Kyowa Kirin Co., Ltd.

Q3 Financial Results Briefing for the Fiscal Year Ending December 2024

October 31, 2024

Event Summary

[Event Name]	Q3 Financial Results Briefing for the Fiscal Year Ending December 2024	
[Date]	October 31, 2024	
[Number of Speakers]	4	
	Masashi Miyamoto	Representative Director, President and Chief Executive Officer
	Takeyoshi Yamashita	Director, Senior Managing Executive Officer and Chief Medical Officer
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer
	Yasuo Fujii	Managing Executive Officer and Chief Strategy Officer

Presentation

Moderator: Thank you very much for joining us today for the online conference on Kyowa Kirin Co., Ltd.'s financial results for Q3 of the fiscal year ending December 31, 2024.

Prior to the online conference regarding Q3 financial results, President Miyamoto will explain the change of Representative Directors, President, which was announced at 15:30 today.

Miyamoto: Thank you all for taking time out of your very busy schedules to gather and participate. This is Miyamoto.

At the meeting of the Board of Directors held today, the Board informally decided on the personnel and structure of the Representative Director, President, who will start in the spring of next year. Although this is a financial results meeting, I think this is an important announcement, so I would like to briefly explain the situation.

The details of today's informal decision will be officially decided at the annual shareholders' meeting to be held in March 2025, next year, and the Board of Directors' meeting to be held after the shareholders' meeting.

I, Miyamoto, have been informally appointed as Chairman and CEO, and a new position of COO has been created, and Mr. Abdul Mullick, Managing Executive Officer, has been informally appointed as President and COO.

Mr. Mullick, who will become President and COO, will oversee the overall execution and execution of operations at the global level, and will further strengthen cooperation among regions and functions while advancing the strategy quickly and steadily.

As CEO, I will continue to lead discussions on the Company's direction and overall strategy, as well as communicate with market participants and other key external stakeholders. In addition, Mr. Osawa, Vice President and Representative Director, will be stepping down from his position.

Kyowa Kirin is working to realize its 2030 Vision by placing three pillars at the center of its strategy: provide pharmaceuticals for unmet medical needs, address to patient-centeric helthcare needs, and retain the trust of society.

As the entire Kyowa Kirin movement is being strengthened and accelerated in line with the Story for Vision 2030 set forth this spring, we have decided to make partial changes to our management structure in order to make the Kyowa Kirin Group an even stronger and more flexible team on a global level.

To reach this decision, the Nomination and Compensation Advisory Committee, chaired by an independent outside director, has continuously discussed succession over a period of more than five years, receiving a variety of opinions from both internal and external committee members.

As a result of our continued efforts to listen to, talk to, and get to know the candidates, I, as well as all the committee members, have come to a common understanding that Mr. Mullick is the most qualified person to be the next leader.

At the end of last month, the Nomination and Compensation Advisory Committee unanimously voted to recommend Mr. Mullick as President and COO, and today the Board of Directors resolved and informally approved it. Mr. Mullick joined the Kyowa Kirin Group in 2018 as part of the global leadership team, serving as the Rare Disease Lead for the EMEA Region and then as Region President, leading overall growth in EMEA.

In 2023, he and his family moved to Tokyo, where he has been leading the growth of global products as Chief International Business Officer. In EMEA and during the phase of leading the transformation of the business in the Asia Pacific region, he not only transforms the organization into what it should be, but also interacts very closely and proactively with the employees, demonstrating high management skills in the business, the organization, and the employees.

He has a great deal of experience, but he never imposes it on us, but rather, based on an accurate understanding of the internal and external situation, he considers what is best for our growth and the smiles of our patients, makes decisions after deep discussions, and steadily implements them.

I am confident that with Mr. Mullick's lead, the Kyowa Kirin Group will become an even greater team and grow as one team to continuously create and deliver life-changing value.

As Chairman and CEO, I will work hand in hand with Mr. Mullick to make the management structure of the Kyowa Kirin Group even more solid and will do everything in my power.

I apologize for being the only person to send greetings today, I would like to say that we are planning to hold a hybrid financial results presentation in February, including a face-to-face meeting, and we are considering having Mr. Mullick speak at the meeting. We look forward to your continued guidance and encouragement. Thank you for the presentation today.

Moderator: We will now convene an online meeting to discuss the Kyowa Kirin Company, Ltd. financial results for Q3 of the fiscal year ending December 31, 2024, 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 people who explained today for a certain period of time as a list of participants.

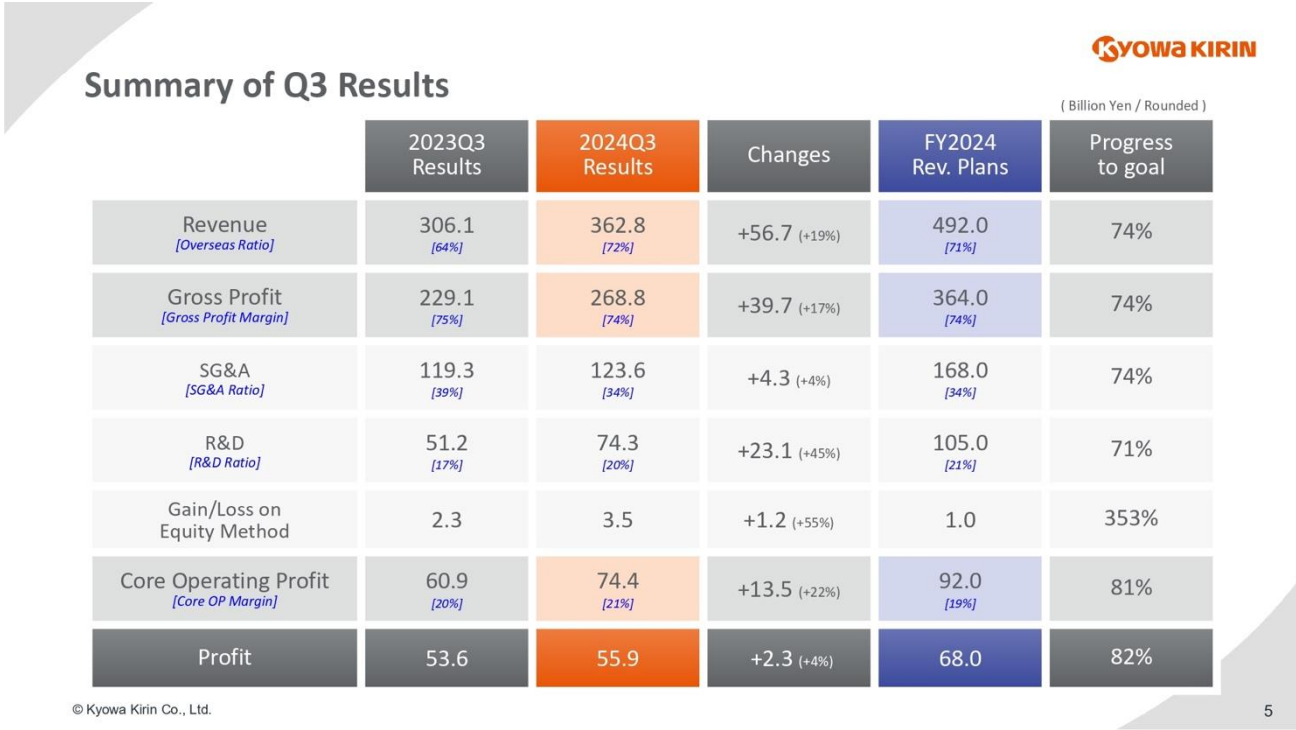
Please also note that the content of this presentation will be available on our website as an on-demand stream and transcript. We would appreciate your understanding in this regard before making any comments.

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

Today's speakers and Q&A session are Takeyoshi Yamashita, Director and Senior Managing Executive Officer, CMO; Motohiko Kawaguchi, Managing Executive Officer, CFO; and Yasuo Fujii, Managing Executive Officer, CSO.

