KISSEI

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

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President and COO

November 7 2024

キッセイ薬品工業株式会社

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Summary of the Interim Financial Results for Fiscal 2024

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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

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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: **YSELTY®**)
  - 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

Interim Financial 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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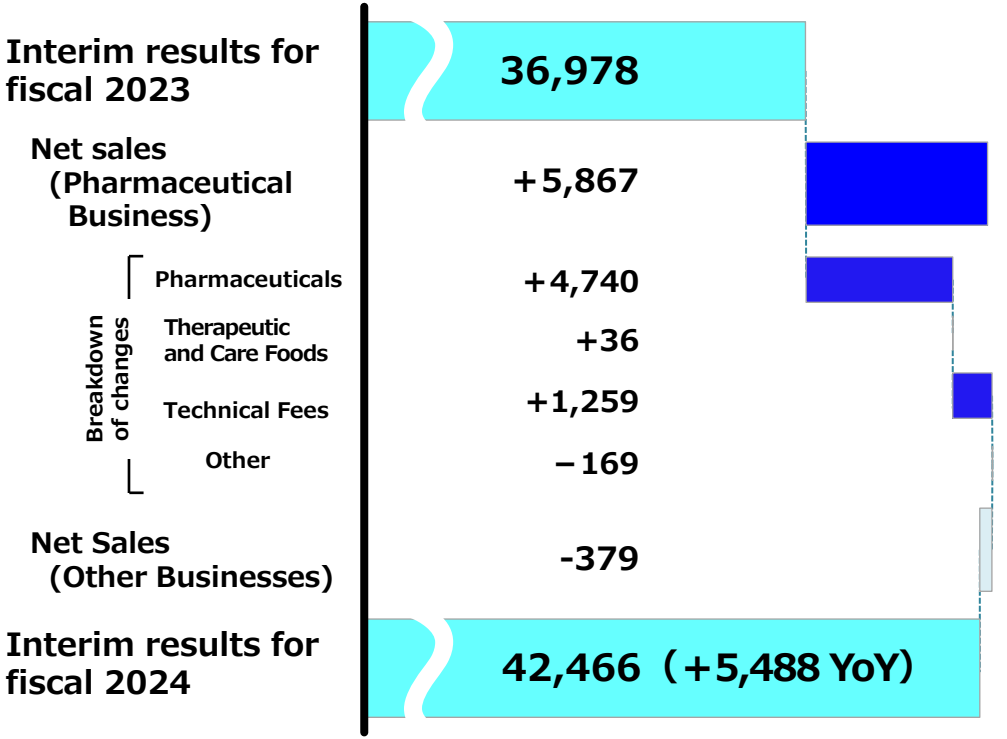
(Millions of yen)



Source of increase	Source of decrease

Increased sales of Beova®, and four new products

Acquisition of milestone payments from Linzagolix due to European launch

Decrease in revenue from Construction and Facility Maintenance Business

Profit Attributable to Owners of Parent Compared with Interim Results for Fiscal 2023

