FUSO VISION 2030

FUSO Pharmaceutical Industries, Ltd.

TSE Prime Market: 4538

Supplementary Material on Financial Results for the Six Months Ended September 30, 2026



November 11, 2026

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FY2026 H1 Financial Highlights

(Millions of yen)	Net sales	Operating profit	Ordinary profit	Profit
	Prev. fcst.: 31,500	Prev. fcst.: 800	Prev. fcst.: 600	Prev. fcst.: 500
FY2026 H1	32,395	1,743	1,434	1,041
YoY	+1,165 +3.7%	+495 +39.7%	+303 +26.8%	+209 +25.2%

- Net sales grew on higher Lixelle sales following clinical practice guideline revisions, along with contributions from Cernilton and other products subject to repricing of unprofitable products
- Expected cost-of-sales increases from soaring raw material and supply prices amid Middle East tensions partly shifted to H2, limiting the H1 impact
- Signing of a new licensing agreement and related payments shifted from H1 to H2, leaving R&D expenses below expectations

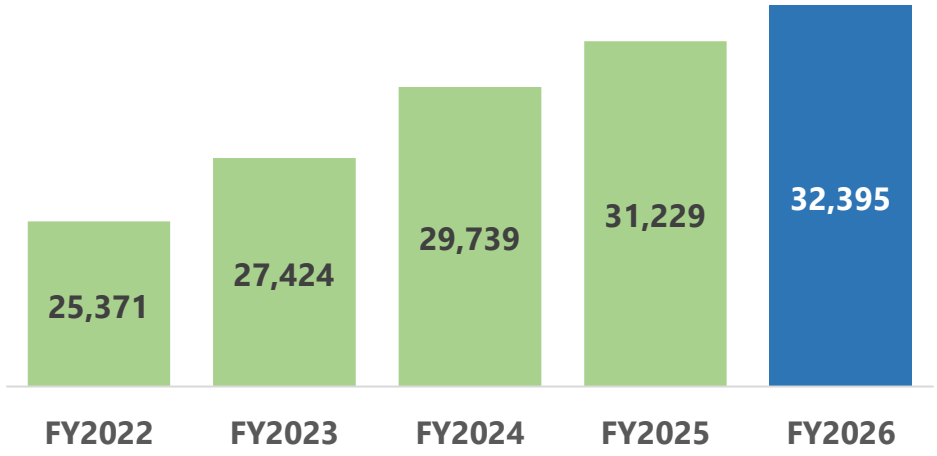
	Net sales	Operating profit	Ordinary profit	Profit
FY2026 Full-Year Forecast	Prev. fcst.: 63,200 +1,600 64,800	Prev. fcst.: 2,000 +400 2,400	Prev. fcst.: 1,400 +400 1,800	Prev. fcst.: 1,300 +200 1,500
Progress	50.0%	72.6%	79.7%	69.4%

- Full-year net sales forecast raised on expected steady sales, although the cost of sales ratio is expected to rise as soaring raw material and supply prices amid Middle East tensions affect costs
- Full-year operating profit, ordinary profit and profit forecasts also raised, reflecting H1 results despite an expected increase in R&D expenses as development progresses
- Progressive annual dividends through FY2030. Interim dividend: ¥45 per share. Planned year-end dividend: ¥46 per share, up ¥1

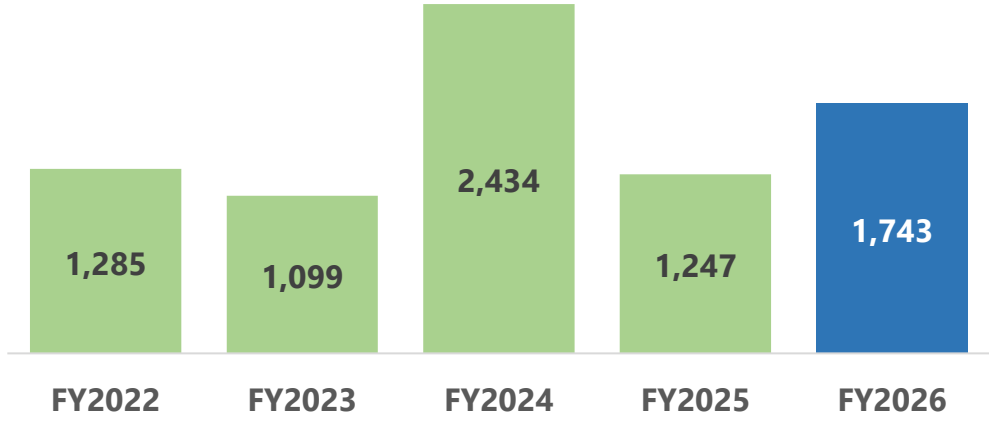
FY2026 H1 Financial Highlights

(Millions of yen)	FY2025 H1	FY2026 H1	Forecast (Before revision)	Forecast achievement rate
Net sales	31,229	32,395	31,500	102.8%
Operating profit	1,247	1,743	800	217.9%
Ordinary profit	1,131	1,434	600	239.0%
Profit	831	1,041	500	208.2%