Today's online meeting is scheduled to last a maximum of 90 minutes and end at a maximum of 18:30. We will provide an overview of the project and then we will take questions from the audience. Please download the documents from our IR website. Please note that Mr. Miyamoto, President, will leave the meeting due to circumstances.

Kawaguchi will now give an overview of the financial results.



Kawaguchi: I will now start with the performance summary for Q3 of 2024. Please see page five of the slide.

First, YoY, revenue was JPY362.8 billion, an increase of JPY56.7 billion, or 19%. Core operating profit was JPY74.4 billion, an increase of JPY13.5 billion, or 22%. Profit was JPY55.9 billion, an increase of JPY2.3 billion, or 4%.

Revenues were up 19% due to growth in global products and the impact of foreign exchange, as well as the early transfer of the intellectual property (IP) for established pharmaceuticals in Europe in Q3.

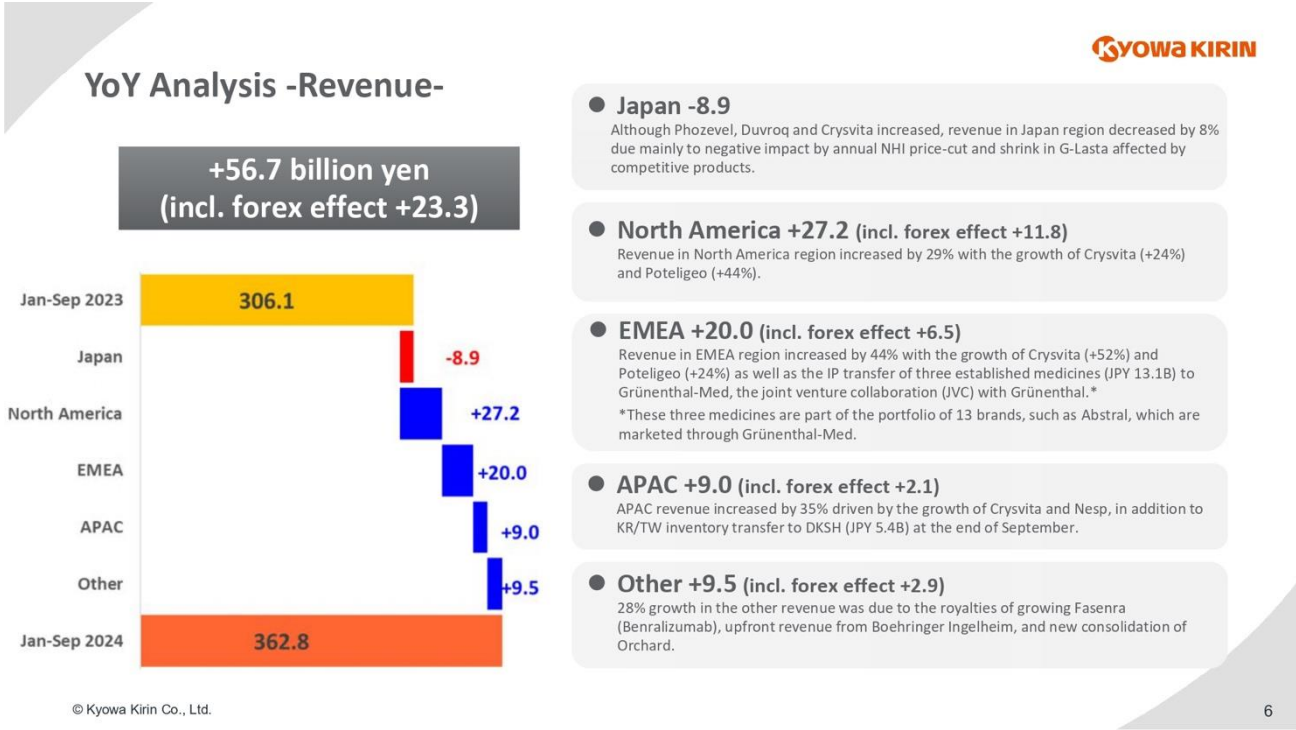
As for core operating profit, R&D expenses increased significantly due to progress in the development of KHK4083 and the new consolidation of Orchard. The 22% increase in gross profit was due to higher revenues.

Profit increased slightly by 4% because in the previous year, gain on sales of 51% shares plus gain on valuation of remaining 49% shares associated with the joint venture of the EMEA established medicine portfolio, was recorded.

As for progress toward the revised plan for the full year, which was revised in Q2, revenue is 74% of the revised plan of JPY492 billion, which is well in line with our plan. Selling, general and administrative expenses are also in line with the plan, at 74% of the revised plan. As for R&D expenses, 71% progress has been made. We plan to continue to invest in research and development, particularly in KHK4083.

Regarding equity in earnings of affiliates, the European Established Pharmaceutical joint venture with Grünenthal has been profitable, resulting in a high rate of progress.

As a result, core operating profit and profit progressed 81% and 82%, respectively. As mentioned above, our overall consolidated performance through Q3 has been on track and in line with the revised plan line, and we hope to steadily achieve our full-year targets.



Next, please see page six. This is a YoY analysis of revenue by region.

In Japan, sales of Phozevel, Duvroq, Crysvita, and other products have been growing, with Phozevel, a new product, in particular performing well since its launch in February. On the other hand, sales in the Japan Region declined 8% due to the entry of biosimilars and a decrease in sales of G-Lasta, which was affected by the NHI price revision.

As for North America, sales grew by 29%, thanks to solid growth in Crysvita and Poteligeo, as well as the impact of the yen's depreciation.

In EMEA, in addition to Crysvita and Poteligeo increasing their sales, the Company recorded a 44% increase in sales as a result of the one-off sales of JPY13.1 billion recorded in July, since the contract for three brands of the bulk transfer of the rights of the 13 established pharmaceutical brands sold by the joint venture with Grünenthal, originally scheduled for 2026, was brought forward to July.

In APAC, in addition to growth in sales of Crysvita, Taiwan's Nesp, and other products, sales of JPY5.4 billion were recorded as a result of the bulk transfer at the end of September of product inventory of established pharmaceuticals' Korean and Taiwanese subsidiaries to its licensing partner, DKSH, in accordance with the reorganization of APAC operations announced in August. As a result, sales increased by 35%.

As for others, revenues increased by 28% due to higher royalties from Fasenra and upfront income in Q1 from Boehringer Ingelheim, as well as revenue from sales of hematopoietic stem cell gene therapy from the newly consolidated Orchard.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2023Q3 Results	2024Q3 Results	Changes	Reasons	2024 Rev. Plans*	Progress to goal
Crysvita	7.4	8.2	+0.8 (+11%)	Market penetration (Launched in Dec 2019)	12.9	63%
Poteligeo	1.4	1.4	-0.1 (-4%)		1.9	72%
Nesp + Nesp-AG[1]	12.7	10.4	-2.2 (-17%)	NHI price-cut & Biosimilars' penetration	14.4	72%
Nesp	2.3	2.0	-0.3 (-14%)		2.8	72%
Nesp-AG	10.3	8.5	-1.9 (-18%)		11.7	72%
Duvroq	6.9	8.9	+2.1 (+30%)	Market penetration (Launched in Aug 2020)	12.2	73%
Phozevel	-	2.9	+2.9 (- %)	Launched in Feb 2024	3.3	88%
Orkedia	7.6	7.5	-0.1 (-1%)		11.7	64%
G-Lasta	23.2	15.3	-7.9 (-34%)	NHI price-cut & Biosimilars' penetration	20.5	74%
Rituximab BS	6.7	5.7	-1.0 (-15%)	NHI price-cut	7.9	72%
Romiplate	8.7	9.9	+1.2 (+14%)	Market penetration (New indication in Jun 2019)	13.2	76%
Nouriast	5.5	5.1	-0.5 (-9%)		7.1	71%
Haruropi	3.2	3.3	+0.1 (+3%)		5.2	64%

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.

