



## **Kyowa Kirin Co., Ltd.**

Q3 Financial Results Briefing for the Fiscal Year Ending December 2023

November 1, 2023



# Event Summary

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[Company Name]	Kyowa Kirin Co., Ltd.	
[Event Name]	Q3 Financial Results Briefing for the Fiscal Year Ending December 2023	
[Date]	November 1, 2023	
[Number of Speakers]	4	
	Motohiko Kawaguchi	Managing Executive Officer, CFO Head of Finance
	Yasuo Fujii	Managing Executive Officer, CSO Head of Strategy
	Yoshifumi Torii	Executive Officer, Head of R&D
	Tomohiro Sudo	Executive Officer, Head of Global Product Strategy



# Presentation

**Moderator:** We will now hold a conference call regarding the financial results for the fiscal year ending December 31, 2023, of Kyowa Kirin Co., Ltd. which were announced at 15:30 today.

Please note the following prior to the start of the briefing. Please be advised that we will keep the names and company names of all participants today for a certain period of time as a list of participants.


Please also note that the content of this presentation will be available on our website as an on-demand audio stream and transcript. We would appreciate your understanding in this regard before making any comments.

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

Today's speakers and questioners are Motohiko Kawaguchi, Managing Executive Officer, CFO Head of Finance; Yasuo Fujii, Managing Executive Officer, CSO Head of Strategy; Yoshifumi Torii, Executive Officer, Head of R&D ; and Tomohiro Sudo, Executive Officer, Head of Global Product Strategy.

Today's conference call is scheduled up to 60 minutes. After explaining the overall financial results we take questions from the audience. Please download the documents from our IR website.

## Summary of Q3 Results



( Billion Yen / Rounded )

	2022Q3 Results	2023Q3 Results	Changes	2023 Revised Plans	Progresses
Revenue <i>[Overseas Ratio]</i>	283.8 <i>[61%]</i>	306.1 <i>[64%]</i>	+22.3 (+8%)	426.0 <i>[64%]</i>	72%
Gross Profit <i>[Gross Profit Margin]</i>	219.6 <i>[77%]</i>	229.1 <i>[75%]</i>	+9.4 (+4%)	326.0 <i>[77%]</i>	70%
SG&A <i>[SG&amp;A Ratio]</i>	117.3 <i>[41%]</i>	119.3 <i>[39%]</i>	+2.0 (+2%)	162.0 <i>[38%]</i>	74%
R&D <i>[R&amp;D Ratio]</i>	44.1 <i>[16%]</i>	51.2 <i>[17%]</i>	+7.0 (+16%)	79.0 <i>[19%]</i>	65%
Gain/Loss on Equity Method	2.6	2.3	-0.4 (-14%)	3.0	76%
Core Operating Profit <i>[Core OP Margin]</i>	60.9 <i>[21%]</i>	60.9 <i>[20%]</i>	+0.0 (+0%)	88.0 <i>[21%]</i>	69%
Profit	49.2	53.6	4.3 (+9%)	76.0→70.0	77%

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**Kawaguchi:** I will now explain the results for Q3. Please see page five of the slides.

Compared to the same period last year, revenue increased JPY22.3 billion or 8%, core operating profit was JPY60.9 billion, the same level as the same period last year, and profit increased JPY4.3 billion or 9%.

Core operating profit was at the same level as the same period of the previous year due to an increase in R&D expenses accompanying progress in the development of KHK4083, etc., while gross profit increased due to an increase in sales revenue.



The main reason for the increase in profit was a gain of JPY14.8 billion from the sale of 51% of the shares of a subsidiary and a gain from the valuation of the remaining 49% of the shares, following the start of a joint venture with Grünenthal in the European established pharmaceutical business in August, despite impairment losses associated with the discontinued development of RTA 402.

As for the percentage of progress toward the full-year forecast revised in Q1, first of all, 72% progress has been made in terms of sales revenue. Global strategic products, centered on Crysvita, continue to grow, and this is in line with our plan, as they tend to grow steadily in H2 of every fiscal year.

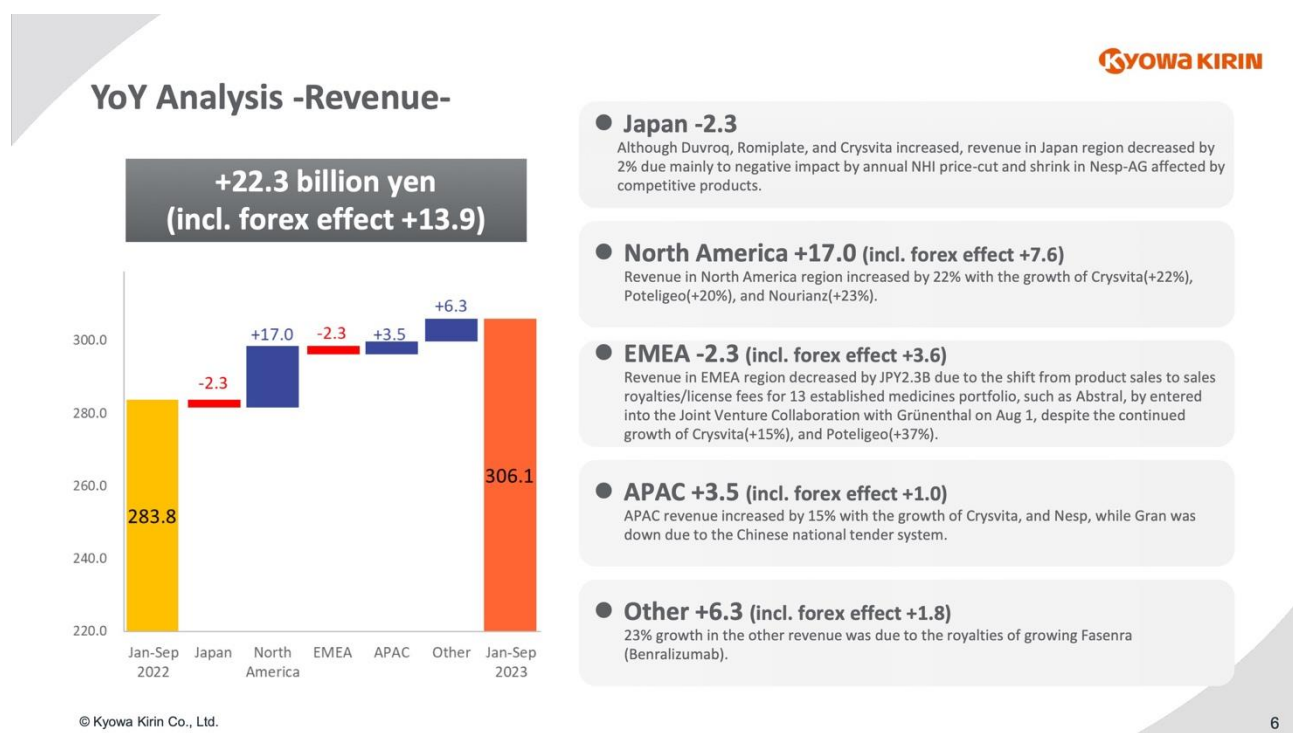
As for selling, general and administrative expenses, progress was 74%. The rate of progress appears to be higher than in previous years because profit-sharing expenses for Ultragenyx were included in SG&A expenses until April, before Crysvita began selling its own products in North America, but the progress is within the plan.

R&D expenses increased significantly by plus 16% YoY, but on a progress basis against the full-year plan, it is 65%. We plan to continue to invest in research and development, particularly in KHK4083.

As a result, 69% progress has been made in terms of core operating profit.

