

Results Presentation Fiscal 2022

協和キリン株式会社



Agenda

2021-2025 Medium Term Business Plan
 - FY2022 Review, FY2023 Plans, Financial KPI progress -
 Shareholders Return
 Commercial Update
 R&D Update
 Q&A

President and Chief Executive Officer **Masashi Miyamoto, Ph.D.**

Managing Executive Officer, Head of Finance **Motohiko Kawaguchi**

Executive Officer, Vice President, Head of R&D **Yoshifumi Torii, Ph.D.**

Executive Officer, Head of Global Product Strategy **Tomohiro Sudo**

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but the actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

This document is used only for the purpose of providing the information to investors. Though it may contain the information concerning pharmaceutical products (including products under development), it is not for the purpose of promotion, advertising, or medical advice.

2021-2025 Medium Term Business Plan

- FY2022 Review -

Qualitative Review for FY2022

Provide pharmaceuticals for unmet medical needs

■ Maximize the value of G3B

- ✓ Crysvita : Revenue reached 127.1 billion yen in five years after launch; Changed scheme to ensure transfer of sales in North America
- ✓ Poteligeo, Nourianz : Steady growth continued

■ Continue to create groundbreaking new drugs

- ✓ Moved forward with main development pipeline products and optimized allocation of management resources
rocatinlimab: Started Ph3 ROCKET program, KW-6356 and ME-401: Discontinued global developments, KHK7791: Filed in Japan, RTA 402: Ph3 AYAME study LPO*¹
- ✓ Early R&D activities: Advanced collaboration with InveniAI, signed a joint research agreement with LUCA Science, established Corporate Venture Capital, etc.

Reinforce human resources and structures that support the creation of Life-changing value

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Established Strategy Division
- ✓ Launched a globally integrated talent management system and global grading
- ✓ Completed introducing the ERP to 3 overseas regions and the global budget system
- ✓ Corporate Culture Transformation: rolled out “KABEGOE” globally
- ✓ Rated “Gold” in the PRIDE Index 2022 (JP)
- ✓ Selected as one of the 2022 Health & Productivity Stock Selection for the first time (JP)

Address patient-centric healthcare needs

■ Patient Advocacy

- ✓ Established the Kyowa Kirin Group Policy for Access to Medicines
- ✓ Advocacy activities featuring Rare Disease Day, International XLH Awareness Day, Blood Cancer Awareness month, etc. : Shine a Light campaign (EMEA, AP), XLH Café (JP), CTCL ambassadors, roundtable discussions (NA)
- ✓ Developed and published white papers on XLH and Parkinson's disease in collaboration with various patient advocacy groups (EMEA, AP, NA)

■ Provide value that goes beyond pharmaceuticals

- ✓ Exploration of initiatives to address patient needs related to XLH

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Completed the introduction of global quality management system (eQMS)
- ✓ Decided to construct HB7 (new biopharmaceutical API manufacturing building) and a new warehouse building at Takasaki Plant
- ✓ Completed the construction of Q-TOWER (quality assurance complex building) at Takasaki Plant

■ Help to protect the global environment

- ✓ Expanded the introduction of renewable energy*²; reduced annual CO₂ emissions by approximately 42% compared to 2019
- ✓ TCFD: Updated the status of responses to risks (presented specific initiatives and the roadmap for the reduction of CO₂ emission)

Quantitative Summary of FY22 Results

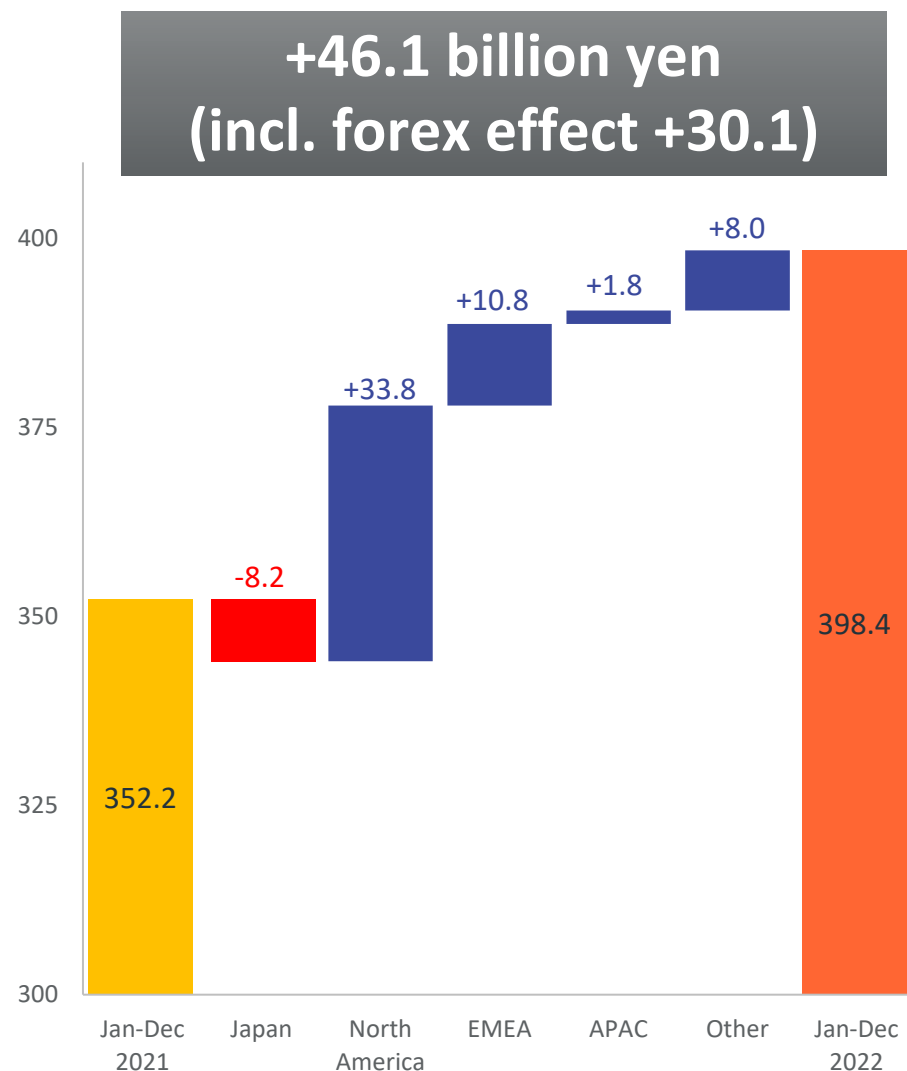
(Billion Yen / Rounded)

	FY2021 Results	FY2022 Results	Changes	FY2022 Revised Plans	Achieved
Revenue [Overseas Ratio]	352.2 [54%]	398.4 [61%]	+46.1 (+13%)	400.0 [62%]	100%
Gross Profit [Gross Profit Margin]	264.4 [75%]	311.5 [78%]	+47.1 (+18%)	312.0 [78%]	100%
SG&A [SG&A Ratio]	145.6 [41%]	166.2 [42%]	+20.6 (+14%)	172.0 [43%]	97%
R&D [R&D Ratio]	57.7 [16%]	62.9 [16%]	+5.2 (+9%)	67.0 [17%]	94%
Gain/Loss on Equity Method	4.6	4.3	-0.3 (-6%)	4.0	108%
Core Operating Profit [Core OP Margin]	65.7 [19%]	86.7 [22%]	+21.0 (+32%)	77.0 [19%]	113%
Profit	52.3	53.6	+1.2 (+2%)	53.0	101%
Return on Equity	7.3%	7.1%			
Dividend Payout Ratio ¹	43.2%	38.9%			

[FOREX]
FY2021-Actual JPY109/USD
FY2022-Actual JPY130/USD
FY2022-Plan JPY128/USD

¹ Figures are based on Core-EPS (EPS calculated using “Core profit,” profit without other income/losses and related taxes).

FY21 vs FY22 -Revenue-



● Japan -8.2

Although Duvroq, Romiplate, Crysvita, and G-Lasta increased, revenue in Japan region decreased by 5% due mainly to negative impact by NHI price-cut in April 2021 & April 2022, and shrink in Patanol, which was affected by generic products entered the market in December 2021, and Nesp-AG, which was affected by biosimilars' growth.

● North America +33.8 (incl. forex effect +18.5)

Revenue in North America region increased by 43% with steady growth of Crysvita (+51%), Poteligeo (+35%), and Nourianz (+43%).

● EMEA +10.8 (incl. forex effect +4.6)

Steady growth of Crysvita (+50%) and Poteligeo (+98%) contributed to the 19% increase in EMEA region, although Abstral fell due to generic products' penetration.

● APAC +1.8 (incl. forex effect +3.0)

APAC revenue increased by 6% with growth of Gran, Nesp, Neulasta, etc, though Regpara was down due to being listed on the Chinese national tender list in Oct 2021.

● Other +8.0 (incl. forex effect +4.1)

25% growth of the Other revenue was due to deferred revenue of USD400M upfront payment from KHK4083 partnership agreement, that was initiated from last July, and royalties of growing Fasenra (Benralizumab).