* 2024 Revised Plan announced on August 1, 2024, there is no changes to the "Revenue of Major Items (Japan)"

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Now, please refer to page seven. Here is the situation by product in Japan.

Crysvita continues to grow steadily with an 11% increase over the previous year, although the rate of progress appears to be low relative to the plan.

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

Duvroq grew steadily with a 30% increase over the previous year and maintained the number one market share within its class.

Phozevel has posted sales of JPY2.9 billion since its launch on February 20 and is steadily penetrating the market at a pace that exceeds the planned line.

G-Lasta sales decreased by JPY7.9 billion, or 34%, from the previous year due to the impact of the entry of biosimilars in last November, the NHI price revision in April, changes in the additional drug creation allowance, and the impact here.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2023Q3 Results	2024Q3 Results	Changes	Reasons	2024 Rev. Plans	Progress to goal
Crysvita	95.7	126.7	+31.0 (+32%)		187.8	67%
North America	70.2	87.2	+17.1 (+24%)	Market penetration		
EMEA	24.5	37.1	+12.7 (+52%)			
APAC	1.1	2.3	+1.2 (+117%)			
Poteligeo	19.9	27.7	+7.8 (+39%)		34.8	80%
North America	15.1	21.6	+6.6 (+44%)	Market penetration	25.1	86%
EMEA	4.8	6.0	+1.1 (+24%)		9.3	64%
APAC	0.0	0.1	+0.1 (- %)		0.5	24%
Libmeldy / Lenmeldy	-	2.2	+2.2 (- %)	New consolidation of Orchard (FDA approval in Mar 2024)	4.9	44%
Nourianz	5.5	6.2	+0.7 (+12%)		9.1	68%
Nesp	7.0	8.8	+1.8 (+25%)		10.7	82%
Gran	5.2	5.4	+0.3 (+5%)		7.2	76%
Tech-licensing	29.3	33.7	+4.4 (+15%)	Upfront revenue from Boehringer Ingelheim and growth of Fasenra	47.8	71%
Benralizumab Royalty[1]	19.1	21.6	+2.4 (+13%)			

1 Sales royalties of Fasenra 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.

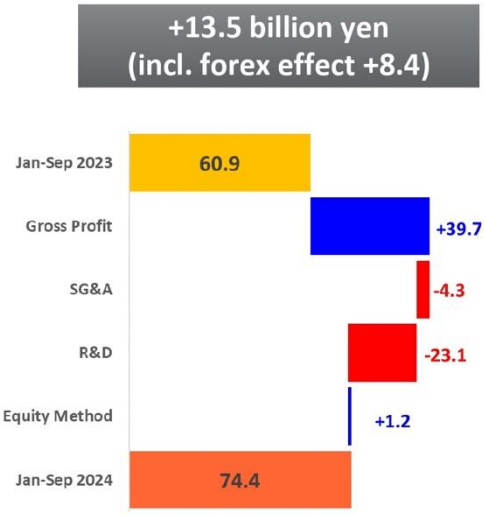
Crysvita continues to grow steadily in each region, with revenues up JPY31 billion, or 32%, over the previous year.

Poteligeo also continued to grow, adding JPY7.8 billion, or 39%, YoY. Sales in North America remained strong, and in EMEA, market penetration increased, resulting in higher sales.

Libmeldy/Lenmeldy, but with the new consolidation of Orchard from January 24, we have recorded JPY2.2 billion of Libmeldy's sales revenue in Europe. Although Lenmeldy was approved in the US in March, we have not yet recorded any sales revenue in the US at this time.

Tech-licensing revenue increased JPY4.4 billion, or 15% YoY, due to an increase in royalties from Fasenra and the recognition of an upfront licensing payment for a new compound licensed out to Boehringer Ingelheim in January.

YoY Analysis -Core OP-



- **Gross Profit +39.7 (incl. forex effect +20.3)**
  Increased in conjunction with JPY 56.7B rise in revenue. COGs have increased due to the North America Crysvita Sales royalty after Apr 27, 2023. Hence, gross profit % declined YoY. (75% →74%)
- **SG&A -4.3 (incl. forex effect -7.2)**
  SG&A increased due to increase in HR expenses, new consolidation of Orchard, and FX impact, despite the decrease in Crysvita profit-sharing expenses because of the North America Crysvita-related scheme change after Apr 27, 2023.
  [HR exp -7.9 / Sales promotion +9.6 (incl. Crysvita profit sharing expenses +10.9)]
- **R&D -23.1 (incl. forex effect -4.9)**
  Increased in clinical study costs of KHK4083 which is undergoing joint global Phase III clinical study and new consolidation of Orchard
- **Gain/Loss on Equity Method +1.2 (incl. forex effect +0.2)**
  JVC with Grünenthal, gain on inventory transfer have occurred in connection with operation transfer to Grünenthal in certain countries.

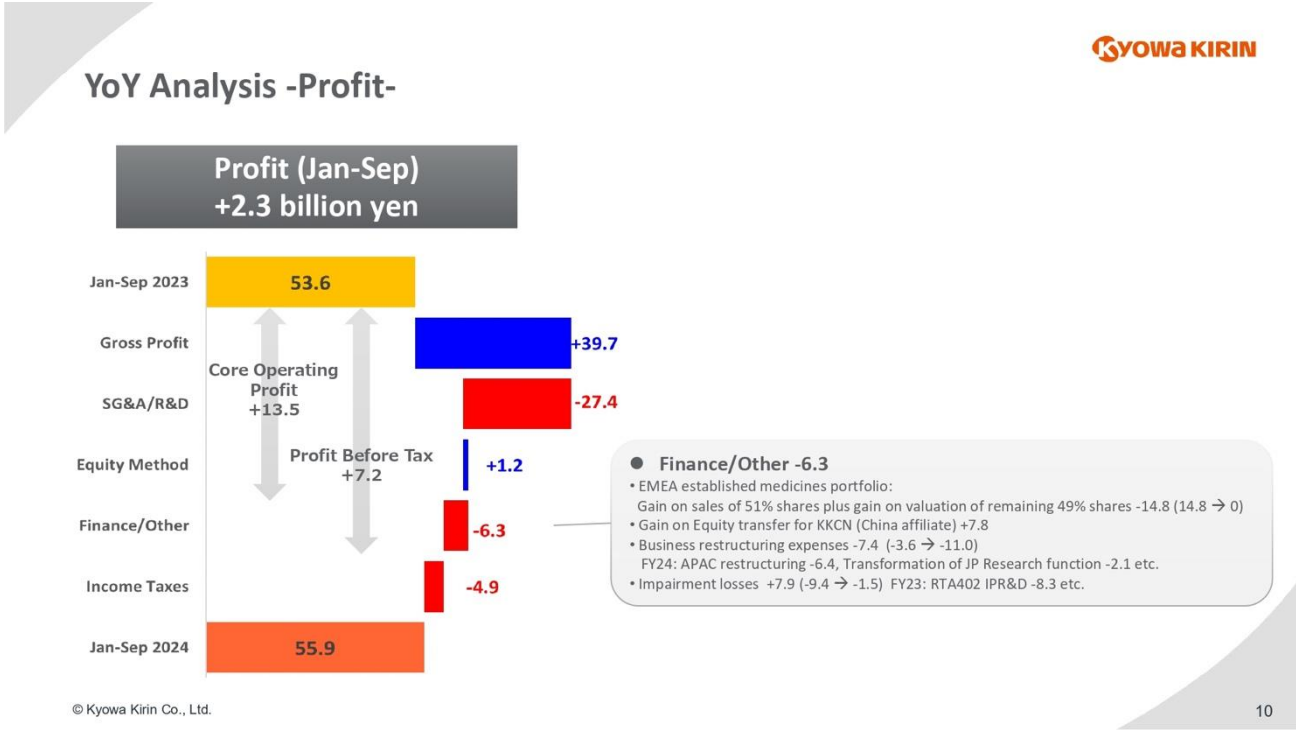
Now, please turn to the next page, nine.

