



Kyowa Kirin Co., Ltd.

Results Presentation Fiscal 2022

February 8, 2023

Event Summary

[Event Name]	Results Presentation Fiscal 2022	
[Date]	February 8, 2023	
[Number of Speakers]	4	
	Masashi Miyamoto	Representative Director, President, and Chief Executive Officer
	Motohiko Kawaguchi	Managing Executive Officer, Director, Finance Department
	Yoshifumi Torii	Executive Officer, Vice President, Head of R&D Division
	Tomohiro Sudo	Executive Officer, Director, Global Product Strategy Department, Strategy Division

Presentation

Moderator: Welcome to a conference call to discuss the financial results of Kyowa Kirin Co., Ltd., for the fiscal year ending in December 2022, which were announced yesterday at 3:30 PM.

Please note the following prior to the start of the conference call. Please be advised that the names and company names of all participants in this conference call will be logged and kept for a certain period of time. Please also note that the content of this presentation will be available on our website as an on-demand video stream and transcript.


The information presented today contains forward-looking statements. Please note that there is uncertainty due to various risks.

Today's speakers are Dr. Masashi Miyamoto, President and Representative Director; Mr. Motohiko Kawaguchi, Managing Executive Officer, Director of Finance and Accounting Department; Dr. Yoshifumi Torii, Executive Officer, Head of R&D Division; and Mr. Tomohiro Sudo, Executive Officer, Director of Strategy Division and Global Product Strategy Department.

Today's conference call is scheduled for a maximum of 90 minutes. After the presentations by Mr. Miyamoto and Torii, we will move onto the question-and-answer session. Please download reference materials from our IR website.

Miyamoto: Good morning, everyone. This is Miyamoto. Thank you very much for joining us today.

The handouts for the meeting were published yesterday and I expect you had time to review the information. We would like to ensure that we spend enough time to answer questions, so I would like to keep my presentation as brief as possible.



Qualitative Review for FY2022

Provide pharmaceuticals for unmet medical needs <ul style="list-style-type: none">■ Maximize the value of G3B<ul style="list-style-type: none">✓ 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<ul style="list-style-type: none">✓ Moved forward with main development pipeline products and optimized allocation of management resourcesrocatinlimab: 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.	Address patient-centric healthcare needs <ul style="list-style-type: none">■ Patient Advocacy<ul style="list-style-type: none">✓ 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<ul style="list-style-type: none">✓ Exploration of initiatives to address patient needs related to XLH
Reinforce human resources and structures that support the creation of Life-changing value <ul style="list-style-type: none">■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others<ul style="list-style-type: none">✓ 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)	Retain the trust of society <ul style="list-style-type: none">■ Ensure stable supplies of high-quality pharmaceuticals<ul style="list-style-type: none">✓ 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<ul style="list-style-type: none">✓ 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)

© Kyowa Kirin Co., Ltd. *1: Last Patient Out, *2: Introduced TEPCO Energy Partner, Inc.'s Aqua Premium at Fuji Plant since January 2022

I would like to begin with the qualitative aspects of our progress in 2022.

On the top left, with regard to “Provide of drugs to meet unmet medical needs”, Crysvida has achieved sales of JPY127.1 billion in its first five years of sales. Preparations for the transfer of sales to North America are also steadily underway. Together with Poteligeo and Nourianz, Global Strategic Products continues its steady growth.

In terms of R&D, while progress was made in the development of KHK4083, KHK7791, and RTA402, the decision was made to discontinue the global development of KW-6356 and ME-401, which means that the allocation of management resources has been optimized. Various initiatives are underway for early-stage activities as well.

Moving to the right, we will discuss “address patient-centric needs”. We formulated the Kyowa Kirin Group Basic Policy on Access to Medicines last April as a part of our efforts to improve access to medicines. Various activities have been carried out. We are engaged in a variety of patient advocacy activities, collaborating globally to raise awareness of the disease and create opportunities for patients to interact with each other.

Then, in the lower right corner, in terms of “Retain the trust of society”, we have completed the implementation of the global quality management system in all regions. In addition, we have decided to construct a new API manufacturing facility and a warehouse at our Takasaki Plant, and we have completed construction of a facility that integrates quality assurance-related functions, which we call Q-TOWER.

In environmental preservation, we continue to reduce CO2 emissions by expanding the introduction of renewable energy. In addition, as part of our information disclosure based on TCFD recommendations, we have updated the report related to risk management. We introduced specific measures and a CO2 reduction roadmap at last year's ESG Meeting.

In the lower left-hand corner, please find “Reinforce human resources and structures that support the creation of Life-changing value.” In the last year, we have continued to work on each of these issues, including human resource development, organizational strength, and digital infrastructure. In particular, in human resource development, we have begun operating a global standardized grading and evaluation system and a global integrated talent management system as the basis for Group-wide efforts to identify and develop human resources.

With regard to digital transformation, we are steadily developing the infrastructure to connect and utilize data globally.

Quantitative Summary of FY22 Results

(Billion Yen / Rounded)

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

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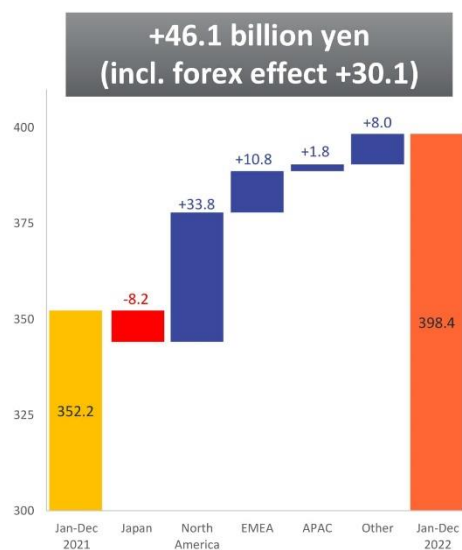
Let me now present the financial results of FY2022.

Revenue was JPY398.4 billion, an increase of JPY46.1 billion, or 13% over 2021; core operating profit was JPY86.7 billion, an increase of JPY21 billion, or 32%; and net profit was JPY53.6 billion, an increase of JPY1.2 billion, or 2%.

Compared to the revised forecast, revenue and gross profit did not reach a little, but SG&A and R&D expenses were lower than planned, resulting in a core operating profit achievement rate of 113%.

As for net profit, the achievement rate was 101%.

FY21 vs FY22 -Revenue-



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● Japan -8.2

Although Duvroq, Romipate, 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 Nouriaz (+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 Fasentra (Benralizumab).

Let me discuss this year-on-year comparison in more detail. Here is an analysis of YoY comparisons by region.

In Japan, Duvroq, Romipate, Crysvita, and G-Lasta are growing solidly, but sales are down 5% due to the impact of the two-time NHI price revision and declining sales of Patanol and Nesp AG.

In North America and EMEA, sales increased by 43% and 19%, respectively, due to continued growth in global strategic products and the impact of foreign exchange rates.

As for APAC, the decline in sales of Regpara in China was recovered by other countries and other products, resulting in a 6% gain.

As for the rest of the Company's business, deferred profit from KHK4083 and royalties from Fasentra increased, resulting in a 25% increase in revenues.

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%
Nouria	8.7	8.0	-0.6 (-7%)	Competitors' penetration	8.1	99%
Haruropi	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.

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These are major items in Japan.

Although Patanol was slightly weaker than the revised forecast, other products such as Duvroq and Romiplate covered the gap, and the revised forecast was achieved for Japan as a whole.

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.

These are major international items.

As mentioned earlier, Crysvita is on track of continuous growth and has landed about JPY2 billion above the revised forecast due to year-end demand as well as the previous year.

In addition, Poteligeo is growing steadily in both Europe and North America, although slightly below the revised forecast.

Overseas technical revenues are affected by the revised revenue deferral period for KHK4083 in Q3, as well as Fasenra's royalties, which have not reached the plan.

FY21 vs FY22 -Core OP-

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



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● 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.

This section discusses the analysis of changes in core operating profit.