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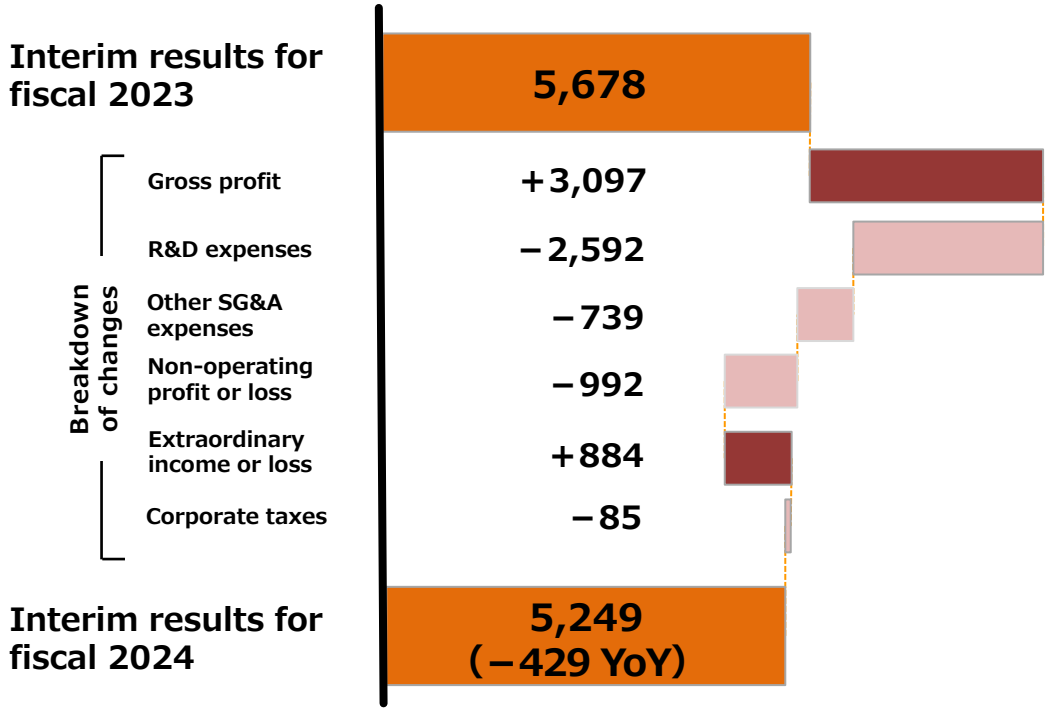
(Millions of yen)



Source of increase	Source of decrease
Increased sales of pharmaceutical products and improved cost of sales ratio	
	In-licensing of olutasidenib, commencement of joint research, and preparations to start clinical trials for new original products
	Increase in promotional expenses for new products
	Increase in loss on valuation of securities, increase in foreign exchange losses
Increase in gain on sale of investment securities	

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 %

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

Pharmaceutical Business | Enhancing Profitability

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Three Growth Strategies

Expand linzagolix globally

- Launched YSELTY® in Europe (Germany and Spain)

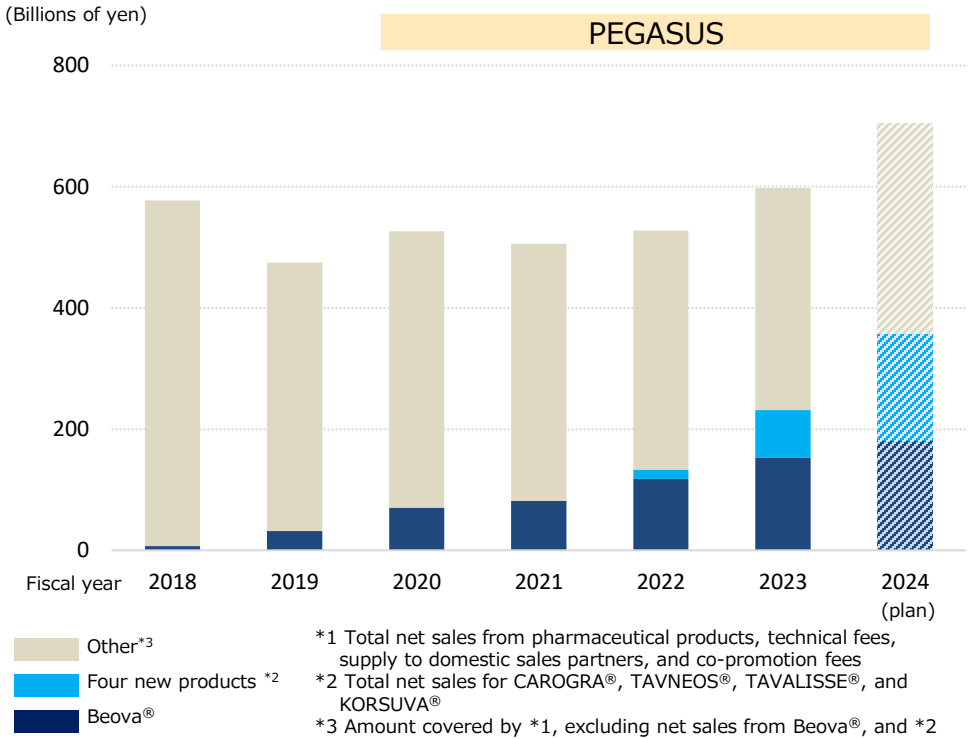
Increase sales of new products, with a focus on rare diseases