Gross profit increased plus JPY39.7 billion, or 17%, in line with the increase in revenue. The gross margin declined by 1% to 74% due to an increase in cost of sales resulting from the recording of sales royalties to sales cost since Crysvita began its own sales in North America last April.

Selling, general and administrative (SG&A) expenses were affected by the absence of profit-sharing expenses recorded since the start of in-house sales of Crysvita in North America, but increased by JPY4.3 billion, or 4%, due to factors including an increase in personnel expenses, the consolidation of Orchard, and the impact of foreign exchange rates.

R&D expenses increased significantly by JPY23.1 billion, or 45%, from the same period last year due to progress in the development of KHK4083 and the new consolidation of Orchard. The ratio of R&D expenses to sales revenue also increased by three percentage points to 20% from 17% in the previous year.

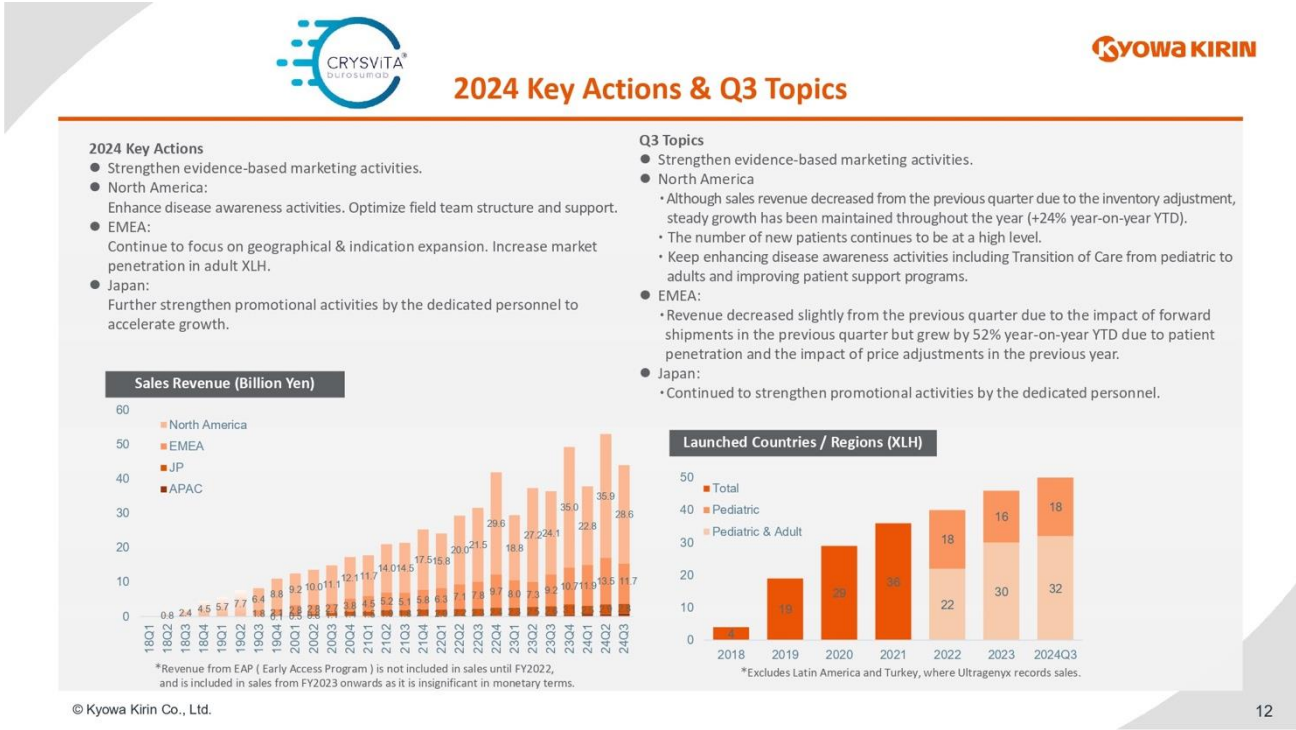
Equity in earnings of affiliates increased by JPY1.2 billion. The European established pharmaceuticals business, a joint venture with Grünenthal, has benefited from the transfer of inventory in connection with the transfer of sales in certain countries. As a result, core operating profit increased by JPY13.5 billion compared with the same period of the previous year. Of this amount, the foreign exchange impact is JPY8.4 billion.



Now, please refer to page 10. In this slide, I would like to show you the part below core operating profit.

Financial and other decreased by JPY6.3 billion. In Q3, there was a gain of JPY7.8 billion from the equity transfer of a Chinese subsidiary, but there was no gain of JPY14.8 billion from the sale and valuation of shares related to the establishment of a joint venture in the European established pharmaceutical business, which was recorded in the same period of the previous year. In addition, business restructuring expenses increased due to the APAC restructuring and other factors, resulting in negative YoY growth.

As a result, quarterly profit increased by JPY2.3 billion, 4%, compared with the same period of the previous year.



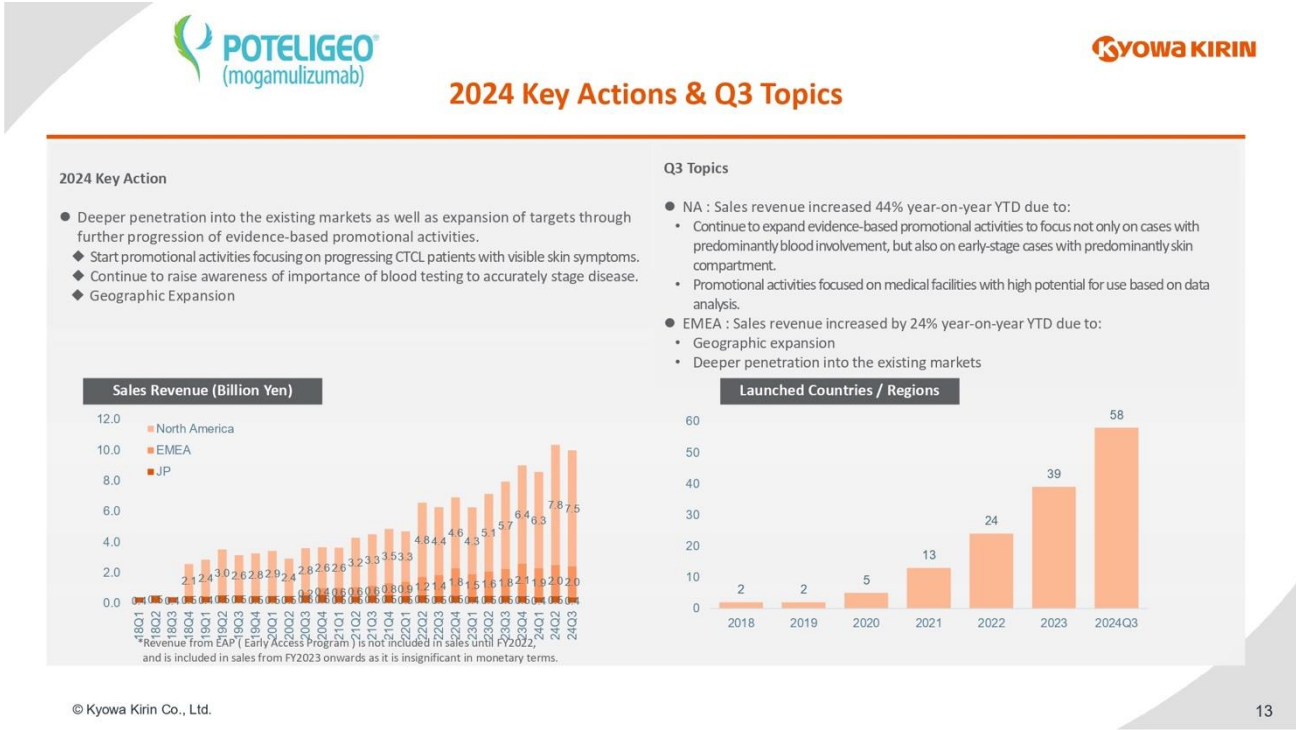
Fujii: Next, Fujii will explain about the commercial update. Please see page 12. First, we will start with Crysvita.