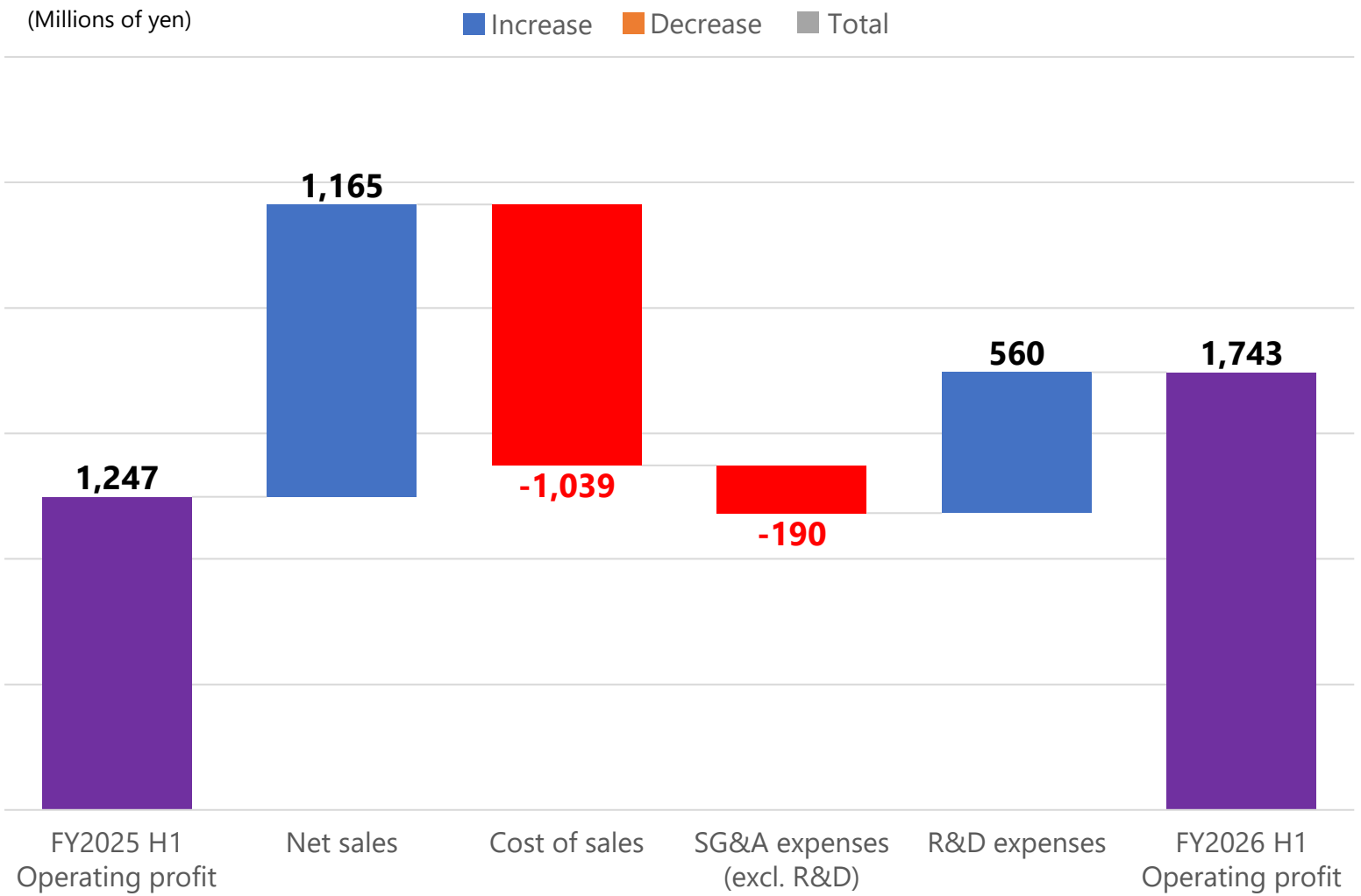
H1 Net Sales Trend (Millions of yen)



H1 Operating Profit Trend (Millions of yen)



Analysis of Changes in FY2026 H1 Operating Profit



Net sales

- Lixelle sales grew following clinical practice guideline revisions
- Cernilton and other products subject to repricing of unprofitable products contributed to net sales growth

Cost of sales

- Soaring prices of raw materials, contract manufactured products, and in-licensed products
- Higher equipment maintenance costs