FY21 vs FY22 -Revenue of Major Items in Japan-

(Billion Yen / Rounded)

Item	FY2021 Results	FY2022 Results	Changes	Reasons	FY2022 Rev. Plans	Achieved
Nesp + Nesp-AG ¹	26.3	21.1	-5.2 (-35%)		20.7	102%
Nesp	4.0	3.4	-0.5 (-14%)	NHI price-cut & Biosimilars' penetration	3.3	104%
Nesp-AG	22.3	17.6	-4.7 (-21%)		17.4	101%
Duvroq	2.6	6.6	+4.0 (+156%)	Market penetration (Launched in Aug 2020)	5.9	111%
Regpara	2.9	2.2	-0.7 (-23%)		2.0	110%
Orkedia	9.9	10.3	+0.4 (+4%)		10.4	99%
G-Lasta	29.4	31.1	+1.7 (+6%)	Market's recovery & penetration	31.5	99%
Poteligeo	2.0	2.0	-0.0 (-2%)		2.0	98%
Rituximab BS	11.2	10.3	-0.9 (-8%)	NHI price-cut	10.3	100%
Romiplate	7.3	10.4	+3.2 (+43%)	Recovery from supply constraints (from Jun 2020 through Mar 2021)	10.0	104%
Allelock	8.0	6.0	-2.1 (-26%)	Generics' penetration & NHI price-cut	5.6	107%
Patanol	10.7	2.8	-7.9 (-74%)	Generics launched in Dec 2021	3.0	93%
Nourias	8.7	8.0	-0.6 (-7%)	Competitors' penetration	8.1	99%
Haruopi	3.1	4.0	+0.9 (+28%)	Market penetration (Launched in Dec 2019)	4.1	97%
Crysvita	7.2	8.9	+1.7 (+23%)	Market penetration (Launched in Dec 2019)	9.2	96%
Tech-licensing	1.6	0.8	-0.9 (-52%)	Deferred process of FKB ² -related upfront revenue completed	0.9	85%

1 AG stands for Authorized Generic. Official product name is Darbepoetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

2 FKB stands for Fujifilm Kyowa Kirin Biologics Co., Ltd.

FY21 vs FY22 -Revenue of Major Items outside Japan-

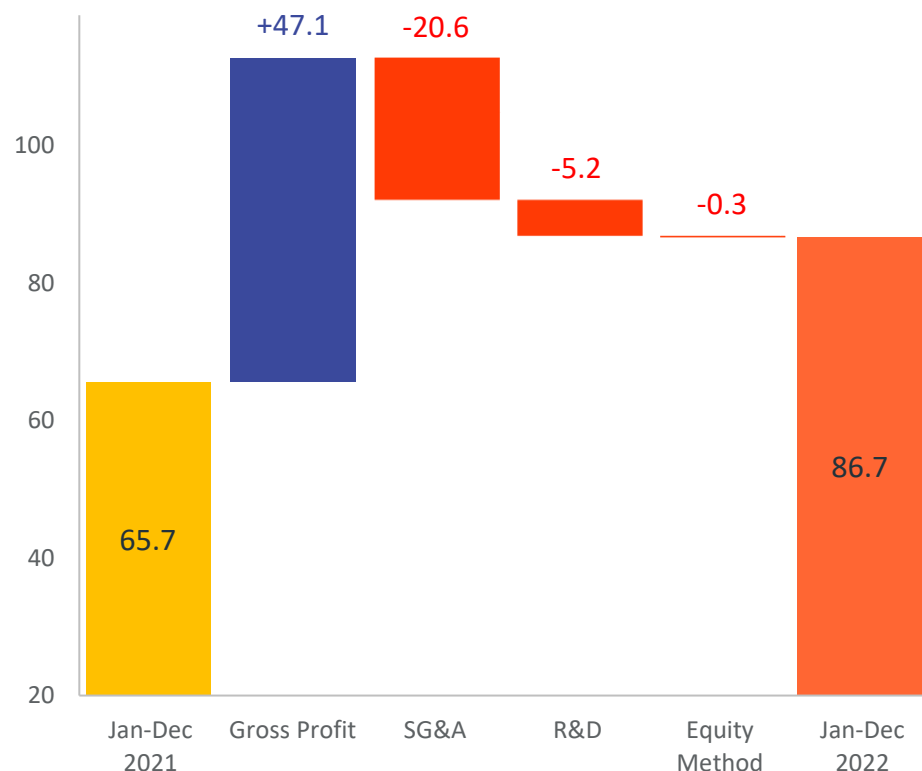
(Billion Yen / Rounded)

Item	FY2021 Results	FY2022 Results	Changes	Reasons	FY2022 Rev. Plans	Achieved
Crysvita	78.3	118.2	+39.9 (+51%)		116.2	102%
North America	57.7	87.0	+29.3 (+51%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication (Adult/TIO)		
EMEA	20.6	31.0	+10.4 (+50%)			
APAC	0.0	0.3	+0.3 (—)			
Poteligeo	15.3	22.3	+7.0 (+46%)		23.6	94%
North America	12.7	17.2	+4.5 (+35%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration	18.1	95%
EMEA	2.6	5.1	+2.5 (+98%)		5.5	94%
Nourianz	4.5	6.5	+1.9 (+43%)	Market penetration	6.1	106%
Abstral	8.5	6.9	-1.6 (-19%)	Generic's penetration	7.2	95%
Regpara	7.4	3.9	-3.5 (-47%)	Listed on Chinese tender list ¹ in Oct 2021	3.8	104%
Tech-licensing	24.5	33.0	+8.5 (+35%)	Deferred revenue of KHK4083 upfront payment (July 2021-) & Growth of Fasenra	35.0	94%
Benralizumab Royalty ²	16.8	21.6	+4.8 (+29%)			

- 1 Volume-Based Procurement (VBP) program that has been introduced since 2018 for reducing healthcare cost in China. A few companies are selected as a supplier through a tender, while their drug prices dramatically drop down.
 - 2 Sales royalties of Fasenra which has been marketed by AstraZeneca, including our own estimation.
- * Revenue from Early Access Program (EAP) are not included in the figures above.

FY21 vs FY22 -Core OP-

**+21.0 billion yen
(incl. forex effect +11.0)**



● Gross Profit +47.1 (incl. forex effect +27.5)

Increased in conjunction with the 46.1 rise in revenue. Margin improved by 3% (75% →78%) due mainly to increased proportion of profitable “Global 3 brands” and tech-licensing revenue.

● SG&A -20.6 (incl. forex effect -13.0)

Increased by aggressive investment in IT/Digital infrastructure and human resources for the maximization of “Global 3 brands” and the early consolidation of global business foundation, in addition to Crysvita profit-share expenses for North America.

[Labor -10.9 / Sales promotion -8.8 (incl. Crysvita profit-share expenses -10.4) / Depreciation & Amortization +0.4 / Other -1.3]

● R&D -5.2 (incl. forex effect -3.5)

Clinical study costs of KHK4083 and ME-401 increased.

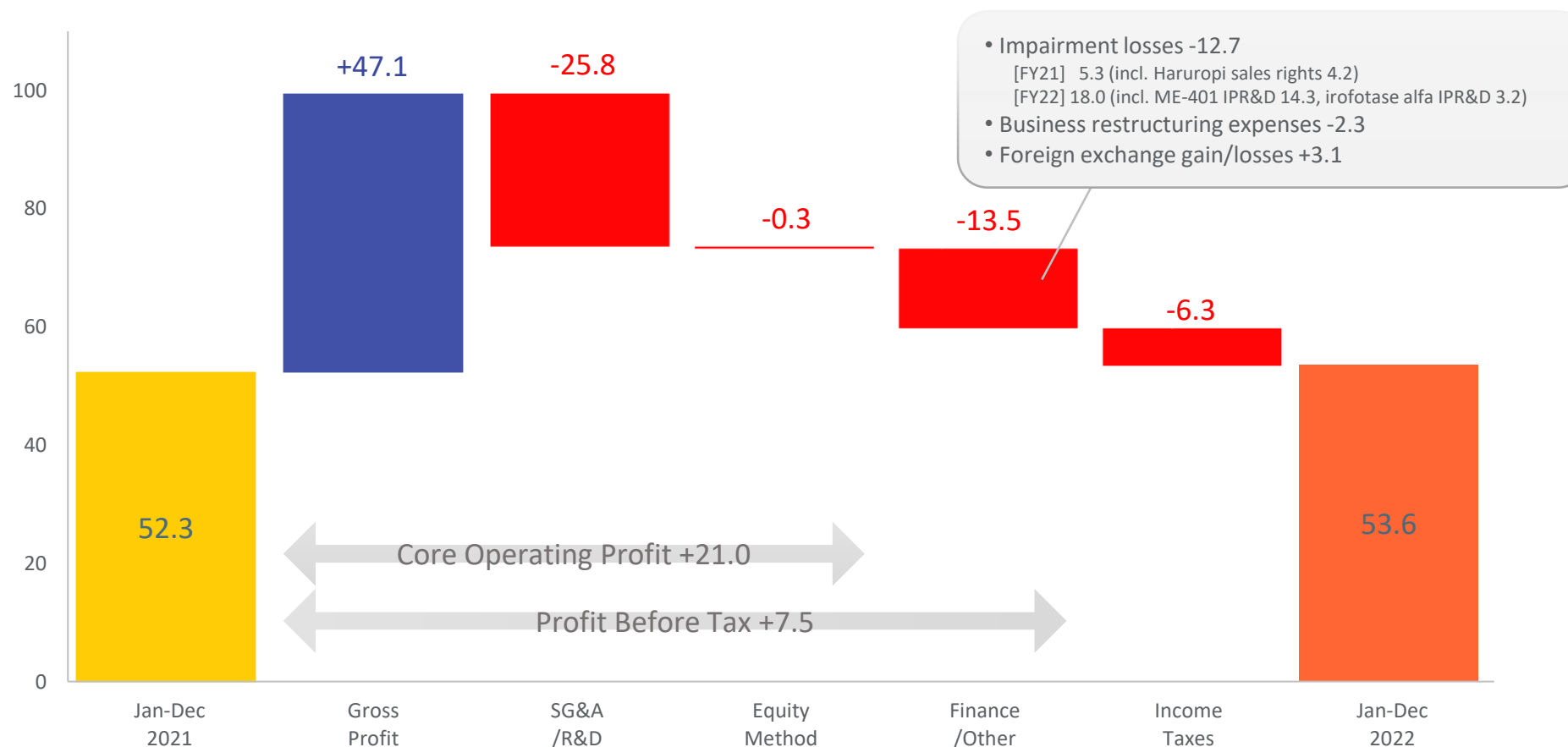
● Gain/Loss on Equity Method -0.3

While revenue of Hulio (FKB327/Adalimumab biosimilar) increased, FKB’s profit was at the same level as last year due to a decreased tax-accounting effect.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