As for profit, 77% of progress has been made due to the aforementioned gains on sales of subsidiaries' stocks and valuation gains on residual interests.

Our consolidated performance up to Q3 so far has been generally steady along the planned line, and we expect to continue to achieve our sales growth centered on global strategic products and continued cost control in Q4, as well as a tailwind from the yen's depreciation, so that both sales revenue, core operating profit, and profit for the year are considered to be at a satisfying level to achieve our full-year targets fully.



I will now explain the YoY comparison, starting with sales revenue. Please refer to page six.

Here is a breakdown of sales revenue by region.



In Japan, despite continued growth in sales of Durvroq, Romiplate, and Crysvita, Japan region sales declined 2% due to lower sales of Nesp-AG and other products affected by the NHI price revisions in April 2022 and April 2023.


In North America, sales increased by 22% due to solid growth of global strategic products, especially Crysvita, as well as the impact of the yen's depreciation.

In EMEA, global strategic products such as Crysvita continued to grow, but following the establishment of a joint venture with Grünenthal in the established pharmaceuticals business, sales revenue from 13 brands, including Abstral, shifted from product sales to sales royalties and license fees in August and decreased by JPY2.3 billion.

In APAC, sales of Gran, which was subject to the national tender system in some areas of China, declined, but sales of Crysvita and other products, which were launched in Australia last November, grew, resulting in a 15% increase in sales.

As for others, sales increased by 23% due to continued growth in royalties from Fasenra and other sources.

## Revenue of Major Items (Japan)



(Billion Yen / Rounded)

Item	2022Q3 Results	2023Q3 Results	Changes	Reasons	2023 Plans	Progresses
Nesp + Nesp-AG <sup>1</sup>	15.7	12.7	-3.1 (-20%)	NHI price-cut & Biosimilars' penetration	16.6	76%
Nesp	2.5	2.3	-0.2 (-8%)		2.8	82%
Nesp-AG	13.2	10.3	-2.9 (-22%)		13.8	75%
Durvroq	4.4	6.9	+2.4 (+54%)	Market penetration (Launched in Aug 2020)	7.8	88%
Orkedia	7.5	7.6	+0.1 (+1%)		11.2	68%
G-Lasta	22.7	23.2	+0.5 (+2%)		33.5	69%
Poteligeo	1.5	1.4	-0.0 (-1%)		2.0	73%
Rituximab BS	7.6	6.7	-0.9 (-12%)	NHI price-cut	8.7	77%
Romiplate	7.5	8.7	+1.2 (+16%)	Market penetration (New indication in Jun 2019)	11.2	77%
Allelock	4.8	4.1	-0.6 (-13%)	NHI price-cut	4.7	88%
Nouria	5.9	5.5	-0.3 (-6%)		7.5	73%
Haruropi	2.8	3.2	+0.4 (+15%)	Market penetration (Launched in Dec 2019)	4.7	68%
Crysvita	6.4	7.4	+1.0 (+16%)	Market penetration (Launched in Dec 2019)	11.1	67%

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.

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Now, please refer to page seven.

Here is the situation by major product in Japan.

Sales of Nesp-AG are progressing well against the plan, although sales are declining due to the NHI price revision and the impact of competing products.

Durvroq continues to grow steadily and maintains the number one market share within its class.

Romiplate is steadily increasing its sales revenue due to market penetration with a 16% increase YoY.

Crysvita also continued to grow steadily with a 16% increase YoY.



## Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2022Q3 Results	2023Q3 Results	Changes	Reasons	2023 Plans	Progresses
Crysvita	78.7	95.7	+17.0 (+22%)		138.0	69%
North America	57.4	70.2	+12.8 (+22%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication (Adult/TIO) [APAC] Geographical expansion		
EMEA	21.2	24.5	+3.2 (+15%)			
APAC	0.1	1.1	+0.9 (+709%)			
Poteligeo	16.1	19.9	+3.8 (+24%)		27.5	72%
North America	12.6	15.1	+2.5 (+20%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration	19.4	78%
EMEA	3.5	4.8	+1.3 (+37%)		8.0	61%
APAC	-	0.0	+0.0 (- %)		0.2	3%
Nourianz	4.5	5.5	+1.0 (+23%)	Market penetration	7.5	73%
Nesp	5.9	7.0	+1.2 (+20%)		8.0	89%
Gran	6.4	5.2	-1.2 (-19%)	Listed on Chinese tender list	8.2	63%
Neulasta	4.4	4.5	+0.1 (+2%)		5.7	79%
Tech-licensing	23.3	29.3	+6.0 (+26%)	Growth of Fasenna	39.0	75%
Benralizumab Royalty <sup>1</sup>	15.4	19.1	+3.8 (+25%)			

<sup>1</sup> Sales royalties of Fasenna which has been marketed by AstraZeneca, including our own estimation.

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Please see page eight.

This is the status of major overseas products.

Crysvita continues to grow in both North America, EMEA, and APAC with a 22% increase in sales over the same period last year.

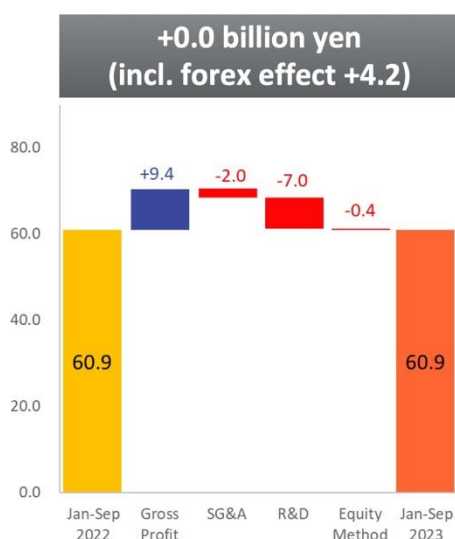
Poteligeo also continued to grow at 24% YoY. Sales in North America remained strong, and in EMEA, sales increased due to the expansion of the number of countries where the product was launched and its market penetration.

Nourianz also continues to grow steadily in the United States.

Technology revenues are Fasenna and benralizumab, and royalties here increased by JPY3.8 billion and progressed favorably.



## YoY Analysis -Core OP-



● **Gross Profit +9.4 (incl. forex effect +12.0)**

Increased in conjunction with JPY22.3B rise in revenue. COGs have increased due to the North America Crysvida Sales royalty after Apr 27, 2023. Hence, gross profit % declined YoY. (77% → 75%)

● **SG&A -2.0 (incl. forex effect -6.2)**

Although decreased in Crysvida profit sharing expenses due to the North America Crysvida-related scheme change after Apr 27, 2023, increased in HR exp, etc by the Crysvida commercial operation. In addition to that, increased due to FX impact. [HR exp -7.1 / Sales promotion +9.1 (incl. Crysvida profit sharing expenses +11.3) ]

● **R&D -7.0 (incl. forex effect -1.8)**

Increased in clinical study costs of KHK4083 which is undergoing joint global Phase III clinical study.

● **Gain/Loss on Equity Method -0.4**

While revenue of Hulio (FKB327/Adalimumab biosimilar) increased, FKB's profit declined due to decrease in tax-accounting effect.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

Please see page nine.

This is an analysis of Core operating profit.

Gross profit increased by JPY9.4 billion in line with the increase in sales revenue. Gross margin was 75%, 2% lower than the same period last year, due to an increase in cost of sales resulting from the recording of sales royalties since the start of Crysvida's own sales in North America on April 27.

Selling, general and administrative expenses increased by JPY2 billion due to an increase in personnel expenses and other expenses associated with this in-house sales of Crysvida in North America, in addition to a JPY6.2 billion foreign exchange impact, despite the impact of the absence of profit-sharing expenses recorded after Crysvida's in-house sales in North America, which amounted to JPY11.3 billion.