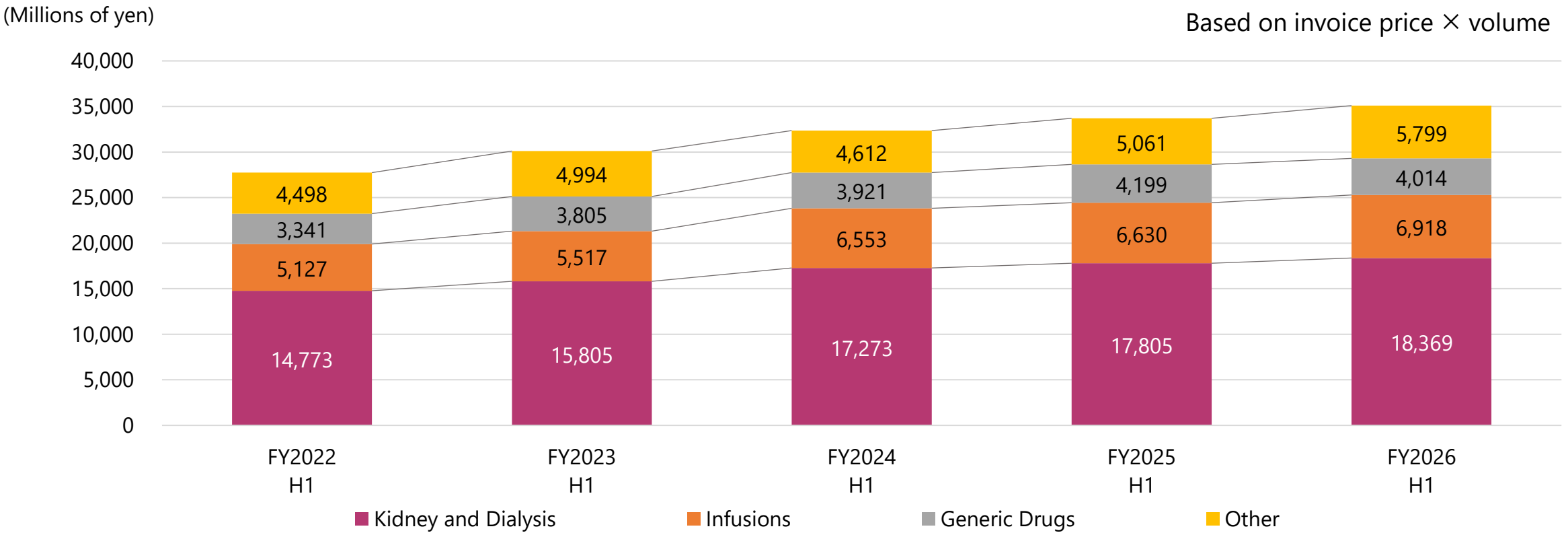
SG&A expenses

- Higher transportation-related costs

R&D expenses

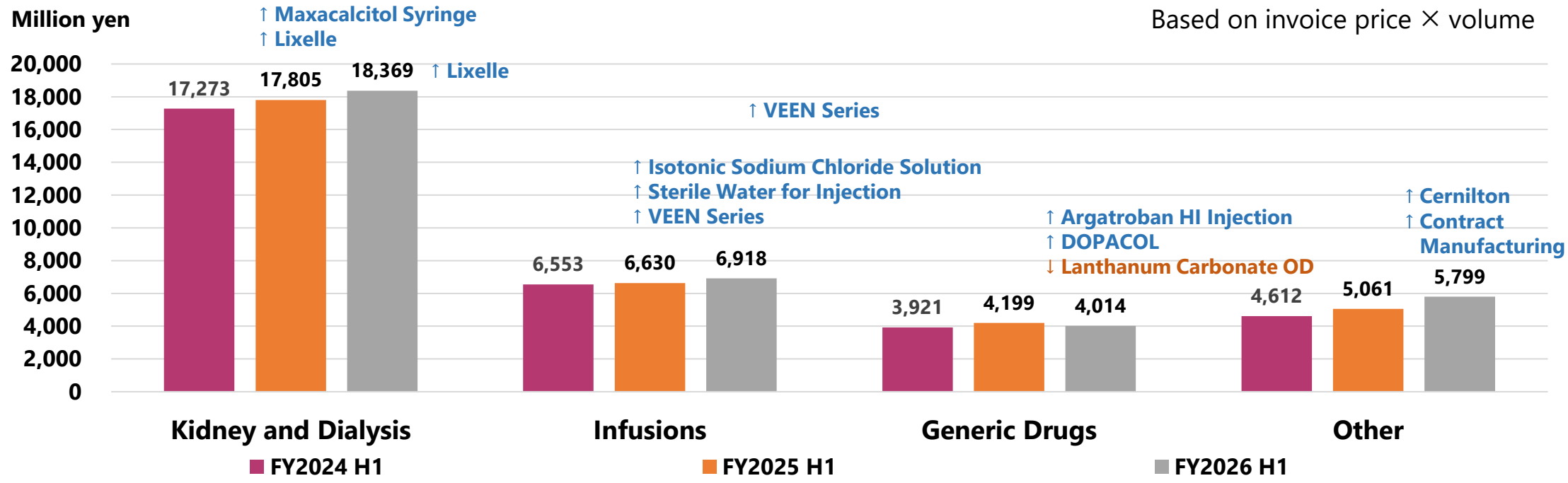
- Milestone payments were made in the same period of the previous fiscal year in connection with the start of domestic clinical trial of DMX-200

Net Sales by Major Therapeutic Area (Historical Trend)



- Net sales rising steadily, driven by growth in dialysis supplies, infusions and injections, and Maxacalcitol Syringe (a dialysis-related generic drug), further supported by strong growth in Lixelle sales since FY2025 following clinical practice guideline revisions, and steady performance in the contract manufacturing, out-licensing and export business
- Aim for further growth by building on stable sales in the kidney and dialysis area and the infusion area, making full use of our strengths in kidney and dialysis to develop and sell new and generic drugs in this field, while steadily advancing ART (assisted reproductive technology) products and the Contract Manufacturing, Out-licensing and Export business

Net Sales by Major Therapeutic Area (Year-on-Year Comparison)



[Key drivers of change]

Kidney and Dialysis: Lixelle sales grew significantly as revised clinical practice guidelines further clarified its evidence level

Infusions: Net sales grew on higher sales of electrolyte solutions, led by the VEEN Series

Generic Drugs: Sales of Argatroban HI Injection grew as it gained traction in acute care. Sales of DOPACOL increased due to switching from originator products, the selective treatment scheme and other factors. Sales of Lanthanum Carbonate OD declined

Other: Cernilton sales increased, driven by repricing of unprofitable products and disease awareness activities; contract manufacturing also grew