FY21 vs FY22 -Profit-

Profit (Jan-Dec) +1.2 billion yen



2021-2025 Medium Term Business Plan

- FY2023 Plans -

Qualitative Plans for 2023

Provide pharmaceuticals for unmet medical needs

■ Maximize the value of G3B

- ✓ Initiate own sales of Crysvita in North America
- ✓ Further growth of Crysvita through establishment of bone metabolism specialists at each branch in Japan
- ✓ Focus on Crysvita and Poteligeo and accelerate their growth under the new EMEA structure
- ✓ Strengthen evidence-based marketing activities

■ Continue to create groundbreaking new drugs

- ✓ Accelerate Global Development of rocatinlimab and KHK4951
- ✓ KW-3357PE Ph3 study top line data and value maximization
- ✓ Start Ph1 study of an antibody with Regulgent® (our proprietary bispecific antibody technology) and promote early-stage drug developments
- ✓ Focus on strategic investments to enhance development pipelines
- ✓ Foster researchers (Mushasyugyo PJ, AI Drug Discovery Talent Development Program)

Reinforce human resources and structures that support the creation of Life-changing value

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Accelerate human resources development: Expand global talent exchange program, renew talent management practices for the manager layers (job-based grading system/JP)
- ✓ Continue the effort to embed Corporate Culture Transformation globally
- ✓ Enrich the infrastructure including Dx human resources development
- ✓ Introduce the development project portfolio management system
- ✓ Strengthen the leadership structure: Enhance CxO structure

Address patient-centric healthcare needs

■ Patient advocacy

- ✓ Standardize patient advocacy activities in the global development process
- ✓ Raise disease awareness of XLH and create opportunities for patient interactions : expand the area of Shine a Light campaign and online platforms, work with XLH ambassadors, etc.
- ✓ CTCL: Disease awareness campaign with centering World Lymphoma Day
- ✓ Continue "Listening to Patients" events in each region to promote a patient-centric corporate culture
- ✓ Host an event at "Healthcare Café" organized by four JP pharmaceutical companies

■ Provide value that goes beyond pharmaceuticals

- ✓ Start initiatives to address patient needs related to XLH

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Proceed to establish the key products supply system with multiple production sites
- ✓ Continue the market monitoring and cross-departmental efforts
- ✓ Strengthen sustainable procurement activities (penetration of the Supplier Code of Conduct, human rights due diligence, etc.)
- ✓ Upgrade and expand anti-counterfeit measures

■ Help to protect the global environment

- ✓ Reduce 2023 CO₂ emissions by 51% compared to 2019
- ✓ Establish the reduction policy of Scope 3 greenhouse gas emissions

Strategic Investment ~For successful creation and delivery of life-changing value

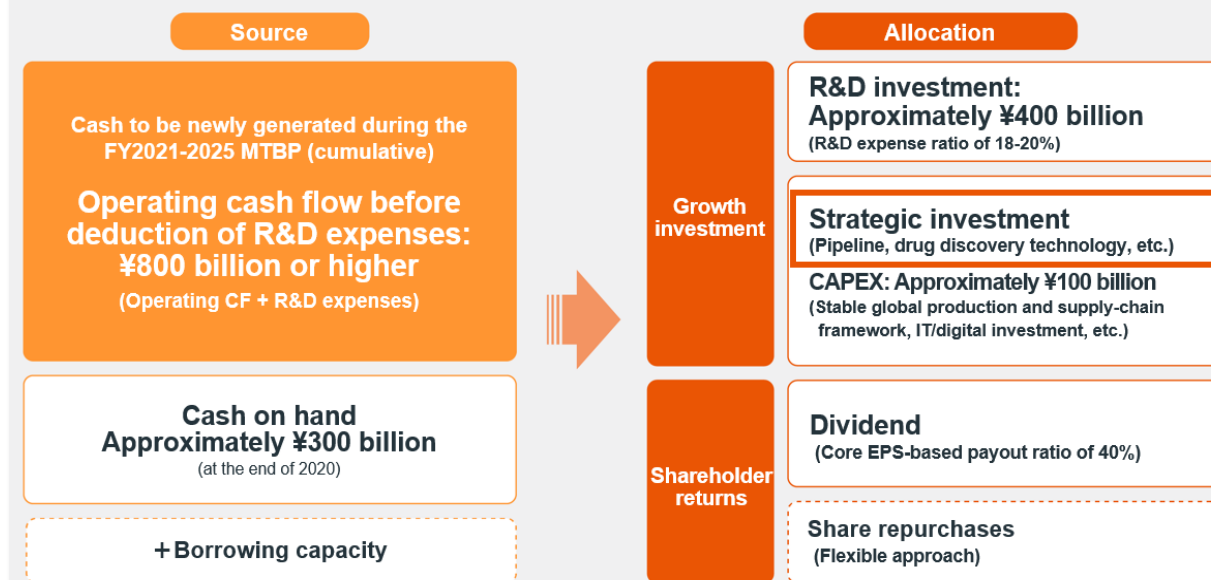
Licensing-in and M&A investments to strengthen the portfolio

- Development pipeline with synergies with Crysvida and Poteligeo
 - ◆ Bone, Mineral ◆ Hematologic oncology
- Implementing the strengths of each region
 - ◆ Nephrology ◆ Hematology / Oncology
 - ◆ Immunology

Investment in science and technology to create new strengths

- Investments aimed at acquiring new drug discovery technologies and early pipelines and accelerating cooperation and collaborations
- VC investment and CVC activities for exploring and accessing information.

2021-2025 Cash Allocation*



*2021-2025 Medium-Term Management Plan Cash Allocation, published 4 February 2021.

Quantitative Summary of FY23 Plans

(Billion Yen / Rounded)

	FY2021 Results	FY2022 Results	FY2023 Plans	Changes
Revenue <i>[Overseas Ratio]</i>	352.2 <i>[54%]</i>	398.4 <i>[61%]</i>	426.0 <i>[64%]</i>	+27.6 (+7%)
Gross Profit <i>[Gross Profit Margin]</i>	264.4 <i>[75%]</i>	311.5 <i>[78%]</i>	326.0 <i>[77%]</i>	+14.5 (+5%)
SG&A <i>[SG&A Ratio]</i>	145.6 <i>[41%]</i>	166.2 <i>[42%]</i>	162.0 <i>[38%]</i>	-4.2 (-3%)
R&D <i>[R&D Ratio]</i>	57.7 <i>[16%]</i>	62.9 <i>[16%]</i>	79.0 <i>[19%]</i>	+16.1 (+26%)
Gain/Loss on Equity Method	4.6	4.3	3.0	-1.3 (-31%)
Core Operating Profit <i>[Core OP Margin]</i>	65.7 <i>[19%]</i>	86.7 <i>[22%]</i>	88.0 <i>[21%]</i>	+1.3 (+2%)
Profit	52.3	53.6	76.0	+22.4 (+42%)
Return on Equity	7.3%	7.1%	9.7%	[FOREX] FY2021-Actual JPY109/USD FY2022-Actual JPY130/USD FY2023-Plan JPY130/USD
Dividend Payout Ratio ¹	43.2%	38.9%	39.9%	

¹ Figures are based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

FY22 vs FY23 -Revenue of Major Items in Japan-

(Billion Yen / Rounded)

Item	FY2021 Results	FY2022 Results	FY2023 Plans	Changes	Reasons
Nesp + Nesp-AG ¹	26.3	21.1	16.6	-4.5 (-21%)	NHI price-cut & Biosimilars' penetration
Nesp	4.0	3.4	2.8	-0.6 (-18%)	
Nesp-AG	22.3	17.6	13.8	-3.8 (-22%)	
Duvroq	2.6	6.6	7.8	+1.2 (+19%)	Market penetration (Launched in Aug 2020)
Orkedia	9.9	10.3	11.2	+0.9 (+9%)	Market penetration
G-Lasta	29.4	31.1	33.5	+2.5 (+8%)	Market penetration & 'BodyPod' launched in Dec 2022
Poteligeo	2.0	2.0	2.0	+0.0 (+2%)	
Rituximab BS	11.2	10.3	8.7	-1.6 (-16%)	NHI price-cut
Romiplate	7.3	10.4	11.2	+0.8 (+8%)	Market penetration
Allelock	8.0	6.0	4.7	-1.3 (-21%)	NHI price-cut & Generics' penetration
Nourias	8.7	8.0	7.5	-0.5 (-6%)	Competitors' penetration
Haruopi	3.1	4.0	4.7	+0.7 (+18%)	Market penetration (Launched in Dec 2019)
Crysvita	7.2	8.9	11.1	+2.2 (+25%)	Market penetration (Launched in Dec 2019)