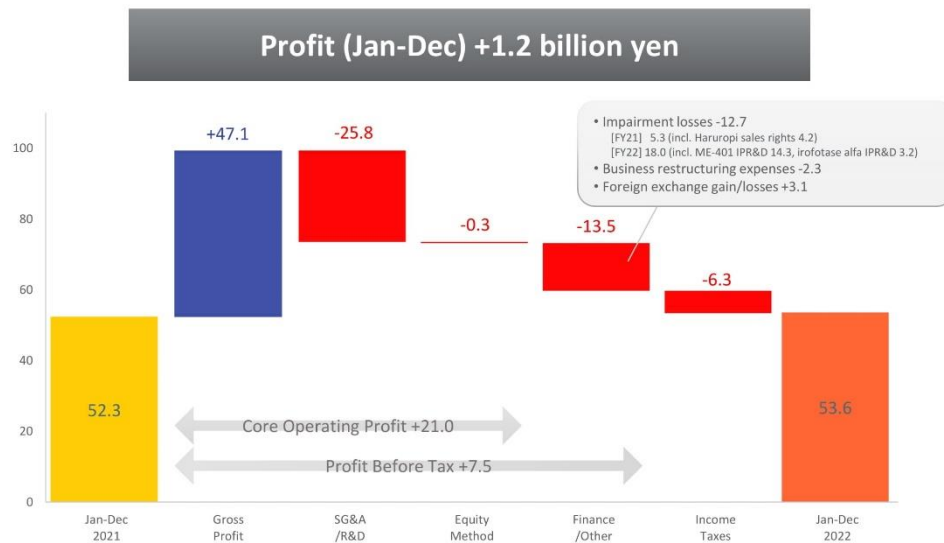
Gross profit increased by JPY47.1 billion. Gross margin improved by 3% to 78% due to an improved product mix, that is, an increased proportion of global strategic products and technology revenues.

SG&A expenses increased by JPY20.6 billion as a result of aggressive investment to maximize the value of global strategic products and to quickly establish a global business foundation. This includes JPY13 billion in foreign exchange impact but is mainly due to increases in personnel expenses resulting from hiring and profit-sharing expenses resulting from the growth of Crysvita in North America.

R&D expenses increased mainly due to higher development costs for KHK4083 and ME-401.

The equity method was essentially unchanged from the previous year, with growth in the FKB business offset by a decrease in the impact of tax effects that existed in the previous year.

FY21 vs FY22 -Profit-



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This is the portion below the core operating profit.

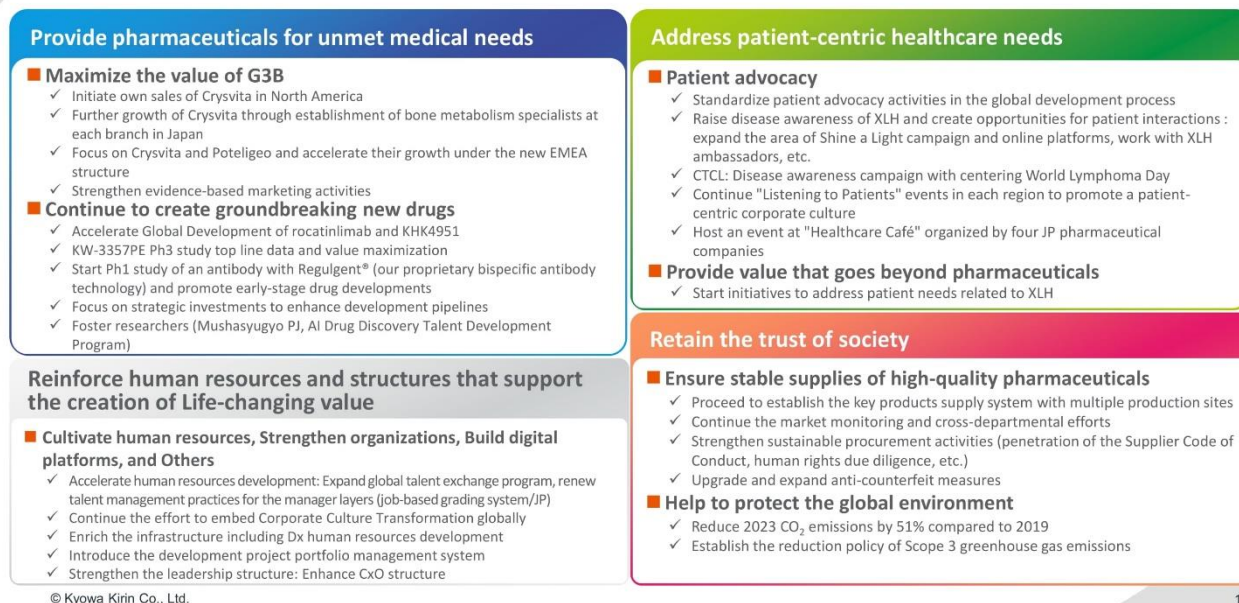
Financial and other activities were minus-JPY13.5 billion. As disclosed in December last year, we discontinued the global development of ME-401 and impaired JPY14.3 billion of related intangible assets in Q4, which means that the impairment loss increased by JPY12.7 billion from the previous year.

In addition, as announced in the November news release, we have decided to form a joint venture with Grünenthal of Germany for the established medicine business in the EMEA region. Advisory and other expenses related to this were recorded as business structure improvement expenses, resulting in a JPY2.3 billion decrease in profit.

As you know, the foreign exchange gains are due to the depreciation of the Japanese yen.

Tax expenses increased by JPY6.3 billion, all of which resulted in a JPY1.2 billion increase in net profit.

Qualitative Plans for 2023



I would like to reflect on the year 2023. It was a half-way year for the medium-term business plan, and we have formulated action plans and begun activities along the pillars of the strategy, taking into account changes in the environment and the progress made to date.

In order to "Provide pharmaceuticals for unmet medical needs," it is important to take over the sales activities of Crysvida in North America without delay. Specific activities for the handover have already begun and are well underway, and we will continue to do this well.

In addition, evidence for both products has been accumulating over the past five to six years since they were launched globally. We believe that making the best use of this evidence and our know-how will be an important initiative.

In R&D, we will accelerate the development of KHK4083 and KHK4951 and aim to initiate clinical studies with antibody drugs that incorporate our proprietary bispecific antibody technology, which we have named Regulgent. Furthermore, we intend to focus on strategic investments for growth.

In the area of "Address patient-centric healthcare needs," we will continue to support patients and patient advocacy groups to raise awareness of the diseases and create opportunities for patients to interact with each other. To "Provide value that goes beyond pharmaceuticals," in 2023 we plan to launch initiatives to address patient needs related to XLH.

In order to "Retain the trust of society," we will first aim for a stable supply and will promote initiatives to establish multiple production site system, market monitoring, and cross-departmental responses based on the results of these efforts.

In addition, we will work with various stakeholders to ensure sustainable business operations throughout the supply chain, including strengthening sustainable procurement and expanding counterfeit drug prevention measures.

On the environmental matters, we will continue our efforts to reduce CO₂ emissions and plan to formulate a Scope Three reduction policy for greenhouse gases.

In order to “Reinforce human resources and structures,” we will further advance our measures, which include, a group-wide human resource development, a global corporate culture fit for a Global Specialty Pharma, human resource and platform design that promotes digital transformation. We will also improve the CxO structure to fortify executive function, as announced yesterday.



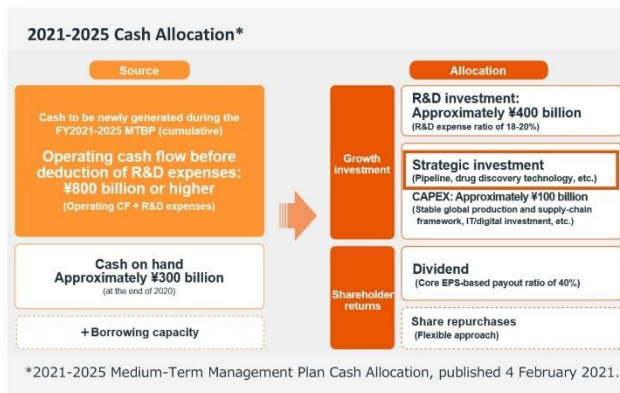
Strategic Investment ~For successful creation and delivery of life-changing value

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.



Here's our Strategic Investment Policy.

Our capital policy is to “Rapidly establish a competitive global business foundation as a Japan-based global specialty pharmaceutical company,, and place the priority on Growth Investment targeting sustainable growth beyond 2025 and maximizing corporate value.”

Among the “Growth Investments,” the expansion of our pipeline and the acquisition of drug discovery technologies through strategic investments are important management issues for us, and we have stated that we will focus on these in our 2023 management plan.

We will briefly discuss how we evaluate and discuss investment projects based on what strategies.

First, in terms of portfolio enhancement, we will place the highest priority on investment in a development pipeline that can obtain global licenses in areas that have synergies with Crysvida and Poteligeo, which are expanding their business globally. In addition, we aim to strengthen our portfolio by investing in areas of strength in each region.

In parallel with this, we will explore a wider range of earlier information and increase opportunities for early access, utilizing VC investments and CVC activities. By leveraging the connections we have obtained there, we aim to continuously create life-changing value over the medium to long term by also investing in science and technology that will create new strengths.

Discussions are based on this strategy, which aims to utilize cash reserves for growth investments to achieve sustainable growth and maximize corporate value.

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%	
Dividend Payout Ratio ¹	43.2%	38.9%	39.9%	

[FOREX]
FY2021-Actual JPY109/USD
FY2022-Actual JPY130/USD
FY2023-Plan JPY130/USD

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

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Let me now present our forecast for the new fiscal year.

