Kyowa Kirin Co., Ltd.

Q1 Financial Results Briefing for the Fiscal Year Ending December 2024

May 7, 2024

Event Summary

[Event Name]	Q1 Financial Results Briefing for the Fiscal Year Ending December 2024	
[Date]	May 7, 2024	
[Number of Speakers]	3	
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer
	Takeyoshi Yamashita	Director of the Board, Senior Managing Executive Officer and Chief Medical Officer
	Yasuo Fujii	Managing Executive Officer and Chief Strategy Officer

Presentation

Moderator: We will now convene an online meeting to discuss the Kyowa Kirin Company, Ltd. financial results for Q1 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 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 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 are Takeyoshi Yamashita, Director of the Board, Senior Managing Executive Officer and Chief Medical Officer; Motohiko Kawaguchi, Managing Executive Officer and Chief Financial Officer; and Yasuo Fujii, Managing Executive Officer and Chief Strategy Officer.

Today's online conference is scheduled for up to 90 minutes. 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.

Kawaguchi will now give an overview of the financial results.

Summary of Q1 Results

(Billion Yen / Rounded)

	2023Q1 Results	2024Q1 Results	Changes	FY2024 Plans	Progresses
Revenue *[Overseas Ratio]*	93.5 *[63%]*	105.6 *[68%]*	+12.0 (+13%)	473.0 *[70%]*	22%
Gross Profit *[Gross Profit Margin]*	74.6 *[80%]*	80.0 *[76%]*	+5.4 (+7%)	348.0 *[74%]*	23%
SG&A *[SG&A Ratio]*	41.8 *[45%]*	40.2 *[38%]*	-1.6 (-4%)	166.0 *[35%]*	24%
R&D *[R&D Ratio]*	*16.6* *[18%]*	23.3 *[22%]*	+6.7 (+40%)	100.0 *[21%]*	23%
Gain/Loss on Equity Method	0.8	0.9	+0.1 (+13%)	3.0	30%
Core Operating Profit *[Core OP Margin]*	17.0 *[18%]*	17.4 *[16%]*	+0.4 (+2%)	85.0 *[18%]*	20%
Profit	12.8	14.6	1.9 (+15%)	63.0	23%

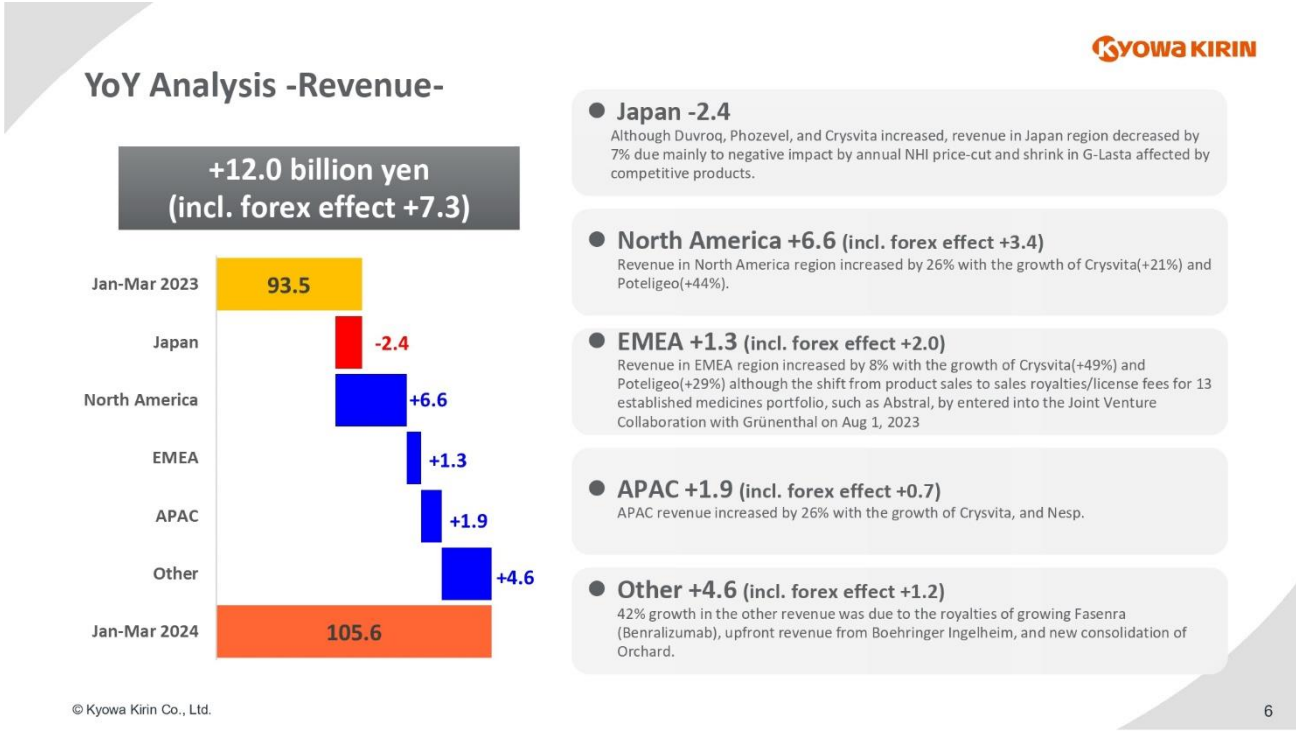
Kawaguchi: I will now start with the financial figures for Q1 2024. Please see page five of the slide.

