

Financial Briefing for the Second Quarter(Interim) of the Fiscal Year Ended March 31, 2025 (Fiscal 2024)

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Summary of the Interim Financial Results for Fiscal 2024



1. Results

✓ **Net sales: ¥42,466 million (+14.8% YoY)**

✓ **Operating profit: ¥1,781 million (−11.6% YoY)**

Net sales driven by Pharmaceutical Business (up 19.1% YoY)

Profit decreased due to higher SG&A expenses, (primarily R&D expenses)

✓ **R&D expenses: ¥7,091 million (57.6% YoY)**

In-licensing of olutasidenib, joint research with Reborna Biosciences, Inc. preparations to start clinical trials for new original products, etc.

2. Pharmaceutical Business

✓ **Net sales: ¥36,633 million (+19.1% YoY)**

Expansion of key products: **Beova®**, a treatment for overactive bladder

Expansion of new products: **CAROGRA®**, a treatment for ulcerative colitis

TAVNEOS®, a treatment for MPA*¹ and GPA*²

TAVALISSE®, a treatment for ITP*³

KORSUVA®, a treatment for pruritis in dialysis patients

*1 Microscopic polyangiitis *2 Granulomatosis with polyangiitis *3 Idiopathic thrombocytopenic purpura

Summary of the Interim Financial Results for Fiscal 2024



3. R&D Pipeline

- **Linzagolix** (treatment for uterine fibroids): Primary endpoint achieved during domestic phase III clinical trials, preparations to submit New Drug Application (NDA) underway
- **CG0070** (treatment for non-muscle invasive bladder cancer): Favorable interim analysis results from international phase III clinical trials
- **KDT-3594** (treatment for Parkinson's disease): Began late-stage phase II clinical trials in August 2024
- **Olutasidenib** (treatment for acute myeloid leukemia): entered technology licensing agreement in September 2024.

4. Global Expansion of Linzagolix

- **Theramex (UK):**
 - For uterine fibroids: Launched in September 2024 in Europe (product name: **YSELT[®]**)
 - For endometriosis: NDA in process in Europe, recommendations for approval given by European Medicines Agency (EMA) and Committee for Medicinal Products for Human Use (CHMP)
- **Bio Genuine (China):** Termination of licensing agreement in China and other countries

Financial Results for the Interim results for fiscal 2024

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(millions of yen)

	Interim results for fiscal 2023		Interim results for fiscal 2024			
	Result	Ratio to sales	Plan	Result	Ratio to net sales	YoY
Net sales	36,978	100.0 %	41,000	42,466	100.0 %	14.8 %
[Pharmaceutical Business]	[30,765]	[83.2 %]	[35,000]	[36,633]	[86.3 %]	[19.1 %]
Pharmaceuticals ^{*1}	26,420	71.4 %	29,000	31,161	73.4 %	17.9 %
Therapeutic and care foods	1,763	4.8 %	1,800	1,800	4.2 %	2.1 %
Technical fees ^{*2}	171	0.5 %	2,000	1,430	3.4 %	736.1 %
Other ^{*3}	2,410	6.5 %	2,200	2,241	5.3 %	(7.0 %)
Cost of sales	18,677	50.5 %	20,500	21,068	49.6 %	12.8 %
Gross profit	18,300	49.5 %	20,500	21,397	50.4 %	16.9 %
Selling, general and administrative expenses	16,284	44.0 %	19,000	19,616	46.2 %	20.5 %
[R&D expenses]	[4,499]	[12.2 %]	[6,600]	[7,091]	[16.7 %]	[57.6 %]
Operating profit	2,015	5.5 %	1,500	1,781	4.2 %	(11.6 %)
Ordinary profit	3,465	9.4 %	2,200	2,237	5.3 %	(35.4 %)
Profit attributable to owners of parent	5,678	15.4 %	5,200	5,249	12.4 %	(7.6 %)
Comprehensive income	9,608			1,447		