Revenue is targeted to increase by JPY27.6 billion, or 7%, to JPY426 billion. In the medium-term business plan, we have set a KPI of a CAGR of 10% or more for the five-years starting from 2020, but the CAGR for three years until 2023 is expected to be 10.2%

Core operating income is targeted to increase by JPY1.3 billion, or 2%, to JPY88 billion, which is a slight increase compared to 2022, due to the upward landing of core operating profit in 2022 and a large increase in R&D expenses in 2023. I will discuss this point in a little more detail later in this section.

Net profit is targeted to increase by JPY22.4 billion, or 42%, to JPY76 billion. Since there was a large amount of impairment loss in the previous year, the Company plans to significantly increase profit, and is targeting an ROE of 9.7%, close to the medium-term business plan KPI of 10%.

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
Haruropi	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.

Japanese Items.

We expect continued sales growth this year for Duvroq, Orkedia, G-Lasta, Romiplate, Haruropi, and Crysvita as a result of further market penetration.

On the other hand, sales of long-term listed drugs and generics such as Nesp, Nesp-AG, Rituximab BS, and Allelock are expected to decline again this year due to the impact of the NHI price revision.

Last year, sales in Japan declined by approximately JPY8 billion, but this year we aim to limit the decline to JPY3 billion.

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.

International Items.

Crysvita aims to reach JPY138 billion by growing JPY19.8 billion, or 17%. Since the plan is JPY11.1 billion for Crysvita in Japan, we are aiming for JPY149.1 billion globally as a whole.

Poteligeo and Nourianz are targeting a 23% and 17% increase to JPY27.5 billion and JPY7.5 billion, respectively. These global strategic products will continue to drive top-line growth.

In terms of technology licensing revenues, we are aiming for an increase of JPY6 billion, including an increase in sales royalties from Fasenra and also Fotivda, which is sold by Aveo, and other licensing revenues.

As a result, we expect a total of JPY23.4 billion increase in revenues from overseas regions and JPY7.3 billion increase in other revenues, including technology revenues, and are targeting 7% growth in overall sales revenues, including those from Japan.

FY2022 vs FY2023 -Core OP-

+1.3 billion yen



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● 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 Crysvita-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 Crysvita (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.

Next, we will break down the changes in core operating profit.

While we are targeting 7% revenue growth, or JPY27.6 billion, gross profit growth is expected to be just over half of revenue, or JPY14.5 billion.

This is because the profit-sharing payment to Ultragenyx for Crysvita in North America, which was previously recorded in SG&A expenses, will switch to royalties and be recorded in cost of sales after the start of own commercialization on April 27. Gross margin is thus expected to deteriorate by about 2%.

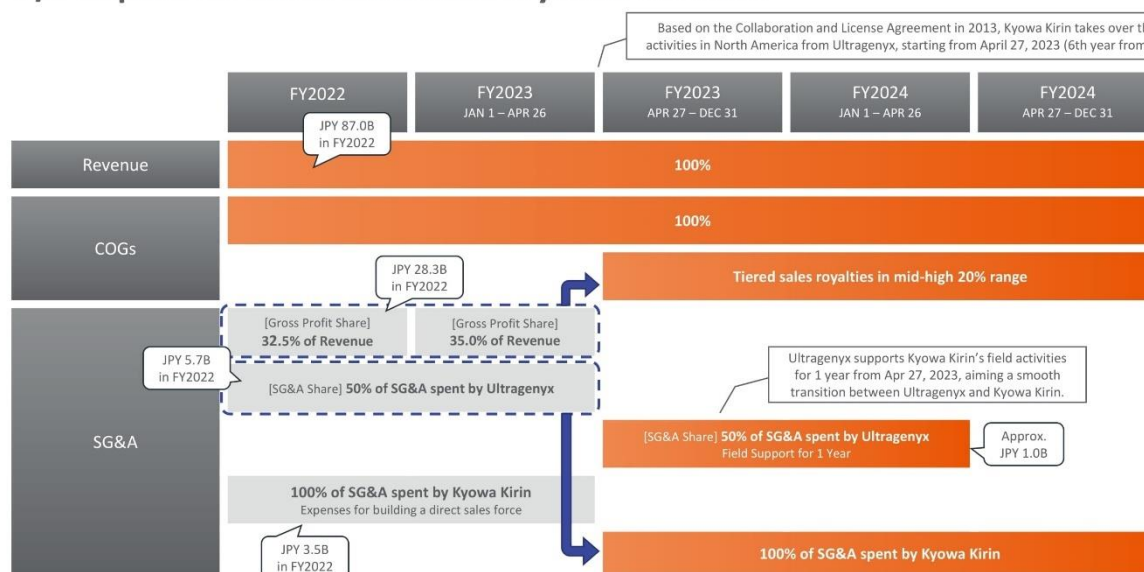
SG&A expenses are expected to decrease by JPY4.2 billion. There is a decrease due to the fact that profit-sharing payments, or more precisely, gross profit-sharing payments, will cease after April 27. On the other hand, sales expenses for Crysvita in North America, which have borne 50% up to now, will increase as the Company will bear 100% of these expenses beginning April 27.

In addition, we had been aggressively investing in human resources and IT last year, and the increase in personnel expenses, software amortization, and system running fees that arise from these investments during the period will take effect for the full year, which will be a factor in the increase in SG&A expenses. As a result, we expect an overall decrease in SG&A expenses of JPY4.2 billion.

As for R&D expenses, the Phase III program of KHK4083 will begin in earnest. In addition, manufacturing of investigational drugs is scheduled to begin in earnest for Phase II of KHK4951 and then for the bispecific antibodies to enter the clinical studies. As a result, R&D expenses are expected to increase significantly by JPY16.1 billion, or 26%. The equity method plans to see continued growth in the business of Hulio, Humira biosimilar, but a decrease in the tax effect is expected, and the equity method plans to see a decrease of JPY1.3 billion.

As a result of the above, core operating profit is expected to increase slightly from the previous year to JPY1.3 billion.

P/L Impact on North American Crysvita Business

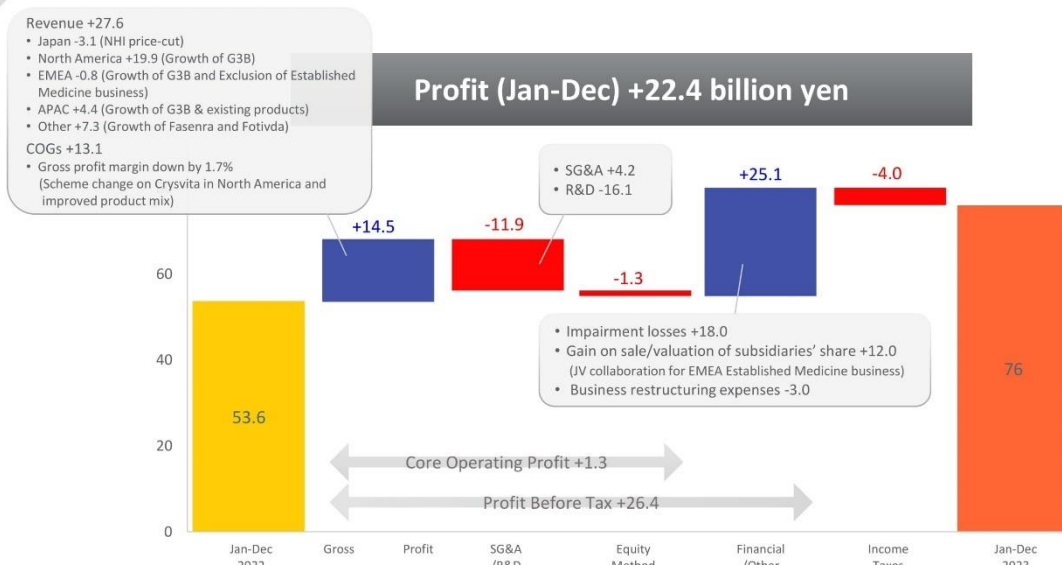


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This chart illustrates the change in the profit/loss impact related to the Crysvita business in North America. We hope that this list of 2022 results will help you understand the scale of each expense and the overall picture. As we have stated in the past, there will be no major change in profitability or the share between us and Ultragenyx before and after the start of the commercialization by Kyowa Kirin on April 27.

