KISSEI

Financial Briefing for the Fiscal Year Ended March 31, 2025 (Fiscal 2024)

Yasuo Takehana
President and COO

May 9, 2025

KISSEI PHARMACEUTICAL CO., LTD.

KISSEI

Summary of Financial Results for Fiscal 2024

KISSEI

1. Results

- ✓ **Net sales: ¥88,330 million (+16.9% YoY), Operating profit: ¥5,773 million (+43.7% YoY)**
  - Net sales reached record highs in the Pharmaceutical Business (+18.9% YoY) and Other Businesses (+6.5%)
  - Operating income increased due to higher revenue and an improved cost of sales ratio, despite an increase in SG&A expenses (mainly R&D expenses)
- ✓ **R&D expenses: ¥12,889 million (+36.0% YoY)**
  - Increased due to in-licensing of Olutasidenib, advancing development themes to the next stage, preparations for clinical trials of new original products, etc.

2. Pharmaceutical Business

- ✓ **✓Net sales: ¥75,299 million (+18.9% YoY)**
  - Domestic pharmaceuticals: Increased sales of Beova®, and New products（TAVNEOS®, KORSUVA®, TAVALISSE®, CAROGRA® ）
  - Overseas license: Increase in Technical Fees revenue and export due to progress in overseas expansion of Linzagolix and Fostamatinib

Linzagolix	Theramex(UK)	Launched in Europe as a treatment for uterine fibroids in September 2024 Acquired an additional indication for endometriosis in November 2024
	JW Pharmaceutical (South Korea)	Entered into a licensing agreement for South Korea in June 2024
Fostamatinib	Tai Tien Pharmaceuticals (Taiwan)	Entered into a licensing agreement for Taiwan in January 2025
	JW Pharmaceutical (South Korea)	Obtained marketing authorization in January 2025

Summary of the Plan for Fiscal 2025

KISSEI

1. Earnings Forecast

✓ **Net sales: ¥91,500 million (+3.6% YoY)、 Operating profit: ¥6,000 million (+3.9% YoY)**

- Net sales are expected to increase as Other Business grow（+22.8%YoY）, despite only a slight increase in the Pharmaceutical Business（+0.3% YoY）
- Operating profit is expected to increase, as higher sales are anticipated to offset the continued high level of R&D expenses, as well as selling, general, and administrative expenses

✓ **R&D expenses： ¥13,000 million（+0.9% YoY）**

- Advancement of four themes in late-stage clinical development（Linzagolix、Rovatirelin、Cretostimogene grenadenorepvec *1、Matsupexole*2）

2. Pharmaceutical Business

✓ **Net sales： ¥75,500 million（+0.3% YoY）**

- Domestic pharmaceuticals（+2.9% YoY）：The increase in sales of Beova®, and New four products（TAVNEOS®, KORSUVA®, TAVALISSE®, and CAROGRA®）will mitigate the impact of drug price revisions and the termination of the contract with Ferring Pharmaceuticals
- Overseas license（−21.5% YoY）：A recoil decline due to the recording of Technical Fees revenue in the previous period

*1 Development code : CG0070　*2 Development code : KDT-3594

Progress of Development Pipeline (Domestic)

KISSEI

Generic name	Expected indications	Development status
Linzagolix	Uterine fibroids Endometriosis	Submitted New Drug Application (NDA) in Japan in February 2025 Began domestic phase III clinical trials in March 2025
Rovatirelin	Spinocerebellar degeneration	Began phase III clinical trials in March 2025
Cretostimogene grenadenorepvec	Non-muscle-invasive bladder cancer	Achieved good clinical results from international phase III clinical trials
Matsupexole	Parkinson’s disease	Began late-stage phase II clinical trials in August 2024
Olutasidenib	IDH1 mutation-positive relapsed/refractory AML	Entered technology licensing agreement in September 2024

Financial Results for Fiscal 2024

KISSEI

(millions of yen)

	Fiscal 2023		Fiscal 2024			
	Result	Ratio to net sales	Plan	Result	Ratio to net sales	YoY
Net sales	**75,579**	**100.0%**	**86,500**	**88,330**	**100.0%**	**16.9%**
Pharmaceutical Business	63,348	83.8%	74,000	75,299	85.2%	18.9%
Domestic pharmaceuticals*1	55,339	73.2%	64,100	63,975	72.4%	15.6%
Overseas license*2	4,463	5.9%	6,300	7,770	8.8%	74.1%
Therapeutic and care foods	3,545	4.7%	3,600	3,553	4.0%	0.2%
Other Business	12,231	16.2%	12,500	13,031	14.8%	6.5%
Cost of sales	**38,238**	**50.6%**	**43,200**	**44,265**	**50.1%**	**15.8%**
Gross profit	**37,341**	**49.4%**	**43,300**	**44,065**	**49.9%**	**18.0%**
Selling, general and administrative expenses	**33,324**	**44.1%**	**38,300**	**38,291**	**43.4%**	**14.9%**
R&D expenses	9,474	12.5%	13,000	12,889	14.6%	36.0%
Operating profit	**4,017**	**5.3%**	**5,000**	**5,773**	**6.5%**	**43.7%**
Ordinary profit	**6,142**	**8.1%**	**6,000**	**6,974**	**7.9%**	**13.5%**
Profit*3	**11,160**	**14.8%**	**11,700**	**11,961**	**13.5%**	**7.2%**
[Comprehensive income]	**[36,044]**			**[(1,914)]**		

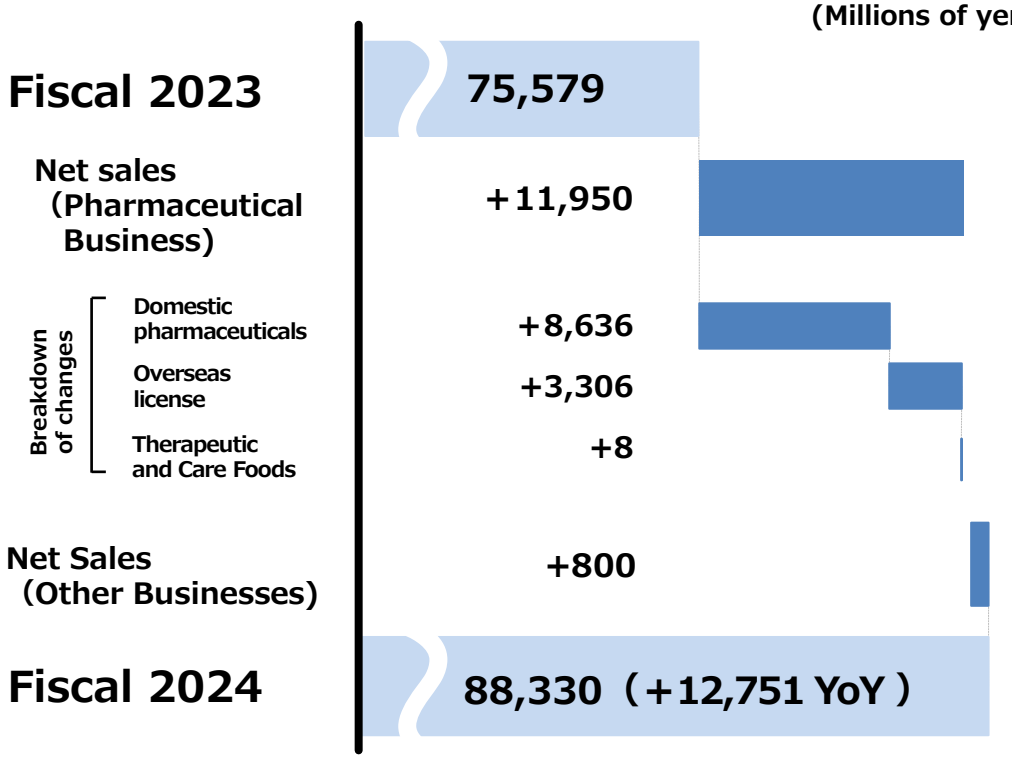
*1 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees
*2 Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports
*3 Refers to profit attributable to owners of parent

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

Net Sales Compared with Results of Fiscal 2023

KISSEI

(Millions of yen)