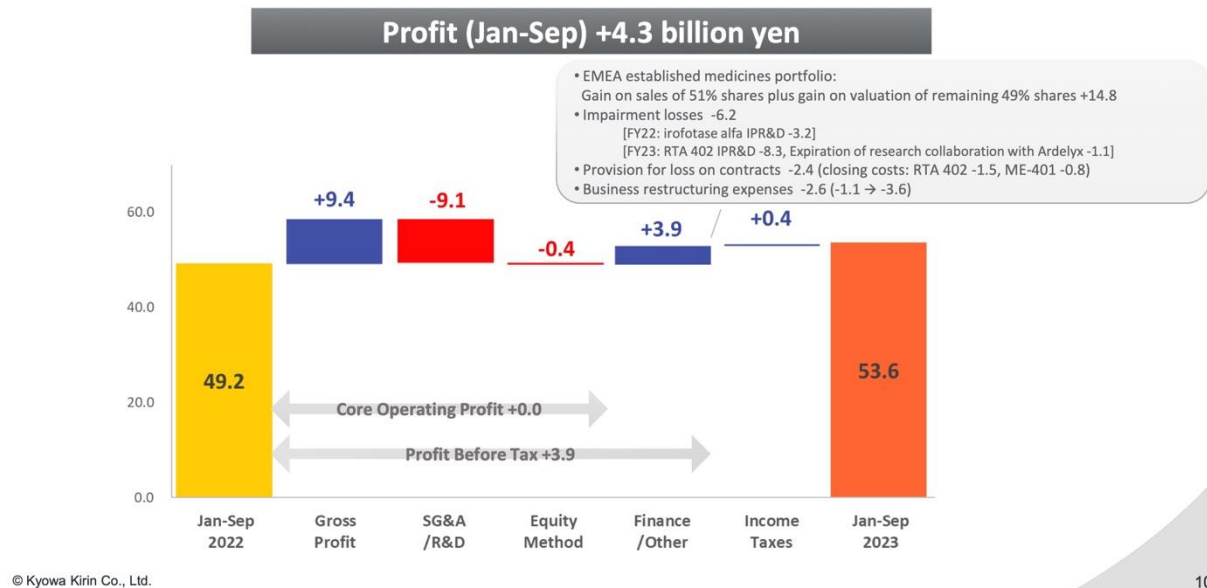
R&D expenses increased by JPY7 billion, mainly due to progress in the development of KHK4083, for which a global Phase III study is being conducted with Amgen.

Equity in earnings of affiliates decreased by JPY0.4 billion. This is because, in the same period of the previous year, we had the effect of additional recognition of deferred tax assets at FUJIFILM KYOWA KIRIN BIOLOGICS, we call it FKB.

As a result, core operating profit was JPY60.9 billion, the same amount as the same period last year.



## YoY Analysis -Profit-



Please turn to page 10.

In this slide, I would like to show you the part below core operating profit.

You can see the balloon there, and it shows a JPY3.9 billion increase in finance and other. The main reason for the increase was a gain of JPY14.8 billion from the sale of a 51% stake and a gain from the valuation of a 49% remaining interest in the European established pharmaceuticals business joint venture completed on August 1.

On the other hand, there are some negative factors such as an impairment loss of JPY8.3 billion due to the discontinuation of RTA 402 development, which was recorded in Q2, a provision for loss on contracts due to closing costs for discontinued clinical trials, and an increase in business structure improvement expenses in Europe, which, in total, resulted in a net increase of JPY3.9 billion.

As a result, quarterly profit increased by JPY4.3 billion from the same period last year to JPY53.6 billion.



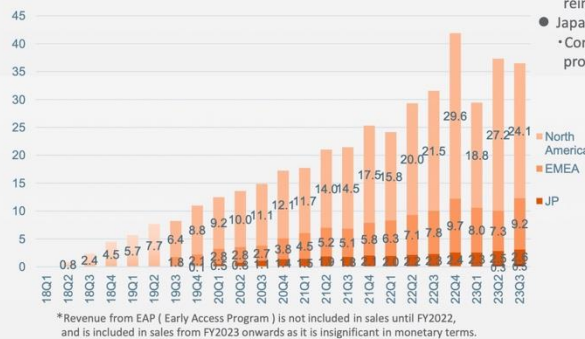
### 2023 Key Actions

- 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.

### Q3 Topics

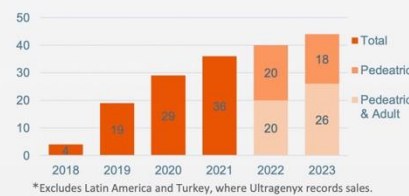
- North America:  
• The number of patient enrollments in the treatment preparation stage and treatment patients continued to increase steadily, through addressing the individual issues in the sales transfer.  
• As for sales revenue, estimated allowances for returns corresponding to the inventory of Ultragenyx-labeled products as of end of September was recorded due to the switch from Ultragenyx-labeled products to Kyowa Kirin-labeled products.
- EMEA:  
• Patient penetration in each country has been steadily increased.  
• Revenues increased 15% YoY, despite the impact of the reduction of insurance reimbursement prices in Germany.
- Japan:  
• Continued to strengthen promotional activities, such as holding webinars for medical professionals.

Sales Revenue (Billion Yen)



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Launched Countries / Regions (XLH)



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**Sudo:** Now, Sudo will continue with the commercial update.

Please move on to page 12.

The graph on the left side shows the sales trend of Crysvita in chronological order since its launch in 2018.

First of all, sales in North America are progressing as planned, with an increase of 22% YoY. Both the number of patients being treated and those in the pre-treatment stage are increasing steadily, and the market is growing strongly.

Although sales for the quarter appear to be a little weak, we believe that this is due to transitory factors that will be resolved by the end of the year, as mentioned a little earlier, and we are not greatly concerned about it.

Ultragenyx's labeled products were still in stock at the wholesale level, but we made a swift transition from Ultragenyx labeled products to the Kyowa Kirin labeled products all at once in September, after the transfer.

At that time, a lump-sum allowance for sales returns was recorded for the inventory before returns at the end of September, but at the end of September, the corresponding sales were not partially recorded, resulting in a temporary negative factor.

Although the current level of wholesale inventories has temporarily declined, this negative factor is expected to gradually recover and decrease toward the end of the year.