1 AG stands for Authorized Generic. Official product name is Darbepoetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

FY22 vs FY23 -Revenue of Major Items outside Japan-

(Billion Yen / Rounded)

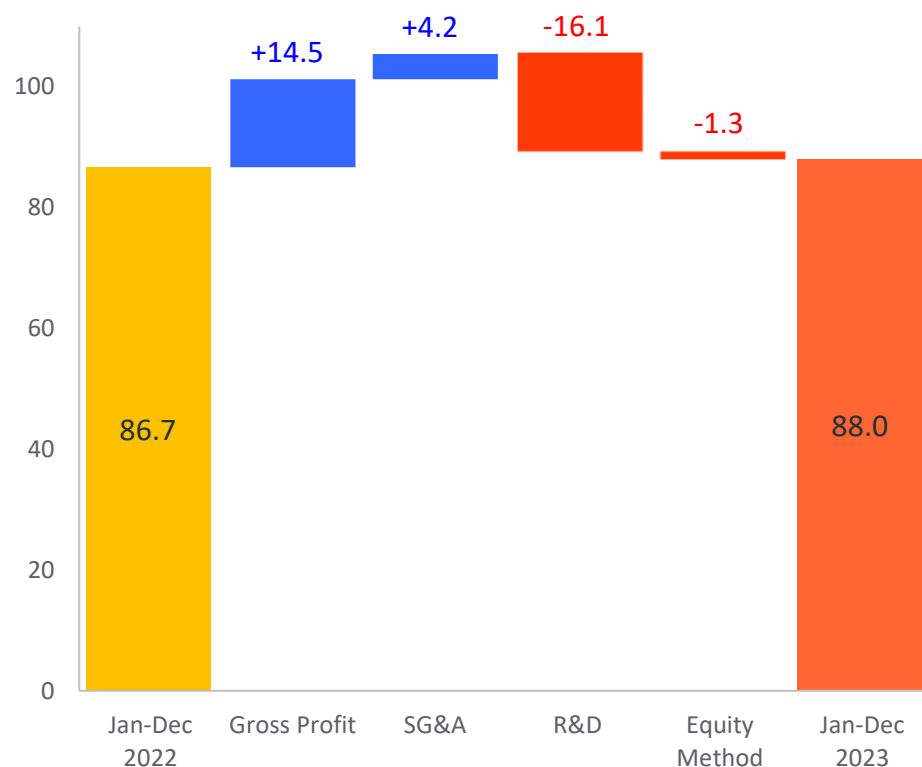
Item	FY2021 Results	FY2022 Results	FY2023 Plans	Changes	Reasons
Crysvita	78.3	118.2	138.0	+19.8 (+17%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication
North America	57.7	87.0			
EMEA	20.6	31.0			
APAC	0.0	0.3			
Poteligeo	15.3	22.3	27.5	+5.2 (+23%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration
North America	12.7	17.2	19.4	+2.2 (+13%)	
EMEA	2.6	5.1	8.0	+2.8 (+56%)	
APAC	—	—	0.2	+0.2 (—)	
Nourianz	4.5	6.5	7.5	+1.1 (+17%)	Market penetration
Nesp	6.4	7.6	8.0	+0.4 (+5%)	Market penetration
Gran	6.3	8.2	8.2	+0.0 (+0%)	
Neulasta	5.3	5.6	5.7	+0.0 (+1%)	
Tech-licensing	24.5	33.0	39.0	+6.0 (+18%)	Growth of Fasenra and Fotivda ²
Benralizumab Royalty ¹	16.8	21.6			

1 Sales royalties of Fasenra which has been marketed by AstraZeneca. Including our own estimation.

2 tivozanib: Kyowa Kirin has licensed its oncology development/commercial rights to Aveo Oncology Inc (an LG Chem company), and Aveo has sub-licensed the rights outside North America to EUSA Pharma. Being marketed in the US and Europe as Fotivda.

FY2022 vs FY2023 -Core OP-

+1.3 billion yen



● Gross Profit +14.5

While gross profit will grow with the 27.6 rise in revenue (Japan-3.1, North America +19.9, EMEA-0.8, APAC+4.4, Other+7.3), COGs will also increase due to the Crysvida-related scheme change from 'Profit-sharing (SG&A)' to 'Sales royalty (COGs)' after Apr 27, 2023. This is expected to result in lowered gross profit margin by about 2% to 76.5%.

● SG&A +4.2

SG&A rate is expected to shrink by about 4% (41.7%→38.0%) since profit-share expenses on Crysvida (CRV) will disappear after April 27, while there also are factors of increase, such as expenses for direct CRV sales force in North America (NA) and HR/IT expenses brought by last year's investment for establishing global business foundation.

[Major factors]

- Down - Profit-share exp on CRV in NA → No gross profit-share after Apr27
- UP - Selling exp on CRV in NA → SG&A share + Prep exp for direct sales force (until Apr26)
 - Direct selling exp + 50% of Ultragenyx's field support exp (after Apr27)
- HR exp → Increased exp for staff hired in mid-2021, base-pay rise, and new recruitment, etc.
- IT exp → Increased exp for systems that went live in mid-2021 and delayed purchases, etc.
- Others → Launch preparation exp and co-promotion fee in China, etc.

● R&D -16.1

R&D rate is to increase by around 3% (15.8%→18.5%) due mainly to full-scale operation of rocatinlimab Ph3 ROCKET program and increase in study drugs to be manufactured.

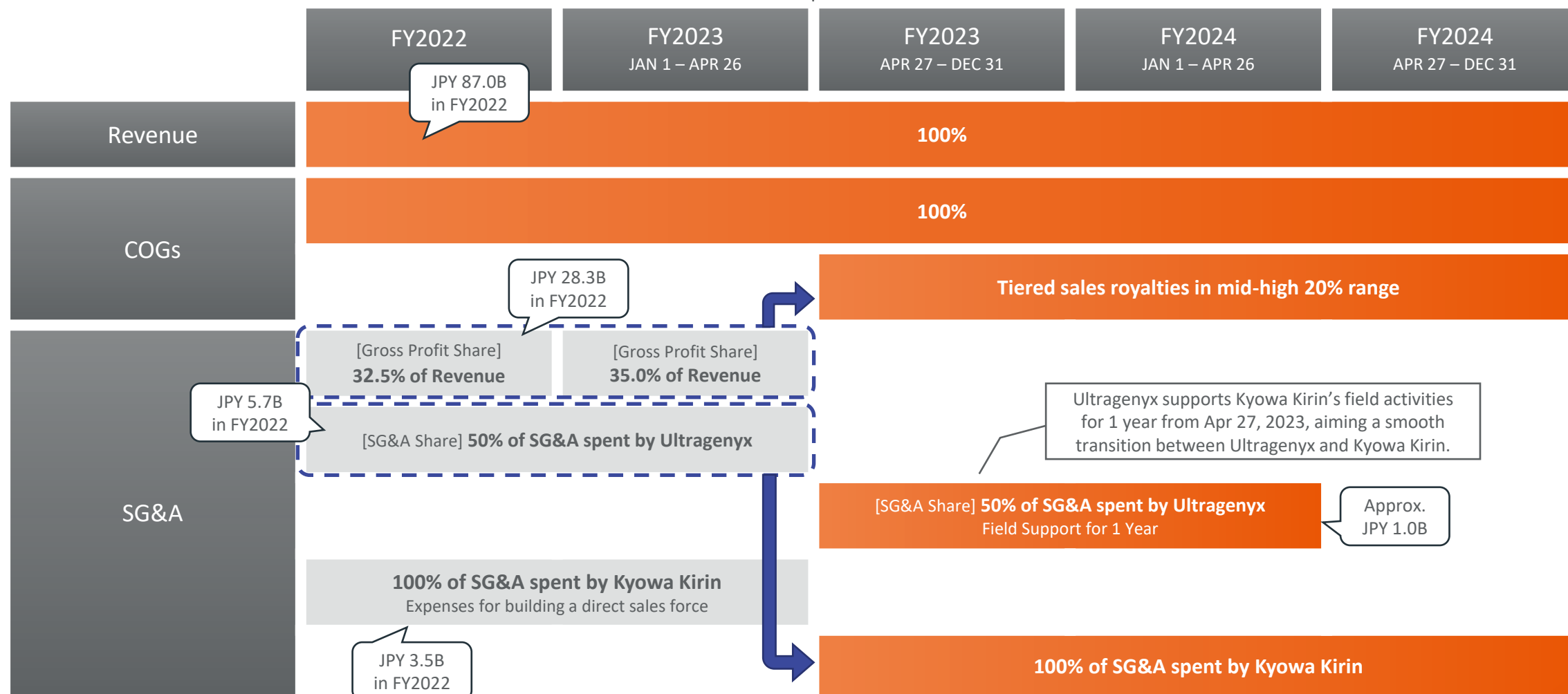
● Gain/Loss on Equity Method -1.3

Equity method gain is expected to decline by 1.3 due to decrease in tax-accounting effect, while FKB's Hulio (FKB327/Adalimumab biosimilar) to see continued growth.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

P/L Impact on North American Crysvita Business

Based on the Collaboration and License Agreement in 2013, Kyowa Kirin takes over the field activities in North America from Ultragenyx, starting from April 27, 2023 (6th year from launch).