The graph at the bottom of the page shows sales revenue and the number of the launched countries or regions since its launch. Although Q3 sales revenue was lower than the previous quarter due to the impact of some shipments scheduled for Q3 being brought forward to Q2 in Europe and inventory adjustments in North America, yearly total revenue was JPY134.9 billion globally, a 31% increase compared to the same period last year. The Company has continued to achieve steady growth with an increase in revenue of JPY31.7 billion in value.

In North America, inventory levels were compressed throughout Q3, which was also a factor in the revenue decline compared to the previous quarter. Inventory is expected to build up again toward the end of the year and is therefore considered a transitory factor.

The number of start forms and new patients continues to grow steadily, and we will continue to strengthen our disease awareness activities, and patient support programs for patients who are transitioning from pediatric to adult health care.

Japan also continued to grow by 11% YoY, although behind schedule.



Please refer to page 13. Next is about Poteligeo.

Poteligeo's sales revenue also grew by 36%, to JPY29 billion globally, an increase of JPY7.7 billion over the same period last year.

In North America, through evidence-based promotional activities, we promoted penetration to patients with tumor cells in the blood and access to patients presenting with skin symptoms. In addition, based on data analysis, we continue our promotional activities, focusing on medical facilities with higher potential for administration. In addition to the boost from foreign exchange, business growth through these initiatives has led to a significant increase in revenues.

In Europe, we continue to grow through regional expansion and disease awareness activities to reach patients. We will continue to focus on further penetration to existing markets and target expansion through the evolution of evidence-based marketing activities to achieve growth.

That's it for the commercial update.

News Flow of Main Development Pipeline Products

KYOWA KIRIN

As of Oct. 31, 2024

Code Generic Name	Events (Completed are in bold)		Timeline (Completed are in orange)
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis	P3 (ROCKET Program)	In progress
		HORIZON Topline Data	Sep 2024
	Asthma	P2	In progress
	Prurigo nodularis	P3	In progress
KHK4951 tivozanib	nAMD	P2	In progress
	DME	P2	In progress
KK4277	SLE, CLE	P1	In progress
KK2260	Advanced or metastatic solid tumors	P1	In progress
KK2269	Advanced or metastatic solid tumors	P1	In progress
KK2845	**AML**	**P1 initiation**	October 2024
KK8123	XLH	P1 initiation	Q4 2024
OTL-203	MPS-IH (Hurler syndrome)	Registrational study[1]	In progress
OTL-201	MPS-IIIA (Sanfilippo syndrome type A)	Proof-of-concept study[2]	In progress

1. Equivalent to P3 study; 2. Equivalent to Ph 1/2 study

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Yamashita: Next, Yamashita will introduce the R&D update. Please turn to page 15.

Of the news items listed on this slide, those that have changed since the last time are indicated in orange. I would like to introduce these changes.

First, rocatinlimab, the Phase III study in atopic dermatitis, the ROCKET program, is underway. To date, enrollment has been completed in six trials with a total of 3,200 patients participating.

Last month, we also announced top-line data on the HORIZON study, which is one of the Phase III study programs. As a result, the primary endpoints, EASI-75 and vIGA, were achieved with significant improvement over the placebo group.

In addition, all major secondary endpoints were also achieved. The safety profile was comparable to that of the Phase II study.

We believe that rocatinlimab may be the drug to realize a new concept called T-cell rebalancing. We will continue to work toward our goal of obtaining approval by the end of 2026 by making good progress in the Phase III study that is currently underway.

The other issue is KK2845. This is also our first ADC formulation, which we introduced at last month's R&D presentation. We are pleased to announce that the Phase I study has started smoothly.

This is the end of the report on R&D for this fiscal year.

Year-to-date Key News Flow

KYOWA KIRIN

As of Oct 31, 2024

Category	Date	Headline
MKT	Sep 19	Presented new research on the real-world experiences of people living with XLH and the impact of Crysvita treatment at American Society for Bone and Mineral Research (ASBMR) 2024 annual meeting
R&D	Sep 25	Announced Top-line Data from rocatinlimab Phase 3 ROCKET HORIZON Trial for Adults with Moderate to Serve Atopic Dermatitis
R&D	Oct 24	A Faculty Member of the School of Life Science and Technology, Institute of Science Tokyo has been Appointed as a Researcher through the Cross-Appointment System
MGMT	Oct 31	Notice Regarding Changes of Representative Directors
		Updates after the previous earnings announcement

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP; strategic partnering MKT; marketing MGMT; management

Fujii: Finally, Fujii would like to explain some news from the beginning of the year.

Please see page 19 for news since the Q2 financial results.

As announced on October 24, a professor from the School of Life Science and Technology, Institute of Science Tokyo has been appointed as a senior researcher at our Tokyo Research Park under the cross-appointment system promoted by the Ministry of Economy, Trade and Industry.

Associate Professor Kadonosono has a high level of expertise in biopharmaceutical design technology, and we aim to combine his talent with our drug discovery technology to create innovative drugs.

Changes of Representative Director

Kyowa Kirin agreed on changes of its Representative Directors. The changes will be formally approved at the Ordinary General Meeting of Shareholders and the Board of Directors meeting to be held on March 2025.

~Reason for change (Abstracts)~

Kyowa Kirin will step into a new stage of its transformation into a Japan-based global specialty pharmaceutical company by making enhancements to the management team at the global level which we believe will help us achieve further heights. In the new structure, we have decided to establish a Chief Operating Officer (COO), and to adopt a dual structure of CEO and COO. The Chairman & CEO will lead discussions on the Kyowa Kirin's direction and overall strategy, while maintaining relationships with stakeholders. The President & COO will oversee the execution of all business operations at the global level, enhancing collaboration across regions and functions, and will promptly and steadily advance the management strategy.

Abdul Mullick
Nominee for the President and COO

	Name	New Position	Current Position
New	Masashi Miyamoto Ph D.	Representative Director Chairman and Chief Executive Officer (CEO)	Representative Director President and Chief Executive Officer (CEO)
New	Abdul Mullick Ph D.	Representative Director President and Chief Operating Officer (COO)	Managing Executive Officer and Chief International Business Officer (CIBO)
Retiring	Yutaka Osawa Ph D.		Representative Director Executive Vice President and Chief Compliance Officer (CCO)

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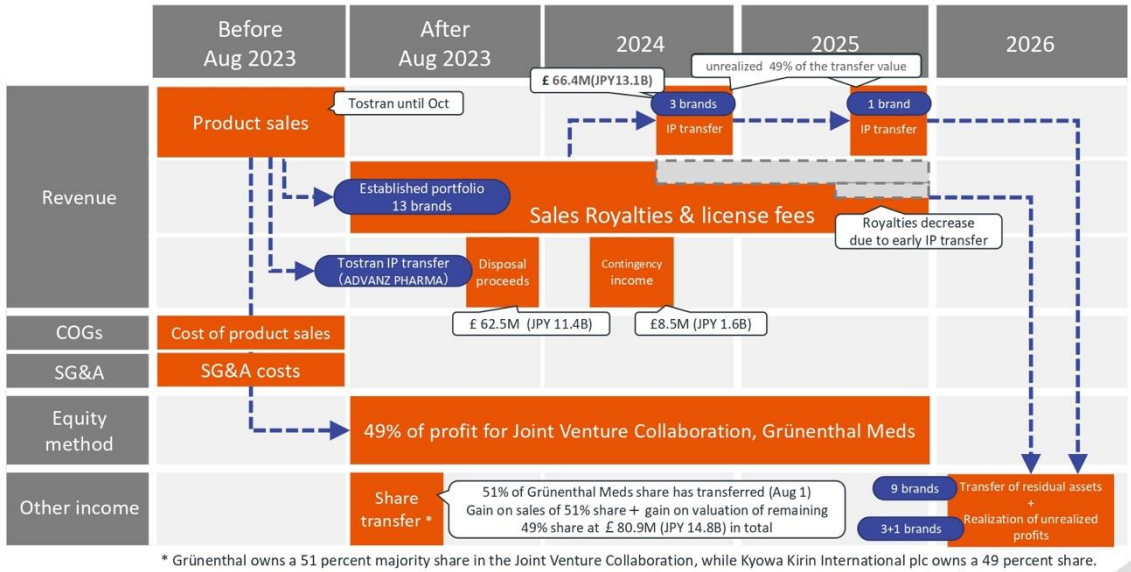
As Miyamoto explained at the beginning of this meeting, today we've announced a change in representative directors. This is an overview of the news, but for more detailed information, please refer to the documents and other materials released today.