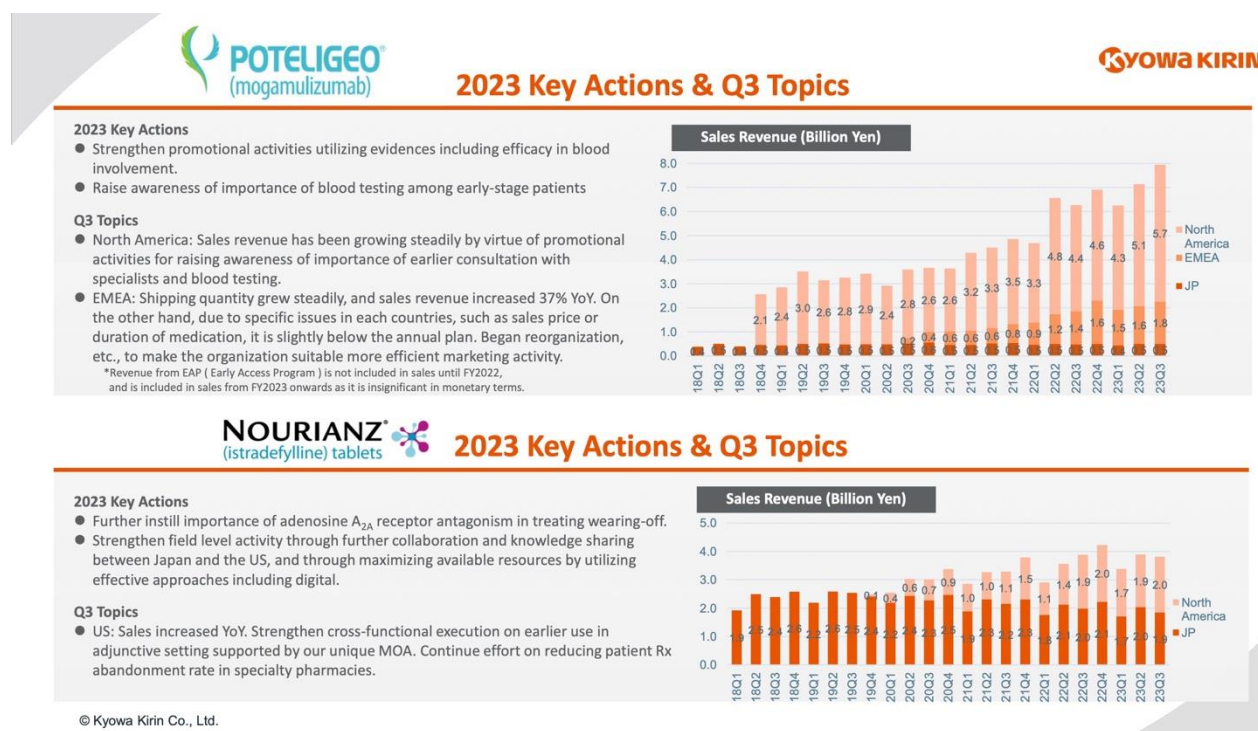
Furthermore, as you can see in the graph, in Q4 of 2022, an extreme wholesale buildup was confirmed last year at the end of the fiscal year, but this year, we will work to avoid inventory levels that deviate too greatly from actual demand this fiscal year.

Next is Europe. Market penetration is also steadily progressing, with sales up 15% YoY through Q3. As I explained in Q2 financial results for the previous fiscal year, we are slightly behind our plan overall due to



price adjustments in Germany and other factors, but we will continue our efforts to expand the adult market and penetrate the market.

As for Japan, we are generally making progress as planned at the beginning of the year. We are currently strengthening various activities to further expand the market, and we hope that you will have high expectations for us in the future.



We will move on to page 13.

Sales of Poteligeo in North America have been on track as planned, and we are continuing our activities to penetrate the market, such as evidence-based marketing, patients in the early phase and in the early consultation, and awareness-raising activities for blood test implementation, and we are steadily penetrating the market.

In terms of sales in EMEA, the number of patients is increasing at a faster pace than in the US, and although we are seeing steady growth, it is still slightly behind the plan.

Each country has its own issues, but there are some differences, such as the price of the public insurance institutions, which have various systems such as mandatorily discounts, and the price and the drug administration period per patient, which is a little shorter than expected in some cases.

In addition to continuing educational activities to encourage patients to start treatment earlier, we have begun to improve our system while also improving our marketing activities as appropriate. We would like to continue our steady activity.

Finally, about Nourianz. In the US, as Kawaguchi mentioned earlier, we are achieving steady growth as planned.

We would also like to strengthen our promotional activities by aiming to improve the quality of communication with medical professionals through information provision activities focused on cases in which the characteristics of the drug are most likely to be demonstrated.



That's it for the commercial update.

Upcoming Events: Main Development Pipeline Products			
Code Generic Name	Events (Completed are in bold)		Timeline (Completed are in orange)
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis Asthma	P3 (ROCKET PROGRAM) P2	In Progress To be initiated
KHK4951 tivozanib	nAMD nAMD DME	P1 data presentation P2 initiation P2 initiation	Oct. 2023 Q4 2023 Q4 2023
KK2260	Advanced or metastatic solid tumors	P1 initiation	Q4 2023
KK2269	Advanced or metastatic solid tumors	P1 initiation	Q1 2024
KW-3357 antithrombin gamma (genetical recombination)	Discontinuation of development for Preeclampsia		Nov. 2023
Cf.) Orchard Therapeutics' development pipelines	OTL-200	MLD <sup>1</sup>	FDA decision to be announced
	OTL-203	MPS-IH <sup>3</sup>	Ph3 Study Initiation
	OTL-201	MPS-IIIA <sup>4</sup>	Ph1/2 Data readout

1. Metachromatic Leukodystrophy; 2. PDUFA date: Mar. 18, 2024; 3. Mucopolysaccharidosis type I, Hurler syndrome; 4. Mucopolysaccharidosis type IIIA (Sanfilippo Syndrome type A)

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**Torii:** Next, I will present an update on R&D-related matters. Please refer to page 15.

Here is a slide about the news flow of the main development pipeline products.

First, KHK4083, which is rocatinlimab, are currently in Phase III, the ROCKET program, for atopic dermatitis. This program is progressing well, with 1,500 patients enrolled to date. For asthma, we are currently discussing the details of the Phase II study with Amgen.

Next, for KHK4951, we presented the results of the Phase I study at the annual congress of Japan Clinical Ophthalmology in October of this year. In addition, preparations for the Phase II study are proceeding diligently with the aim of starting the study this year.

In addition, we are planning to start a Phase II study for the indication of diabetic macular edema. Information on these two Phase II trials is currently being disclosed in jRCT.

We will be able to provide more detailed information on the Phase I study I just mentioned and the two Phase II studies at the R&D presentation scheduled for December of this year.

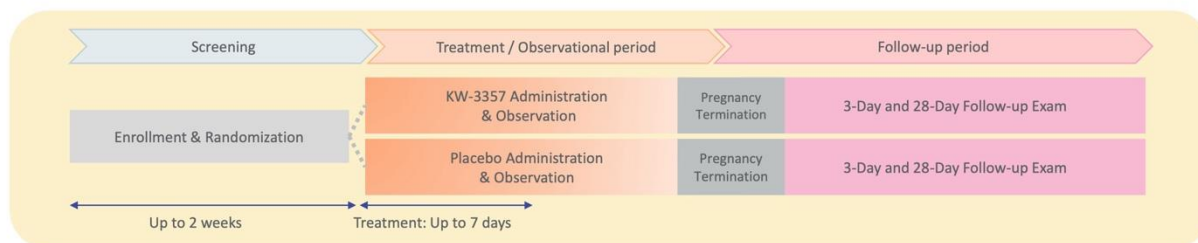
Next, we would like to announce our proprietary bispecific antibodies, which we have been telling you about for some time. They are KK2260 and KK2269 shown here. Both of these projects are currently under preparation to begin in Q1 of 2024. We will provide an overview later.

Finally, regarding KW-3357, preeclampsia, we recently reported in a press release that the top-line data from Phase III did not meet the primary endpoint. Based on these discussions, we have decided to discontinue development for this disease. I will explain about it in the next slide.

In addition, the development pipeline of Orchard Therapeutics, with which we recently announced the conclusion of an agreement to acquire shares, is shown at the bottom of the slide for your reference.



## KW-3357 Preeclampsia Ph3 data



■ **Primary Endpoint : Days of maintaining pregnancy**  
(Days from the start date of investigational drug to the date of pregnancy termination)

The trend toward prolongation was observed compared with the placebo group, but no statistically significant improvement was observed

■ **Safety**      Amount of blood lost during delivery  
Bleeding-related events and anemia

No significant difference was observed compared with placebo  
Occurred 3 times more frequently than in the placebo group\*

\* Bleeding-related events: KW-3357 28%, Placebo 9%    Anemia: KW-3357 27%, Placebo 10%

Due to the failure to meet the primary endpoint and the higher incidence of bleeding-related events and anemia in KW-3357 group, we have decided to discontinue the development of this product for preeclampsia.