FY2022 vs FY2023 -Profit-

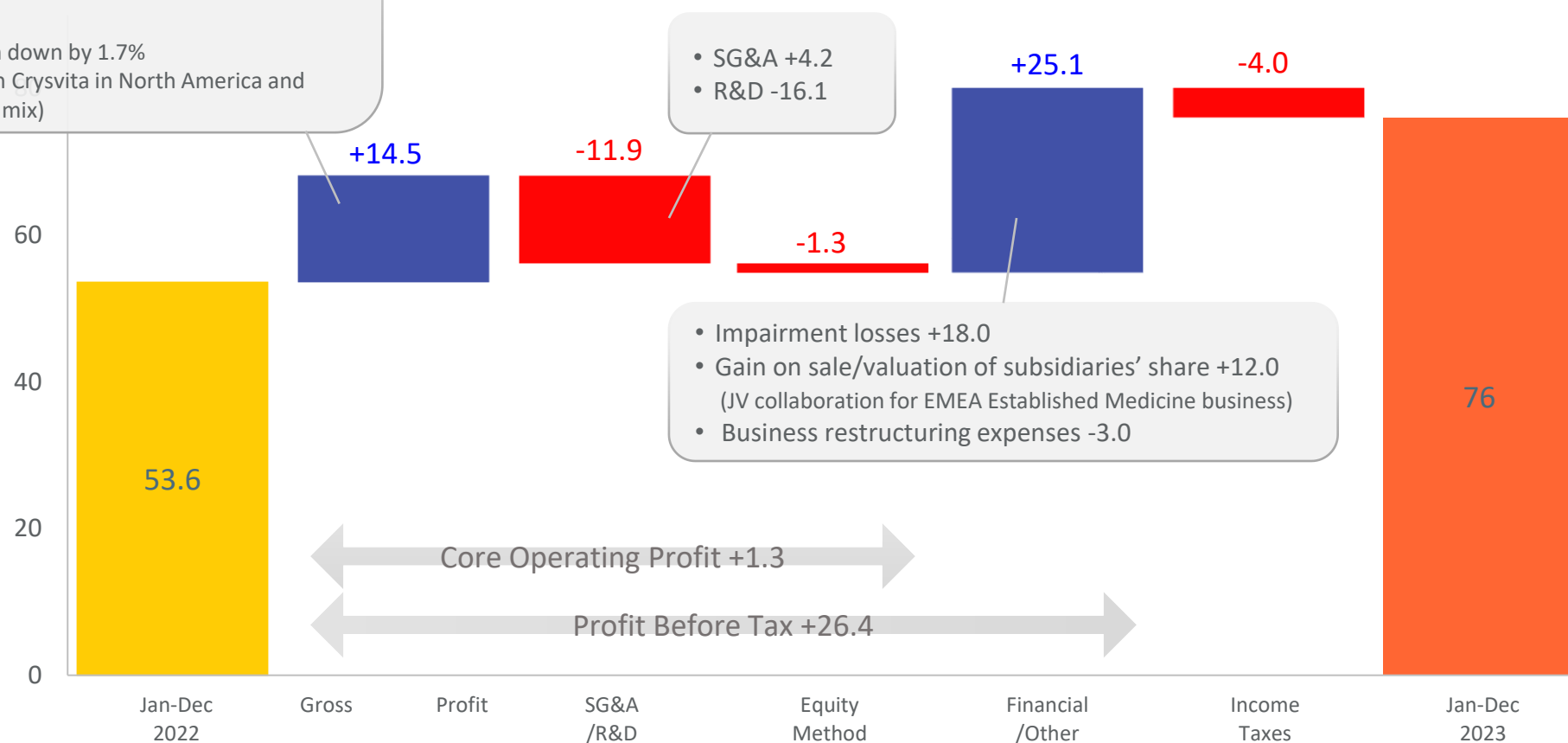
Revenue +27.6

- Japan -3.1 (NHI price-cut)
- North America +19.9 (Growth of G3B)
- EMEA -0.8 (Growth of G3B and Exclusion of Established Medicine business)
- APAC +4.4 (Growth of G3B & existing products)
- Other +7.3 (Growth of Fasentra and Fotivda)

COGs +13.1

- Gross profit margin down by 1.7% (Scheme change on Crystvita in North America and improved product mix)

Profit (Jan-Dec) +22.4 billion yen

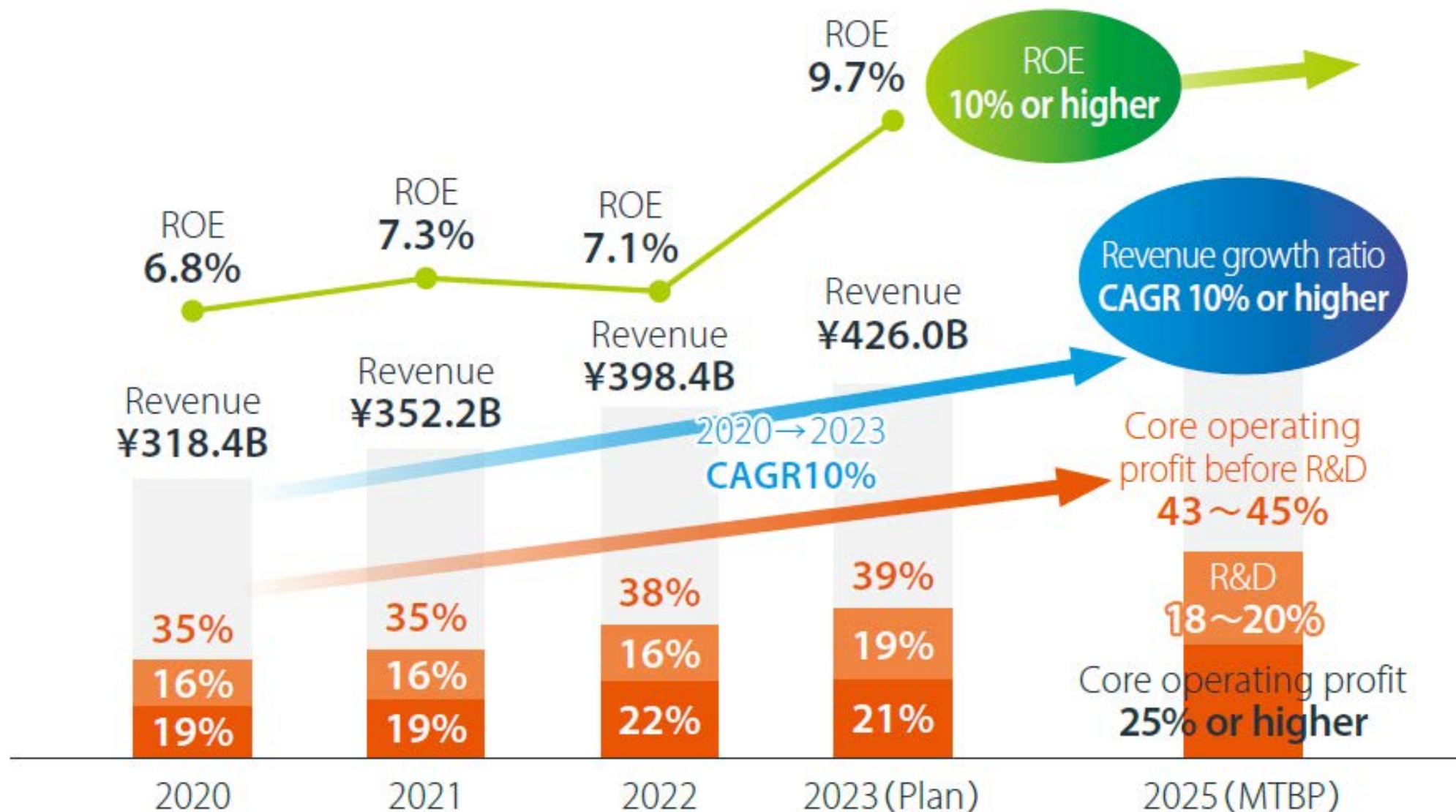


2021-2025 Medium Term Business Plan

- Financial KPI Progress -

2021-2025 Medium Term Business Plan

Progresses of Financial KPIs (Numerical Guidance)

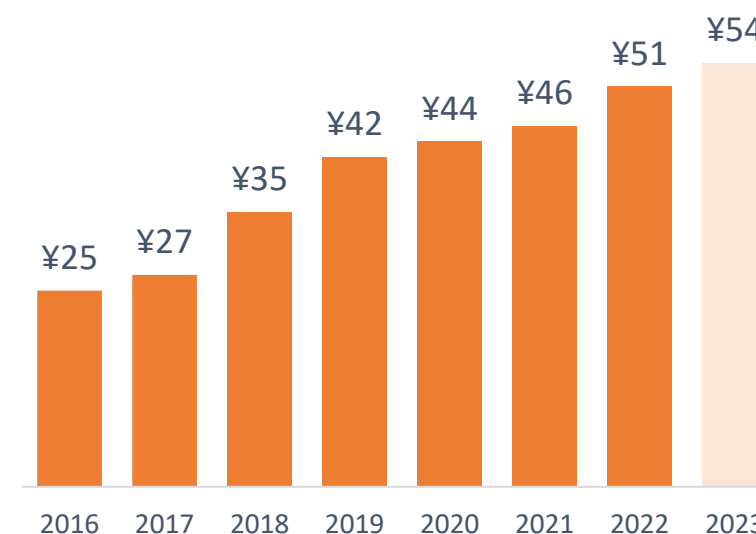


Shareholders Return

Shareholders Return

- ✓ FY22 dividend is **51 yen**, and FY23 to be **54 yen** (plan)
- ✓ Plans **7-year consecutive rises** since FY17
- ✓ FY21-23 weighted average payout ratio is **40.5%** (plan)
(Mid-term guidance for payout ratio “Targeting sustained dividend hikes with 40%”)