^{*1} Including active pharmaceutical ingredients (APIs) and bulk exports

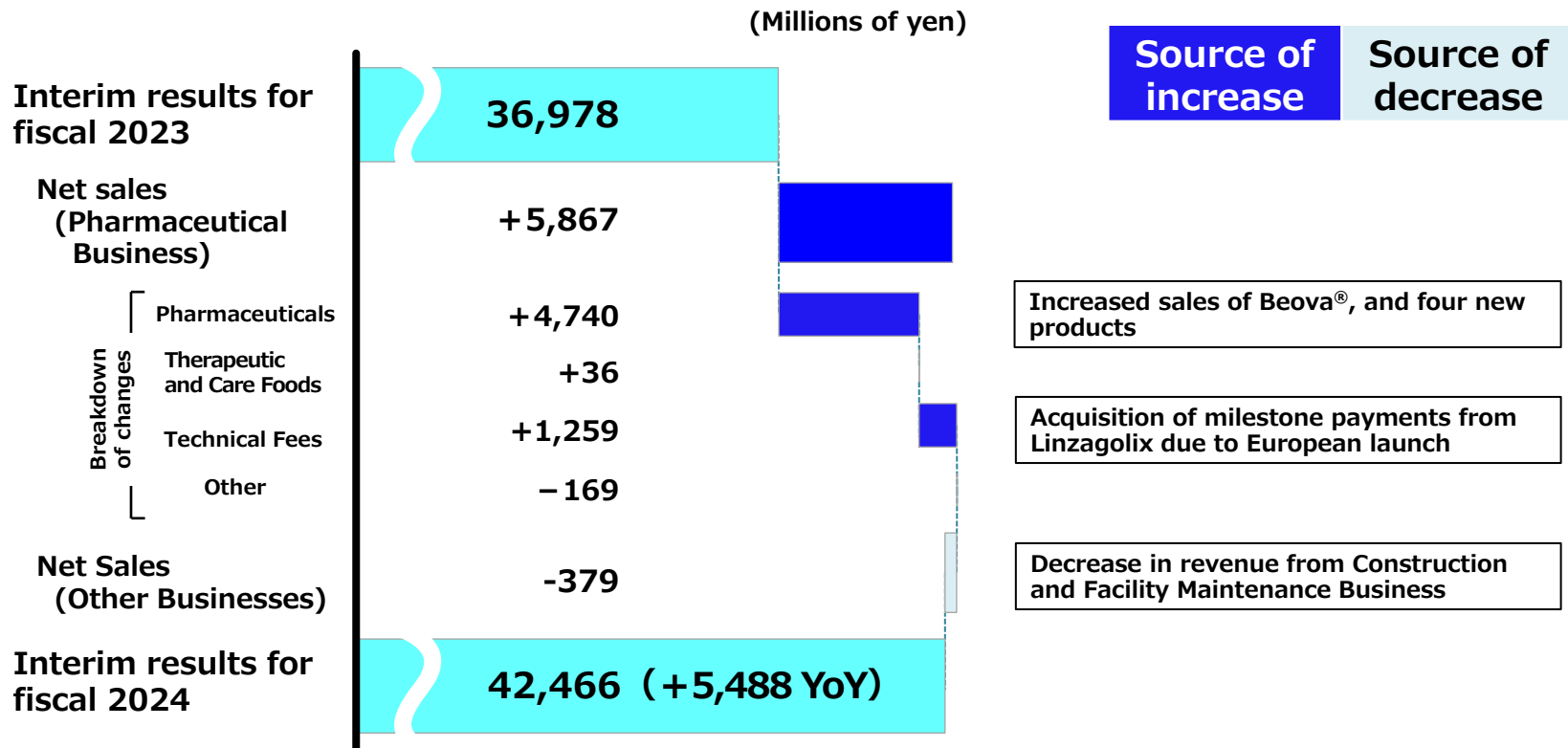
^{*2} Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties

^{*3} Includes revenue from supply to domestic sales partners and revenue from co-promotion fees

Please refer to pages 2, 3, and 8 of the Supplementary Explanatory Materials on Financial Results