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Next, please see page 16.

A summary of the results of the Phase III study of KW-3357, preeclampsia, is presented here.

The primary endpoint is the number of days of pregnancy continued, i.e., days from the start date of investigational drug to the date of pregnancy termination.

Unfortunately, no statistically significant improvement was observed here, although a trend toward prolongation was observed versus placebo.

In terms of safety, there was no significant difference in the amount of blood loss during delivery compared to placebo, but bleeding-related events, including subcutaneous hematoma, and anemia were observed more frequently in the study group than the placebo group.

As described above, we have decided to discontinue the development of this drug for preeclampsia because the primary endpoint was not met and we observed many bleeding-related events and anemia in the actual drug group, which made it difficult to continue the development of this drug.



## Overview of KK2260 and KK2269

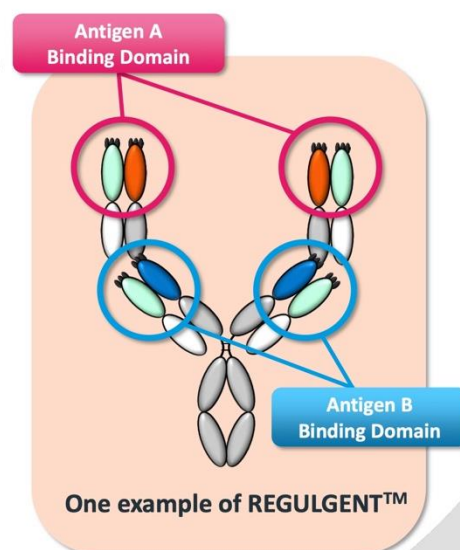
- Both are Kyowa Kirin's proprietary bispecific antibodies with REGULGENT™ technology
- The phase 1 studies information for both products have been disclosed on jRCT\*

\* Trial ID KK2260: jRCT2031230372, KK2269: jRCT2031230419

	KK2260	KK2269
Countries/ Regions	Global (Japan and US for Phase 1)	
Indications	Advanced or metastatic solid tumors (esophageal cancer, head and neck cancer, etc.)	Advanced or metastatic solid tumors (gastric cancer, lung cancer, etc.)
Method	Single	Single or combination

Further details will be presented in our R&D Meeting (2023 December)

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Next, please see page 17.

Here, we would like to introduce two products created from our proprietary bispecific antibody technology, REGULGENT technology.

The figure on the right shows an example of a bispecific antibody produced by REGULGENT technology. As you can see, not only can it bind to two types of antigens, but it also has two binding sites for each antigen, allowing so-called bivalent-bivalent binding.

The bispecific antibodies derived from REGULGENT technology are also characterized by a structure using their common light chain, which allows them to achieve high stability and productivity, and by their natural sequence structure, which is expected to maintain low antigenicity.

Next, regarding the development pipeline, the development numbers are KK2260 and KK2269, respectively, and information on the Phase I study was disclosed in the jRCT in October.

Both of these projects are for the development of products for solid tumors, and both are planned for global development.

I am very sorry, but this is the end of today's explanation of these pipeline products. We are currently preparing to explain the details at the R&D briefing to be held in December, so please be patient.



## Year-to-date Key News Flow

Category	Date	Headline	As of November 1, 2023
ESG	Mar 8	Kyowa Kirin Selected for a "Health & Productivity Stock" and awarded as a "Certified Health & Productivity Management Outstanding Organization"(White 500) (Japan)	
R&D	Mar 17	Presented New data from Phase 2b clinical study of Rocatinlimab in Atopic Dermatitis at the American Academy of Dermatology Annual Meeting 2023	
SCM	Mar 28	Completed construction of a new building at Ube Plant (Japan)	
ESG	Apr 6	Introduced RE100 renewable electricity to all purchased electricity at its two plants and three laboratories (Japan)	
SCM	Apr 7	Completed construction of a multipurpose facility relating to Quality Assurance (Q-Tower) at Takasaki Plant (Japan)	
R&D	Apr 27	Started collaboration in drug discovery technology with School of Life Science and Technology, Tokyo Institute of Technology (Japan)	
R&D	May 10	Announced Phase III Study Results of bardoxolone methyl (RTA 402) in Japan and Discontinuation of Development (Japan)	
LCM	Jun 23	Approval for partial change of Antineoplastic Mitomycin C Agent. (Japan)	
LCM	Jul 18	Launched of Topical Ophthalmic Mitomycin C Agent and resumed the supply of Antineoplastic Mitomycin C Agent. (Japan)	
LCM	Jul 24	Application for partial change of approved indication of G-Lasta® for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation. (Japan)	

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; BS: business strategy  
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## Year-to-date Key News Flow

Category	Date	Headline	As of November 1, 2023
LCM	Aug 23	Approval for partial change of LUMICEF® for Palmoplantar Pustulosis (Japan)	
LCM	Aug 30	Approval for Calcimimetics Agent ORKEDIA® TABLETS 4mg (Japan)	
LCM	Sep25	Approval for Partial Change of Romipate® for Aplastic Anemia (Japan)	
R&D	Sep 25	Approval of PHOZEVEL® for Improvement of Hyperphosphatemia in Chronic Kidney Disease Patients on Dialysis (Japan)	
R&D	Sep 28	Disclosing Top-Line Results of Phase 3 Clinical Study of KW-3357 for the Treatment of Preeclampsia (Japan)	
LCM	Sep 29	Approval for Partial Change of Rituximab Biosimilar Received by Sandoz (Japan)	
SI	Oct 5	Conclusion of Agreement to acquire Shares of UK biopharmaceutical company Orchard Therapeutics plc	
R&D	Oct 11	Presented the posthoc analysis data from the Phase 2b study of rocatinlimab (AMG 451/KHK4083) at European Academy of Dermatology and Venereology (EADV) Congress 2023	
R&D	Oct 17	Presented the Results of Phase 3 Studies of PHOZEVEL® at the American Society of Nephrology Meeting (ASN Kidney Week 2023)	

Kyowa Kirin and Grünenthal have entered into a Joint Venture Collaboration for Kyowa Kirin International's 13 established medicines portfolio on Aug 1.  
The transfer of global rights for Tostran, an established medicine, from Kyowa Kirin International to ADVANZ PHARMA has been completed on October 13.

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment  
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Last but not least, pages 19 through 20 contain a list of news releases from the beginning of the year. As for this one, Mr. Fujii, please explain.

**Fujii:** Regarding the strategic investment announced on October 5 and the briefing held on that day, we have concluded an agreement to acquire shares of Orchard Therapeutics, a UK biopharmaceutical company.

As noted outside the column, I would like to report on two matters concerning the transfer of the European established pharmaceuticals business held by our subsidiary Kyowa Kirin International, which I have been explaining to you since last year.



With regard to our joint venture with Grünenthal for 13 brands of established pharmaceuticals, as we mentioned earlier, the joint venture started on August 1.

The transfer to ADVANZ PHARMA of the rights related to Tostran, which were not included in the scope of the transfer to Grünenthal, was completed on October 13. Sales revenue from the transfer will be reflected in Q4 financial results.

Many of you may have attended the briefing on the day of the meeting regarding the acquisition of Orchard shares, but I would like to briefly explain again.