Source of increase | Source of decrease

Increased sales of Beova®, TAVNEOS®, KORSUVA®, TAVALISSE®, and CAROGRA®,

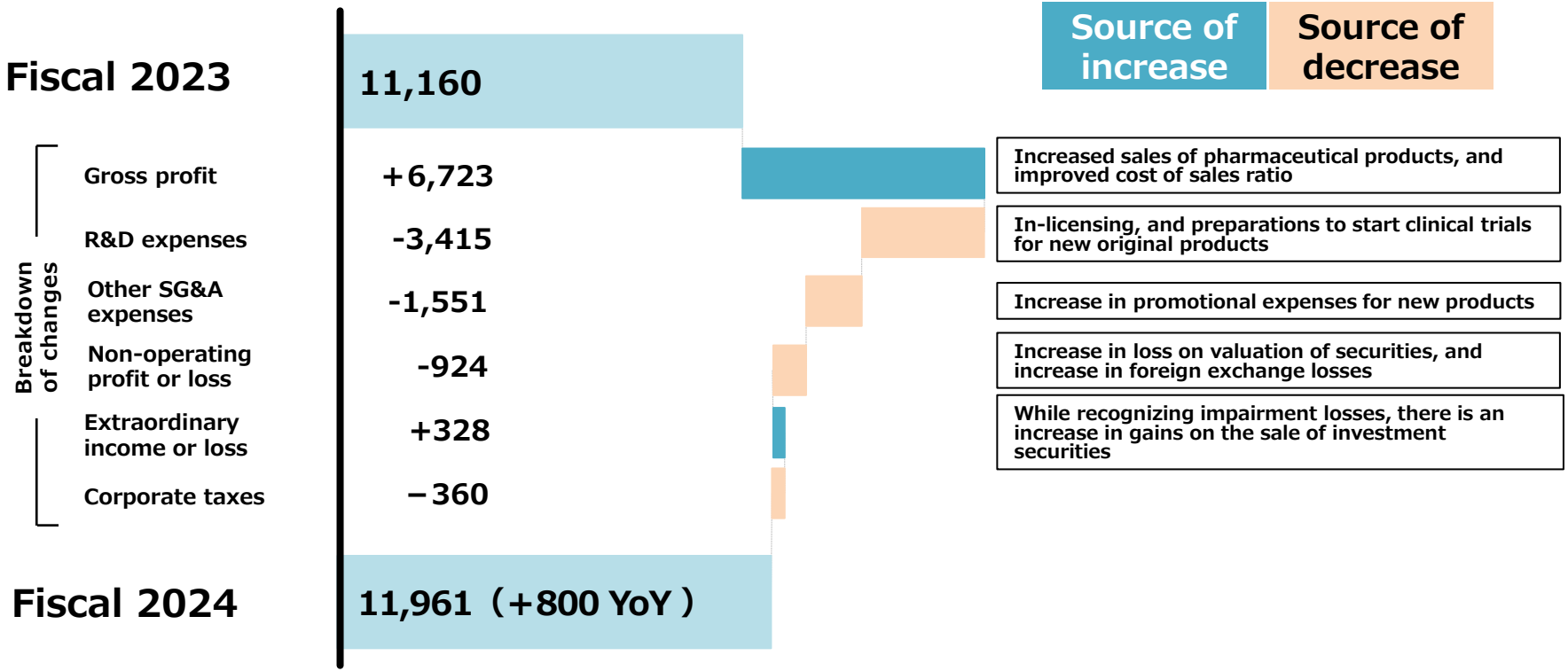
Increased Export sales and Technical Fees

Increased sales of Information Services Business, Construction and Facility Maintenance Business, and Merchandising Business

Profit Compared with Results for Fiscal 2024

KISSEI

(Millions of yen)



Plan for Fiscal 2025 (Consolidated)

KISSEI

(millions of yen)

	Fiscal 2024		Fiscal 2025 Forecast			
	Result	Ratio to net sales	Full year	Ratio to net sales	YoY	First half
Net sales	**88,330**	**100.0%**	**91,500**	**100.0%**	**3.6%**	**44,300**
Pharmaceutical Business	75,299	85.2%	75,500	82.5%	0.3%	37,200
Domestic pharmaceuticals	63,975	72.4%	65,800	71.9%	2.9%	32,200
Overseas license	7,770	8.8%	6,100	6.7%	(21.5%)	3,200
Therapeutic and care foods	3,553	4.0%	3,600	3.9%	1.3%	1,800
Other Business	13,031	14.8%	16,000	17.5%	22.8%	7,100
Cost of sales	**44,265**	**50.1%**	**47,100**	**51.5%**	**6.4%**	**22,400**
Gross profit	**44,065**	**49.9%**	**44,400**	**48.5%**	**0.8%**	**21,900**
Selling, general and administrative expenses	**38,291**	**43.4%**	**38,400**	**42.0%**	**0.3%**	**19,600**
R&D expenses	12,889	14.6%	13,000	14.2%	0.9%	6,600
Operating profit	**5,773**	**6.5%**	**6,000**	**6.6%**	**3.9%**	**2,300**
Ordinary profit	**6,974**	**7.9%**	**7,400**	**8.1%**	**6.1%**	**3,100**
Profit	**11,961**	**13.5%**	**12,300**	**13.4%**	**2.8%**	**6,200**

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

Shareholder Return

KISSEI

- **Basic Policy on the Distribution of Profits**
  Progressive dividend (ordinary dividend), 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	**Fiscal 2025 Forecast**
Annual dividend per share	¥54	¥56	¥80	¥82	¥100	**¥120**
Dividend payout ratio (consolidated)	47.7%	20.0%	35.0%	33.3%	36.5%	**40.4%**
Total return ratio	72.1%	20.0%	35.0%	87.1%	80.6%	**82.8%**
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)	**¥5.2 billion (1,370,000 shares)**
Treasury stock canceled (number of shares)				¥5.7 billion (2,500,000 shares)	¥4.0 billion (1,400,000 shares)	**¥4.2 billion (1,370,000 shares)**

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

MEDIUM-TERM MANAGEMENT PLAN

Beyond 80

- BEYOND 80 YEARS OF OUR FOUNDING,

CHALLENGES AND CHANGES -

PERIOD: FISCAL 2025–FISCAL 2029

The Five-Years Mid-term Management Plan “PEGASUS”(fiscal years 2020 to 2024)

Recap of of PEGASUS: Results of Qualitative Goals

KISSEI

Basic Policy	Results
Increase domestic sales	• Commercialized seven products in Japan, including newly launched TAVNEOS®, KORSUVA®, TAVALISSE®, and CAROGRA® • Entered rare and intractable diseases field, and strengthened presence in key fields (urology, renal diseases and dialysis)
Strengthen our overseas earnings base	• Regarding Linzagolix, the application for approval in the United States has been withdrawn, and the overseas commercialization scheme has been restructured. In Europe, it is set to be newly launched in September 2024. Additionally, in South Korea and Taiwan, development is being promoted by partner companies • Outlicensed TAVALISSE® to South Korea and Taiwan. In South Korea, obtained marketing authorization through a partner company, and preparations for launch are underway.
Expand development pipeline	• Preparations are underway to initiate clinical trials for three drug discovery projects (CC-001–CC-003*1) • In-licensed the oncolytic virus Cretostimogene grenadenorepvec and the acute myeloid leukemia treatment drug Olutasidenib, we have strengthened our development pipeline in the field of rare and intractable diseases • Drug discovery research has been strengthened through initiatives such as digital drug discovery capabilities, collaborative research with Reborna Biosciences, Inc., and the establishment of an information-gathering hub in the United States.
Strengthen the management base to cope with the changes in the business environment	• Enhanced quality control and stable supply system through organizational reforms and the construction of a new building for formulations • Enhancing governance and sustainability promotion systems

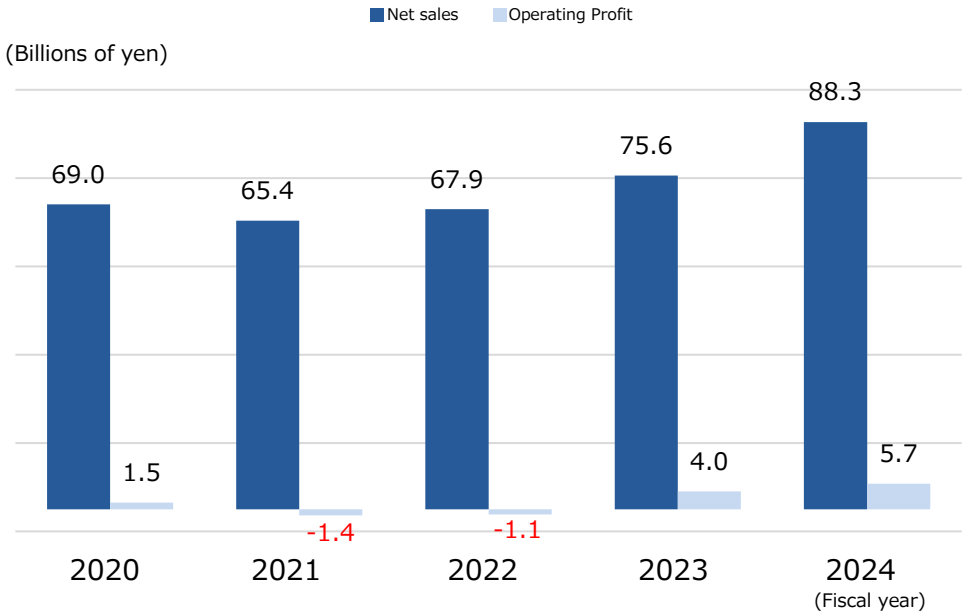
*1 CC-001（Graves’ disease）、CC-002（Overactive bladder、Interstitial cystitis Bladder pain syndrome）、CC-003（Narcolepsy） *2 Development code : CG0070