Net Sales by Major Therapeutic Area (Ethical Drugs by Product)

Based on invoice price × volume

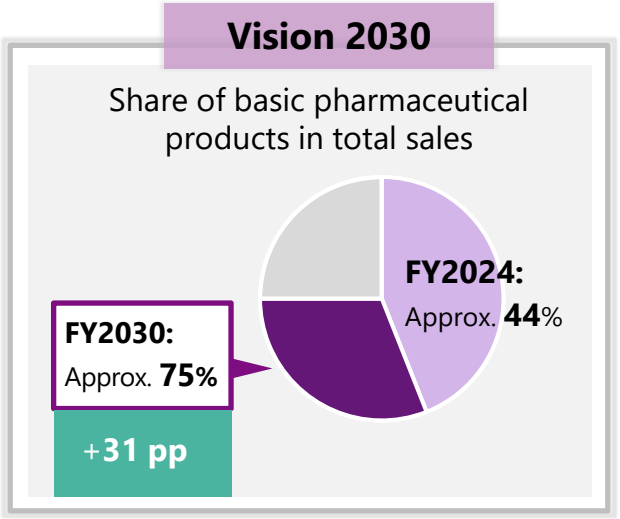
(Millions of yen)

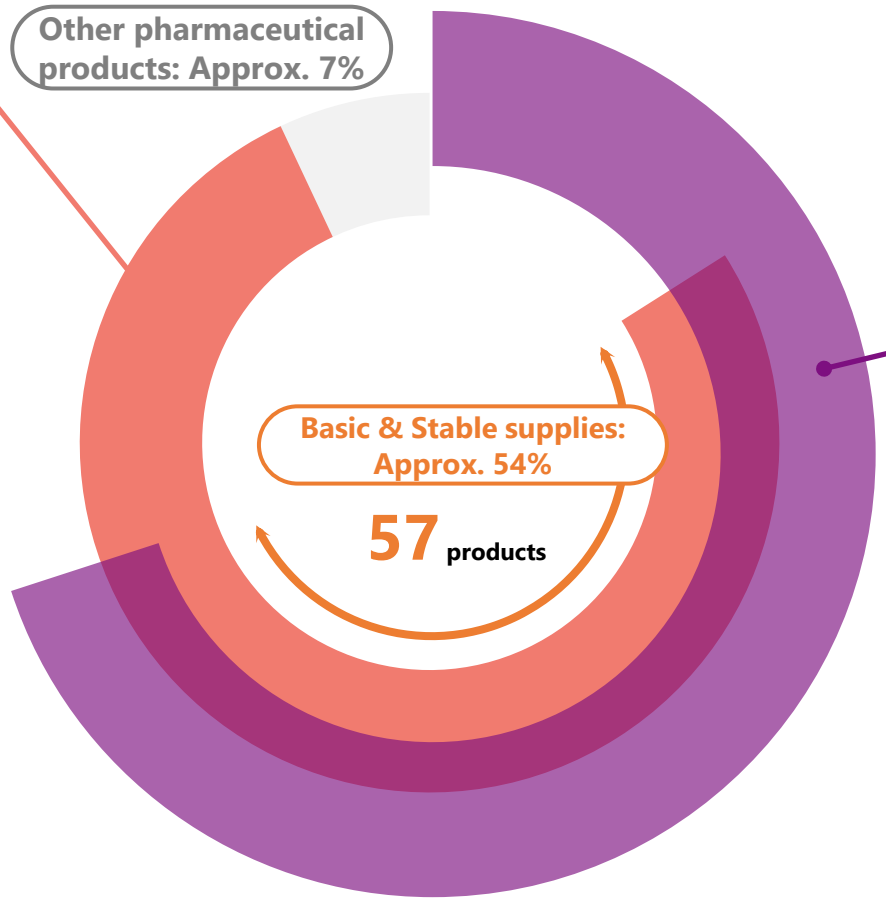
Product name (Therapeutic class)	FY2025 H1 Results	FY2026 H1 Results	YoY Change (%)	FY2026 Full-year plan
KINDARY Hemodialysis Agents (Dialysis agents)	10,951	10,761	-1.7%	22,122
Isotonic Sodium Chloride Solution (Blood substitute)	4,173	4,192	0.5%	8,214
Maxacalcitol Syringe (Secondary hyperparathyroidism agents)	2,268	2,325	2.5%	4,557
Cernilton (Prostatic disease agents)	1,696	1,967	16.0%	3,931
DOPACOL (Antiparkinsonian agent)	1,057	1,183	11.9%	2,139

Sales composition of ethical drugs

(Based on FY2025 actual sales volumes; NHI drug prices and classifications are for FY2026)

Basic pharmaceutical products + Stable supplies = **93%**





Stable supplies: Approx. 77%

107 products

Stable supplies

Designated pharmaceuticals specified by the Minister of Health, Labour and Welfare as pharmaceuticals for which there is a high need to ensure a stable supply, after hearing the opinions of the Health Sciences Council and taking into consideration the following matters:

1. The severity of the medical condition in the event of contracting the disease for which the designated pharmaceutical is used
2. Whether there are other designated pharmaceuticals or treatment methods that can serve as alternatives to the designated pharmaceutical
3. Whether special technologies are required for its manufacture, the circumstances surrounding the supply of raw materials or other materials, and other matters requiring consideration concerning its manufacture or supply
4. Other matters specified by the Order of the Ministry of Health, Labour and Welfare

Basic pharmaceutical products: Approx. 70%

94 products

Basic pharmaceutical products

Pharmaceuticals subject to measures that maintain their NHI drug prices under certain conditions because of their high necessity for medical care covered by health insurance, their widespread use in clinical practice over many years, their established efficacy and safety, and the need to ensure their continuous and stable supply to the market.