- 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



*1 Total net sales from pharmaceutical products, technical fees, supply to domestic sales partners, and co-promotion fees
*2 Total net sales for CAROGRA®, TAVNEOS®, TAVALISSE®, and KORSUVA®
*3 Amount covered by *1, excluding net sales from Beova®, and *2

New Drug Development (In-Company)

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Generic name / Development code	Expected indications	Development stage: Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	NDA approved	Development classification
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

Rovatirelin (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)

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Development stage

Generic name	Expected indications	Countries and regions	Clinical trials under preparation	Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	Partner company
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)

*1 Idiopathic thrombocytopenic purpura *2 Benign prostatic hyperplasia

Distribution of Profits

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- **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

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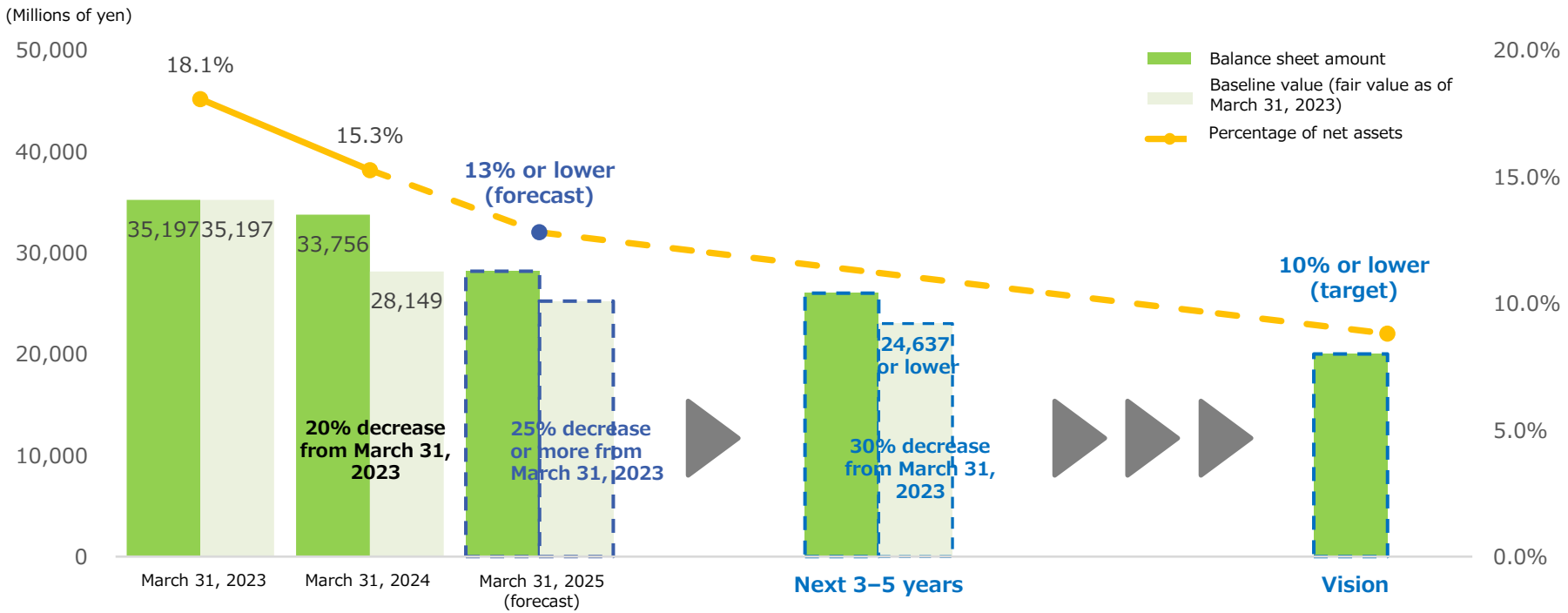
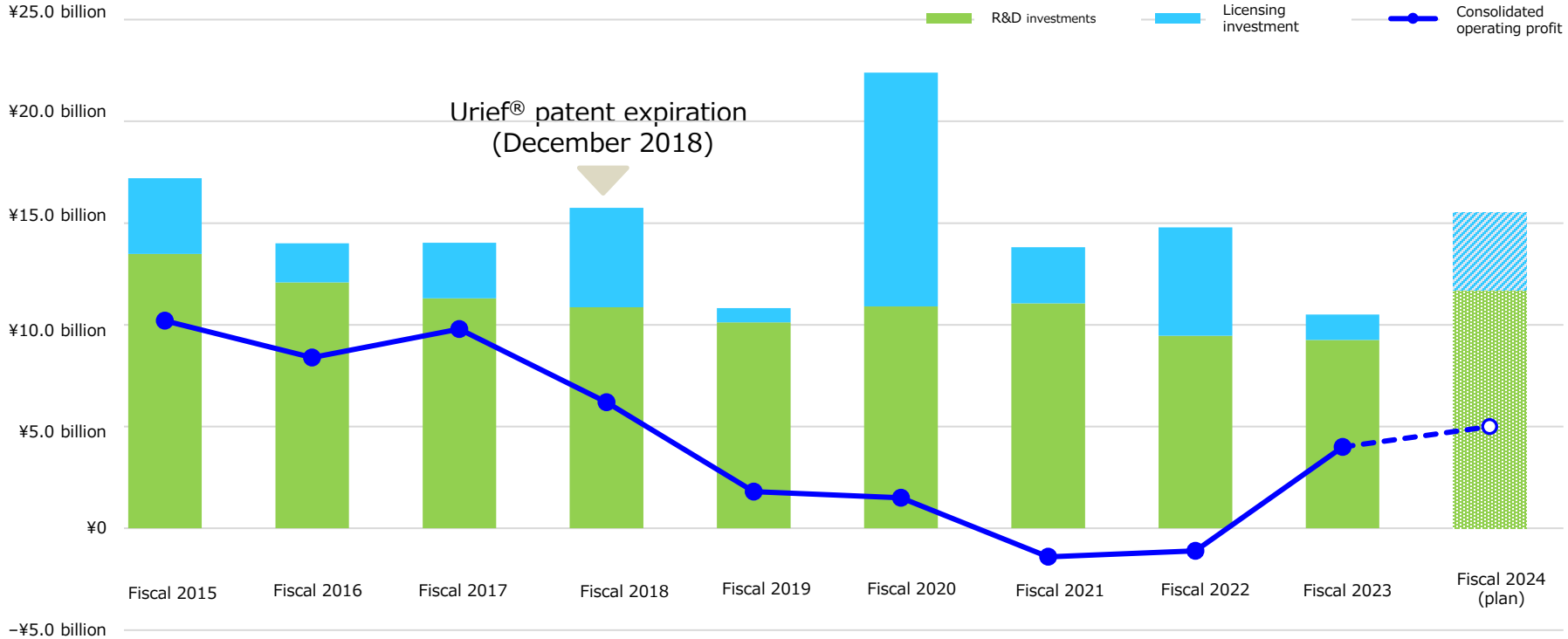
- **Three to Five Year Target: 30% decrease compared with the fair value as of March 31, 2023**
  (¥35,197 million ⇒ ¥24,637 million yen or less)
- **Vision: Percentage of net assets: 10% or lower**