The Five-Years Mid-term Management Plan “PEGASUS”(fiscal years 2020 to 2024)

Recap of of PEGASUS: Results of Financial Targets

KISSEI

- The expansion of Domestic pharmaceuticals has resulted in an update to the record-high sales
- Due to the restructuring of the overseas commercialization scheme for Linzagolix, the operating profit fell short



(Billions of yen)

Item	PEGASUS Final-Year Targets	Results	Difference
Net sales	**87.0**	**88.3**	**+1.3**
Pharmaceutical Business	75.0	75.2	+0.2
Domestic pharmaceuticals*1	57.0	63.9	+6.9
Overseas license*2	13.5	7.7	-5.8
Therapeutic and care foods	4.5	3.5	-1.0
Other Businesses	12.0	13.0	+1.0
Operating Profit	**9.0**	**5.7**	**-3.2**
R&D expenses	**13.0**	**12.8**	**-0.2**
ROE	**5.0%**	**5.6%**	**+0.6%**

*1 Including revenue from supply to domestic sales partners and co-promotion fees
*2 Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports

Toward Growth as an R&D-Oriented Pharmaceutical Company

KISSEI

Focus on unmet medical needs and provide new treatment options to patients around the world

Domestic Operations

- ✓ Strengthen rare and intractable diseases field
- ✓ Strategies for the fields of urology, and renal diseases and dialysis

Global Operations

- ✓ Out-licensing for original products (active pharmaceutical ingredient (API) and product supply)
- ✓ Sublicensing of in-licensed products

CMC/ Manufacturing

- ✓ CMC system for supplying high-quality pharmaceuticals

Development

- ✓ Addressing a variety of diseases and modalities

Drug Discovery Research

- ✓ Deepening small molecule drug discovery
- ✓ Promotion of open innovation

In-Licensing

- ✓ Target all modalities
- ✓ Utilize financial assets

The business foundation and strengths acquired through PEGASUS

Kissei's 8 Material Issues For Achieving the Management Philosophy

Our Vision and the Positioning of Beyond 80

KISSEI

PEGASUS
Fiscal 2020–Fiscal 2024

Transition from patent cliff to growth phase

P/B ratio	0.79
ROE	5.6%
Basic earnings per share	274 yen
Net sales	¥88.3 billion
Operating profit before R&D expenses	¥18.6 billion

Beyond 80
Fiscal 2025–Fiscal 2029

Growth investment toward future sustainable growth

P/B ratio	1.0 or higher
ROE	8% or higher
Basic earnings per share	400 yen Or higher
Net sales	¥110.0 billion or higher
Operating profit before R&D expenses	¥29.0 billion or higher

◎80th anniversary (2026)

Fiscal 2030–Fiscal 2034

Growth as an R&D-oriented pharmaceutical company

- Expansion of business through the continuous launch of innovative products
- Strengthening the research and development pipeline with a focus on drug discovery
- Establishment of a new overseas revenue base through global development
- Contribution to the realization of a decarbonized and circular society

ROE	10% or higher	
10-year average growth rate (CAGR)	Net sales	5% or higher
	Operating profit before R&D expenses	10% or higher

Beyond 80—Growth Strategy

KISSEI

Investment in future growth to increase the profitability of our core business, to
raise our P/B ratio over 1.0 at an early stage

1. Invest in Future Growth

- ✓ Engage in aggressive growth investment focused on R&D, IT, and facilities
- ✓ Reduce shareholders' equity and strengthen shareholder returns

2. Expand drug discovery themes and acquire growth drivers

- ✓ Begin early development of CC-001–CC-003
- ✓ Promote in-licensing that matches growth strategies for each field
- ✓ Promote drug discovery research focused on small molecules

3. Expand and grow domestic pharmaceuticals

- ✓ Launch of four products to market with six indications
- ✓ Expand the market for the four new drugs launched under the PEGASUS
- ✓ Enhance information provision system for rare and intractable diseases

4. Increase overseas licensing income

- ✓ Promote global development and expand for Linzagolix (Yselty®)
- ✓ Out-license drug discovery themes at an early stage

Fiscal 2029

ROE	8% or higher
Net sales	¥110.0 billion or higher
Operating profit before R&D expenses	¥29.0 billion or higher
Shareholders' equity	Under ¥200.0 billion
Basic earnings per share	¥400 or higher
Ratio of cross-shareholdings to net assets	10% or lower
Clinical Development Themes	10 projects or more

Numerical Targets

KISSEI

Item	Fiscal 2024	Beyond 80 (Fiscal 2029)
Net sales	**¥88.3 billion**	**¥110.0 billion or higher**
Non-consolidated net sales	¥75.2 billion	¥95.0 billion or higher
Domestic pharmaceuticals*1	¥63.9 billion	¥80.5 billion or higher
Overseas license*2	¥7.7 billion	¥10.0 billion or higher
Therapeutic and care foods	¥3.5 billion	¥4.5 billion or higher
Other (consolidated subsidiaries)	¥13.0 billion	¥15.0 billion or higher
Operating profit before R&D expenses	**¥18.6 billion**	**¥29.0 billion or higher**
ROE	**5.6%**	**8.0% or higher**

*1 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees
*2 Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports

Growth Investment (Cash Allocation)

KISSEI

We will step up investments for future growth and actively return profits to shareholders.

PEGASUS (Fiscal 2020–Fiscal 2024)

Funding	Investment	
Operating CF (before R&D expenses) ¥56.0 billion	R&D	¥77.0billion
Utilization of financial assets on hand ¥77.0 billion	IT investment	¥13.0billion
	Production facilities, other investments	¥14.0billion
	Stable dividends	¥16.0 billion
	Share buybacks	¥13.0billion

Total: ¥133.0 billion

Beyond 80 (Fiscal 2025–Fiscal 2029)

Funding	Investment	
Operating CF (before R&D expenses) ¥125.0 billion	R&D	¥100.0 billion
	IT investment	¥20.0 billion
Utilization of financial assets on hand ¥72.0 billion	Capital Investment	¥20.0 billion
	Stable dividends	¥27.0 billion
	Share buybacks	¥30.0 billion

Total: ¥197.0 billion

Promotion of Growth Investments for the Future

KISSEI

Beyond 80 (Fiscal 2025–Fiscal 2029)

Investment		Main Investment	Outcomes
R&D Investment	¥100.0 billion	● Promotion of drug discovery research ● Advancement of clinical development themes ● In-licensing	● Revenue expansion through continuous drug launches ● Acquisition of new growth drivers ● Expansion of research and development pipeline
IT Investment	¥20.0 billion	● Renewal of ERP system ● Strengthening of security	● Promotion of DX (Digital Transformation) and productivity improvement ● Strengthening Business Continuity Systems through Cybersecurity Measures
Capital Investment	¥20.0 billion	● Research facilities ● Manufacturing facilities ● ESG investment	● Establishment of a stable supply system ● Strengthening of drug discovery research framework ● Improvement of work engagement ● Promotion of environmental management

Capital Policy : Reduction of Equity Capital and Enhancement of Shareholder Returns

KISSEI

Stable Dividends

◆ **Progressive dividend (ordinary dividend)**

Over the period of Beyond 80
¥27.0 billion

Higher Capital Efficiency

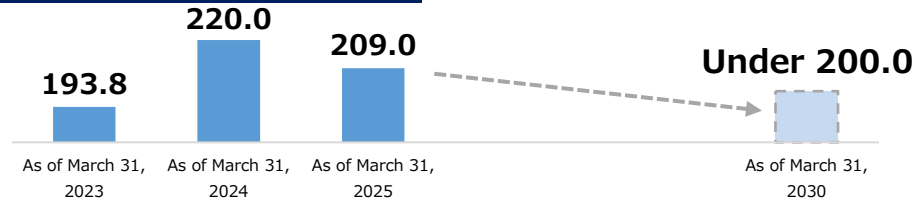
◆ **Flexible share buybacks**

Over the period of Beyond 80
¥30.0 billion

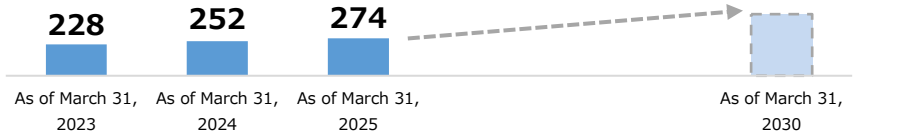
Beyond 80

Dividend payout ratio	**: 40% or higher**
Shareholders' Equity	**: Under 200.0 billion**
Basic earnings per share	**: 400 yen or higher**
Cross-Shareholdings	**: 10% or Lower** (Ratio to Net Assets)