FY2026 Full-Year Earnings Forecast

(Millions of yen)	FY2025 full-year results	FY2026 full-year forecast				FY2026 H1 results
		(Before revision)		(After revision)		
	Amount	Amount	YoY Change	Amount	YoY Change	Amount
Net sales	62,307	63,200	+893	**64,800**	+2,493	32,395
Cost of sales	46,312	47,500	+1,188	**48,700**	+2,388	24,164
(Cost of sales ratio)	74.3%	75.3%	–	**75.2%**	–	74.6%
SG&A expenses	13,355	13,700	+345	**13,700**	+345	6,487
(R&D expenses)	(2,013)	(2,100)	+87	**(2,100)**	+87	(665)
Operating profit	2,639	2,000	-639	**2,400**	-239	1,743
Ordinary profit	2,349	1,400	-949	**1,800**	-549	1,434
Profit	2,011	1,300	-711	**1,500**	-511	1,041

[FY2026 Full-Year Earnings Forecast: Upward Revision Highlights]

Net sales: Revised upward by ¥1.6 billion, with Lixelle, Cernilton, DOPACOL and other products that performed well in H1 expected to remain strong in H2.
Cost of sales: Expected to rise in H2 as the impact of soaring raw material and supply prices amid the Middle East situation materializes, following a limited impact in H1.
R&D expenses: Expected to be broadly in line with the original full-year budget, as payments for the licensing deal under consideration are expected to arise during the current fiscal year.
Operating profit/Ordinary profit/Profit: Forecasts raised by ¥0.4 billion each for operating profit and ordinary profit, and by ¥0.2 billion for profit, reflecting H1 results and the factors above.

Progress in Research and Development

Ethical drugs

Development code (Generic name)	Target indication	Mechanism of action	Development stage					Development arrangement
			Phase I	Phase II	Phase III	Application	Approval	
DMX-200 (Repagermanium)	Focal Segmental Glomerulosclerosis (FSGS)	C-C chemokine receptor type 2 (CCR2) inhibitor			Ongoing			Joint development

DMX-200: A drug candidate with a novel mechanism of action for Focal Segmental Glomerulosclerosis (FSGS). In combination with an angiotensin II receptor blocker (ARB), it is expected to inhibit CCR2 more strongly, suppress excessive accumulation of inflammation-causing immune cells (macrophages) in the kidneys, and prevent tissue inflammation and damage.

Fertility and In Vitro Fertilization products

Development product	Intended use	Development arrangement
Embryo culture medium	Assisted reproductive technology	Joint research

Embryo culture medium (joint research)
An embryo culture medium based on a new concept that uses an antibody to inhibit a protein involved in the deterioration of embryo quality.

Progress in Research and Development
Development Status of DMX-200

Development code / Planned indication	Phase 1	Phase 2	Phase 3	Application	Approval/ Launch
Kidney and urology DMX-200 Focal Segmental Glomerulosclerosis (FSGS)	DMX-200-101 Overseas (2017)	DMX-200-202 Overseas (Target: FSGS) (2018–2020)	ACTION3 DMX-200-301 Overseas (May 2022–) Japan (May 2025–)	Japan Application planned in FY2029	Japan Launch expected in FY2030

Focal Segmental Glomerulosclerosis (FSGS)