P/L Impact on EMEA established medicines portfolio (updated Q3 2024)



* 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 → 9 brands, via exercising an option in Q1, 2026

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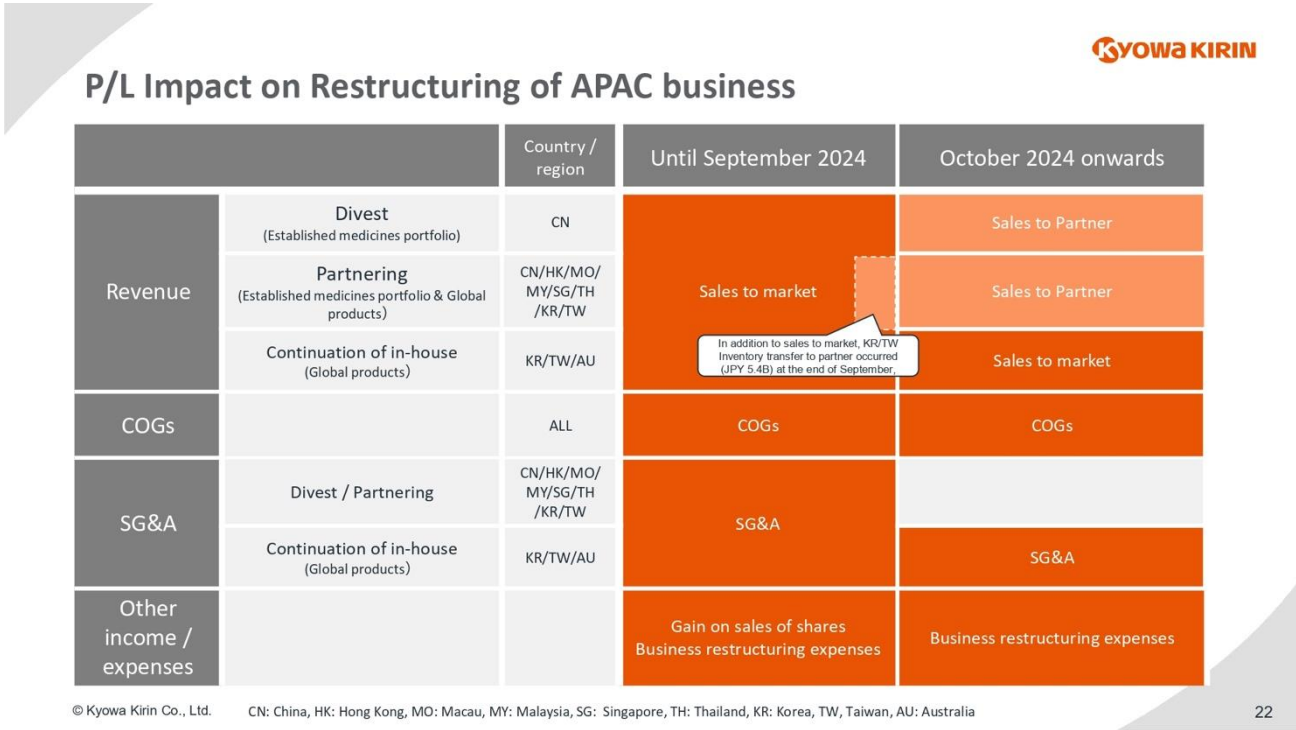
As partially mentioned in our financial review, in July of this year we transferred the licenses of three of our 13 EMEA established pharmaceutical brands to our joint venture with Grünenthal.

When we announced the joint venture partnership in 2022, we explained that if Grünenthal would exercise its option rights, the transfer would be scheduled for Q1 of 2026. So this early transfer will result in the planned revenue in Q1 of 2026 being recorded separately in 2024 and 2025.

The total amount transferred has traditionally been undisclosed, but the impact on revenue for the current fiscal year of the amount of the items transferred early this time is shown in the balloon.



Next is an update on the restructuring of the APAC business.

We had assumed that the commercials would be affected from October onward, but some of the inventory in Korea and Taiwan was transferred to our partner DKSH at the end of September, so we have added this point in the balloon.

This completes today's presentation.

Question & Answer

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

If you have any questions, please click the raise your hand button on the center bottom on the screen and wait. We will nominate you in order. If you have been requested to unmute on the screen, please unmute yourself and ask your question after your company name and your name. If you wish to cancel your question before your turn, please click on the "put down the hand" button.

To allow us to receive questions from as many people as possible, we will limit the number of questions to a maximum of two per question. Well then, please begin.

Wakao [Q]: I'm Wakao from JPMorgan. Thank you. I have a routine question, and I apologize for the first one. About Crysvita in the United States. You mentioned that progress appears to be somewhat slow but steadily increasing, but I am still concerned about the decline in Q3, so I would like to know what happened in this Q3 when I look at QoQ.

In addition, I would like to know when you expect the LOE of Crysvita in terms of lifecycle management. This is my first question.

Fujii [A]:

In Q3 in North America, there was a perception that inventories at the end of Q2 were higher than usual, but we think that the low inventory level in Q3 was one of the first influences.

Also, the number of new patients, which is the start form, has definitely already appeared at a high level. In local currency terms, we have also maintained a double-digit growth rate. Also, we have recently recognized that there are patients whose treatment is temporarily interrupted during the transition from childhood to adulthood or other life events, and I think this is the case. In addition to the inventory, we are thinking that this may have an impact on the level of Q3.

Wakao [Q]: I understand. I think your plan has not changed, so we can expect a certain amount of inventory to be accumulated or shipped in Q1 again, so I was wondering if it is correct to say that the plan will be met. I was a little surprised to hear that there are patients who interrupt the treatment.

In other words, the safety of the treatment is at a very high level, and I was wondering if the symptoms could worsen or progress if the treatment is stopped. Why would they stop?

Fujii [A]: I meant about compliance with the medication, that there are patients whose interval is extended a little longer than usual.

For example, when a student who has gone from high school to university moves into a dormitory, the normal rhythm of life in the dormitory changes, and this may cause a temporary deterioration in treatment compliance. I mean those cases.

As you pointed out, there is a possibility that symptoms may worsen or even revert to their original state due to discontinuation of treatment. So we will continue to make efforts to convey the usefulness of compliance through patient services.

Wakao [Q]: And is my understanding correct that the plan can be accomplished? And sorry, I also asked about LOE first.

Fujii [A]: The plan for this fiscal year is quite challenging, but as you said, we normally tend to build up inventory in Q4, so I think we are headed for a very challenging Q4.

And as for LOE, the substance patent currently in North America. Do you mean North America?

Wakao [Q]: Both North America and Europe. The reason I ask is that I think Ultragenyx has a patent for Q2W until 2035, but I wonder if there is a patent for Q4W that will expire. I was wondering if Ultragenyx and your company's approach is different to begin with. A little bit of that.

Fujii [A]: We are aware that substance patents will be granted until 2033 in Japan, 2033 in Europe, and 2032 in the United States.

Also, there is a DOSE patent in addition to the substance patent, and the patent term is 2035, so I think we are aware of the same thing as Ultragenyx.