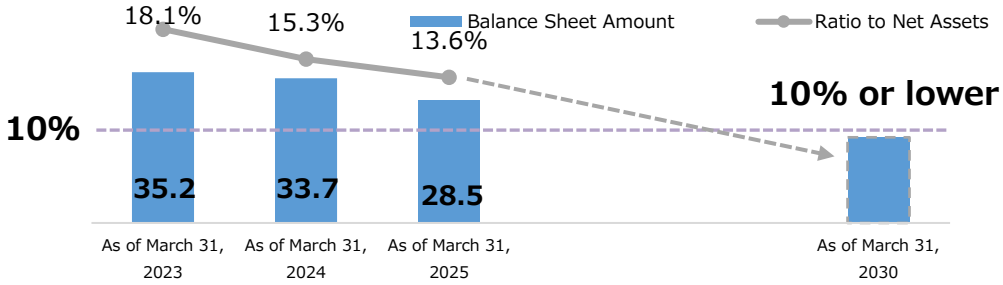
Shareholders' Equity (Billions of Yen)



Basic earnings per share (Yen)



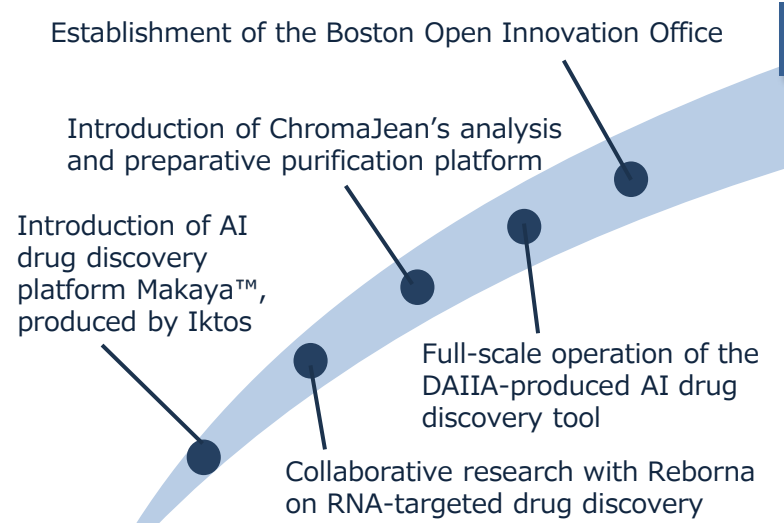
Cross-Shareholdings (Billions of Yen)



Expand Drug Discovery Themes and Acquire Growth Drivers

KISSEI

Continuous drug discovery and expansion of the pipeline



A faster, more efficient drug discovery process

- **Strengthening and utilization of the technological foundation for small molecule drug discovery**
- **Business innovation for medicinal chemists and efficiency improvement of analysis and purification processes through standardization and automation**
- **Shorten compound creation periods for drug discovery projects**
- **Promote open innovation**

Utilization of digital technology and promotion of open innovation

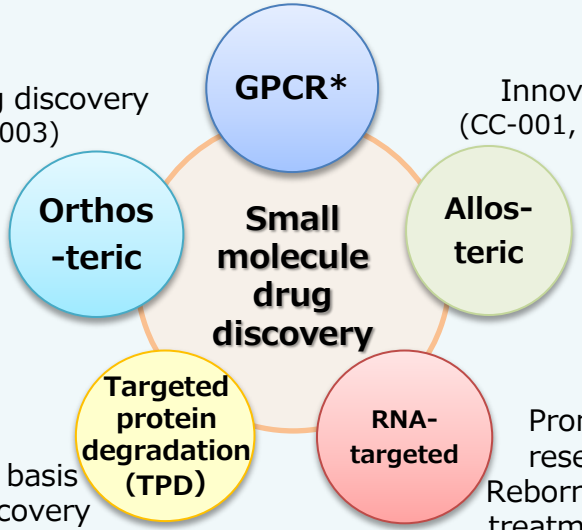
Expand Drug Discovery Themes and Acquire Growth Drivers

KISSEI

Expand the development pipeline by promoting small molecule-focused drug discovery research

【Small Molecule Drug Discovery】

Expertise cultivated for over 30 years
(Silodosin, Linzagolix, Matsupexole)



Establish a basis for drug discovery for undruggable target molecules

Promote joint research with Reborna to develop treatments for rare genetic diseases

＊ G protein-coupled receptor

【In-Licensing】

Disease areas with no treatment options or low satisfaction with existing treatments.

Meet unmet medical needs

Acquisition of growth drivers

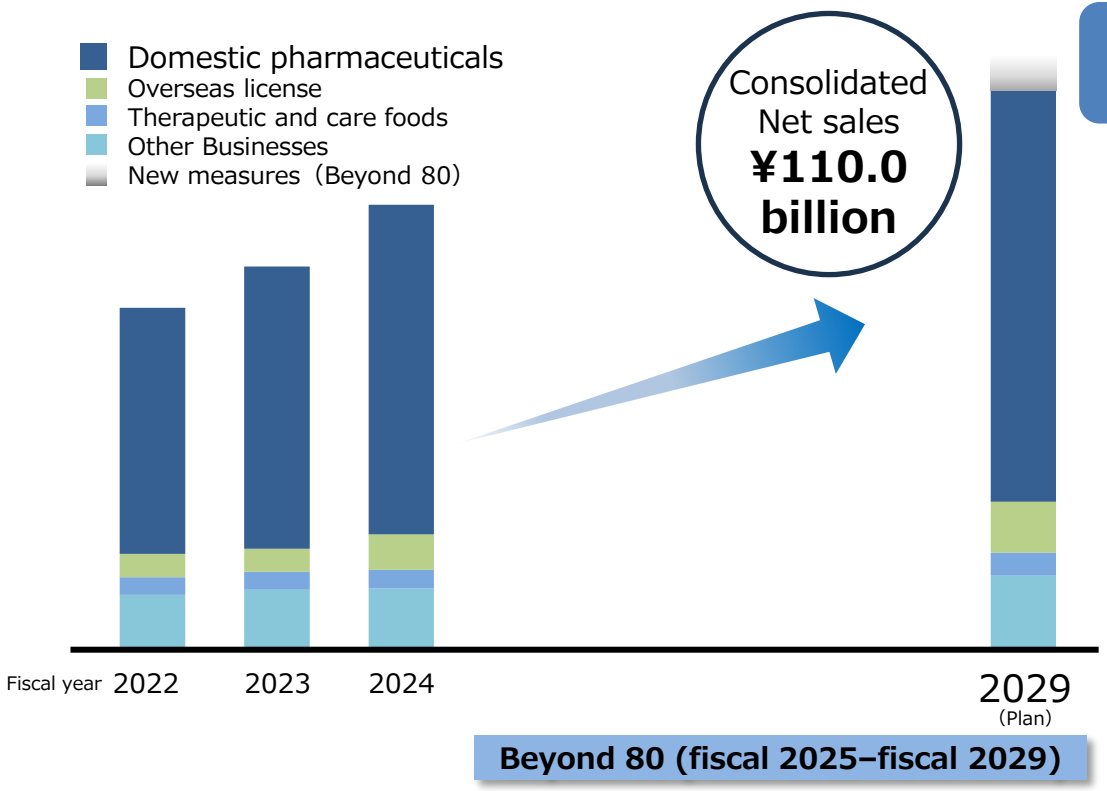
In keeping with growth strategy

Synergy with domain strategy and strengths

Capturing the full range of modalities

Including antibodies and biopharmaceuticals

Expand and Grow Domestic Pharmaceuticals



Sustainable Expansion of Domestic Pharmaceutical Products

- Maximize sales of key products
  - ✓ Beova®, TAVNEOS®, KORSUVA®, TAVALISSE®, CAROGRA®
- Develop the products scheduled for launch over Beyond 80 as growth drivers (four products with six indications)
  - ✓ Linzagolix (Uterine fibroids、Endometriosis)
  - ✓ Cretostimogene grenadenorepvec (High-risk／Medium-risk Non-muscle-invasive bladder cancer)
  - ✓ Rovatirelin（Spinocerebellar degeneration）
  - ✓ Olutasidenib（IDH1 mutation-positive relapsed/refractory AML）