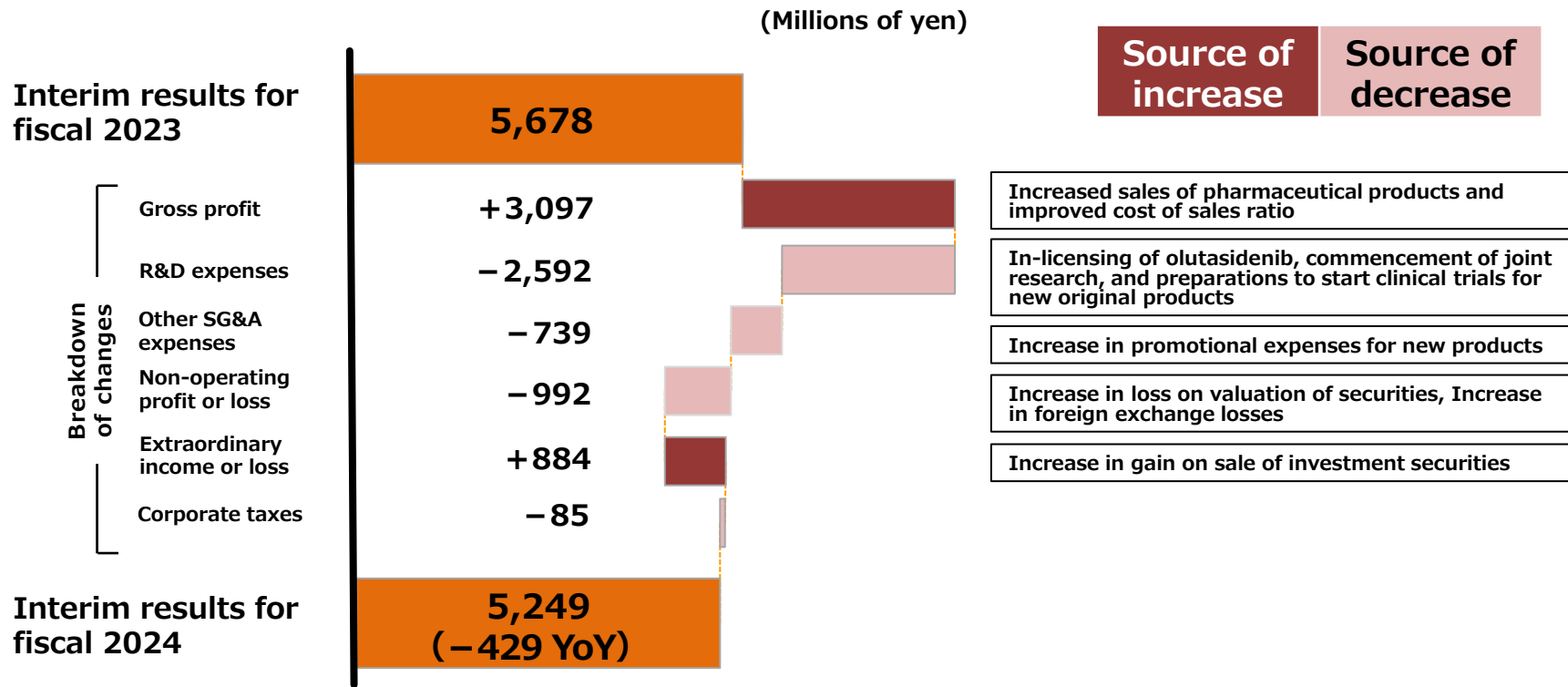
Net sales Compared with Interim Results of Fiscal 2023

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Profit attributable to owners of parent Compared with Interim results for fiscal 2023

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Revised Plan for Fiscal 2024

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(millions of yen)