Year	Dividend (yen)			Payout Ratio ^{*1}	Return on Equity
	Interim	Year-end			
2016	12.50	12.50	25.00	44.9%	5.3%
2017	12.50	14.50	27.00	34.4%	7.2%
2018	15.00	20.00	35.00	35.2%	8.6%
2019 ^{*2}	20.00	22.00	42.00	33.7%	10.1%
2020	22.00	22.00	44.00	50.3%	6.8%
2021	23.00	23.00	46.00	43.2%	7.3%
2022 ^{*3}	24.00	27.00	51.00	38.9%	7.1%
2023 (Plan)	27.00	27.00	54.00	39.9%	9.7%



^{*1} Payout ratio for FY2021/beyond are payout ratios against the Core EPS that is calculated based on the Core Earnings (= Profit - Other income/losses - Related income taxes)

^{*2} Repurchase of 10.7M own shares (¥22.6B) executed on February 6, 2019. Total return ratio for FY2019 is 67.3%.

^{*3} Year-end dividend of 27 yen/share will be submitted to the 100th Ordinary General Meeting of Shareholders to be held on March 24, 2023.

Commercial Update

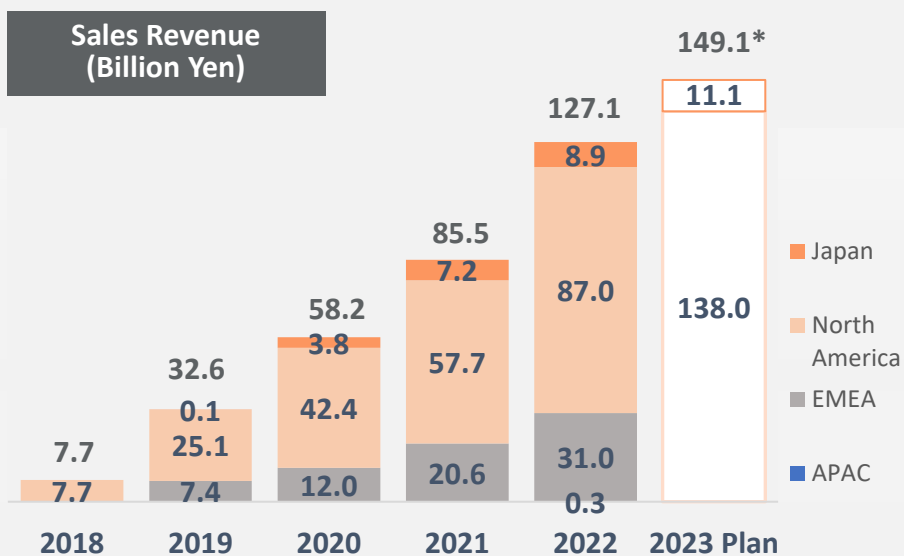
2022 Review & 2023 Key Actions

2022 Review

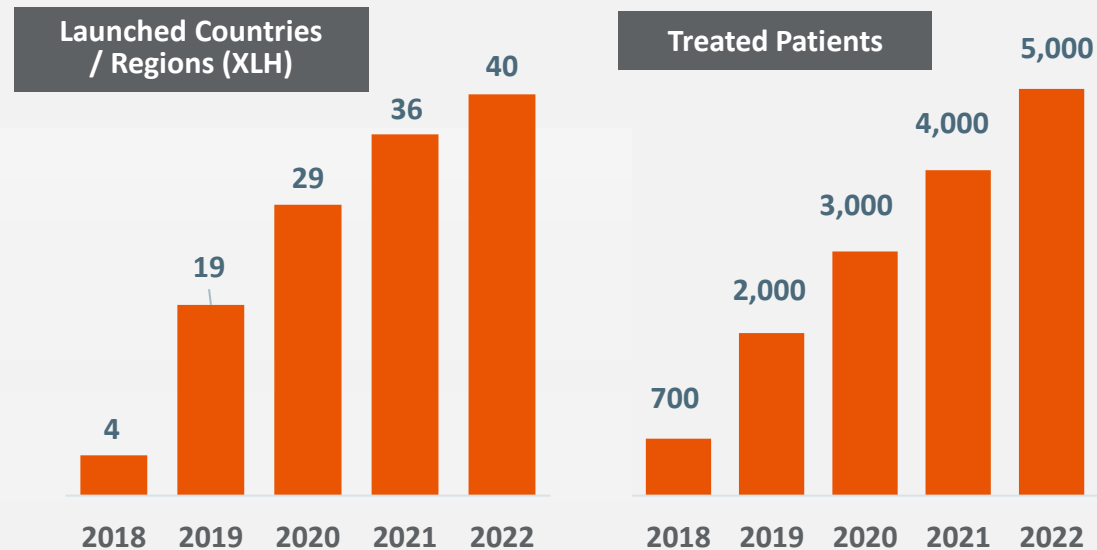
- Sales revenue reached JPY 127.1 bn.
- North America:
Amended the contract with Ultragenyx for smooth transition.
Disease awareness activities by Kyowa Kirin started in 4Q.
- EMEA
Expanded markets geographically.
Received additional approval for TIO indication and started commercialization.
- Japan
Dedicated personnel was assigned to each branch.

2023 Key Actions

- North America:
Start own sales (Establish and start own operation of the direct sales force).
- EMEA:
Continue to focus on geographical & indication expansion.
- Japan:
Strengthen promotional activities centered by the dedicated personnel.



*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.



*Excludes Latin America and Turkey, where Ultragenyx records sales.

*Excludes EAP patients in patient number.

2022 Review & 2023 Key Actions

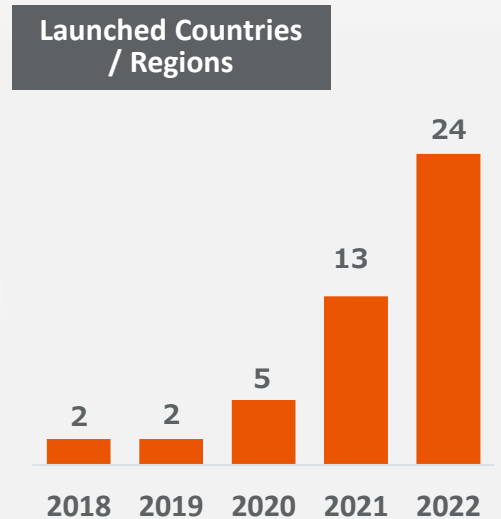
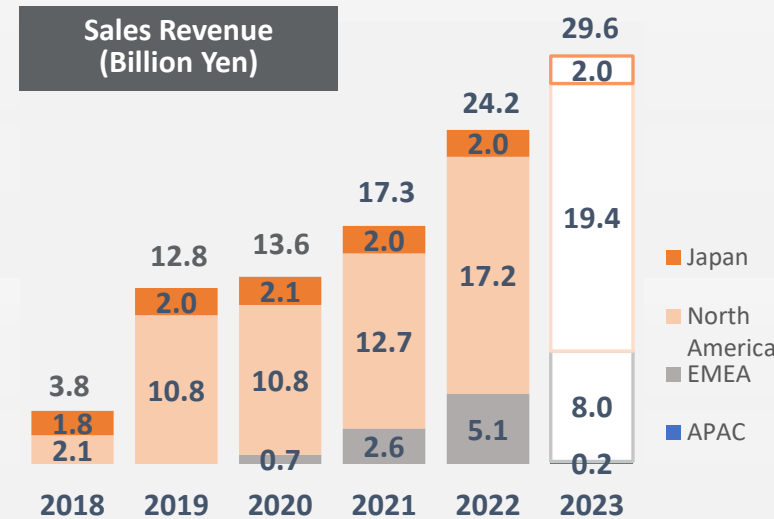
2022 Review

- North America/EMEA:
Increase product perception and sustain growth by evidence-led promotional activities focused on patients with blood tumor.
- EMEA:
Launched countries/regions increased (+11).

2023 Key Actions

- Strengthen promotional activities utilizing evidences including blood tumor data.
- Raise awareness of importance of blood testing among early-stage patients.

*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.



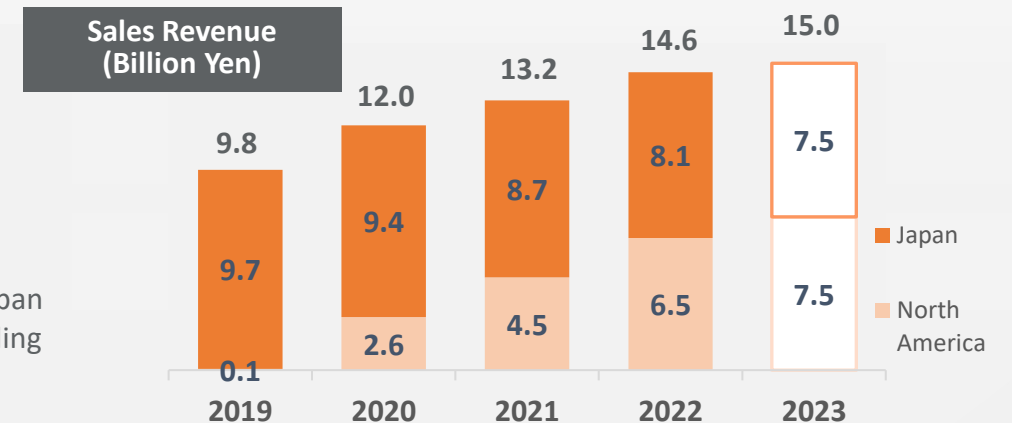
2022 Review & 2023 Key Actions

2022 Review

- North America:
Steadily grew through promotional activities to both HCPs and Consumers by promoting Nourianz's important features.

