, as Beova)

FY2024

Initiatives

- New patients acquisition rate : 50%
- DTC
→ Aim to achieve a 45% the patients' share

Aimed status

By FY2025

Goal

First-line treatment for OAB

- **No.1 in OAB market as Beova in FY2023 Achievement**
- **50% of patients' share of OAB market**

*Copyright © 2024 IQVIA. Calculated based on JPM 2024/3 MAT Reprinted with permission

Lasvic®

Status

- Classified Covid-19 to the Category V caused market expansion
- Listed in guidelines as a recommended drug
- Growth rate of No.1 (25%*) in expansion of oral NQ market

FY2024

Initiatives

- First choice for the elderly/patients with respiratory infection
- Growth in number of medical institution with prescription of Lasvic (internal medicine/otorhinolaryngology)

Aimed status

First-line antibacterial agent for elderly or patients with underlying disease in respiratory infection

By FY2025

Goal

- No.1 sales in oral NQ market by FY2023 **Achievement**
- 40% share of NQ market as Lasvic

Lyfnua®

Status

- **Sales target was not achieved**
- FY2023(second half) GP: 6,300, HP: 1,300
- Period of taking drug was shorter than expected

FY2024

Initiatives

- Enhancement of better understanding for product characteristic (adverse event on target)
- Initiative to extend the patient's period of taking drug (appealing effectiveness/safety including long-term data)
- FY2024(second half) GP: 9,700, HP: 1,700



Only one treatment for chronic cough

By FY2025

Goal

- **Number of customers in FY2025**
 - GP **Approx. 10,000**
 - HP **Approx. 2,000**

Aim to being a first-line treatment for the patients with chronic cough despite treatment

Takaoka New Plant Operation Started

Purpose

Strengthen supply capacity with increase in manufacturing volume of drugs

Increase in manufacturing volume of generic drugs

- Production function of Inami plant are transferred to Takaoka
- In-house manufacturing of outsourcing products

Manufacturing of new drugs

- Increase production of Mucodyne

Significantly reduce CO₂ emissions, actively utilize LNG and renewable energy

Outline of the Takaoka Plant

Location	IC Park 8, Takaoka-City, Toyama
Site Area	42,457 m ²
Building	Three floors, Building area about 7,262 m ² , Total floor area about 21,091 m ²
Product capacity	two billion tablets/year



Aim to achieve cost reduction by increase in manufacturing volume of generic drugs and shift to in-house manufacturing of outsourcing products

Vision 110 Stage 1

	Result in FY2023	Initiatives in FY2024
Strengthening drug discovery capability to create high-value new drugs that meet medical	Focus on research area Steady progress in clinical trials	Promote in-house research activities and utilize external technology Enrich drug discovery pipeline
Expansion of development pipeline through in-licensing	No in-licensed product	Acquire in-licensed products
Maximization of the ratio of new drugs	Sale increased in new drugs (36.1 to 45.6 billion yen) Ratio of new drugs improved (42% to 47.4%)	Emphasize proliferation of new drugs
Promoting healthcare-related businesses that have synergies with the new drugs business	Solution-based marketing activities Sales in infection-related products FY2023 9.5 billion yen Starting operation of Takaoka plant	Promote solution-based marketing activities Sales in infection-related products FY2024 11.2 billion yen Full-operation of Takaoka plant Establish production increase structure of Mucodyne
Building a sustainable corporate foundation	Relocation of head office etc. Promote Health Management Implement voluntary retirement program Support TCFD	Operational efficiency and cost reduction

Performance target

Performance targets (consolidated basis)		Performance target (FY2025)	FY2023(Actual)	FY2024(Forecast)
Growth potential	“Net sales” CAGR	At least 2%	5.5%	4%
Profitability	Operating profit before deduction of R&D expenses (operating profit + R&D expenses)	At least 16%	12%	12%

Capital policy and shareholder returns

Increase capital efficiency through investment for growth and shareholder returns, with a constant awareness of the cost of capital and return on capital, while maintaining a sound financial base
 Maintain stable dividends taking DOE (Dividend on Equity ratio) into account

Accomplish reform of drug discovery

Expand of development pipeline

Maximize the expansion of sales

Improve cost competitiveness

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 