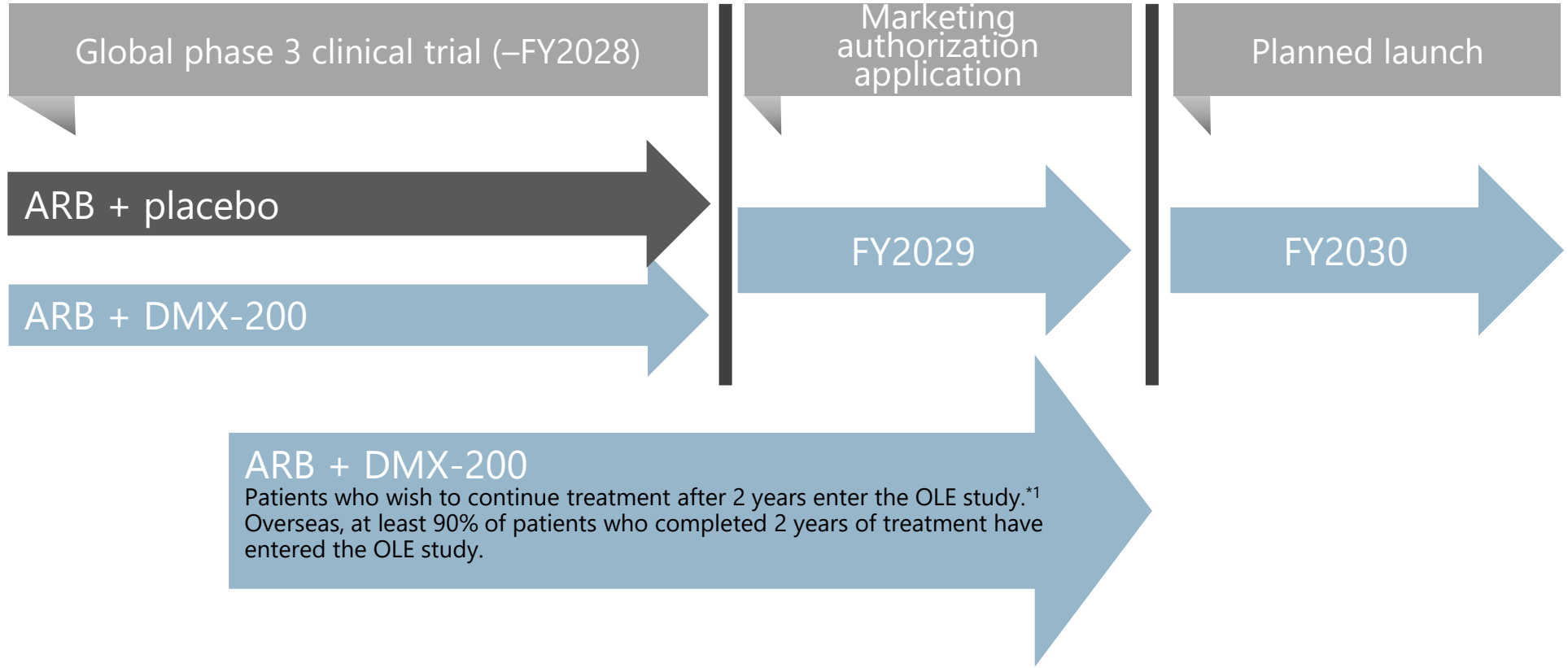
- Focal Segmental Glomerulosclerosis (FSGS) is one of the major causes of primary nephrotic syndrome [*1] (designated intractable disease 222)
- The number of FSGS patients in Japan is approximately 1,400[*2, 3, 4]
- With existing treatments, patients may develop treatment resistance or experience recurrence (40%[*5]), and there is a high risk of progression to renal failure
- Recurrence may also occur in FSGS patients who have undergone kidney transplantation
- Currently, there are no drugs approved with an indication for FSGS in Japan, and there is a need to develop new drugs that offer long-term therapeutic benefits with fewer side effects, without relying on steroids or immunosuppressive agents
- DMX-200 has been designated as an orphan drug in major regions (U.S. and Europe), as well as in Japan, where it received the designation on September 29, 2025

*1: A disease characterized by massive leakage of protein into the urine, caused by increased protein permeability resulting from glomerular tuft injury, and by the associated hypoproteinemia (hypoalbuminemia)
*2: Number of holders of specified medical expenses recipient certificates (designated intractable diseases), by age group and designated disease, 2022
*3: Japan Intractable Diseases Information Center, primary nephrotic syndrome (designated intractable disease 222)
*4: Evidence-based clinical practice guidelines for nephrotic syndrome 2020
*5: Clinical and Experimental Nephrology (2020) 24:526–540

Progress in Research and Development
Global phase 3 clinical trial (ACTION3)