Wakao [Q]: I understand. So is it safe to expect until 2035?

Fujii [A]: The question is how strong the patent is, and we can't guarantee that it will be okay or not, but the DOSE patent exists until 2035, which is the year we took it.

Wakao [Q]: Thank you very much. Secondly, I would like to know if there have been any changes in rocatinlimab from the time the data was presented to this point in time. If you have any information, I would appreciate your referral. And if anything, I feel that the external environment is changing more. I would like to know if there is any change, because I think it would be difficult to obtain marketable results with the results you have obtained so far.

Recently, there has been some data regarding Ebglyss, Lilly's lebrikizumab, that says it works for people with Dupixent-failure, and I think your company is probably aware of the news. With results like these, if the results of the future trial are similar to the results of this first trials, how do you think rocatinlimab will be used in the market?

Yamahista [A]:

First of all, as to the first point about whether there is any new information, unfortunately there is not. This is in accordance with the information presented at the last R&D debriefing.

So, to repeat, we have only one study result, and I am sure there will be a lot of discussion about comparing the results of different studies under different conditions. We are conducting eight Phase III trials under various conditions, and as we see the results of these trials, the value of rocatinlimab will become clearer, and we are moving forward with high expectations for it.

Then, I think the news of Ebglyss was released just recently. The fact that Dupixent was effective for patients who had lost the efficacy of Dupixent, we are very positive about this idea, as one idea.

If the mode of action is different, even with Dupixent-failure, it may not work for IL-4, but may be fine for IL-13, and similarly, we think OX40 can be used for such patients. We would like to consider areas where we can use in the future with such expectations. I think we can clarify such things with data. That is all.

Wakao [Q]: Thank you very much. Incidentally, is it correct that rocatinlimab has been proven to be effective for the face and hands as well?

Yamashita [A]: I didn't quite catch what you said just now.

Wakao [Q]: Does it work for the face? I think that Dupixent does not work a lot for the face, though.

Yamashita [A]: Well, I don't have data on that either, and those data are not identified, I guess. As you say, we have heard that Dupixent is not effective for the facial area very much, and I hope that such areas will be clear and work beautifully.

Wakao [M]: I see. Thank you. That is all.

Sakai [Q]: This is Sakai. Excuse me, just to confirm, rocatinlimab which comes next would be IGNITE and SHUTTLE, right? I would like to confirm the timing of the disclosure of data on them.

If you do a data readout by the end of the year, the timing of the disclosure is, therefore, a bit irregular in the form of this ROCKET, which was a surprise disclosure by Amgen. We would like you to avoid such surprises, but could you please clarify a bit more the timing of when you or Amgen will disclose the information?

Yamashita [A]: First, I suppose Amgen, in their last presentation, had some kind of diagram that suggested the timing of the lead-out of the development trial.

I think the timing is such that if the examinations go well, we should be able to see the top line of results as the time goes by. We are still thinking of various possibilities, such as disclosing it immediately or doing it in conjunction with other exams. We have not yet fixed what we mean by timing of disclosure at this time.

Regarding the method of disclosure, I think it was not very appropriate last time, so we are now in the process of exchanging opinions and discussing with Amgen based on some issues to ensure that the method of disclosure is appropriate.

Sakai [Q]: I don't know if there is a rule that says that academic societies have priority, or whatever you call it. Apart from that, since one has already been released, have you expressed your intention to announce the next two trials in agreement with Amgen, regardless of such bindings? Is this a very soft level of story or response, like "We will discuss this issue further?" Could you please clarify these points a little more?

Yamashita [A]: We don't have any particular rules about prioritizing academic conferences or anything like that. We have to decide and disclose how we should disclose the clinical trial data appropriately when they are ready. As I mentioned earlier, we have not yet decided on some of the methods that will be used at this point in time.

Sakai [Q]: Well, I am sorry, I am a little persistent. At any rate, I think there is a slide that Amgen prepared, as you mentioned, so I take it as a lead out within the year. Regarding that slide, you will not deny it, but you will affirm it, is that correct? So there are no changes at this time, right?

Yamashita [A]: Yes, this is also being put out by Amgen, and I think they probably have a more accurate idea of the progress of the trial. Since this is only a forecast at the time of disclosure, I think it is difficult to say whether this is the promised timing or not now. However, I hope you understand that if we proceed in the standard way, this is the timeline that we will follow.

Sakai [Q]: I understand. And one more thing, Crysvita. When you talk about switching from pediatric to adults, are you referring mainly to the US? So I guess the question is whether switching insurance would be necessary in the US. Also, age. Are you saying that an adult is 18 years of age or older? Could you give us a little idea or view of this area, including the definition of pediatric?

Fujii [A]: We understand that it is being administered while the growth plate is still growing. Beyond that, as I mentioned earlier as an example of a life event, we have learned that there are some patients whose compliance with medication, or the interval between dosing, seems to be different when life events change, or when life patterns change due to life events.

As I said before, we are trying to educate these people that if they do not comply with the medication, there is a possibility that their symptoms will reappear.

Sakai [Q]: I think what you are talking about in terms of life events is, for example, going on to higher education or finding a job, that sort of stories. But anyway, I understand. Am I correct in my understanding that the insurance coverage will continue? If switching is not necessary, especially in the US.

Yamashita [A]: There are cases where pediatric patients start treatment at a large local children's hospital or children's center, and continue to be treated there for a long time. Then, when they change to adult care, there are many cases where the doctor or facility where they receive treatment changes, such as when they move to a new place of residence due to higher education, as mentioned earlier. That's where the interruption occurs.

I don't know the details. I don't know if the insurance and reimbursement procedures mentioned earlier are a barrier or not. Maybe when you try to do something like that in a very local clinic, maybe the paperwork takes a little longer or something like that. That is a little bit how I understand it.

Sakai [M]: I understand. In any case, I understand that there is no problem if they continue the treatment. Thank you.

Yamaguchi [Q]: I am Yamaguchi from Citi. Excuse me, I'm sorry to ask such a basic question, but I would just like to confirm a few things about the content of your presentation.

The European topic, of this JPY13.1 billion about Grünenthal is the one that happened in Q3, right? Is it correct that it was originally included in the Company's forecast, but you did not disclose where it would happen, and now that it happened in Q3, it looks like that part is temporarily raising the results in Europe.

Kawaguchi [A]: As you understand exactly, this event itself occurred in July.

Yamaguchi [Q]: I see. Thank you. Also, you talked about the progress of a product, Libmeldy, or maybe it's a slightly different name. The rate of progress is a little weak because of the high cost of drugs in the US, as the US market is just getting started.

Including Europe and America, what is your assessment of the prospects for achieving your full-year targets? There is only about a month left, though.

Fujii [A]:

As for Libmeldy in Europe, we believe that this is on the plan line, but the US is very behind. As background, Lenmeldy was approved in March, and though there are considerably more patients identified than I had expected, newborn screening is still not being conducted so much in the United States at present. Almost all of the patients who have advanced symptoms have already exceeded the Lenmeldy indication.

So I think it will become full-scale after the newborn screening is implemented and becomes more widespread in the future. At present, we think that if someone in the family is diagnosed with MLD and there is a sibling there, for example, the patient could be tested and identified in a timely manner before symptoms appear, which would lead to the prescription of Lenmeldy.

Yamaguchi [Q]: Thank you very much. I think there was some talk like that in Europe at first. However, although it is unfortunate that the patients found in the US were already too late, I remember seeing a diagram or something that compared two sibling's patients. You haven't gotten that far yet in the US. You found it, but it was too late. After that, what do you call it? So, in the current situation, you haven't been able to find any patients who are still in time for treatment in the people around patients?

Fujii [A]: Yes.

Yamaguchi [Q]: I see. Though it looks like you won't reach your target for this year, of course if new born screening start, the story will change completely, and if patients are found in that way or you can find them in that way, you can see that they will expand little by little, like in Europe. There are patients, after all.