Expand and Grow Domestic Pharmaceuticals

KISSEI

Major Products

Field	Product	Fiscal 2025 (forecast) (Millions of yen)	Ideal Outcome
Urology	**Beova®**	20,400	Beova® becomes a first-line treatment for OAB*1, capturing a 50% share of patients in fiscal 2025
Rare and Intractable Diseases	**TAVNEOS®**	11,400	TAVNEOS® becomes the standard treatment for ANCA-associated vasculitis*2, replacing steroid treatments
Renal Diseases and Dialysis	**KORSUVA®**	7,100	KORSUVA® becomes the first choice for second-line treatment of pruritis in dialysis patients thanks to its ease of use and high efficacy
Rare and Intractable Diseases	**TAVALISSE®**	3,700	TAVALISSE® becomes a second-line treatment option for chronic ITP*3
Rare and Intractable Diseases	**CAROGRA®**	1,400	CAROGRA® becomes the first choice for treatment in cases where patients have an inadequate response to oral 5-ASA*4

*1 Overactive bladder *2 Microscopic polyangiitis, granulomatosis with polyangiitis *3 Idiopathic thrombocytopenic purpura *4 5-aminosalicylic acid

Expand and Grow Domestic Pharmaceuticals

KISSEI

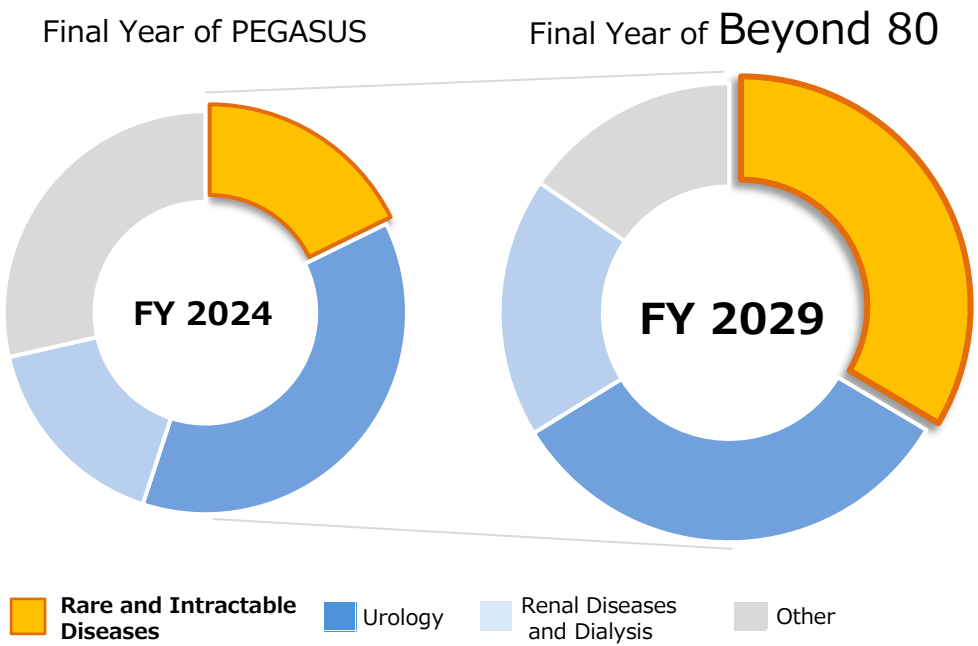
Products to be Launched over Beyond 80 (Four Products with Six Indications)

Field	Product name /Development code	Expected indications	Estimated number of domestic patients	Notable features
Gynecology	Linzagolix/KLH-2109	Uterine fibroids	Approx. 3.5–7.0 million*1	Linzagolix is Kissei's first original drug since silodosin. Linzagolix may serve as a new treatment option as the number of target patients increases with each year.
		Endometriosis	Approx. 1.34 million to 2.68 million*1	
Rare and Intractable Diseases	Cretostimogene grenadenorepvec/CG0070	High-risk Non-muscle invasive bladder cancer	Approx. 7,000*2	Local administration of the drug is expected to serve as a bladder-sparing [treatment/alternative] for patients who would otherwise require radical cystectomy.
		Medium-risk Non-muscle invasive bladder cancer (NMIBC)		
Rare and Intractable Diseases	Rovatirelin/KPS-0373	Spinocerebellar degeneration	Approx. 37,000*3	Rovatirelin is highly demanded by patients, and it is expected to improve satisfaction with treatment.
Rare and Intractable Diseases	Olutasidenib	IDH1 mutation-positive relapsed/refractory AML	Approx. 240–360*4	Olutasidenib features a good remission rate and a long remission period, and enables treatment that does not require blood transfusions.

*1 "The Frontline of Endometriosis Treatment" (Tokyo: Igaku-Shoin, 2008)., "Medical Clinics of Uterine Diseases and Endometriosis" (Nihon Rinsho, 2009). (Japanese only)
*2 According to the cancer statistics put forth by the National Cancer Center Japan'sCancer Information Service, of the new bladder cancer patients in Japan each year (23,230), 70% (16,261) had NMIBC, of which 30% (4,878) had carcinoma in situ. Of these patients, 49% (2,389) had received ineffective Bacillus Calmette-Guérin (BCG) treatment or suffered a relapse.
*3 Number of recipients of a certificate for receiving medical expense assistance for designated intractable diseases provided by the Japan Intractable Diseases Information Center (as of March 31, 2024).
*4 Number of patients [with relapsed/refractory AML that is IDH1 mutation-positive] calculated by taking the number of AML patients in Japan (13,000 according to the Ministry of Health, Labor and Welfare 2023 Patient Survey), multiplied by the number of patients that are IDH1 mutation positive (6–9% of patients, according to NCCN Guidelines 2025 V1), then multiplied by the number of patients with relapsed/refractory cases (approx 40% according to Blood (2015) 126 (3): 319-27.)
(13,000×a×b= Approx. 360)

Expand and Grow Domestic Pharmaceuticals

KISSEI



Expansion of rare diseases and difficult illnesses field and development of domain strategy

- Expand the product lineup in the field of rare diseases and intractable diseases from 3 projects to 6 projects*, and increase the scale of the business
- Strengthen the organization with a view to entering the oncology field
- Developing a strategy in the fields of urology, and renal diseases and dialysis leveraging our corporate presence
- Improving medical access through disease awareness and other means

＊TAVNEOS®, TAVALISSE®, CAROGRA®, Cretostimogene grenadenorepvec, Rovatirelin, Olutasidenib

New Drug Development (In-Company)

KISSEI

Generic name / Development code	Expected indications	Development stage: Phase: Pre-IND	Phase: I	Phase: II	Phase: III	Preparation to submit application	NDA in process	NDA approved	(As of May 2025) Development classification
Linzagolix ／KLH-2109	Uterine fibroids								Original product
	Endometriosis								Original product
Cretostimogene grenadenorepvec ／CG0070	Non-muscle-invasive bladder cancer								In-licensed ／CG Oncology Joint global Phase III clinical trial
Rovatirelin ／KPS-0373	Spinocerebellar degeneration								In-licensed ／Shionogi
Matsupexole ／KDT-3594	Parkinson's disease								Original product
Olutasidenib	IDH1 mutation-positive relapsed/refractory AML								In-licensed ／ Rigel Pharmaceuticals
CC-001	Graves' disease								Original product
CC-002	Overactive bladder								Original product
	Interstitial cystitis Bladder pain syndrome								Original product
CC-003	Narcolepsy								Original product

Increase overseas licensing income

KISSEI

Promote Global Development and Business Expansion for Linzagolix

■ Countries where Linzagolix is available (as of March 2025)

Germany, Spain, Poland, Italy, the U.K, Belgium

■ Benefits of prescribing Linzagolix

- ✓ Flexibility—can be used with or without add-back therapy
- ✓ Quick effect—rapid improvement of symptoms
- ✓ Effective in cases where other treatments are inadequate
- ✓ Effective in shrinking fibroids

Strengthening the overseas revenue base

- ■ Achieving the licensing out of new innovative products
- ■ Sublicensing of in-licensed products (mainly in Asia)

Work with global companies to promote global development
Increase the number of countries set for launch and expand business

Overseas license*

¥7.7 billion (Fiscal 2024) ▶ **¥10.0 billion or higher (Fiscal 2029)**

＊Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports

New Drug Development (Out-Licensing)

KISSEI

Generic name	Expected indications	Countries and regions	Development stage (As of May 2025)							Partner company
			Phase			Preparation to submit application	NDA in process	NDA approved	Preparation for launch	
			Ⅰ	Ⅱ	Ⅲ					
Linzagolix	Uterine fibroids	4 countries*1								Theramex
		Taiwan								Synmosa Biopharma
	Endometriosis	Europe								Theramex
Fostamatinib	Chronic ITP*2	South Korea								JW Pharmaceutical
Silodosin	Dysuria associated with BPH*3	Vietnam, other countries								Eisai

*1 Switzerland、Brazil、Israel、South Africa　*2 Idiopathic thrombocytopenic purpura　*3 Benign prostatic hyperplasia

The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends as of May 2025. 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.