2023 Key Actions

- Further instill importance of adenosine A_{2A} receptor antagonism in treating wearing-off.
- Strengthen field level activity through further collaboration and knowledge sharing between Japan and the US, and through maximizing available resources by utilizing effective approaches including digital.

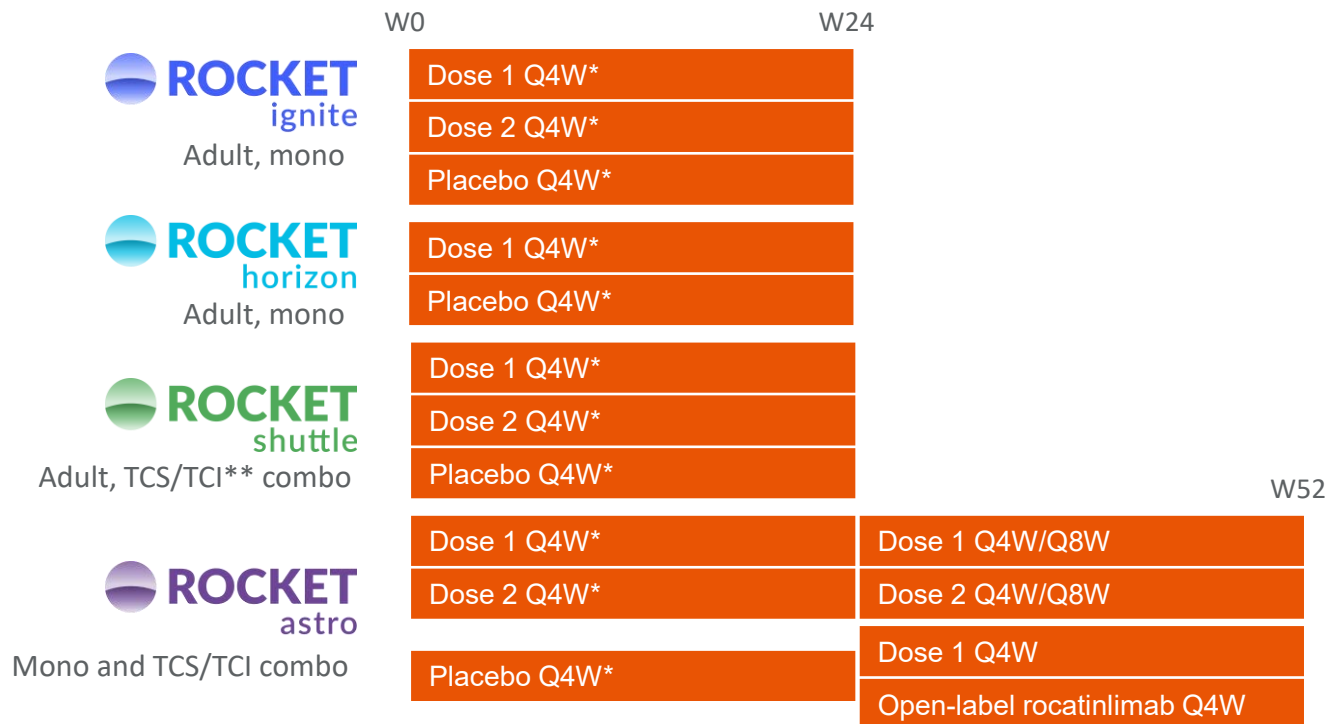


R&D Update

Upcoming Events: Main Development Pipeline Products

Code Generic Name	Event (Completed is in bold)	Month Completed Time Expected
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis P3 Initiation	Dec. 2022
KHK4951 tivozanib	nAMD P1 LPO P2 Initiation	Aug. 2022 H2 2023
ME-401 zandelisib	iB-NHL (mono, 3L+) P2 topline data (JP) Discontinuation of development outside Japan	Nov. 2022 Dec. 2022
RTA 402 bardoxolone methyl	Diabetic kidney disease P3 LPO P3 topline data	Dec. 2022 H1 2023
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis submission (JP)	Oct. 2022
KW-3357 antithrombin gamma (genetical recombination)	Preeclampsia P3 LPO	H2 2023

FPI: first patient in; LPO: last patient out; CLL: chronic lymphocytic leukemia; iB-NHL: indolent B-cell non-Hodgkin lymphoma; nAMD: Neovascular age-related macular degeneration



Primary Endpoint: Achievement of EASI 75 at Week 24 and achievement of vIGA-AD 0/1 at Week 24



Primary Endpoint: Number of Participants with Treatment-emergent Serious Adverse Events

- Another study will be conducted to evaluate the safety and efficacy of long-term administration in adults and adolescents
- Interim analysis from long term efficacy and safety data will be used to support filling.

Main Development Pipeline Products

	Diseases under development ^{*1}	Planned Approval Year ^{*2}	Development status	Total addressable market ^{*3}	No. of Patients ^{*4}
KHK4083/ AMG 451 rocatinlimab	Moderate and severe Atopic Dermatitis	2026/2027	Ph3 (Global)	★★★★★	16M
KHK4951 tivozanib	Neovascular (wet) age-related macular degeneration	TBD	Preparing for Ph2 (US and JP)	★★★★	2,300K~
ME-401 zandelisib	indolent B-cell non-Hodgkin lymphoma	2025	Ph2 (JP) Top line data disclosed	★	80K
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis	2023	Filed (JP)	★	250K
RTA 402 bardoxolone Methyl	Alport syndrome	TBD	Filed (JP)	★	2,500K~
	Diabetic kidney disease	2024	Ph3 (JP) LPO	★★★	
	Autosomal dominant polycystic kidney disease (ADPKD)	TBD	Ph3 (JP)	★	
KW-3357 antithrombin gamma (genetical recombination)	Preeclampsia	2024	Ph3 (JP)	★	15K

^{*1} Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities

^{*2} Expected year of first approval

^{*3} Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in ^{*1}, not projected sales or the Company's targets. **Colored areas represent estimates for global, and the rest are for Japan.**

★: less than ¥50Bn、★★: ¥50Bn-¥100Bn、★★★: Over ¥100Bn-¥500Bn、★★★★: Over ¥500Bn-¥1Tn、★★★★★: Over ¥1Tn

^{*4} Total number of estimated patients by Kyowa Kirin. **Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan.**

News Flow in 2022

Year-to-date Key News Flow ①

AS of February 7, 2023

Category	Date	Headline
ESG	Jan 11	Introduction of renewable energy “Aqua Premium” for Fuji Research Park and CMC R&D Center
LCM	Jan 31	NDA submission of Topical Ophthalmic Mitomycin C agent (Japan)
LCM	Feb 25	Approval for partial change of approved indication of G-Lasta (Japan) (for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogenic Blood Stem Cell Transplantation)
ESG	Mar 9	Selection as “Health & Productivity Stock” for the first time (Japan)
R&D	Mar 31	Regulatory update on Zandelisib following meeting with the FDA
LCM	Apr 4	Publication of safety data from a clinical trial of automated injection device of G-Lasta (Japan)
SCM	May 17	Construction of a new biopharmaceutical API manufacturing building at Takasaki Plant
R&D	May 18	Joint research agreement with LUCA Science on mitochondrial disease treatment with novel mitochondria modality
R&D	May 31	Achievement of first milestone in research collaboration with InveniAI
LCM	Jun 1	Positive data from Phase 3 study of Lumicef in Systemic Sclerosis (EULAR 2022 Congress)

Year-to-date Key News Flow ②

AS of February 7, 2023

Category	Date	Headline
R&D	Jun 5	New clinical data on Zandelisib (American Society of Clinical Oncology Annual Meeting 2022)
R&D	Jun 10	Clinical data on Zandelisib (European Hematology Association 2022 Hybrid Congress)
LCM	Jun 27	Positive CHMP opinion for use of Crysvita for TIO
R&D	Jul 15	Discontinuation of developing KW-6356
R&D	Jul 19	Data from Phase 1b clinical study of Zandelisib in patients with relapsed or refractory B-cell malignancy (The Lancet Oncology)
LCM	Aug 1	Approval of “G-Lasta Subcutaneous Injection 3.6mg BodyPod” (Japan)
LCM	Aug22	Approval of Crysvita for TIO from European Commission
LCM	Sep7	Positive data from Phase 3 study of Lumicef for Palmoplantar Pustulosis (EADV 2022 Congress)
LCM	Sep15	Application for partial change of approved indication of Lumicef for Palmoplantar Pustulosis (Japan)
R&D	Oct5	Initiated CVC activities and made first investment in a startup company

Year-to-date Key News Flow ③

AS of February 7, 2023

Category	Date	Headline
LCM	Oct 17	Application for partial change of approved indication of Lumicef for Palmoplantar Pustulosis (Japan)
R&D	Oct 20	Data from Phase 3 clinical study of Tenapanor Hydrochloride (KHK7791) for hemodialysis patients on dialysis with hyperphosphatemia in Japan (American Society of Nephrology Meeting)
R&D	Oct 28	NDA submission of Tenapanor Hydrochloride (KHK7791) for improvement of hyperphosphatemia in chronic kidney disease patients on dialysis (Japan)
R&D	Nov 4	Final results of TIDAL Phase 2 clinical study FL cohort of Zandelisib, etc. (American Society of Hematology 2022 Annual Meeting)
LCM	Nov 11	Application for partial change of Romiplate of indication for Aplastic Anemia (Japan)
R&D	Nov 18	Release topline data from the Phase 2 study evaluating Zandelisib in patients with iB-NHL (Objective response rate is 75.4%, Patients achieved a complete response is 24.6%)
LCM	Nov 24	Signed a joint venture collaboration agreement of Kyowa Kirin International plc's Establish Pharmaceuticals business.