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

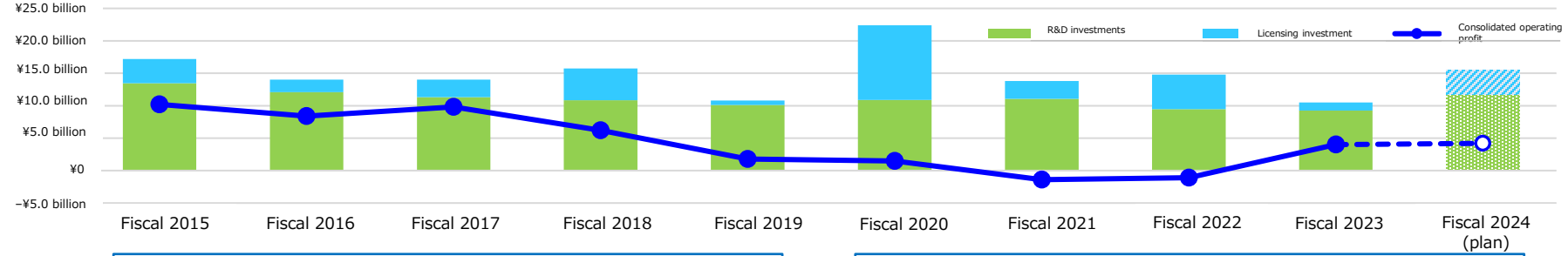
R&D/Licensing Investments | 10-Year Period



Five-Year Period Prior to PEGASUS

PEGASUS (Current Medium-Term Management Plan)

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



	Five-Year Period Prior to PEGASUS	PEGASUS (Current Medium-Term Management Plan)
R&D investments	**Emphasis on developing new drugs** ・Global expansion of linzagolix ・Drug discovery research with a focus on small molecules	**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
Licensing investments	**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

Realizing Our Management Philosophy

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Management Philosophy

Contribute to society through high-quality, innovative pharmaceutical products
Serve society through our employees

Environment

- **Reduce environmental impact and risks across the value chain**
- **Promote climate change and biodiversity measures**
- **Promote resource recycling and aim for 100% renewable energy usage**
- **Achieve carbon neutrality by 2050**

Key Initiatives to Date

- Endorsement of TCFD recommendations
- Reduction of waste and CO2 emissions
- Capital investment with consideration toward energy conservation and reducing environmental impact
- Introduction of renewable energy and achievement of 2030 target for rate of renewable energy use ahead of schedule
- Promotion of activities aimed at environmental conservation

Social

- **Create sustainable value as an R&D-oriented pharmaceutical company**
- **Improve access to medical care, provide support to patients, and improve customer satisfaction**
- **Integrate employee growth with Kissei's sustainable development**
- **Participate in social contribution activities**

Key Initiatives to Date

- R&D and launch of products that meet unmet needs, focusing on drugs to treat rare diseases
- Beginning operations of the KISSEI Safety Link safety information system
- Promotion of health management, diversity, and employment of people with disabilities
- Contributions to culture, the arts, and sports

Governance that Realizes Our Management Philosophy

Governance

- **Enhance corporate governance**
- **Enhance risk management**
- **Enhance business resilience by establishing a business continuity management (BCM) system with an all-hazards approach**
- **Enhance compliance and legal compliance systems**

Key Initiatives to Date

- Compliance with all principles of Japan's Corporate Governance Code
- Enhancement of the Board of Directors' functions
- Appointment of a female director and an Audit & Supervisory Board Member
- Introduction of the executive officer system
- Establishment and operation of BCM system
- Implementation of compliance program

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.