FY2022 vs FY2023 -Profit-



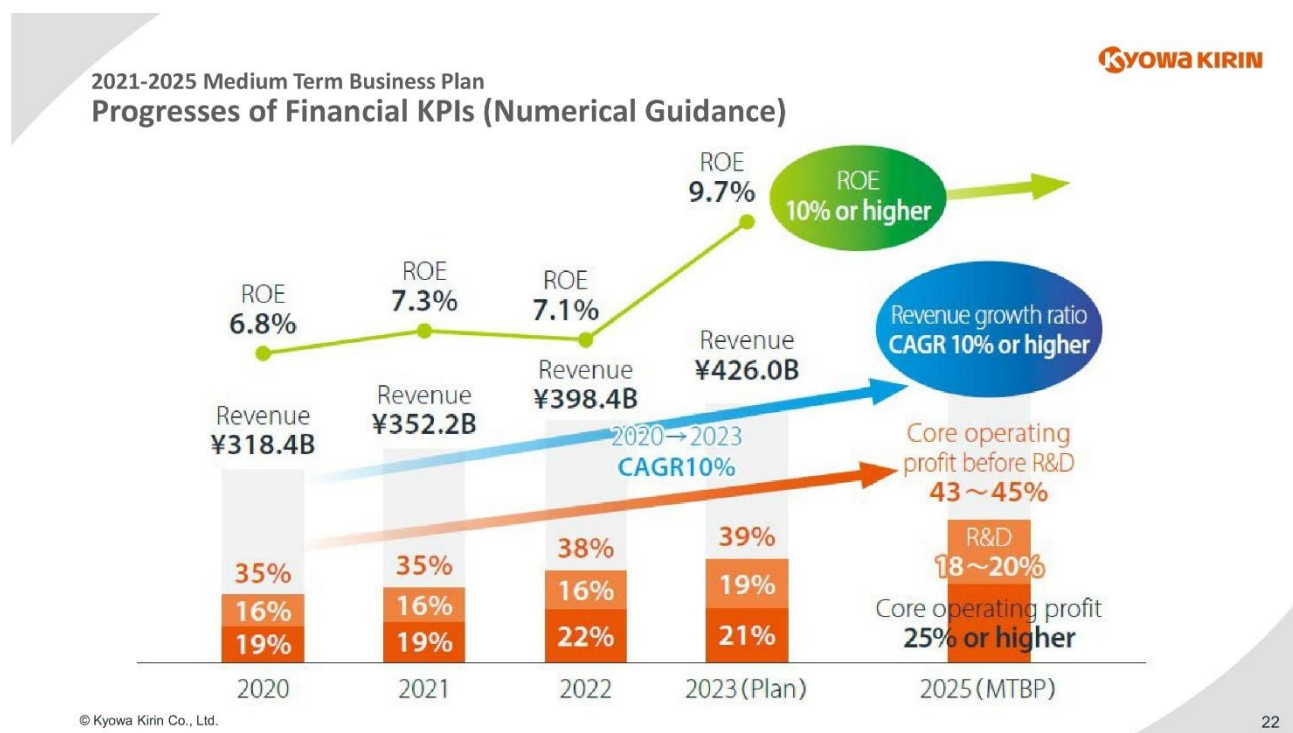
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Core operating profit is below. In 2023, we plan to improve at financial and other gain/losses by JPY25.1 billion. As for impairment losses, the elimination of JPY18 billion incurred in the previous year is a factor in the increase.

Then, we expect a gain of JPY12 billion on the sale and valuation of shares of subsidiaries related to the joint venture partnerships for the established medicine business. We also expect an increase of JPY3 billion in business restructuring expenses, which are likewise advisory expenses and setup expenses for the joint venture company for the established medicine business.

As a result, the net profit is expected to be JPY22.4 billion.



Progress on the Five-Year Medium-Term numerical guidance is presented here.

Sales revenue has fallen short of the plan in many respects due to the lack of approval of Istradefylline in Europe, the delayed of Poteligeo's geographical expansion, and the centralized purchasing of Regpara in China. However, with a boost from the weak Japanese yen, we plan to continue growing at our mid-term targeted CAGR of 10% until 2023.

On the other hand, the core operating margin is forecast to improve only by 2% to 21% in 2023. It is obvious at a glance that the factor that is putting pressure on profits is the increase in R&D expenses, but I think it is difficult to see that we are making good progress toward our goal of 25% or more. Therefore, we have added here the "Core operating profit before R&D." You will see that the profit margin, which was 35% in 2021, has been steadily improving each year.

Thus, profitability, which is the foundation before the investment of R&D expenses, is steadily growing every year. We plan to make a large R&D investment in KHK4083 beginning in 2023, with the R&D expense ratio increasing by 3% each year.

So, although it will be lower as a core operating margin, we hope to build a strong and lean business foundation and further improve profitability toward a core operating margin of 25% or more.

We look forward to your continued support.

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.

I would also like to briefly introduce shareholder returns.

The year-end dividend for 2022 is expected to be JPY27, up JPY3 from the previously announced forecast of JPY24, for a total annual dividend of JPY51, up JPY5.

For 2023, we plan to increase the annual dividend by JPY3 per share to JPY54 per share.

The guidance for the dividend payout ratio in the medium-term business plan is 40% with continuously increasing dividends, and we plan to achieve a three-year weighted average dividend payout ratio of 40.5%, calculated using the 2023 forecast.



2022 Review & 2023 Key Actions

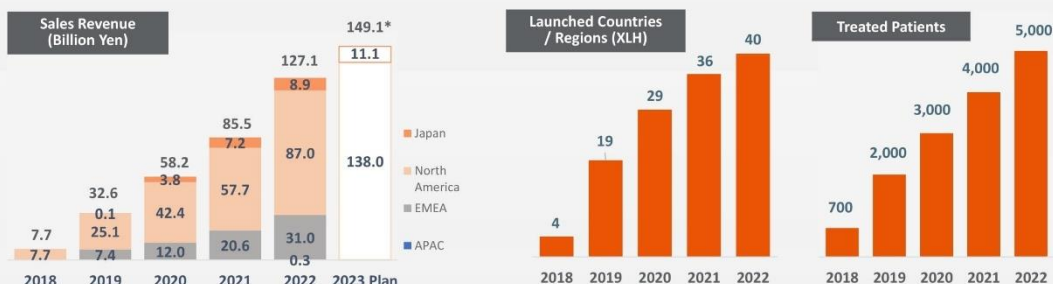


2022 Review

- 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.



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Next, I would like to introduce our global strategic products.

Crysvita.

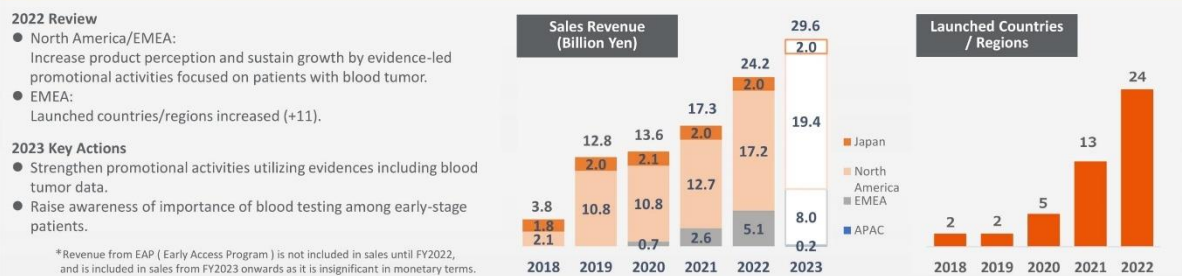
The graphs in the bottom rows show, respectively, changes for five-year period from 2018, the year of launch, in actual sales and 2023 sales forecast, the number of launched countries, and the number of patients.

As you can see, as of the end of 2022, both the number of launched countries and the number of patients is steadily increasing, and we believe that we are delivering the value of Crysvita to more and more patients. In Europe, we have also received approval for the TIO indication in 2022 and have begun marketing the product.

As a result, sales revenue for 2022 reached JPY127.1 billion. In the five years since the product was launched, it has become the first product by Kyowa Kirin to exceed JPY100 billion in sales.

This spring, as planned, we will start our own sales in North America. In order to ensure the completion of the transfer, we will continue to work closely with Ultragenyx, as we did last year, to establish the foundation of our own sales system as Kyowa Kirin and begin steady operations.

In addition, five years have passed since the start of sales, and we accumulated know-how and evidence through years of activities. In addition to steadily advancing measures in each region, we will intend to strengthen our marketing activities using this kind of know-how and evidence, and we expect to deliver the value of Crysvita to more patients, thereby lead to continued growth.



Poteligeo.

Poteligeo's sales revenue has also continued to grow throughout the five years period. In 2022, we focused on increasing product perception by promotional activities focused on patients with blood tumors.

In EMEA, the launch schedule had been delayed compared to the plan at the beginning of the year due to difficult insurance reimbursement negotiations, which were partly caused by the harsh environment of insurance financing in each country, but we were still able to launch in new 11 countries and regions.

In 2023, we will strengthen our promotional activities by devising ways to utilize evidences including blood tumor data. We will also continue to focus on promotional activities focused on patients with blood tumors, such as educating patients to perform blood tests in the early stages of their disease.

Nourianz.

Although sales revenue in 2022 deviated significantly from the growth line assumed when the medium-term business plan was formulated, we had focused on promotional activities in the North America that promote the drug's safety, ease of use, and distinctive mechanism of action, and had increased sales.