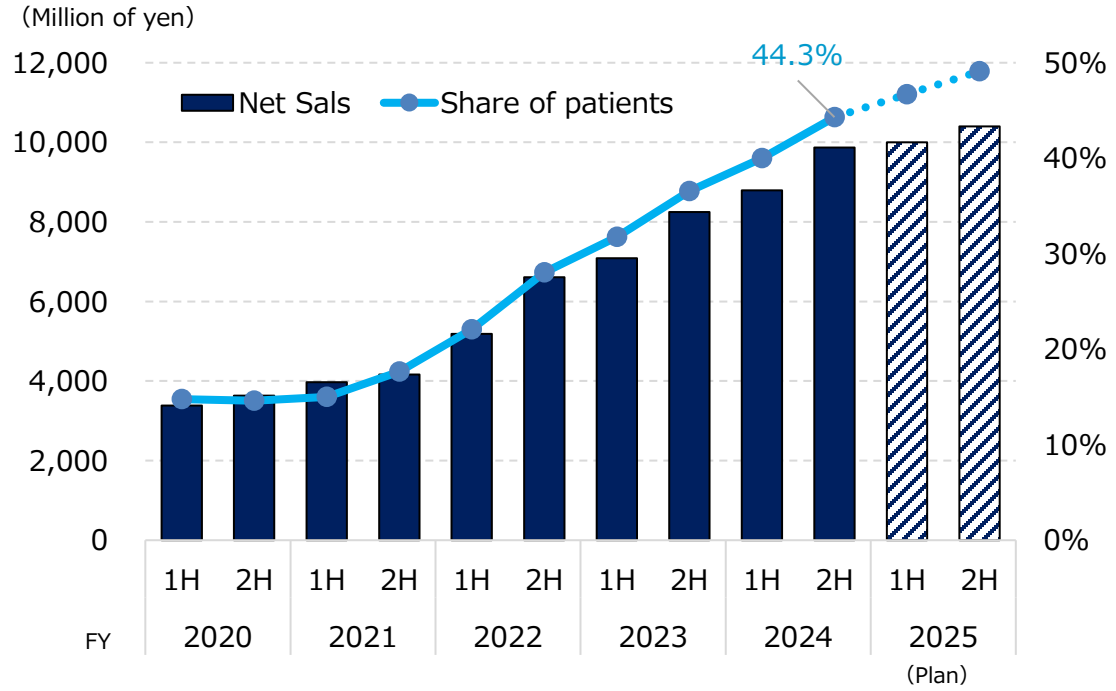
APPENDIX

Treatment for overactive bladder

Beova® | Achieving 50% patient share by fiscal year 2025

KISSEI

Net Sales (Sales by Kissei) and Share of Patients*1 (Two Companies)



As a leading company in lower urinary tract symptom (LUTS *2) treatment medications, we aim to deliver the optimal treatment (Beova) to all patients suffering from OAB *3 symptoms

<Activity Policy>

- Appeal of ease of use for a wide range of patients
- Promote the superior efficacy and high safety of the first-choice medication for OAB
- Disease awareness for potential patients

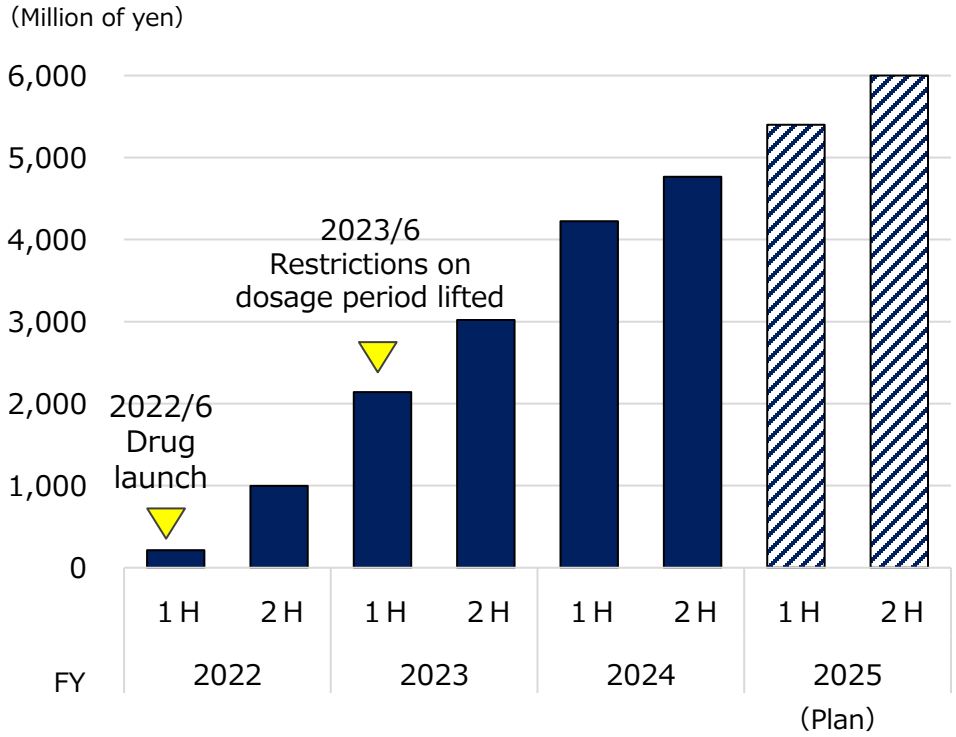
Plan for fiscal 2025: ¥20.4 billion (+9% YoY)

*1 Share of patients receiving overactive bladder treatment. Compiled in-house based on JPM PATDY 2020/4-2025/3 , Reprinted with permission, Copyright © 2025 IQVIA.
*2 LUTS : Lower Urinary Tract Symptom *3 OAB : Overactive Bladder

Treatment for MPA*1 and GPA*2

TAVNEOS® | To become the standard treatment drug for ANCA-associated vasculitis

KISSEI



Resolve the 'steroid dilemma' in the treatment of ANCA-associated vasculitis (AAV) and establish the positioning of a standard treatment drug for AAV that can replace steroids

<Activity Policy>

- Sharing of prescription experiences from doctor to doctor
- Providing and collecting information on cases reported in papers and at conferences
- Providing appropriate feedback on interim aggregated data from post-marketing surveillance (PMS)

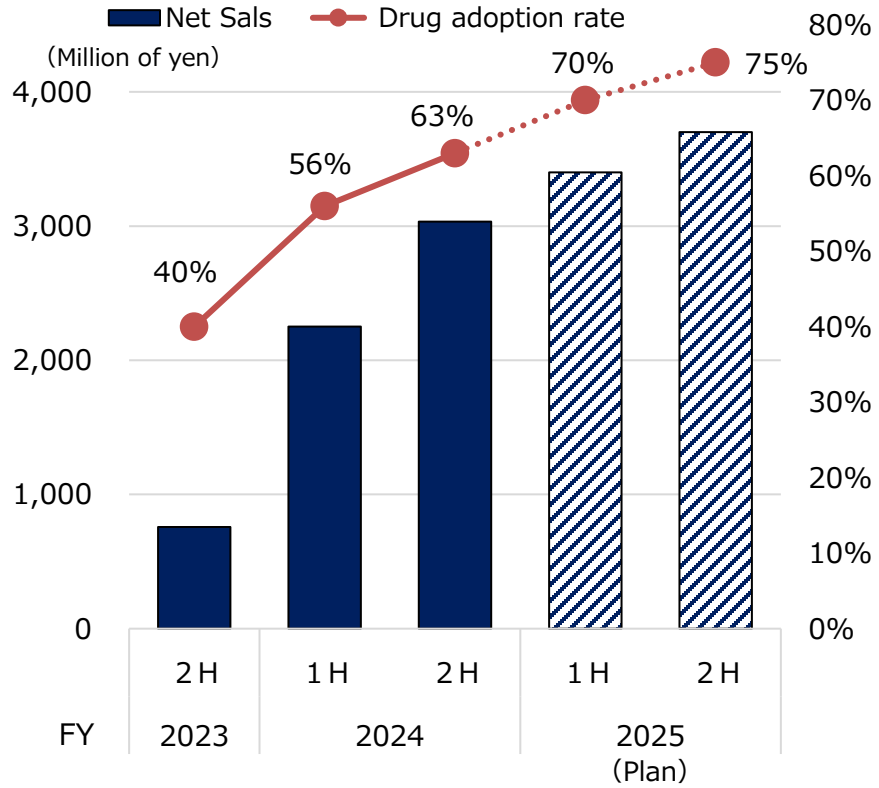
Plan for fiscal 2025:
¥11.4 billion (+27% YoY)

*1 MPA : Microscopic polyangiitis *2 GPA : Granulomatosis with polyangiitis

Treatment for pruritis in dialysis patients

KORSUVA® | Becoming the first-choice medication for second-line treatment of dialysis-related pruritus

KISSEI



Identify the challenges of existing treatments and improve the quality of life (QOL) for dialysis-related pruritus patients through treatment proposals

<Activity Policy>

- Proposal for treatment to patients with insufficient existing treatment effects by promoting the product characteristics of KORSUVA® and differentiating it from existing medications
- Highlighting patients with insufficient existing treatment effects for itching through dialysis staff (nurses, technicians, pharmacists, etc.)