	Fiscal 2023		Fiscal 2024			
	Result	Ratio to net sales	Initial plan	Revised plan	Ratio to net sales	YoY
Net sales	75,579	100.0 %	83,000	86,500	100.0 %	14.4 %
[Pharmaceutical Business]	[63,348]	[83.8 %]	[70,500]	[74,000]	[85.5 %]	[16.8 %]
Pharmaceuticals	54,237	71.8 %	60,000	63,500	73.4 %	17.1 %
Therapeutic and Care Foods	3,545	4.7 %	3,600	3,600	4.2 %	1.6 %
Technical Fees	714	0.9 %	2,100	2,100	2.4 %	194.1 %
Other	4,850	6.4 %	4,800	4,800	5.5 %	(1.0 %)
Cost of sales	38,238	50.6 %	42,000	43,200	49.9 %	13.0 %
Gross profit	37,341	49.4 %	41,000	43,300	50.1 %	16.0 %
Selling, general and administrative expenses	33,324	44.1 %	36,800	38,300	44.3 %	14.9 %
[R&D expenses]	[9,474]	[12.5 %]	[12,000]	[13,000]	[15.0 %]	[37.2 %]
Operating profit	4,017	5.3 %	4,200	5,000	5.8 %	24.5 %
Ordinary profit	6,142	8.1 %	5,400	6,000	6.9 %	(2.3 %)
Profit attributable to owners of parent	11,160	14.8 %	11,300	11,700	13.5 %	4.8 %

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Three Growth Strategies

Expand Linzagolix Globally

- Launched YSELT[®] in Europe (Germany and Spain)

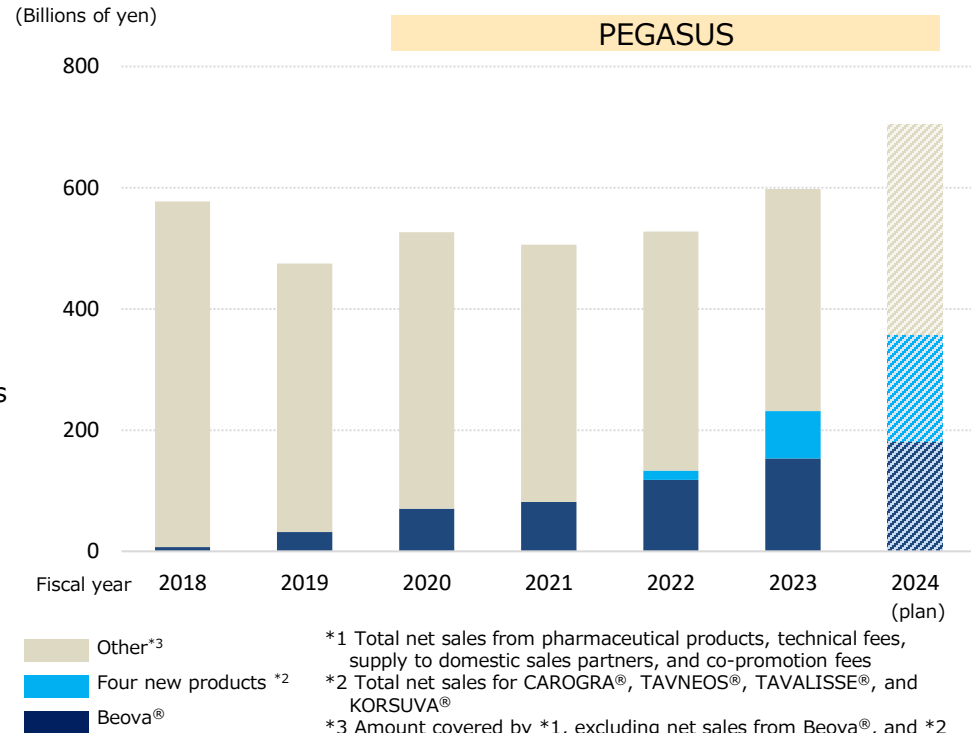
Increase sales of new products, with a focus on rare diseases

- Continue to cultivate Kissei's four new products
 - Increases sales ratio of new products to over 25% in fiscal 2025
- Increase market presence of KORSUVA[®]
 - KORSUVA[®] used in 56% of facilities that provide dialysis

Expand sales of mainstay products, focusing on primary care

- Increase sales centered on OAB treatment Beova[®]
- Provide information using field-specific strategies, centered on the key areas of urology and renal diseases and dialysis

Net Sales for Pharmaceutical Products^{*1}



New Drug Development (In-Company)