**Acquire shares of Orchard Therapeutics**  
~Strategic Rationale~

**Our New Vision toward 2030**

Kyowa Kirin will realize the successful creation and delivery of life-changing value\* that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

\* Make patient smile through dramatic improvement in quality of life by identifying the unmet medical needs of people battling with medical conditions and by creating and supplying new drugs or services that help them overcome those challenges

**Our purpose of the acquisition:**

- To enrich our pipeline to address the UMNs\*\* for which there is still no cure
- To obtain capabilities in Cell Gene Therapy R&D to address the future UMNs

\*\* Unmet medical needs

- Strengthen the business following Crystiva and Poteligeo as a Global Specialty Pharmaceutical company
- Enhance ability to address UMNs in the future by combining with our strength in biologics
- Commitment to life by providing not only pharmaceuticals but also treatments

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Please refer to page 21.

First, let me explain the strategic significance of this deal.

As we have explained since the beginning of the year, investments to strengthen our portfolio and in science and technology that will create new strengths are both important management challenges in realizing our vision of continuously creating life-changing value, and we believe that the acquisition of Orchard Therapeutics is a major step toward addressing these challenges and realizing our vision.

Orchard is one of the leading providers of hematopoietic stem cell gene therapy, with one marketed product and two in development based on this technology. All three assets target rare diseases classified as lysosome diseases, for which there is a very high unmet medical need, and aim to realize treatments that can only be achieved with hematopoietic stem cell gene therapy technology.

This technology has the potential to fundamentally cure diseases and is one of the modalities to meet increasingly sophisticated medical needs. However, the hurdles to establish a value chain to provide this technology and commercialize it are extremely high, and Orchard is one of the few companies that have established this as a business.



Thus, we believe that Orchard's know-how and technology, including its products, development products, and business platform, are of high strategic significance to us, as they address our business challenges and fit well with our vision.

## Acquire shares of Orchard Therapeutics

### ~Transaction Summary~



Items	Summary
Target	<ul style="list-style-type: none"> <li>Orchard Therapeutics plc (London)</li> <li>Listed on NASDAQ</li> </ul>
Purchase Price*	<ul style="list-style-type: none"> <li>\$16.00 per ADS / approx. \$387.4 million (approx. JPY 57.3 billion)</li> <li>Orchard shareholders will hold additional contingent value rights (CVR) of \$1.00 per ADS.</li> <li>Additional \$1.00 CVR will be paid for a total of \$17.00 per ADS, or approximately \$477.6 million (approx. JPY 70.7 billion) if OTL-200 is approved by the U.S. Food and Drug Administration for the commercial marketing and sale in the U.S.</li> </ul>
Funding Method	<ul style="list-style-type: none"> <li>Cash on balance sheet</li> </ul>
Financial Impact	<ul style="list-style-type: none"> <li>To be announced once allocation of goodwill and intangible assets are determined</li> </ul>
Transaction Structure and Process	<ul style="list-style-type: none"> <li>Scheme of Arrangement (SoA)</li> <li>Requires the approval by Orchard's shareholder meeting, UK court, and regulatory authorities</li> <li>Closing is expected in 2024Q1 through implementation of SoA</li> </ul>

\*Refers to the amount required to make payments related to all outstanding Orchard common shares, ADS purchases, options, Restricted Stock Units, and other instruments.

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Next, it is a summary of the transaction.

Orchard is a company that exists in the UK but is listed on Nasdaq in the US.

The acquisition of the shares will be made by way of a scheme of arrangement under the UK Companies Act, whereby the shares held by all shareholders of Orchard will be acquired for cash.

The acquisition price is USD16 per ADS, but Orchard shareholders retain the right to receive an additional USD1 per ADS as contingency consideration if OTL-200 receives US marketing approval from the FDA, for a maximum payment of USD17 per ADS.

The total acquisition price is estimated to be USD387 million or JPY57.3 billion, assuming payment of USD16 per ADS, and approximately USD478 million or JPY70.7 billion if OTL-200 receives US marketing approval.



## Acquire shares of Orchard Therapeutics ~Expected Synergy~



### Further Development as a Global Specialty Pharmaceutical Company

- To be a Japan-based Global Specialty Pharmaceutical Company providing life-changing value to high unmet medical needs in concert with our existing business through Crysvita and Poteligeo

### Reinforcement of New Drug Discovery & Development

#### Kyowa Kirin

- Experience and expertise of R&D and commercialization in Biologics and Antibody Drugs
- Proprietary next-generation antibody technology
- Continuous efforts to new modalities



#### Orchard Therapeutics

- Experience and know-how in the marketing HSC-GT\* in EU
- High technology in HSC-GT<sup>1</sup> (Research, CMC, SCM, etc.)
- Patient access and collaboration with medical institutions
- Efforts and experience to new modalities

- A key step toward delivering advanced value to patients
  - Pursuing the potential for "One-time treatment in life"
  - Challenge to correct the underlying cause of a genetic disease
  - Personalized medicine / Precision medicine
  - Providing treatment beyond the existing drugs

\* Hematopoietic Stem Cell Gene Therapy

- Address a broader range of UMNs

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Finally, the synergies we expect.

Again, Orchard has a product and development products using hematopoietic stem cell gene therapy that has the potential to fundamentally cure for diseases with a single treatment, as for diseases with a very high unmet medical need and has established the necessary platform for its business.

In addition to maximizing the value of Orchard, we believe that combining Orchard's experience, technological capabilities, and unique business model with high barriers to entry, with our own strengths will help us further develop as Japan-based Global Specialty Pharmaceutical company and strengthen our R&D capabilities in the creation of new drugs.



## P/L Impact on EMEA established medicines portfolio

	Before 2023 Q2	2023 Q3	2023 Q4	2024	2025
Revenue	Product sales	Until the end of July (for Tostran, until Oct 12)	From August		
		Established portfolio 13 brands	Sales Royalties & license fees		
COGs	Cost of product sales		Disposal proceeds	contingency income	
SG&A	SG&A costs	Until the end of July	Transaction value at £ 62.5M (Oct 13)	£ 8.5M	
Equity method			49% of profit for Joint Venture Collaboration, Grünenthal Meds		
Other income		Share transfer *	51% of Grünenthal Meds share has transferred (Aug 1) Gain on sales of 51% share + gain on valuation of remaining 49% share at £ 80.9M (14.8 billion yen) in total		

\* Grünenthal owns a 51 percent majority share in the Joint Venture Collaboration, while Kyowa Kirin International plc owns a 49 percent share. Grünenthal will have the option to fully acquire the remaining 49 percent share, including intellectual property (IP) of 13 brands, via exercising an option in Q1, 2026

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On August 1, the sale of a 60% stake in a subsidiary with the European established pharmaceuticals business was completed and the joint venture was launched. We will focus on key points and explain the profit/loss impact.

The profit-and-loss impact related to the European established pharmaceutical business can be divided into three main components.

The first are the sales revenue and the business profit/loss related to the 13 brands transferred to the joint venture with Grünenthal, the second is the gain on sale of shares and valuation gain related to the transfer of shares in the joint venture, and the third is the sales revenue from the transfer of the rights of Tostran business, which was not subject of business transfer to the joint venture.

First of all, sales revenue related to the 13 brands transferred to the joint venture company, will be recorded as sales as sales royalties and license fees of Kyowa Kirin International instead of product sales from August onward, since Kyowa Kirin International will continue to own the intellectual property of the 13 brands.

In addition, an amount equivalent to 49% of the joint venture's current income will be recorded as equity in earnings/loss of affiliates.

Next, regarding the profit and loss related to the transfer of shares in the joint venture, we sold 51% of the shares in our established pharmaceutical business subsidiary to Grünenthal on August 1, based on the alliance agreement we signed with Grünenthal last November and launched the joint venture. In connection with this sale, a gain on sale of a subsidiary shares were recorded.