Plan for fiscal 2025:
¥7.1 billion (+34% YoY)

Two drugs for rare and intractable diseases

TAVALISSE® | CAROGRA®

KISSEI

	TAVALISSE®	CAROGRA®
Target Position	As a new treatment option for cases with insufficient control, resolve the treatment dilemma associated with steroids	
	Second-line treatment drug for ITP *1 therapy	First-line drug for cases with insufficient response to oral 5-ASA *2 preparations
Activity Policy	• Expand target facilities and promote the significance of this drug as a second-line treatment • Provide feedback on long-term safety in Japanese ITP patients, as well as the efficacy and safety when used in combination with other ITP treatments, using interim aggregated data from post-marketing surveillance (PMS)	• Introduction of personal case examples by Dr. to Dr. and dissemination of suitable cases for CAROGRA® • Strengthening the promotion of CAROGRA® and RECTABUL® through collaboration EA Pharma Co., Ltd. • Establish the positioning of the next choice for oral 5-ASA formulations with CAROGRA® and RECTABUL®
Plan for fiscal 2025 (YoY)	**¥3.7 billion** (+69%)	**¥1.4 billion** (+21%)

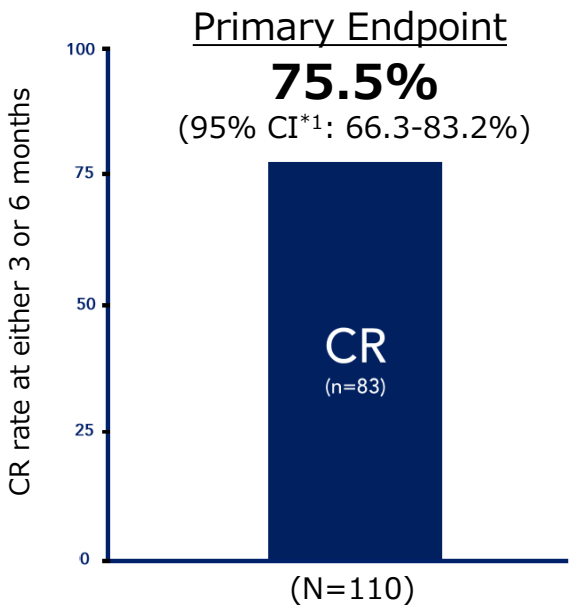
*1 ITP : Idiopathic thrombocytopenic purpura　　2) 5-ASA : 5-Aminosalicylic acid

BOND-003 Trial Results

(Announced at the American Urological Association (AUA) Annual Meeting on April 26, 2025)

KISSEI

Design : Single-arm, open label study (international phase III clinical trial)
Participants : Patients with high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ who are unresponsive to Bacillus Calmette-Guérin (BCG) treatment
Dosage method : Intravesical administration once a week for six weeks (once a week for three weeks after six months)
Primary endpoint: Complete response (CR) rate at either 3 or 6 months



Efficacy data cutoff: March 14, 2025

	CR rate (95% CI*1)
12 months	46.4% (36.9, 56.1) *2
24 months	33.7% (24.8, 43.8) *3

- Percentage of patients free from progression to muscle-invasive bladder cancer at 24 months*4: 97.3%
- Cystectomy-free survival rate at 24 months*5: 91.6%

Prevents recurrence and progression of bladder cancer in most patients while avoiding radical cystectomy

*1 Confidence interval *2 As of 12 months : 51/110 patients *3 As of 24 months : 34/101 patients
*4 The percentage of patients who have not progressed to muscle-invasive bladder cancer
*5 The percentage of patients who survive and do not undergo radical cystectomy

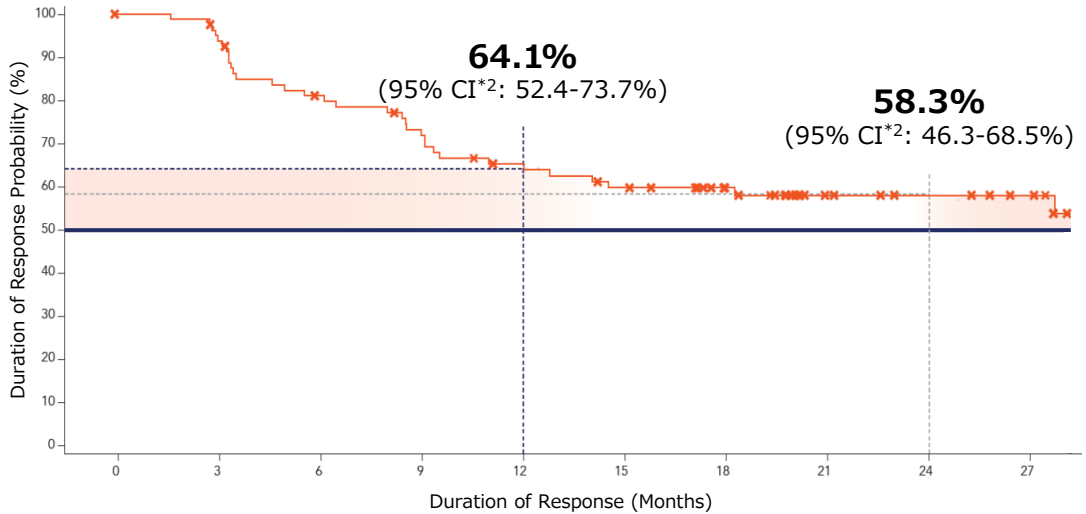
BOND-003 Trial Results

(Announced at the American Urological Association (AUA) Annual Meeting on April 26, 2025)

KISSEI

Efficacy data cutoff: March 14, 2025

Secondary Endpoint: Duration of Response*1



Median duration of response among patients with a CR (83 patients) was 27.9 months or more

Favorable & Well-Tolerated Safety Profile

	Cretostimogene (N=112)	
Number of treatment-related adverse events	71	(63.4%)
Main treatment-related adverse events*3 (PTs)		
Bladder spasm	28	(25.0%)
Pollakiuria	24	(21.4%)
Urgency	23	(20.5%)
Dysuria	18	(16.1%)
Hematuria	15	(13.4%)
Serious treatment-related adverse effects	2	(1.8%)
Treatment-related discontinuations	0	(0.0%)

No deaths or cases of adverse effects rated CTCAE Grade 3 or higher*4

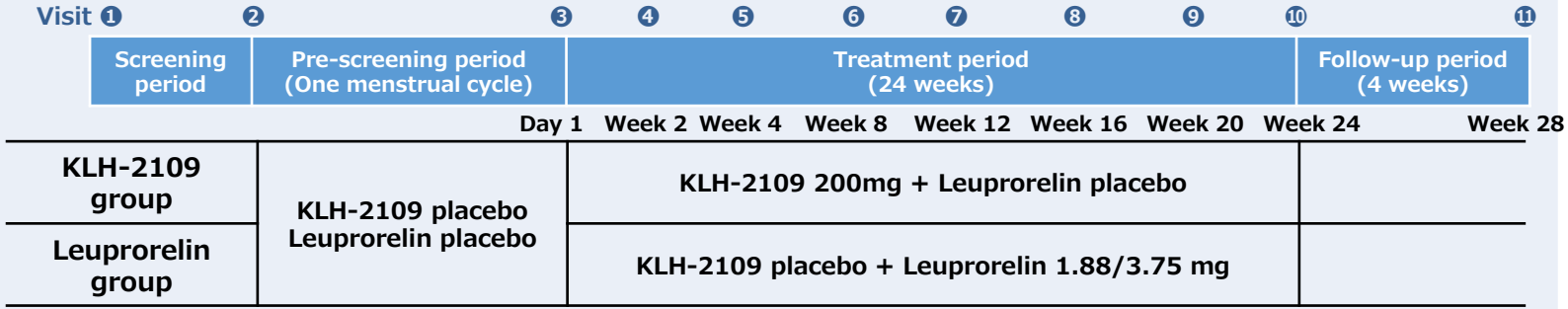
- **In Japan, Cretostimogene grenadenorepvec has been designated as a rare disease regenerative medicine for BCG-unresponsive non-muscle invasive bladder cancer (March 2025)**

*1 Kaplan-Meier estimates of response duration in patients with a CR *2 Confidence interval *3 Side effects with an incidence rate of 10% or more
*3 Common Terminology Criteria for Adverse Events Grade 3. Side effects that are severe or medically significant but not immediately life-threatening. Grade 3 side effects require hospitalization or prolongation of hospitalization and limit self care activities of daily living.