In 2023, we will continue to focus on activities to promote the usefulness of the drug's unique mechanism of action. And we will also work to strengthen the field level activity through further collaboration between Japan and the North America and effective use of digital, and plan to increase our total sales budget in Japan and the North America over the previous year.

These are the commercial updates we have provided.

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

Torii: Next, I would like to introduce the R&D Update from Torii of the R&D Division.

First, we will touch on some of the major news flows in the main development pipeline.

First, KHK4083 (rocatinlimab) resumed the Phase III Rocket Program for atopic dermatitis at the end of last year. Details will be presented in the next slide.

Next, regarding KHK4951 (tivozanib) ophthalmic solution, which is introduced for the first time at the earnings presentation, we completed the Phase I study for neovascular Age-related Macular Degeneration in August last year. Some of the results were presented at the R&D briefing last December. We are currently working diligently to prepare for the start of Phase II.

Then for ME-401, we released topline data from the domestic Phase II study in November last year in a press release. In addition, as we announced in a press release last December, we have decided to discontinue development outside of Japan.

Next, regarding RTA402, we completed its domestic Phase III study, the AYAME study, and we plan to report topline data in H1.

Finally, regarding KW-3357, which is also making its first appearance, we schedule to complete Phase III study currently underway in Japan for Preeclampsia, which we are calling stork study, and is scheduled to be completed in H2.



ROCATINLIMAB IN ECZEMA TRIALS

Rocatinlimab Phase 3 PROGRAM



- 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.

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

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*With a loading dose at Week 2, ** Topical corticosteroid/Topical calcineurin inhibitor

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Here is an overview of Phase III of KHK4083, the Rocket Program.

This is a Phase III trial program for moderate to severe atopic dermatitis consisting of six trials.

Several tests are shown on the slide. We set up this program for monotherapy or in combination with topical steroids or topical calcineurin inhibitors, with dosing frequencies of once every four weeks or once every eight weeks, with a loading dose for the second week only.

Overall, we are considering this schedule for the test.

In addition, we plan to further evaluate the safety and efficacy of long-term dosing in a separate study. We plan to submit an application for approval together with the results of an interim analysis of this long-term dosing data.

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 rocatinilimab	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-¥100Bn, ★★★★★: Over ¥100Bn

*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.

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This slide lists the current status of the major development pipeline.

Since the announcement of the medium-term business plan in 2021, there have been several development pipeline product replacements and changes in the development schedule. On the other hands, in addition to the progress of KHK4083 and KHK7791, new pipelines such as KHK4951 and KW-3357 have been added.

We will continue our efforts to create a pipeline that is expected to contribute to our future growth.

That's all from me.

Miyamoto: This is Miyamoto speaking. I have listed the news from the beginning of last year on page 33 and beyond. Please refer to it as necessary.

In addition, as Mr. Torii just discussed, however there are several situations that have arisen in 2022 that were not anticipated in the medium-term plan, the next development pipeline, such as KHK4951, is also emerging.

We will continue to strive for future growth while also continuing to maximize the value of our global strategic products.

That is all for today's explanation.

Question & Answer

Moderator [M]: Now, we would like to move on to the Q&A session.

Yamaguchi [Q]: This is Yamaguchi from Citigroup. Thank you for this opportunity. I have two questions.

The first is the change in gross margin due to direct sales of Crysvita. For the first four months it remains the same as the current, and then during the remaining eight months or so it will be new. This mix impacts the gross margin to shift.

The handout says that the gross margin or royalty will be a little over 20%, and this new royalty rate will start in May. Is it correct to assume that a flat rate is going to be applied? Or are there more steps involved that may impact royalty to further shift? Sorry, it is about the details. That is my first question.

Kawaguchi [A]: Thank you for your questions. This is Kawaguchi speaking and I would like to take this question.

The royalty rate is basically a tiered structure and it will be a mid to higher figure between 20% and 30%, however, we set multiple scaled rates that correspond to annual sales volume. It means that the lower rate starts around 25%, and as the sales increase, so does the rate.

In fact, since our sales have already grown considerably, we will actually start the current fiscal year with a royalty rate in the upper 20-30% range, and I hope you understand that there will not be a significant change in that rate in the future.

Yamaguchi [Q]: I understand. It will change, but it is already quite high.

Kawaguchi [A]: Correct.

Yamaguchi [Q]: Okay, thank you.

My second question is about KHK4951. As you discussed at last year's R&D meeting, I think the potential is quite high, if it indeed goes global. For your next steps, will you do global, Japan-U.S. development in Phase 2 and release the product once you have prospect? Or will you manage the research and development on your own?

Of course, it will depend on the data, but please let us know what your thoughts are on the approach in this new domain.

Miyamoto [A]: Thank you, Mr. Yamaguchi. We believe that this is a very important discussion. However, as you mentioned, I think that the first step will depend on what we find in the data, and we will decide what options we will take after analyzing the results of Phase I in detail, and we will monitor various feedback as we move into Phase II. We have a wide range of options to choose from.

Yamaguchi [Q]: But it doesn't seem to take a long time to develop, since it's ophthalmology.

Miyamoto [A]: Yes, I don't think this will be an examination that will take a long time to complete, so even if we consider various options, we think we should decide early and move in that direction.

Yamaguchi [Q]: Is it next year rather than this year if anything is going to happen?

Miyamoto [A]: I can't tell you exactly, but as I said before, we will be looking at the data.

Yamaguchi [M]: Thank you. That's all from me.

Miyamoto [M]: Thank you very much.

Kohtani [Q]: I'm Kohtani with Nomura Securities.

First, it might be a little too early to ask this, but what is your view of 2024? The guidance for this quarter is very good and the stock price is strong right now, but if we think about the next 24 years, one thing that could work in the negative direction is the biosimilar of G-Lasta. Of course, your company has BodyPod, so that will alleviate some of the problems, but it is hard to imagine that you would come out with no pain. Also, the transferred products in Europe has been gone. Maybe even the Nesp biosimilars and other things will decrease.

On the other hand, the positive aspect is that RTA402 will not be ready in time and will not contribute much. There is only tenapanol. It is hard to imagine that Poteligeo or anything else or Nourianz will grow much either. I am unsure how the royalties will play a part.

Please talk us through your scenario and your confidence in your ability to increase profits in 2024. Also if there is anything inaccurate in my statement, please feel free to point it out. That is my first question.

Miyamoto [A]: Thank you, Mr. Kohtani. This is Miyamoto.

As for 2024, we have only just started 2023 and detailed plans will be made in the future, so I am unable to give you details. However, let me just tell you how I feel as president. Of course, we are committed to making our products grow.

Those factors listed in your statement are spot on. Mr. Kohtani, your insight is impressive. Yes, we agree with your perspective. We believe that Crysvita and Poteligeo will continue to grow and that we can also expand in Japan, as well as in Asia by continuing to implement a variety of measures. We are going to start making plans for 2024.

As the President of the Company, I aim to grow the business and that is all I can say at this moment.

Kohtani [Q]: If you assess the situation closely and find that there is not much growth, do you plan to cut costs to secure an increase in profits?

Miyamoto [A]: As for costs, we will spend on research and development in terms of investment for the future. I mentioned this as we started the medium-term business plan. We have invested considerably this year and last year to establish the foundation of a global structure.

We will again spend a great deal this year but I think in 2024 we do not expect to make a big investment in new things. Rather than cutting back on what we have, I think it would be possible to reduce the rate of growth much more. I think we may extend in that way.

Kohtani [Q]: I understand.

The second question relates to the Phase III program of rocatinlimab. You started from the surface of the earth – Ignite, Horizon, Orbit, and Shuttle – and now you have finally reached the stars with ROCKET-Astro, where Q8W has come up. Six programs, one more to go. I thought this long term trial was nuanced to be once every 8 weeks for Adult/Adolescent, but I was expecting something more like once every 12 weeks, like ROCKET-galaxy. They are all the same, aren't they?

This may be difficult for you to discuss, but can you elaborate? To me it looks like it is going to end up like just an adult version of ROCKET-Astro, but what is your take?

Miyamoto [A]: Thank you very much. I will ask Torii to comment on this later.

It is very important to consider the market and appeal product strengths, so we are discussing this with Amgen in various ways. However, if we go beyond Galaxy, I think it would be easier to understand if we include, for example, not only atopic disease but also other indications such as an expansion of indications.

Torii [A]: This is Torii. We are working with Amgen on this, so I can't be too specific beyond what Mr. Miyamoto just mentioned. However, there is also the administration interval and the fact that this drug is quite effective for a long period of time, so we hope to demonstrate its superiority over competing products not only in terms of administration frequency but also in other areas. That's all from me.

Kohtani [Q]: You mentioned earlier that you are expanding the indications for the program, but the ROCKET program is completely atopic, so what about that decision, is there a possibility that other programs will be launched this year?