Fujii [A]: There are patients. They are certainly there. As you say, I believe that once the newborn screening is initiated, a reasonable number of patients will be found and prescribed for the indications.

Yamaguchi [M]: I understand. That is all.

Hashiguchi [Q]: I'm Hashiguchi. Thank you. The first question is to confirm the situation of Crysvita in the US. You mentioned earlier that at the end of Q2, there is a bit more inventory. And at the end of this Q3, on the contrary, there is less inventory. Is this right?

In other words, would it be correct to say that sales in Q2 are slightly greater than the capacity, sales in Q3 are slightly less than the capacity. Is it correct to understand that your real capacity is about the average of these two?

Fujii [A]: I suppose your understanding is correct. However, we have been able to make steady progress year after year. And as I mentioned earlier, we have been able to acquire new patients through the start form, so I think we will continue to see an upward trend.

Hashiguchi [Q]: Yes, I understand. Secondly, I would like to confirm the impact of the transfer of the rights to the established pharmaceuticals business in Europe ahead of schedule. Is it my understanding that it was JPY13.1 billion that you recorded as sales in Q3, and the 49% or JPY12.5 billion that is eliminated as unrealized income will be recorded as other income in FY2026?

Kawaguchi [A]: I am Kawaguchi. As you understand, the actual amount of JPY13.1 billion for the transfer of the brand is 51% of this amount, so the total amount is about twice the sum of them.

However, for accounting purposes, 49% of the total is attributable to the joint venture, which is our equity portion, so that portion will be realized in 2026, when our equity is removed. At that time, it will be realized as a gain on the sale of stock, so the realization will come in under other income, not sales, as you understand it.

Hashiguchi [Q]: Thank you. I think there is one brand in FY2025 and nine brands of option rights remaining in FY2026, and the consideration to be received when these rights are transferred is roughly proportional to the number of brands. In other words, if the total for these three brands this time is JPY13.1 billion, then next year, it will be roughly one-third of that, or something like that. I hope this is not too far off.

If these three brands this time are relatively large or small, and if such a simple calculation would be quite off, I would appreciate it if you could give me some hints.

Kawaguchi [A]: As a maximum hint, these three brands in this issue are major and large brands. We are also planning to sell one brand at a similar level in 2025, so the remaining nine brands will be a little smaller, or rather, the brands will remain. That is the image.

Hashiguchi [M]: I understand very well. Thank you. That is all.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. Thank you. Sorry, I don't understand the numbers properly for a moment, my mind is a little jumbled. In talking about the current one-time profit/loss impact, the operating income for this July-September period is JPY30.3 billion in core operating income, and as you mentioned earlier, there was also JPY13.1 billion for Grünenthal.

Where was it? The JPY5.4 billion gain on the transfer of APAC inventory is also included in the three months from July to September, and the total of JPY18 to 19 billion is included in the core operating income of JPY30.3 billion for the period from July to September as a one-time gain.

Kawaguchi [A]:

First of all, you understand that this JPY13.1 billion is also a positive sales revenue and a positive profit as it is, which leads to a one-time increase in core operating profit in Q3.

Also, JPY5.4 billion was realized at the end of September, and in addition to the normal sales from July to September, it was the inventory that local affiliates had at the end of September. So if we were to say that it was a one-off transfer of inventory that would normally be carried over from October to next year, then it would be a one-off transfer gain, in terms of sales.

This does not mean that the profit is the same as the amount, but rather that the profit is the amount obtained by subtracting the cost from this amount, so JPY5.4 billion here does not directly lead to an increase in profit, it's very minute but I would like to make a small point here.

Muraoka [Q]: I see. Nevertheless, there is no doubt that a certain percentage of this JPY5.4 billion is also included in the core operating income of JPY30.3 billion for the period.

Kawaguchi [A]: That is correct. This is one of the reasons why the progress rate looks good.

Muraoka [Q]: Right, so when you say that sales by region, European sales and Asian sales in the supplemental material are a little high for the past three months, is it correct to say that they are having an impact?

Kawaguchi [A]: That is correct.

Muraoka [Q]: In other words, the reason Q3 is so profitable despite such low Crysvita sales is that JPY13.1 billion is particularly significant. You mean, though, as budgeted.

Kawaguchi [A]: Yes.

Muraoka [Q]: I see. Thank you. Also, Lenmeldy, you mentioned earlier about the US, this quarter is tough, I understand, but I think there have been a few times when you mentioned that the Newborn screening is slowly and gradually starting.

When we look ahead to about 2025 or 2026, where do we start to really get up to speed, or how many more quarters of zero or near-zero quarters should we be prepared for?

Even if we do get out, should we be prepared for another reaction in the next quarter? Or is it still 2025, 2026, one or two years of that kind of thing? Or are you already talking about starting up in the next quarter, in which state and where? I think you mentioned before, in which state and where. A little hint would be helpful.

Fujii [A]:

The MLD has decided that Illinois will start screening, and we are in the process of investigating the feasibility of this.

Also, as I have announced, there is a panel called the Recommended Uniform Screening Panel (RUSP), which determines whether or not newborn screening is required for MLDs.

We are now at the stage of a full-fledged evidence-based review of MLDs based on the submitted data to determine whether they should be included in the newborn screening process. Therefore, I believe that if progress is made in this area, the possibility of finding patients who are truly eligible for Lenmeldy will increase considerably.

So, I heard that the order will be different from state to state, not all 50 states at once. But once the review is completed and MLD enters the newborn screening process, we are hopeful that it will be administered to patients.

Muraoka [Q]: I'm sorry, I'm going to ask the same thing one more time, but I think it is a good drug and wonderful for patients. But I'm talking about the preparedness of the people who make the numbers, but is there a possibility that we will still be having this kind of discussion a year from now? Or do you think you are saying that it will be standing up firmly in a year's time? What kind of image do you have?

Fujii [A]: I think right now, this review depends on how fast progress is made. I don't expect to be having discussions like today's after one year, because there are actually patients in the US who are scheduled for treatment, and I think those people will be expected to receive treatment in 2025.

It's hard to say that there will be zero this quarter and zero this quarter, and I think it won't happen in 2025. However, I don't think there will be a significant increase in the number of patients.

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

Wakao [Q]: I'm Wakao from JPMorgan. Please tell me about one point.

I'm afraid I'm being a bit persistent, but I'm not sure how the equity method investment income/loss will turn out. I know Grünenthal's story is profitable, but it is JPY3.5 billion until the end of September, but the plan is JPY1 billion. What would you call this, is it my understanding that something negative occurs within FKB in Q4 and that it lands as planned by the Company?

Kawaguchi [A]: As for FKB, you are right, and we expect a negative to come in. However, one factor that was not taken into account when we made our revised forecast was that, as I explained earlier, the joint venture with Grünenthal was selling established pharmaceuticals. But in order to accelerate the transition and streamline costs, the scheme was accelerated so that in some countries, Grünenthal would sell directly.

Then the inventory held by the joint venture at that stage would be sold to Grünenthal. The events I mentioned earlier in APAC are also happening in joint ventures, which is a completely different story, but also in joint ventures.

Therefore, in a sense, the profit from the portion of sales that was eaten up in advance came out as equity in earnings of about JPY1.5 billion. We have not factored in this part in our estimates. Though I understand that there will be a slight decrease in sales afterwards, that a certain amount profit will remain, so there is a possibility of a slight upward swing in this part of the sales.

Wakao [Q]: I'm sorry, I think it's something like adding JPY10 [million] to JPY1.5 billion, right? I didn't really understand, but then how much of a landing is it?

Kawaguchi [A]: That is correct. So there is a possibility that up to JPY1.5 billion could remain in the part where JPY1.5 billion was not anticipated.

Wakao [M]: All right. I see. Thank you. Sorry. That is all.

Moderator [M]: Does anyone have any other questions?

There being no further questions, this concludes the online meeting on the financial results for Q3 of the fiscal year ending December 31, 2024.

Thank you very much for your participation today. Thank you for your continued support of Kyowa Kirin.

[END]