Overview of Phase III Clinical Trial (KLH1301)

KISSEI

	Description
Goal	Verify non-inferiority of KLH-2109 to effective drug (leuprorelin) and assess safety
Participants	Patients with endometriosis suffering pelvic pain
Design	Randomized, double-blind, active-controlled, parallel-group comparative study (administered once daily)
Number of Patients	288 (144 in each group)
Primary Endpoint	Change from baseline maximum NRS* score for pelvic pain from the 28-day period prior to 12 weeks of drug administration
Secondary Endpoints	Severity of temporary pain (pain during defecation, pain during pelvic examination, pain during sexual intercourse) and severity of objective findings (induration of the pouch of Douglas, restriction of uterine mobility) Ovarian chocolate cysts and uterine volume Endometriosis-related quality of life Incidence rate of adverse events and side effects, clinical test values, vital signs, 12-lead electrocardiogram, bone density, etc.

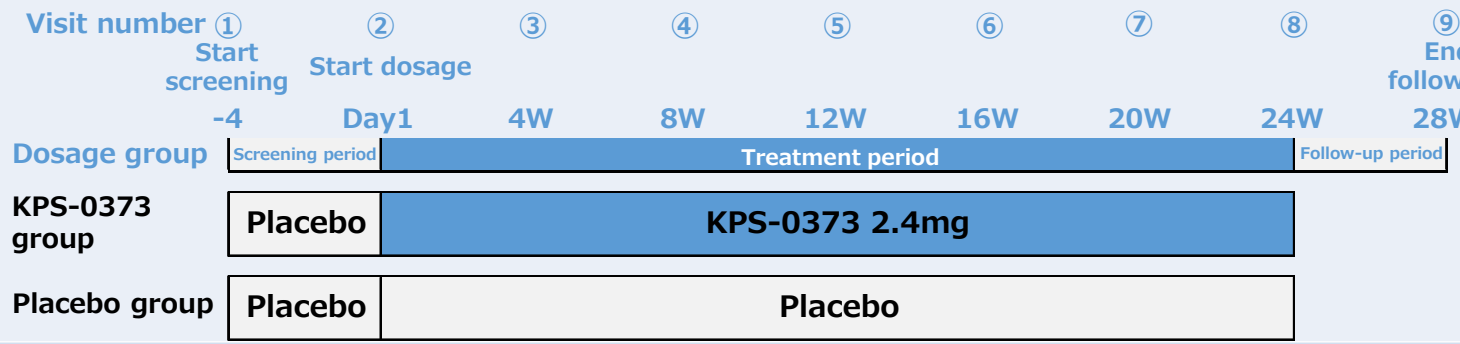


* Numerical Rating Scale

Overview of Additional Phase III Clinical Trial (KPS1306)

KISSEI

	Description
Goal	Verify superior efficacy of KPS-0373 over a placebo and assess safety
Participants	Spinocerebellar degeneration
Design	Randomized, double-blind, placebo-controlled, parallel-group comparative study (administered once daily)
Number of Patients	142 (71 in each group)
Primary Endpoint	Change from baseline in total SARA*1 score at the end of the treatment period
Secondary Endpoints	Symptom maintenance rate based on the total SARA total at the final evaluation of the treatment period (proportion of improved and unchanged cases) Change from baseline in SARA score per category at the end of the treatment period SF-8 results at the end of the treatment period Incidence rate of adverse events and side effects, clinical test values, vital signs, abnormal findings in the 12-lead electrocardiogram

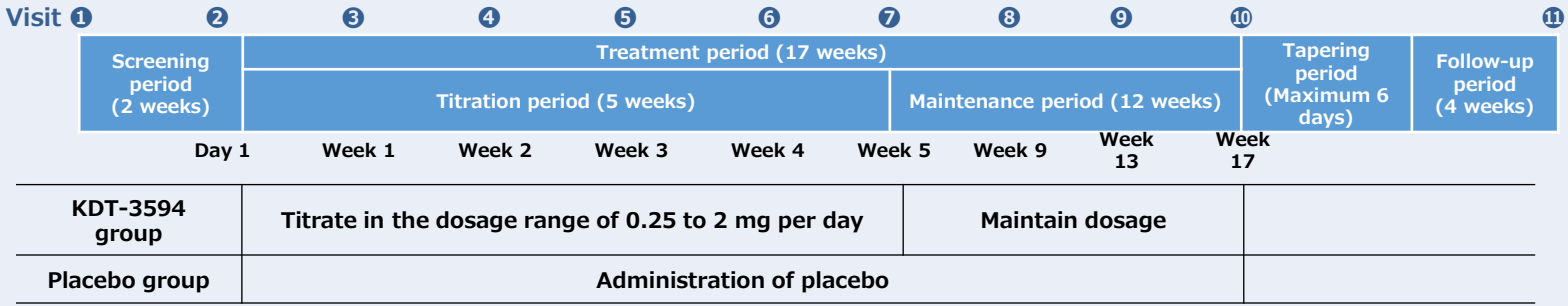


* Scale for the assessment and rating of ataxia

Overview of Late-Stage Phase II Clinical Trial (KDT1203)

KISSEI

	Description
Goal	Verify superior efficacy of KDT-3594 over a placebo and assess safety and pharmokinetics
Participants	Patients with advanced Parkinson's disease who are receiving treatment in combination with levodopa
Design	Randomized, double-blind, placebo-controlled, parallel-group comparative dose escalation study (administered once daily)
Number of Patients	150 (75 in each group)
Primary Endpoint	Change from baseline in the total MDS-UPDRS* score for Part II and Part III in the "on" period at 17 weeks of treatment
Secondary Endpoints	Change from baseline in percentage of awake time spent in an off period Improvement effect on motor symptoms, non-motor symptoms, QOL, nighttime sleep disorders, and the overall severity of the disease Incidence of adverse events and side effects and changes from baseline in vital signs, weight, clinical tests, etc. Plasma concentration of KDT-3594



*Movement Disorder Society-Unified Parkinson's Disease Rating Scale

Current Situation Regarding Implementation of Management that is Conscious of Cost of Capital And Stock Price

KISSEI

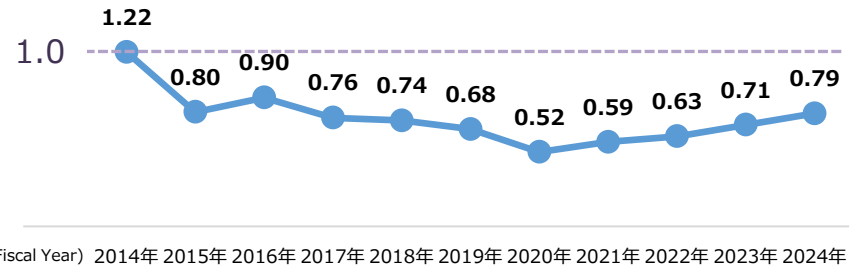
① Current cost of equity capital is between 6–8%
Assumption based on CAPM formula

Cost of equity capital Approx. 6–8%	=	Risk free rate Approx. 1.5% (10-Year Japanese government bonds)	+	Beta value 0.7–1 (Assumed by Kissei)	×	Risk premium Approx. 6%

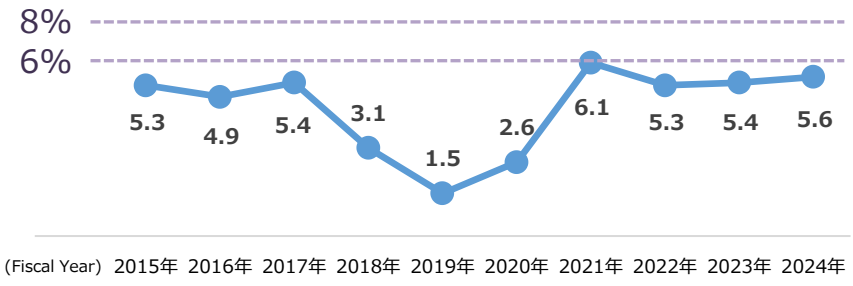
② We recognize the following three issues:

- ✓ Profitability of core business
- ✓ Provision of information regarding state of R&D
- ✓ Capital Policy

Price-to-Book Ratio (P/B Ratio)



Return on Equity (ROE) (%)



Price-to-Earnings Ratio (P/E Ratio)