		Development stage							
Generic name / Development code	Expected indications	Phase			Preparation to submit application	NDA in process	NDA approved	Development classification	
		I	II	III					
CG0070	Non-muscle-invasive bladder cancer								In-licensed / Co- development with Maruishi Pharmaceutical
Linzagolix / KLH-2109	Uterine fibroids								Original product
	Endometriosis								Original product
KDT-3594	Parkinson’s disease								Original product
KSP-0243	Ulcerative colitis								Original product

Rovatrielin (Spinocerebellar ataxia) Discussions into the possibility of additional clinical trials underway

Linzagolix (Uterine fibroids) Phase III clinical trials → Preparation to submit application (phase III clinical trials ongoing)

KDT-3594 (Parkinson's disease) Phase II clinical trials (early-stage) → Phase II clinical trials (late-stage)

New Drug Development (Out-Licensing)

			Development stage						
Generic name	Expected indications	Countries and regions	Clinical trials under preparation	Phase			Preparation to submit application	NDA in process	Partner company
				I	II	III			
Linzagolix	Uterine fibroids	Australia							Theramex
		Taiwan							Synmosa Biopharma
	Endometriosis	Europe							Theramex
Fostamatinib	Chronic ITP ^{*1}	South Korea							JW Pharmaceutical
Silodosin	Dysuria associated with BPH ^{*2}	Vietnam, other countries							Eisai

Linzagolix (uterine fibroids, Europe) NDA approved → Launched in Germany and Spain, and other countries

Linzagolix (uterine fibroids, Australia) → NDA in process (newly added)

Linzagolix (uterine fibroids, China) Phase III clinical trials → Termination of licensing agreement with Bio Genuine (removed from table)

Linzagolix (endometriosis, Europe) Phase III clinical trials → NDA in process

Linzagolix (endometriosis) Phase III clinical trials → Termination of licensing agreement with Bio Genuine (removed from table)

Distribution of Profits

◆ **Basic Policy on the Distribution of Profits**

Provide stable, consistent returns to shareholders while aiming for a dividend payout ratio of 40% or higher

◆ **Purchase and Disposal of Treasury Stock**

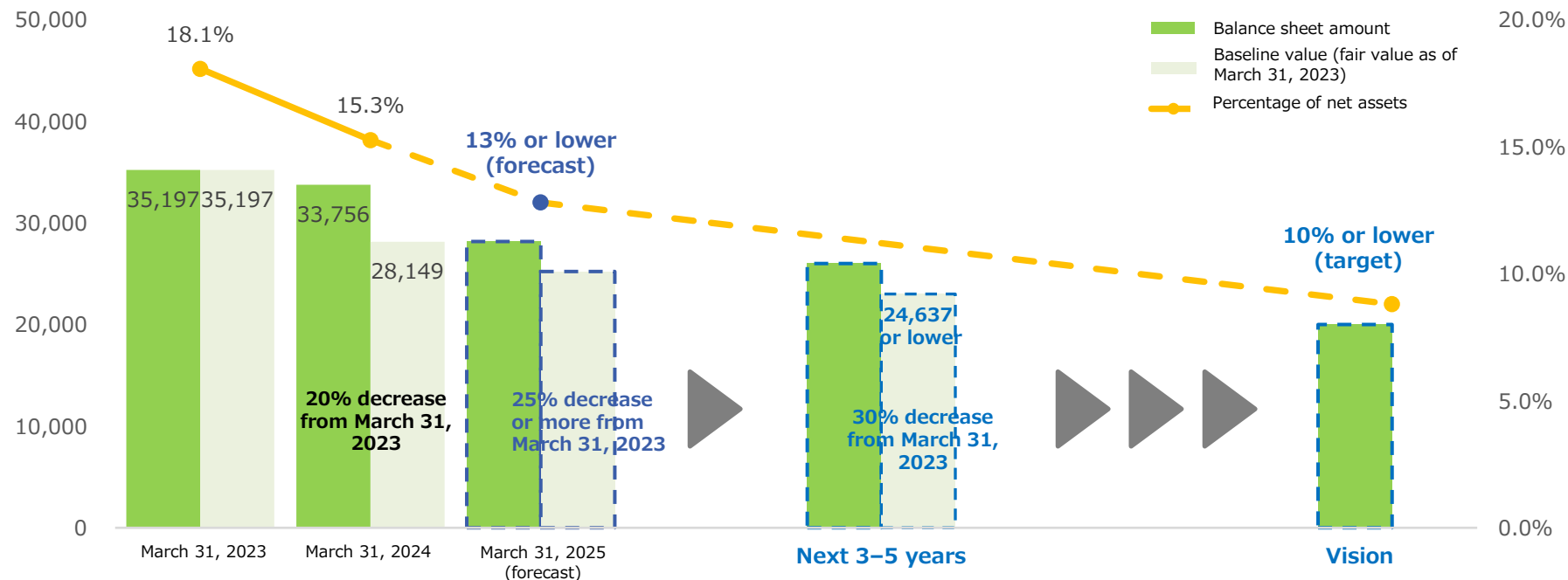
Improve capital efficiency and increase shareholder returns