Miyamoto [A]: We are discussing various possibilities with Amgen right now, so we will be looking forward to including such things, and as I mentioned earlier, we are willing to invest in research and development. As for the possibility, sorry, I can't mention it now.

Kohtani [M]: Okay, thank you.

Hashiguchi [Q]: I'm Hashiguchi.

The first question is about the prospects for the development of rocatinlimab. How much data do you think is needed to submit an application for approval for the various studies you have described? Could you comment on this?

Also, on page 31, there is a range of approval schedules for 2026 and 2027. What do you think of the possibility of delay? Or is your aim pretty much set for the end of 2026 or the beginning of 2027?

Torii [A]: Hi this is Torii with Research and Development.

First, I would like to consider a critical path for approval. As I mentioned earlier, we are presenting five studies, and there are also long-term studies, so in general, the application will include an interim analysis of the long-term part. So, we are aware that these parts will be necessary for the application.

We have stated that the approval period will be 2026 to 2027, but since we believe that this is a beneficial drug for patients with atopic dermatitis, we are working to have it approved as early as possible, during the fiscal year 2026. That's all from me.

Hashiguchi [Q]: Thank you. Can you comment on the numbers, such as how long you are talking about for the long-term study and how long the interim analysis will take once the data has been accumulated?

Torii [A]: I am sorry, but I hope you understand that this is non-disclosed information since we are working together with Amgen in some areas.

Hashiguchi [Q]: Thank you. The second question I would like to ask is about the prospects of G-Lasta. How do you sum up the introduction of AG in Nesp in terms of progress so far? I think sales started up all at once and have been steadily declining ever since.

I know that Nesp has a variety of related products, so I don't think that its value can be simply expressed in terms of sales, but when do you see biosimilars coming out in G-Lasta, which you didn't deny in your earlier question? Based on the level of BodyPod penetration so far, what are your thoughts on the possibility of introducing AG?

Miyamoto [A]: Thank you, Mr. Hashiguchi. This is Miyamoto.

First, there are many ways to evaluate Nesp AG, but I think that it is fulfilling the role we considered when we launched the AG to a certain degree. Basically, there is an argument that we should give way to latecomers, and I think that is true, but it is very important to maintain the various data and parts that have been accumulated so far as a first mover. In particular, since biological medical products are difficult to use in some areas, I believe that we have achieved a certain level of positioning in terms of business performance and business performance while covering such areas.

I am very glad that we have been able to keep our AG out there. The supply of biological medical products has become more difficult in recent years, but I am proud that we have been able to continue supplying patients thanks to the fact that we have kept a good footprint. So, as far as NESP is concerned, I believe that AG is fulfilling a certain role exactly as it was originally intended.

Then, as for the BS of G-Lasta, it's probably around the end of this year, if you think about it normally. I think it would not be a surprise if they do, and I have heard that several companies are actually doing it, so I am wondering if it will happen.

I think there is a part of the market that can be maintained to a certain degree by offering body pods, but the market for G-Lasta is not entirely an outpatient market; it is also used by inpatients, so I think there is a certain amount of BS that comes in in those areas. I hope this answers your question.

Hashiguchi [Q]: What are the chances of introducing AG of G-Lasta?

Miyamoto [A]: This is not something we are considering at this time.

Hashiguchi [Q]: Can you comment on how much you expect the replacement of BodyPod to proceed this fiscal year?

Miyamoto [A]: We have that assumption for internal only, so we can't disclose it. I think it would be very beneficial for many outpatients, especially those with breast cancer, for example, who use it in the outpatient setting. I think it is a very beneficial product for both the patient and the hospital facility if the BodyPod is used as soon as possible for the patient's benefit. Therefore, from this perspective, we would like to replace them as swiftly as possible, and we are putting considerable effort into our sales efforts.

Hashiguchi [M]: Thank you.

Miyamoto [M]: Thank you very much.

Muraoka [Q]: My name is Muraoka from Morgan Stanley. Thank you for the opportunity.

I think you indicated Crysvita had very strong Q4 sales and demand but inventory volume does not tell the whole story. Could you give us different evidence to support your view, for example, the penetration rate has suddenly increased recently or that sort? And is the price increase being done in January?

Sudo [A]: Thank you. This is Sudo of Global Product Strategy speaking and I would like to answer the question.

First, the biggest reason for this Q4 sales hike is certainly the heightened demand for building up inventory, but in fact, sales are actually higher this time than expected.

My current view is that the market is still growing, and I am positive that its inventory has been increased in anticipation of this growth. Therefore, rather than building up inventory in a flat market, they must have built up inventory in a way that solidified their footing where the market was expanding, and I understand it that way because it was beyond my imagination.

The January price increase is actually a 3% increase, which I think has been partially announced, but it is out there. I think that was also the reason for the December sales increase. That is all from me.

Muraoka [Q]: Thank you. When you say that the market is expanding, did you mean that adult patients are responding favorably to your products quite recently? I'm referring to the North America market.

Sudo [A]: Mr. Muraoka, the data does not indicate any rapid changes. That said, we see a solid increase in the number of adult patients. Penetration is also increasing. The sales soared and it impacted Q4 results.

Muraoka [Q]: I understand. For adults and children alike, the market grew well around Q4.

Sudo [A]: Yes. So its inventory has been loaded up in anticipation of that.

Muraoka [Q]: Okay, thank you.

I understand the reason why you don't break down Crysvita's forecast by region. When I analyze the sales target for this quarter, it appears to grow by around 10% in US dollars. Based on what you shared just now I feel like the Q4 forecast can be stronger. Could you elaborate on that?

Sudo [A]: I would like to briefly touch on the market prospect.

As far as market assumptions are concerned, not much has actually changed. In other words, there is a reason that we looked at the number of patients and other factors slightly lower, but the figures for this landing in 2022 are considerably affected by the depreciation of the yen, and also, as mentioned earlier about price increases, we raised prices last year more than we did this year. And we have done it twice. Some of the price increases were mentioned earlier, but we raised prices last year and that was even higher than that of this year.

The difference is very noticeable, partly due to these effects and partly due to the higher-than-expected rise in the fourth quarter that you mentioned in your question. However, when we look at the growth over the past few years on a pay-as-you-go basis, etc., we do not understand that this is a significant decline. Rather, we understand that it is just one of the processes that will allow us to successfully expand the market over the next three, five, and seven years.

In summary, we didn't lower our expectations for any particular reason.

Kawaguchi [A]: This is Kawaguchi speaking. I would like to follow up on the financial figures.

While the growth of Crysvita overseas between 2021 and 2022 was JPY39.9 billion, this year, 2023, it is JPY20 billion, and the increase appears to have decreased by about half. However, as you understand, the increase in 2022 was affected by the exchange rate, which we roughly estimate at about JPY16 billion, and excluding the exchange rate, we estimate that the increase was about JPY24 billion.

In contrast, the 2023 figure was JPY20 billion, a slight decline in monetary terms due to the effects of the inventory buildup I mentioned earlier, but basically, the trend has not changed significantly.

Muraoka [M]: I understand. That's all. Thank you.

Wakao: This is Wakao from JP Morgan.

I would also like to know about Crysvita plans for this year. The trend has not changed much, and the number of patients has increased by about 1,000 each year so far, but is it correct to imagine that the number of patients treated this year will increase by about 1,000, although this may be a figure for Europe and North America?

I am wondering if the plan you made is rather organic based on the trend up to last year. On the other hand, I guess there might be some factors that would cause a slight upturn in growth this fiscal year.

As for North America, I believe that Ultragenyx have joined your salesforce for support. In addition, I believe that last year was partially a steppingstone due to COVID-19. As for Europe, I thought that the number of patients might rather trend up as the indication for adults becomes more widespread. What is your company's view on this area?

Sudo [A]: Thank you for your question, Mr. Wakao.

First, in terms of the number of patients, as you can see, the number of patients is increasing by 1,000 each year. I cannot give you specific numbers, but I can say that we are aiming to enlist more than 1,000 patients, as Mr. Wakao assumed. This is one thing.

And, as you mentioned, there is also the influence of COVID-19 last year. Especially H1. We had a pretty tough start. As for this year, I am thinking about that as well, with the hope that the current numbers could be higher if we exclude the effects of those areas for sure.

However, I feel that the market as a whole has run its course and that most of the patients who should be treated first have been treated. There is still a market, but we need to be creative in the future and, as Dr. Miyamoto mentioned, we need to make efforts to increase the number of patients by creating a solid body of evidence and delivering it to them. I would like to expand the market with sales and MSL activities, which is one step up. Did that answer your question?

Wakao [Q]: Thank you very much. What about Europe?

Sudo [A]: Regarding Europe, we actually saw a big stock sale of drugs in December in relation to our partner. Because of the impact, for 2023 plans, some areas may look slightly lower, but like in North America, we are seeing strong growth in the number of patients, and we want to do well.