Year-to-date Key News Flow ④

AS of February 7, 2023

Category	Date	Headline
R&D	Dec 6	Discontinuation of Zandelisib joint development with MEI Pharma outside of Japan, and impairment losses recorded
LCM	Dec 6	Launch of “G-Lasta Subcutaneous Injection 3.6 mg BodyPod” (Japan)
R&D	Dec 13	Lancet publication of phase 2b study results for Rocatinlimab for moderate-to-severe Atopic Dermatitis
ESG	Dec 22	Decision of introduction a large-scale solar power generation system at the Ube plant (Japan)
SCM	Dec 22	Decision of construction of a new warehouse building at Takasaki Plant (Japan)
LCM	Dec 26	Approval of Topical Ophthalmic Mitomycin C Agent (Japan)

Appendix

FOREX Information

Average FOREX Rates (yen)

	FY2021	FY2022	Changes	FY2023 Plans
USD	109	130	+21	130
GBP	150	161	+11	160
EUR	130	137	+7	135

FY22 FOREX Impacts (vs FY21, billion yen)

	Revenue	Core OP
USD	+22.1	+8.2
GBP	+4.6	+1.2

FY23 FOREX Sensitivities (vs FY23 Plan, billion yen)

	Changes	Revenue	Core OP
USD	+1 yen	+1.2	+0.4
GBP	+1 yen	+0.2	-0.0
EUR	+1 yen	+0.3	+0.2

Crysvita - Collaboration with Ultragenyx -

Economic Terms

US & Canada

- Kyowa Kirin books sales
- 50/50 profit share for 5 years from the U.S. launch
 - Supply price: 35% of net sales through 2022, 30% thereafter (No impact on the sales royalties stated below)
- After 5 years (April 27, 2023-), Kyowa Kirin pays tiered sales royalties in mid-high 20% range to Ultragenyx
 - *Ultragenyx has sold 30% of its royalty interest, subject to a 1.45x cap, to OMERS Capital Markets

Europe

- Kyowa Kirin books sales
- Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx
 - *Ultragenyx has sold its royalty interest, subject to a 1.9x or 2.5x cap depending on when the cap is achieved, to Royalty Pharma

Latin America

- Ultragenyx books sales
- Kyowa Kirin receives low single-digit sales royalties from Ultragenyx
- Supply price: 35% of net sales through 2022, 30% thereafter

Turkey

- Ultragenyx books sales
- Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx

Asia & Others

- Kyowa Kirin books sales

* Kyowa Kirin supplies commercial products in all territories.

KHK4083/AMG 451 - Collaboration with Amgen -

	US	Europe & Asia (ex. JP)	JP
Development	<ul style="list-style-type: none"> Amgen leads development Share development cost 	<ul style="list-style-type: none"> Amgen leads development Share development cost 	<ul style="list-style-type: none"> Kyowa Kirin leads development
Commercialization	<ul style="list-style-type: none"> Amgen commercializes and books sales Kyowa Kirin co-promotes and shares promotion cost 	<ul style="list-style-type: none"> Amgen commercializes and books sales Kyowa Kirin has opt-in rights for co-promotion 	<ul style="list-style-type: none"> Kyowa Kirin commercializes and books sales
Sales Royalties	<ul style="list-style-type: none"> Double-digit royalty to Kyowa Kirin 	<ul style="list-style-type: none"> Double-digit royalty to Kyowa Kirin 	
Commercial supply	<ul style="list-style-type: none"> Amgen supplies 	<ul style="list-style-type: none"> Amgen supplies 	<ul style="list-style-type: none"> Kyowa Kirin supplies

Amgen makes a \$400 million up-front payment (done) and future contingent milestone payments potentially worth up to an additional \$850 million, as well as royalty payments on future global sales, to Kyowa Kirin.

Main Development Pipeline Products: Future Plans

As of 2023, February 7th

T : Topline data

Code Generic Name	Target Disease		2022	2023	2024	+
KHK4083/ AMG 451 rocatinlimab	Atopic dermatitis	P3				IGNITE
		P3				HORIZON
		P3	"ROCKET PROGRAM"			SHUTTLE
		P3				ASTRO
		P3				ORBIT
KHK4951 tivozanib	Neovascular age-related macular degeneration	P1				
		P2				
ME-401 zandelisib	iB-NHL (mono, 3L+)	P2		T		MIRAGE
RTA 402 bardoxolone Methyl	Alport Syndorome	Filed				
	Diabetic kidney disease	P3		T		AYAME
	ADPKD	P3				FALCON
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis			MA	★	
KW-3357PE antithrombin gamma (genetical recombination)	Preeclampsia	P3				KOUNO-TORI

iB-NHL: indolent B-cell non-Hodgkin's lymphoma; MA: marketing application; ★: Anticipated timing of regulatory decision

Estimated Patient Numbers

Disease	Country/ Region	Incidence	Prevalence*	Reference
ATL	JP	1,150 / y		Survey and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report (Yamaguchi, 2010)
PTCL	JP		2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
CTCL	JP		2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
	US	1,500 / y		SEER Data (2001-2007)
XLH	JP	1:20,000	Adult: 5,000 Ped: 1,000	Estimate based on reported prevalence of 1 in 20,000 people; Nationwide survey of fibroblast growth factor 23 (FGF23)-related hypophosphatemic diseases in Japan: prevalence, biochemical data and treatment. (Endo I et al., Endocr J., 2015)
	EU	1:20,000	Adult: 12,000 Ped: 3,000	Estimate based on reported prevalence of 1 in 20,000 people
	US	1:20,000	Adult: 12,000 Ped: 3,000	Estimate based on reported prevalence of 1 in 20,000 people; New perspectives on the biology and treatment of X-linked hypophosphatemic rickets. (Carpenter TO, Pediatr Clin North Am., 1997)
TIO	JP		30	2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
	US		500-1,000	Survey by Ultragenyx Pharmaceutical
AD	JP, NA, EU		30,000,000	Study by Decision Resources
PD	JP		162,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
	US	60,000 / y	~1,000,000	Cited from Parkinson's Foundation https://www.parkinson.org/Understanding-Parkinsons/Statistics Accessed February 7, 2022.
FL	JP	6,750 / y		Cited from Cancer Registry and Statistics. Cancer Information Service, National Cancer Center, Japan (Ministry of Health, Labour and Welfare, National Cancer Registry) and Epidemiology of malignant lymphoma and recent progress in research on adult T-cell leukemia/lymphoma in Japan (Miyoshi H et al., Int J Hematol, 2018)
MZL	JP	1,060 / y		Cited from Cancer Registry and Statistics. Cancer Information Service, National Cancer Center, Japan (Ministry of Health, Labour and Welfare, National Cancer Registry) and Epidemiology of malignant lymphoma and recent progress in research on adult T-cell leukemia/lymphoma in Japan (Miyoshi H et al., Int J Hematol, 2018)
AS	JP		1,200	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/4348 Accessed February 7, 2022.
ADPKD	JP		31,000	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/295 Accessed February 7, 2022.
CKD	JP		13,300,000	Japanese Society of Nephrology, Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease (2012)
CKD (Dialysis)	JP	40,885 / y	344,640	The Japanese Society for Dialysis Therapy, An Overview of Regular Dialysis Treatment in Japan (As of 31 December 2019)
nAMD	US, JP		2,300,000	Study by Decision Resources
PE	JP		15,000	Estimate based on the Demographic Survey by the Ministry of Health, Labour and Welfare and the estimated incidence of this disease

*Prevalence represents the estimated patient number per the entire population of each country or region.

List of Acronyms

AD	Atopic Dermatitis
ADPKD	Autosomal Dominant Polycystic Kidney Disease
AG	Authorized Generic
AP, APAC	Asia-Pacific
AS	Alport Syndrome
ATL	Adult T-Cell Leukemia/Lymphoma
BS	Biosimilar
CKD	Chronic Kidney Disease
CLL	Chronic Lymphocytic Leukemia
DKD	Diabetic Kidney Disease
EMEA	Europe, the Middle East and Africa
FL	Follicular Lymphoma
iB-NHL	Indolent B-cell Non-Hodgkin Lymphoma
JP	Japan
LCM	Lifecycle Management
MZL	Marginal Zone Lymphoma
NA	North America
nAMD	neovascular Age-related Macular Degeneration
PD	Parkinson's Disease
PE	Preeclampsia
PTCL	Peripheral T-Cell Lymphoma
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia



Kyowa Kirin Co., Ltd.
Corporate Communications Dept., IR Group
+81-3-5205-7206 / ir@kyowakirin.com