	Fiscal 2020	Fiscal 2021	Fiscal 2022	Fiscal 2023	Fiscal 2024 Forecast
Annual dividend per share	¥54	¥56	¥80	¥82	¥90
Dividend payout ratio (consolidated)	47.7%	20.0%	35.0%	33.3%	33.5%
Total return ratio	72.4%	20.0%	35.0%	87.1%	78.7%
Treasury stock purchased (number of shares)	¥1.3 billion (600,000 shares)			¥6.0 billion (1,910,000 shares)	¥5.3 billion (1,400,000 shares)
Treasury stock canceled (number of shares)				¥5.7 billion (2,500,000 shares)	¥5.3 billion (1,400,000 shares)

Cross-Shareholdings | Status of Reduction and Future Outlook

- **Three to Five Year Target: 30% decrease compared with the fair value as of March 31, 2023**
(¥35,197 million ⇒ ¥24,637 million yen or less)
- **Vision: Percentage of net assets: 10% or lower**

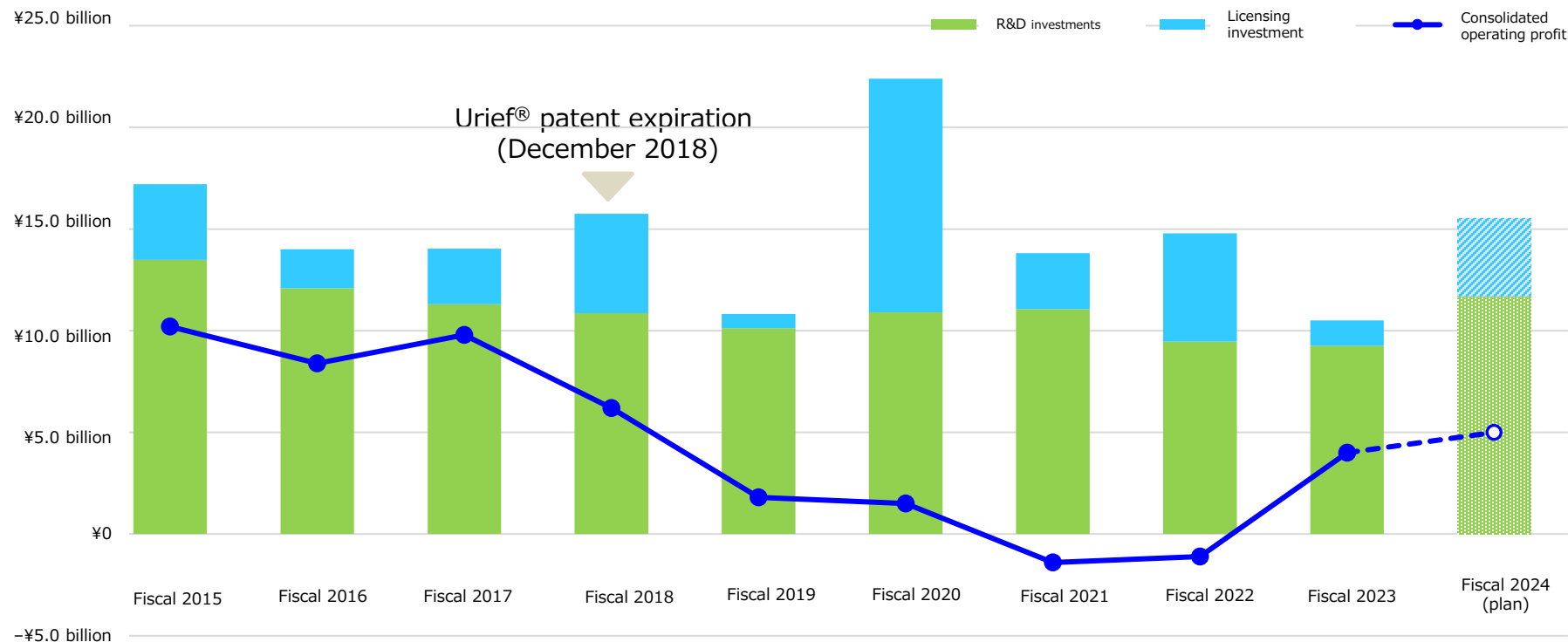
(Millions of yen)