In addition, a fair value appraisal gain on the loss of control was recorded for the remaining 49% of the joint venture shares that are still held. The combined gain on the sale of 51% shares in the subsidiary and the gain on the valuation of the remaining 49% shares, amounting to GBP80.9 million or approximately JPY14.8 billion, were collectively recorded under other income in Q3.

Finally, Tostran, which is no longer subject to the joint venture with Grünenthal, has signed an agreement to be transferred to ADVANZ PHARMA, which was closed on October 13. As a result, the Company expects to



record GBP62.5 million in sales revenue from the rights transfer in Q4. In addition, an additional GBP8.5 million is expected to be recorded in sales revenue in Q1 of 2024, when certain contractual conditions are expected to be met.



## Question & Answer

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**Moderator [M]:** We would like to start the question-and-answer session.

Before I go any further, I would like to make one correction.

Slide 15, this is the news flow of the main development pipeline. In the previous explanation, we said that we are aiming for the start of Q1 2024 for KK2260 and KK2269, but please note that the slides are correct, with 2260 in Q4 2023 and KK2269 in Q1 2024.

**Yamaguchi [Q]:** This is Yamaguchi from Citigroup Global Markets. Thank you.

The first one is where you talk about Crysvita. I think there was a similar story about labels in Ultragenyx's earnings call, but I don't understand it well and would like to ask again.

Regarding your company's handling of inventory in actual sales, it came in negatively, and we are seeing the effects of that in July to September. However, in the future, there will be no impact, or it will be positive again because of the inventory buildup. Please confirm these two points.

**Kawaguchi [A]:** Thank you for your questions, Mr. Yamaguchi. I, Kawaguchi, will answer the question.

We are aware that this has no impact on actual demand, and that inventory levels to wholesalers, the so-called special pharmacies, are low at the end of September due to this impact. It is our understanding that sales were affected on a shipment basis.

So, we could return to normal if the inventory of Ultragenyx products is reduced to zero and the inventory of Kyowa Kirin products is at the same level. However, as of the end of September, that level was lower than before and ended. Therefore, we are saying that we are assuming that this will come back in Q4.

**Yamaguchi [Q]:** So, looking at H2, the impact on sales is zero?

**Kawaguchi [A]:** Basically, we think there will be no impact.

On the other hand, as Sudo just mentioned, the back action from last year's high inventory and shipments that occurred in the first quarter, which Sudo just mentioned, may not all be recovered. We recognize that last year's level was too high, and we are considering bringing it to a normal level this year, so our current assumption is that a certain amount of negative impact will remain on the shipment base.

**Yamaguchi [Q]:** Thank you very much. Are you saying that the allowance for returned goods is not reflected in the P&L?

**Kawaguchi [A]:** The story about the reserve for returned goods is only for the end of September, and this is reflected in the P&L. Even if the Ultragenyx-labeled products are still partially in the special pharmacy, the company accounted for them as having been returned completely. Based on this, we have recorded negative sales for that amount, and for accounting purposes, the return process has been completed, and the inventory of Ultragenyx-labeled products is now zero.

**Yamaguchi [Q]:** I understand. Thank you.



My second question is, I think there is a PDUFA in the US at Orchard, and of course, that is going to work, and I think there will be various, then, conditional consideration variations. For this PDUFA, there is the fact that it has been approved in Europe, and I don't know if there is an AdCom, but I think your company thinks that the probability of approval is very high, but is it high, not high, or maybe there is a risk, if any. Any comments would be appreciated.

**Fujii [A]:** Thank you for your question.

We have conducted the appropriate due diligence and checked various documents, including data, and we believe that the probability of approval is very high.

**Yamaguchi [Q]:** Is there such a thing as AdCom? You don't have any idea?

**Fujii [A]:** I think that has not been decided yet.

**Yamaguchi [M]:** So it hasn't been decided. I understood. Thank you. That's all.

**Wakao [Q]:** I'm Wakao from JPMorgan. Thank you.

The first is the outlook for the next fiscal year. I think you mentioned that you wanted to increase profits in the next fiscal year as of Q2, but I am asking how you are doing at this point in time.

I think the base business has been doing well in Q3, so I think it is possible to increase profits, but if Orchard is included, I think there is a high possibility that profits will decrease. Is my understanding right?

In addition, since you are completing the Orchard acquisition in this Q1, will the Orchard acquisition impact be included in the beginning-of-period guidance that comes out in Q4 next year? Will there be an earnings forecast that incorporates the acquisition once it is completed? Please tell me about it.

**Kawaguchi [A]:** Thank you for your question, Mr. Wako.

First of all, I would like to refrain from giving an answer to the forecast for the next fiscal year at this time, as it is being diligently formulated, partly due to the inclusion of Orchard.

Then, in answer to your question about whether we will show an earnings forecast that incorporates the Orchard acquisition once it is completed, you are correct. For our part, we believe there is a high probability that the closing will take place when the financial results are announced in February next year. In that case, we would like to announce our earnings forecast, naturally factoring it in. If there is a delay, we would like to present the earnings forecast without Orchard once.

**Wakao [Q]:** I understand. Basically, you are saying that you will announce the forecast which incorporates Orchard in the next Q4, right?

**Kawaguchi [A]:** That's right.

**Wakao [Q]:** On the other hand, although it is being diligently formulated, I wonder if it would be difficult to create an increase in profits on the current base, excluding Orchard, considering that profits have not yet been generated with respect to Orchard, is that idea wrong?

**Kawaguchi [A]:** I hope you understand that we are now firmly committed to including this as well.

**Wakao [Q]:** I understand.



The second question I would also like to know from you is about Crysvita. In the end, if the allowance you just explained are added back, would it be correct to assume that Q2 and Q3 are almost flat? I would like to know how it was on a local currency basis.

Also, you mentioned that Europe is slightly behind, but what happened in Europe? I believe that in Q2, you incorporated the German price reduction factor, but I understand that this had already been done in Q2, so I didn't understand why in Q3 you were behind against the plan. Is this what happened in Q2? Was there any other new factor which lowered the results than planned in Q3? Please tell me about this point.

**Sudo [A]:** Okay, Sudo will answer your question.

For the first point, as I mentioned earlier, in the US, the number of patients has been growing steadily in this quarter, rather than remaining flat.

However, the change in the National Drug Code number, which was mentioned earlier, has had quite a large impact on the current situation, and we do not believe that the market trend itself has changed significantly. It is our understanding that the growth continues to be strong.

As Mr. Wakao mentioned, what I said the "behind" is due to the price adjustment in Germany in Q2, and the "behind" is due to the effect of this. However, if you look at the overall picture, I hope you will understand that the number of patients is growing steadily.

**Wakao [Q]:** So you mean the understanding is right that nothing specific happened in Q3, is that correct?

**Sudo [A]:** Yes, you are right.

**Wakao [Q]:** Also, I think that in Europe, outside of Germany, the prices are becoming much more severe, but we don't have a situation now where something like Germany happens in other countries, do we?

**Sudo [A]:** Overall, I would say that prices in Europe, as well as in Poteligeo, are in a difficult situation, but to put it simply, I think they have reached a plateau. We have negotiated the price several times while expanding the indications, but I think you can understand that major events like this one will not occur at this level in the future. There are also external factors, and we will explain the situation again when we know more.

**Wakao [M]:** Thank you. I understand very well. That's all.

**Ueda [Q]:** This is Ueda from Goldman Sachs.

First, I would like to ask you about the Poteligeo in Europe. I believe that there was some talk about the spread of the mandatory discount in Q2, but since there was no mention of this impact this time, am I correct in understanding that this has been settled?

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

I think it is fine as you understand it, Mr. Ueda. This mandatory discount is especially famous in Germany, and also famous in the UK and France, which will be affected by the policies for the coming year, but at this point, the effects are as already mentioned, and I hope you understand that the situation will not get worse toward the end of the year.