By the way, one thing I would like to mention is that European adults have not yet been launched in Italy, Spain, and UK, although we have received approval. In this sense, the penetration of the adult population is very low in Europe as a whole. Roughly speaking, it is about one-fifth of that in North America. We are hopeful that improvements in these areas will have a significant impact on earnings in 2023, 2024, and 2025.

Wakao [Q]: Understood. Second, I would like to talk about the strategic investment that you have shown us with your slides. I have a good understanding of your company's targets and how you are currently working on this, but I would like to know when this will happen and if you have any updates from that perspective.

Why, after all, while some things are going well, others are changing the outlook. In the mid- to long-term, we have KHK4083, but the patent for Crysvita will expire in 2032, so considering the long development period of the drug, I think it is necessary to proactively incorporate assets even at this point. I know this part is difficult because you need to agree with partners, but is there anything you can comment on in terms of the certainty of realizing strategic investments? That's all from me.

Miyamoto[A]: Thank you very much. This is Miyamoto.

You are absolutely right, and we believe this is one of the biggest issues we will face this year. Since the global development of KW-6356 and ME-401 was discontinued last year, the thinness of the late-stage development pipeline from a global perspective is a big challenge. We would like to include as much late-stage or near-late-stage pipeline as possible in the areas shown on the slide on page 14, if possible.

But, as you know, the closer you get to the later stages of the project, the higher the price will be, and the more competition there will be, which means that it will be a very difficult project. However, we are working very hard to intensify our efforts, and we really hope to do something about it this year. I am sorry but I am unable to comment as this involves third parties and I can only say that we are doing our best.

Wakao [M]: I understand the situation. Thank you for this opportunity. I'm hoping for the best.

Miyamoto [M]: Thank you very much.

Ueda [Q]: I'm Ueda from Goldman Sachs Japan.

First, I would like to ask you about trends in R&D expenditures. Regarding the reasons for the downward swing in 2022, I wonder if the interruption of Phase III of KHK4083 and other factors had an impact, and what will be the increase in this fiscal year, which is the opposite of what we saw in the previous fiscal year.

Also, should we expect that from next year onward, progress will be in line with sales trends, in line with the medium-term target of 18% to 20% of sales? Could you please discuss how you see the past, the current period, and the next period and beyond?

Kawaguchi [A]: Thank you for your question. This is Kawaguchi and I'm happy to answer you.

For 2022, our initial plan at the beginning of the year was to use up 18%. However, as mentioned earlier, the development of KW-6356 was cancelled, resulting in a large unspent. Unfortunately, this has had the greatest impact. The next agenda is a temporary suspension of KHK4083 in Phase III, again below the planned multi-billion development cost.

Finally, even where the global development of ME-401 was discontinued, the R&D expenses incurred after the decision have been transferred to other expenses, deeming as they are not R&D expenses. That portion also appears to be an underspent for when viewed in terms of R&D expenses themselves. These three changes in plans are the main reasons for the drop to 16%.

Regarding our plans for the coming years, the first and biggest is the Rocket program for KHK4083, which we will spend much for that. The other is KHK4951, which is about to enter Phase II, or a bispecific antibody that

we are aiming to bring into clinical study phase. We plan to invest in the manufacturing of investigational drugs well in advance of that, so these two points are the major points of increase for this fiscal year.

We will continue to invest in R&D for KHK4083 aiming for a range between 18% and 20% in line with the medium-term business goals, starting 2024 or 2025.

The other point is that, as Dr. Miyamoto mentioned, when we carry out strategic investments, there may be a burden of new development costs associated with these investments, especially if we introduce a late-stage pipeline, and there may be expenditures there as well. In some cases, it may be possible to exceed 20% as a future growth, depending on whether the pipeline can be introduced.

Ueda [Q]: I understand, thank you. The second question is about the progress in the development of bispecific antibodies, which you mentioned a little earlier. You discussed that you will be entering clinical phase this year. What is the timing of Phase I entry and, if possible, in what therapeutic areas?

Also, what is the pace of entry into clinical trials, for example, how many products per year? Please share with us any information you have on this.

Miyamoto [A]: Thank you, Mr. Ueda. This is Miyamoto.

We probably can't answer most of your questions, but as the President of the Company, I would like to see we enter Phase I as soon as possible, and since it is an interesting platform technology, I am also putting pressure on Dr. Torii to create several pipelines from that. I think it would be better to get a comment from Dr. Torii.

Torii [A]: The two projects we are planning this year are basically in the area of oncology. Also, Regulgent antibody technology is actually being researched in other formats now, so we are eagerly studying advanced bispecific antibody technology, not limited to this Regulgent. We are in a situation where we expect to see more and more pipelines coming out of there. That's all from me.

Ueda [M]: I understand. Thank you very much. That's all from me.

Sakai: I am Sakai from Credit Suisse Securities in Japan.

This may be a deviation from the topic of business performance, but with the establishment of the joint venture by Kyowa Kirin International and Grünenthal, what do you think of your management resources or assets in Europe? I would like to ask for your assessment, or rather confirmation, how your company is considering the allocation of assets and resources in international markets other than North America.

The other thing, I think there was an announcement about the change of president of FKB. I think there has been little interest in this FKB for a while, or rather, not much attention, but can this joint venture clearly be considered an asset for your company now? Since you have not disclosed the contents at all, we can only watch from the sideline. Each year, we tend to be limited to something like, "how much is the gain in equity method?" What are your plans for management resources, including this reorganization or recombination in Europe, during the medium-term plan and beyond?

Miyamoto[A]: Thank you very much.

First, about Europe, as you know, one business is for global products, which are rare-disease type, including Crysvita and Poteligeo. And another is with rather a little bit older "established" medications with some newer medications, which had been possessed by ProStrakan and Archimedes, which we acquired in the past. So,

this is a quite different activity. Therefore, we had originally developed our business in two slightly separate ways.

For the established medicine business, it is quite difficult for us to keep investing such as introducing pipeline from outside. I think it is also a very important perspective to make this business more sustainable, as we are selling very important medicines.

From this perspective, we chose Grünenthal as the best partner for the joint venture, and with help from Grünenthal, we have set a course to ensure that our business is also sustainable or, if possible, growing. As for Kyowa Kirin, we would like to consider Europe in the direction of two products that we call global strategic products, and, if possible, as mentioned earlier, something from other companies to be included in the lineup.

FKB is also a joint venture with Fujifilm Corporation, so I am sorry there is limited information that can be disclosed without agreement between the two companies.

I also think this is a very important asset from the viewpoint that we achieved to show our ability to manufacture biological products properly. However, we do not think it is our direction to make a very large investment and expand the biosimilar business here in the future.

Of course, we have to discuss this with Fujifilm, so it is not a decision that we can make on our own. However, we would like to invest in facilities for new drug development, rather than invest heavily in the BS business, for example, in facilities for BS production. Of course, to a certain extent, we will be considering many things in our discussions with Fujifilm.

Sorry, I'm rambling, but I hope I've answered your question.

Sakai [Q]: I understand that you will consider a lot of things over time. Could you provide a quick confirmation about the Rocket program? Steroids at the combination, I know this. But, Calcineurin, this is a name I haven't seen in a while, is it correct to say that this is used as a concomitant drug, and in a manner of speaking, this is considered the standard therapy and was brought into the concomitant use?

Torii [A]: That is correct. One thing I would like to add is that the Phase II results showed that it takes a little more time for the drug to show efficacy than Dupixent and other drugs, so in order to accelerate the onset of efficacy, this kind of combination is also meaningful in a real clinical setting, and we are incorporating this kind of studies in the program. That's all from me.

Sakai [Q]: Do you hope for approval with monotherapy if possible? Are there some topical drugs that you still want to refrain from using?

Torii [A]: I think there will be many uses for this product once it is approved, so we are planning to have a certain degree of flexibility in the clinical trial, although it is within the constraints of the clinical trial.

Sakai [M]: I understand. Thank you very much.

Miura [Q]: My name is Miura from Jefferies Securities. I have two questions as well.

First, on the first point, in KHK4951 wet AMD, the details of the results of this Phase I, you are talking about publishing document, but when and what kind of paper is it likely to be published? Or, since there are conferences such as ARVO in April, is there any possibility of any comments being made at such conferences? This is my first question please.

Miyamoto [A]: Thank you for your questions. We are currently working on this, including detailed analysis of the data, so we have not yet reached a concrete schedule, but we hope to disclose it at an early stage.

Miura [Q]: Okay, thank you. The second point, which overlaps with Mr. Wakao's question, is the strategic investment part. In particular, I feel that there are many investments, including ME-401 and RTA402, where there is a large discrepancy between the original assumptions and the current situation when they were first introduced.

On the other hand, in terms of your in-house developed products, Crysvita and KHK4083 are excellent products, and KHK4951 may be the same in the future. You are able to develop great products in-house, but when you introduce them from outside, it appears that you are not able to do so.