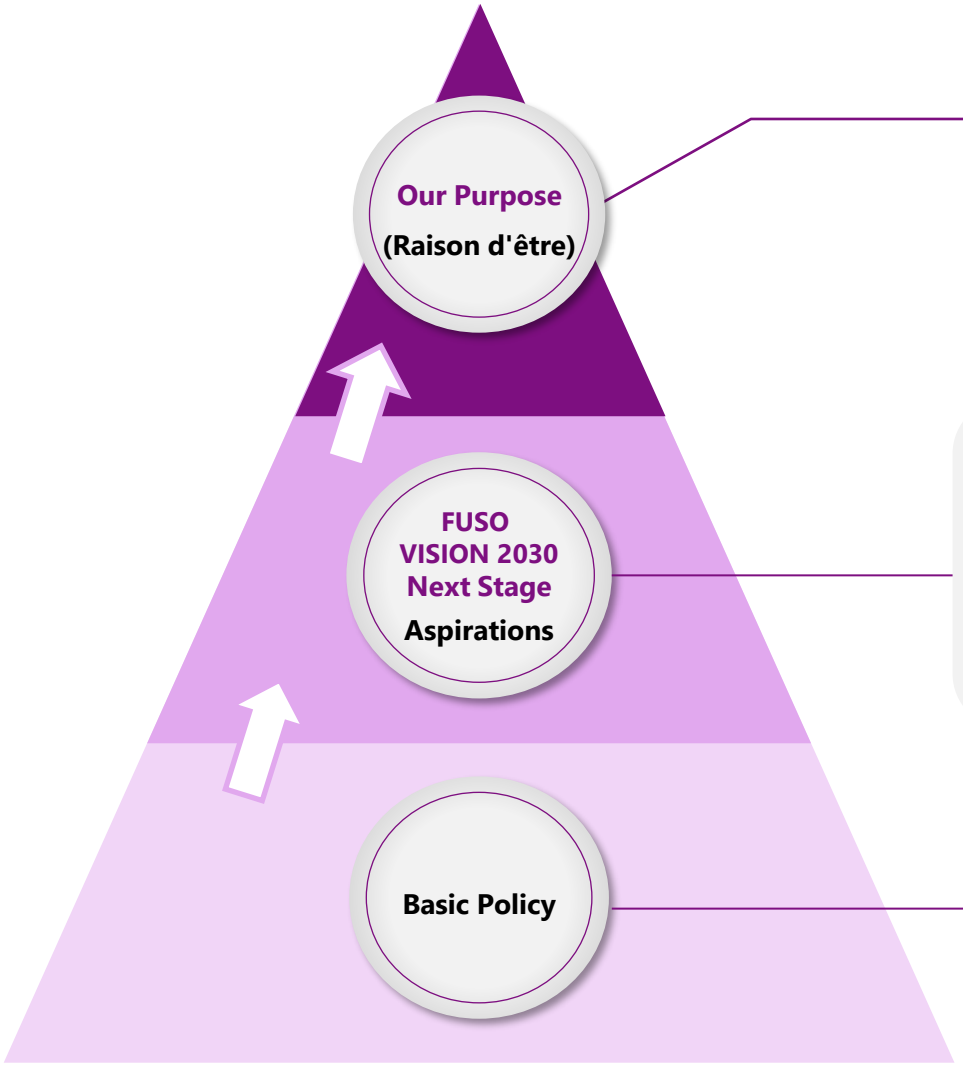
ACTION3
FSGS CLINICAL STUDY

The trial has enrolled 333 patients across 21 countries and regions, including Japan, exceeding the planned enrollment of 286 patients



*1: Open-label-extension (OLE) study: A study to evaluate the long-term efficacy and safety of a drug by continuing to administer the drug to patients who wish to continue treatment after the completion of the clinical trial

Progress in the Medium-Term Management Plan



Purpose (Our Reason for Being)

Supporting Life, Nurturing Life

We continue to make indispensable medicines that support lives



FUSO VISION 2030: Our Aspirations

Become an indispensable company that supports society through healthcare, both as a manufacturer of basic pharmaceutical products committed to rigorous quality control and a stable supply over the long term, and as a specialty pharmaceutical company addressing unmet medical needs in the renal and urological fields.

Basic Policy

- R&D
- Production
- Sales & Marketing
- Management Framework
- Human Capital
- Sustainability

Progress in the Medium-Term Management Plan (Production)

Construction of Okayama Second Factory

Estimated investment amount:

Approx. ¥14.0 bn

- ✓ **Steel-framed, 5 stories / Formulation building Approx. 7,000 square meters (total floor area) + Automated warehouse**
- ✓ **Dec. 2026: Start of construction→ Mar. 2028: Completion →End of 2028: Start of production**
- ✓ **Developing concrete plans to strengthen production capacity and enhance our stable supply capabilities**



Planned Construction Site



Artist's Rendering

Production line upgrades for infusions and injections

Assumptions announced in 2025

Upgrades to be completed by 2030

Investment amount: Approx. ¥12.0 bn

Reassessing assumptions

- ✓ **Reassess investment scale and timing based on market conditions and costs**

Progress in the Medium-Term Management Plan (Human Capital)

Basic policy

Strategically strengthen recruitment and talent development to support future growth, and actively implement initiatives to improve employee engagement

Priority theme

Enhancing employee engagement

Key progress to date

01 Asset-building support
Increased the company incentive contribution rate for the employee shareholding association

02 Flexible working arrangement
Introduced a flextime system

03 Dialogue with management
Management held town hall meetings across all sites

04 Family connections
Family Day planned

Doshomachi Head Office after renovation





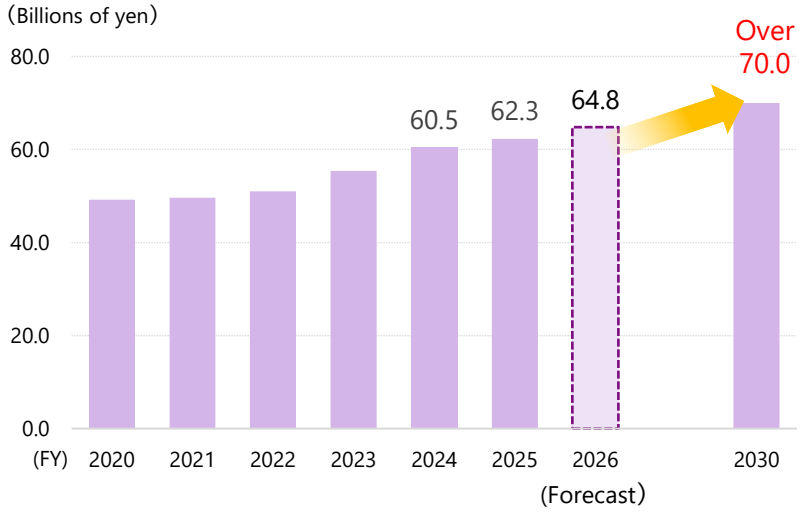


Progress in the Medium-Term Management Plan (KPIs)