**Ueda [Q]:** Thank you very much.

The second point is the concept of SG&A expenses. I see that SG&A expenses have been decreasing since Q3. I understand that there are several factors, such as the effect of the change in scheme with Ultragenyx and



changes in the European established pharmaceuticals business, etc. What kind of impact did these factors have on your SG&A expenses and what should we base the SG&A expenses for the next fiscal year and beyond on? Please give me some suggestions. Thank you.

**Kawaguchi [A]:** Thank you. Kawaguchi will answer.

Regarding SG&A expenses, the profit-sharing expenses have been eliminated since April 27. This part is conversely switched to the royalty portion of the cost of goods sold. There is a kind of a flow of things in and out between SG&A and cost of goods sold. This will contribute to the full year in the next fiscal year, so this part will be seen as a factor that will reduce SG&A expenses to a certain degree, or rather, negative, in the next fiscal year.

Also, as you pointed out, the establishments business, the SG&A expenses here will also be eliminated. This is after August in this fiscal year. These two factors will work as special factors to reduce SG&A expenses in the next fiscal year.

On the other hand, as for the increase in SG&A expenses, the transfer of sales of Crysvita has incurred a considerable amount of personnel expenses, including those incurred before the transfer, which is the reason for the increase in SG&A expenses this term compared to the previous term. In this sense, however, this part of SG&A expenses will not be a major factor in the increase in the next fiscal year.

Did I answer your questions?

**Ueda [Q]:** Thank you very much.

Looking at the quarterly trends, the amount of money from Q2 to Q3 has decreased more than from Q1 to Q2, although it is in yen terms. How can I interpret this background?

**Kawaguchi [M]:** From the first to the second?

**Ueda [Q]:** I think the second to the third probably has a bigger drop in your company's data.

**Kawaguchi [A]:** As I mentioned earlier, the profit-sharing expenses have been eliminated since April 27, so in effect two months of May and June were affected in Q2, and Q3 is three full months gone. I guess that might be the largest reason, but we have not yet been able to analyze these figures thoroughly, so if necessary, please check with the IR department.

**Ueda [M]:** I understand. Thank you very much. That is all.

**Sakai [Q]:** This is Sakai from UBS Securities.

I understand that the method of settlement with Ultragenyx has been switched to sales royalty payment on this time, which is now recorded as the cost of goods sold, resulting in a lower gross profit margin rate, or in other words, the rate of the cost of goods sold is rising.

I think this 75% is a little lower than what your company assumed, the original plan for the year. That is what I am thinking, but of course royalties will accrue not only this year, but also in the next fiscal year and beyond. I would like to know if you have any views on how the rate will change in the future, or if anything has changed in the situation. I wonder if there is any influence of exchange rate or something like that. I think your company is paid in dollars, but please let me know if there are any changes in that area.

**Kawaguchi [A]:** Thank you for your question, Mr. Sakai.



You are quite right about that. One is that reason for the year over year decline in profit margin rate is largely and mostly due to the impact of the switch to royalty payments. In comparison to the plan, the gross profit margin rate is a little below the plan, as the forecast of 77% for the year ending, and 75% for Q3, as you can see.

This is a one-time charge for the cost of goods sold, which includes a portion of manufacturing-related problems that resulted the disposal of some items. That part will be negative compared to the plan, so if there are no such factors, the gross profit margin rate would be the normal level for this fiscal year as assumed in the earning forecast.

From the next fiscal year onward, the same concept as the profit-sharing mentioned earlier will be applied, but the impact of the royalty payments will come in throughout the year, which will have a slight negative impact on the cost of goods sold. On the other hand, this will be partially offset by the effect of the improvement in the product mix, as the ratio of high-margin global products is increasing year by year. We hope you can think of it as such.

**Sakai [Q]:** I understand. Is it my understanding that the guidance for the next fiscal year will be announced in January, or February, probably when the financial results are announced, gross profit margin rate for the next fiscal year will return to about 77% of sales?

**Kawaguchi [A]:** I have told you as much as I could about qualitative factors, so I would like to refrain from discussing specific figures.

**Sakai [Q]:** I understand.

Regarding R&D, have there been any changes or progresses with tivozanib?

And KK2260 and KK2269 will enter clinical study phase soon, on the other hand, the development of KW-3357 has been discontinued, though I am not sure how much of an impact these has had.

You said that you schedule an R&D briefing in December. Sorry, I wasn't quite sure of the dates, so tell me about your thoughts on the development pipeline, including the date of the meeting. As President Miyamoto said, you still have to enhance the late stage development pipeline, even if you have to spend more money. I think if you can spend the money, you can get it anything, but please tell me if your thought on strategic investment will remain the same.

**Torii [A]:** Torii will answer your question.

As for the KHK4951 (tivozanib), as it was mentioned earlier, we are now working diligently to prepare for the start of Phase II. The FDA's 30-day review has been added and is expected to begin on schedule.

KK2260 and KK2269, and that the first-in-human test would run on two projects. On the other hand, there is quite a bit of change of going in and out, as the development of 3357 is discontinued.

However, as only KHK4083 is the only global development pipeline in the late clinical stages, we still need to expand our late-stage pipeline. Although we have acquired Orchard this time, we will continue to pursue this strategy to enhance our pipeline in the future.

That's all.

**Sakai [Q]:** Am I correct in understanding that both Neovascular age-related macular degeneration and Diabetic macular edema are started at the same time from Q4 of 2023?



**Torii [A]:** Yes, we will conduct a parallel Phase II test at the same time.

**Sakai [Q]:** Do you feel that it would cost a lot of money there?

**Torii [A]:** Yes, to a certain extent, we were prepared for that and decided on the policy.

**Sakai [Q]:** I understand.

Also, what are the dates for the R&D briefing in December?

**Torii [A]:** We schedule it on December 11.

**Sakai [M]:** I see. Thank you.

**Hashiguchi [Q]:** My name is Hashiguchi from Daiwa Securities. Thank you.

Firstly, regarding the impact of the change in Crysvida's US label and the replacement with the new label, can you give us some concrete figures on how much it affected in Q3?

**Kawaguchi [A]:** I am sorry about the specific numbers, let us keep them undisclosed.

As for sales, as I mentioned earlier, we expect that that will recovered over the full year, and on the other hand, we need to dispose of items that have been returned or labeled as Ultragenyx products, but the cost of disposal associated with these items is about JPY0.1 billion, so the cost impact will not be large.

**Hashiguchi [Q]:** Thank you very much.

Related to that, I think Q2 is when the shipment of Kyowa Kirin-labeled products started, but at that time, did you experience a situation where there were slightly more sent products than returned products?

**Sudo [A]:** Mr. Hashiguchi, Sudo will answer your question.

In fact, there was a plan to do it gradually from Ultragenix NTC number to our products, but considering the confusion in the market, we thought it would be better to switch at one time, within a week or two, and that's why the changeover occurred in September.

**Hashiguchi [Q]:** Thank you very much.

The second point is the status of G-Lasta in Japan, and I believe the launch of the biosimilar is imminent. Could you please provide information on the share of sales of bodypod formulations with no biosimilars, and to what extent the share of bodypods in G-Lasta's sales has now risen?

**Fujii [A]:** I'm Fujii. Thank you for the questions.

The figures for just the bodypods of the G-Lasta are that we are unable to disclose them at this time.

**Hashiguchi [M]:** I see. I understood. That's all. Thank you very much.

**Moderator [M]:** Thank you.

There being no further questions, this concludes the online presentation on the financial results for Q3 of the fiscal year ending December 31, 2023.