What are you planning to do in the future to increase the certainty of the introduced products? Of course, there are some aspects that you probably can't say for sure since you are working with a partner, but what do you think you can do and achieve to introduce something better?

Miyamoto[A]: Thank you Mr. Miura. You made some good points.

We had a lot of things going on, especially ME-401 and ilofotase alfa stopped in the middle of Phase III. I am sure you are right, and I have been reflecting on some of the things that have not been going so well with the introduction of the pipelines recently. This is a very difficult issue, and I think it all comes down to how to make sure that the evaluations are done properly before they are included.

We have now been establishing the foundation for our activities on a global scale. Up to now, our investment evaluation activities have been conducted mainly by the Japanese members; however, I now work with various people with a wider range of global experiences in the international arena, so we will continue to engage in in-depth discussions with these people. I would like to have more opportunities to discuss with our global members when we introduce a global pipeline. I am still not sure if that will really improve the accuracy of the results, but since we are talking about spending quite of money in that area, I think this is an issue that really needs to be taken seriously.

Miura [Q]: Thank you, I am looking forward to it. By the way, do you have any qualitative goals, such as how many items you would like to introduce by the end of this year?

Miyamoto [A]: I have internal plans, but these are undisclosed. Since they relate to our finances. Mr. Kawaguchi on my side is making a sour face. It is quite hard to release these plans but I can assure you that we have targets.

Miura [M]: Okay, thank you. That's all from me.

Akahane: My name is Miura from Akahane, Tokai Tokyo Research Center. Thank you very much. My question includes one for actuals and another for predictions.

First, the excellent financial results, the profits were up significantly, and on page 22, the core operating profit before R&D, I could see very clearly that it has improved very much and that it is progressing toward the plan.

Looking at that in the segment on page 7, there was certainly some support from foreign exchange, but I think North America and EMEA were very strong and good last fiscal year. I see that the sales composition ratio of North America and EMEA is up about 7 percentage points. As I read this, I think the profits of both North America and EMEA can be explained almost entirely by Crysvita and Poteligeo; I have the image that the profit contribution from EMEA and North America has increased. Is this incorrect?

Kawaguchi [A]: You are right. I think this is the main reason for the 3% improvement in gross profit margin that I discussed in the section on gross profit margin improvement.

Akahane [Q]: Last year's sales in China were affected by VBP. There was a lot of talk about China at other companies, some using Corona as the reason and others using Buy China as the reason. Should we assume that the environment is quite bad for your company as well? Is it better to view it as a transient situation, just a bad situation that happened to be affected by VBP this time?

Miyamoto [A]: Thank you, Mr. Akahane. This is Miyamoto.

As you know, regulations in China are changing at a tremendous pace, and I think one major point is that it is extremely difficult to predict. Before we can say whether the environment is good or bad, we need to know how well we can make predictions when doing business, and only when we can make predictions can we make investments. However, as you know, it is a very populous country and the economy as a whole is still growing, so the potential is definitely there.

But again, our Regpara is also subject to VBP earlier than we expected, and the insurance system changes like a chameleon, so there is no doubt that this is a very difficult country.

Akahane [Q]: I understand very well. Lastly, on the forecast, as you explained earlier, the increase in Crysvita sales will be reduced by half, but in terms of comparison excluding the impact of foreign exchange, is it correct to assume that the current fiscal year will be so-so, and that North America and EMEA will continue on the same trend as last fiscal year?

Miyamoto [A]: I think you understand.

Akahane [M]: I understood very well. Thank you for your answers.

Yamaguchi [Q]: This is Yamaguchi from Citigroup. This is the second time, but may I briefly confirm two things?

RTA402 has been successfully Last Patient Out, so you have no doubts about the topline coming out in the first half of this quarter, but I have received inquiries from all over the world, and Let me check if there is really no problem. Does that summarize your current situation?

Torii [A]: Hi this is Torii with Research and Development.

As you mentioned, H1, or rather Q2, we will be releasing data from the AYAME trial, which will involve 1,000 cases. This is not just a surrogate marker, but the hard endpoints will be important, so there is a considerable impact here. We are still working double-blind, so there is nothing to say at this stage, but looking at the data from Phase II and other Phases so far, we are waiting for the top line to emerge with considerable anticipation.

Yamaguchi [Q]: Since you mentioned Q2, is it correct that it is between four to six, since it is February?

Torii [A]: Yes, this will be Q2.

Yamaguchi [Q]: Okay, thank you. This is also a review of the previous term, but I remember that at the beginning of the term, you started out with JPY5 billion for direct sales in North America, and that ended up being a little down in the middle of the term. How much did you end up spending and is there any portion of it that will carry over to the current fiscal year or not? Please tell us about it.

Kawaguchi [A]: Thank you for your questions. The actual numbers are shown at the bottom of page 19. For 2022, the forecast was JPY5 billion, but we actually made JPY3.5 billion. However, since there is a foreign exchange effect here, the actual amount unaccounted for, including foreign exchange, is about 2 billion yen.

Yamaguchi [Q]: Are there any more left in this quarter?

Kawaguchi [A]: As the gray line continues in the current fiscal year, we will incur expenses up to the point where we own 100% of the company. Regarding expenses, we expect to gradually shift to an in-house sales structure starting in April. Our current cost burden is 5.7 billion yen, but this will double in 2023, when the burden will become 100%, including preparation costs. I hope this gives you a general idea of the increase in expenses.

Miyamoto [A]: Mr. Yamaguchi, this is Miyamoto. A significant portion of the unspent funds is related to the hiring of personnel, so the entire JPY2 billion that was not spent last year will have to be spent this year, and it is not a matter of taking the entire JPY2 billion and using it as extra.

Yamaguchi [M]: I understand. Thank you, that is all.

Kohtani [Q]: I'm Kohtani with Nomura Securities. I have two questions.

My first question is about bardoxolone methyl. In the end, I think the FDA was very paranoid and suspected hyperfiltration because the mechanism was not clearly understood.

Since this is Japan, the situation is completely different. What I would like to ask is whether the Japanese authorities and doctors will be satisfied when this bardoxolone methyl is shown to be effective in terms of the hard endpoint of eGFR. The mechanism is not well understood, but eGFR is improving, and moreover, during Phase II of your Tsubaki trial, the effect was properly obtained on the really hard endpoint, GFR.

I am not sure if everyone is convinced that the eGFR is improved, which equals that this is useful, and that renal function is improved. I would like to ask you about that point.

Miyamoto [A]: Thank you, Mr. Kohtani. This is Miyamoto.

That is where the data actually comes in, and unless we talk about this with the authorities, of course, we will never know the final point. However, when we started the trial, we discussed with the PMDA that eGFR is a surrogate marker, and the guidelines from academic societies are the basis. The guidelines also state that a 40% or 30% drop in eGFR is one marker we can use.

If you look at it that way, if the eGFR is not obviously worse, this is one big achiever. Do doctors actually use inulin to evaluate the actual GFR every time they put a patient on dialysis, or do they absolutely look at the eGFR? So you look at it in terms of other clinical symptoms. Therefore, we believe that it is a stretch to say that eGFR is not a single marker.

I am sure that the doctors will definitely support this, as we have discussed, but how the PMDA will decide will also be influenced by the FDA, of course, so I think we will have to actually see the data and discuss that.

Mr. Torii, would you like to add something?

Torii [A]: In addition to eGFR, the AYAME study will also compare patients who actually went on to dialysis, and this part of the study will also be compared to a placebo. As for the primary endpoint, we are actually doing a composite that combines the transition to dialysis and the change in eGFR, but we will have data on

those actual events as well. We would like to negotiate with PMDA from now on, together with such data. That's all from me.

Kohtani [Q]: I think it is probably very important to have your opinion on what is struggling, but as far as the paper is concerned, I think it is probably quite positive. Is it my understanding that doctors in the renal field have a positive view in Japan, so far?

Torii [A]: We have had a number of Japanese KOL doctors participate in the development of this RTA402, and as you are aware, they have a positive view of this drug. That's all from me.

Kohtani [Q]: I understand. This is the second and last question. I will not ask what Regulgent is, since it is not disclosed, but I would like you to give me a hint. Until now, bispecific antibodies in the field of oncology have actually been a one-shot deal. In the end, most of them capture CD3 and T cells and allow them to attach and attack cancer cells, with only a few others. Also, a company called Regeneron is doing something like costimulatory bispecific for CD28.

I would like to ask, your company is not going to do such an uninspiring thing as to follow suit and do CD3, is it? What I want to say is, can we expect it to be a new class of bispecific antibodies?

Torii [A]: I can't give you specifics on this either, but I am aiming for a place other than the one you just mentioned.

Kohtani [M]: I am very relieved. Thank you for this opportunity.

Moderator [M]: Thank you very much. This concludes the conference call for the financial results for Q2 of the fiscal year ending December 2022.