Efforts to Implement Management that is Conscious of Cost of Capital and Stock Price

R&D/Licensing Investments | 10-Year Period

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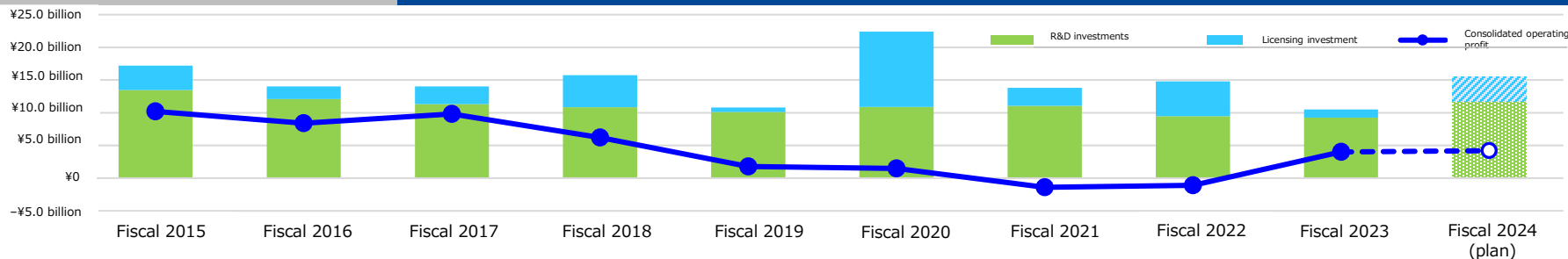


**Five-Year Period Prior to
PEGASUS**

**PEGASUS (Current Medium-Term
Management Plan)**

R&D/Licensing Investments | Continuous Launch of New Drugs to the Market

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Five-Year Period Prior to PEGASUS

Emphasis on developing new drugs

- Global expansion of linzagolix
- Drug discovery research with a focus on small molecules

PEGASUS (Current Medium-Term Management Plan)

Moving original products to the next development stage

- Linzagolix launched in Europe, domestic preparations to submit application underway
- Original products (KDT-3594 and KSP-0243) undergoing clinical trials
- Three projects for original products moved to preclinical development

Strengthening the foundation and developing human resources for continuous new drug discovery

- Promotion of AI drug discovery system and other DX initiatives
- Promoting open innovation
- Multi-platform small-molecule drug discovery research

In-licensing and development highly competitive new drugs

- Beova®, CAROGRA®, TAVNEOS®, TAVALISSE®, KORSUVA®

Current growth drivers

Acquisition of future growth drivers

- In-licensing for CG0070
- In-licensing for olutasidenib
- Promoting licensing activities

R&D investments

Licensing investments



The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends as of November 2024. Actual results may differ from forecasts due to risks and uncertainties that may affect business. Although drug information, including information pertaining to drugs under development, is reported in these materials, the contents are not intended as marketing or medical advice.