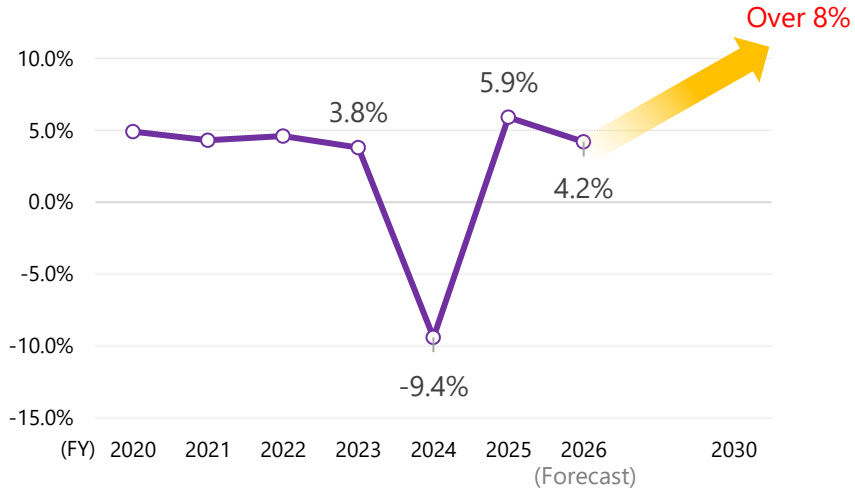
Growth investment costs are expected to weigh on profit levels until around 2028. Profits are then expected to recover from FY2029 as these investments begin to deliver results. We aim for ROE of over 8% in FY2030.

- **FY2028 Planned start of operations at Okayama Second Factory**
- **FY2030 Planned launch of DMX-200**

Net sales



ROE



* Provision for litigation loss of ¥8,744 million was recorded as an extraordinary loss for FY2024.

Shareholder Return Policy

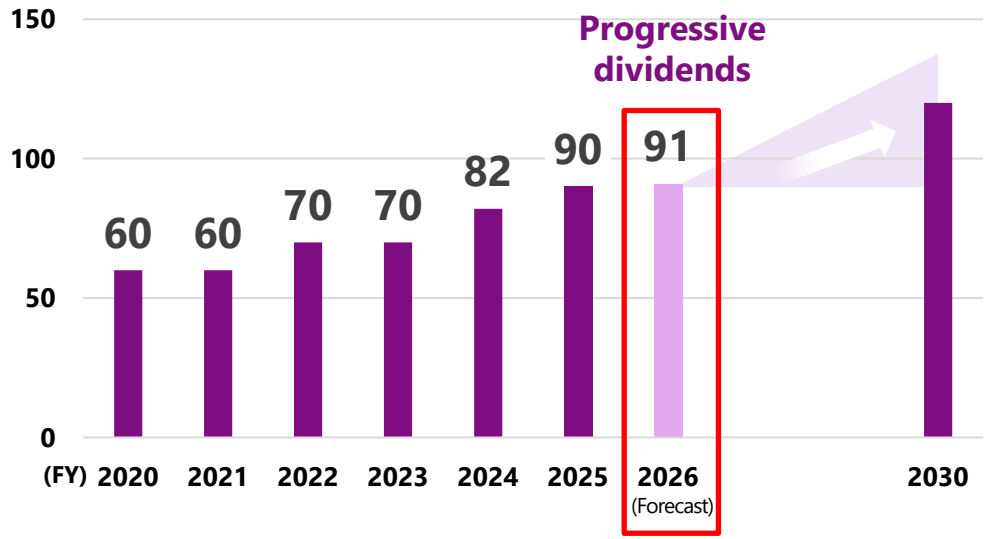
Basic policy: Maintain regular, stable dividend payments while preserving sufficient retained earnings

Medium-term policy

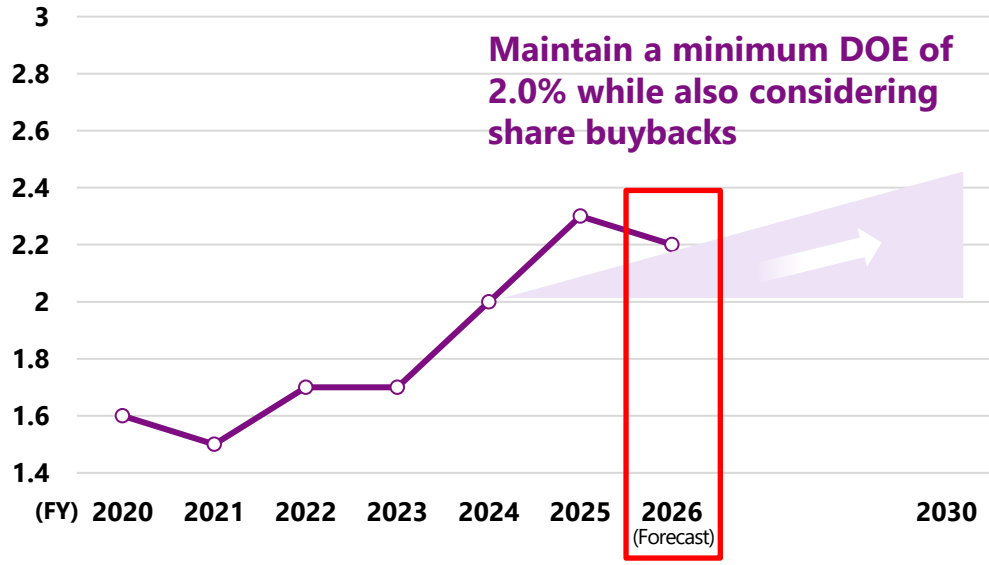
- Aim to maintain progressive dividends through FY2030, balancing shareholder returns with investments to strengthen stable supply capabilities and investments in growth areas
- Set a minimum ratio of dividends to net assets (DOE) of 2.0%, and consider share buybacks as appropriate, taking cash flow trends and other factors into account

An annual dividend forecast for FY2026: ¥91 (interim: ¥45 / year-end: ¥46)

Annual dividends per share



Ratio of dividends to net assets (DOE)



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