Compared to the same period last year, revenue was JPY105.6 billion, an increase of JPY12 billion, or 13%; core operating profit was JPY17.4 billion, an increase of JPY0.4 billion, or 2%; and quarterly profit was JPY14.6 billion, an increase of JPY1.9 billion, or 15%.

Core operating profit increased only 2% due to a significant increase in R&D expenses resulting from progress in the development of KHK4083 and the new consolidation of Orchard, while gross profit increased due to higher sales. Quarterly profit increased by 15% due to an increase in other income, mainly from gains on sales of fixed assets.

As for the percentage of progress toward the full-year forecast, revenue and gross profit were 22% and 23%, respectively, which are less than 25%, a quarter of the full-year forecast; however, as usual, revenue and profit tend to increase in H2, so the Q1 results were generally in line with our plan. SG&A expenses and R&D expenses are also relatively weighted toward H2 and are trending in line with the plan.

As a result, 20% progress has been made in terms of core operating profit. Quarterly profit progressed slightly higher than core operating profit, mainly due to gains on sales of fixed assets. As for the Q1 results, we made good progress against our plan in general.



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

As for Japan, Duvroq and Crysvita continue to show solid growth, and the initial response to Phozevel, a new product, has been favorable. On the other hand, sales in the Japan region declined 7% due to the impact of the NHI price cut last April, as well as a decrease in sales of G-Lasta, which was affected by biosimilars.

As for North America, sales grew by 26%, thanks to solid growth in Crysvita and Poteligeo, as well as the impact of the yen's depreciation.

For EMEA, sales revenues from 13 brands including Abstral were affected by the shift of sales revenues from product sales to sales royalties and license fees from last August, following the joint venture with Grünenthal in the Establish Pharmaceuticals business, while sales grew by 8% due to growth in the global strategic products, Crysvita and Poteligeo and the impact of foreign exchange rates.

APAC sales grew by 26%, led by growth in Crysvita and Taiwan's Nesp.

As for others, revenues increased by 42% due to an increase in royalties from Fasenra and upfront income 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	2023Q1 Results	2024Q1 Results	Changes	Reasons	2024 Plans	Progresses
Crysvita	2.3	2.5	+0.2 (+7%)	Market penetration (Launched in Dec 2019)	12.9	19%
Poteligeo	0.4	0.4	+0.0 (+1%)		1.9	23%
Nesp + Nesp-AG[1]	4.2	3.5	-0.8 (-18%)	NHI price-cut & Biosimilars' penetration	14.4	24%
Nesp	0.8	0.7	-0.1 (-9%)		2.8	25%
Nesp-AG	3.5	2.8	-0.7 (-20%)		11.7	24%
Duvroq	1.8	2.5	+0.7 (+37%)	Market penetration (Launched in Aug 2020)	12.2	20%
Phozevel	-	0.6	+0.6 (- %)	Launched in Feb 2024	3.3	19%
Orkedia	2.2	2.2	-0.1 (-2%)		11.7	19%
G-Lasta	7.0	5.8	-1.3 (-18%)	Biosimilars' penetration	20.5	28%
Rituximab BS	2.2	1.9	-0.3 (-13%)	NHI price-cut	7.9	24%
Romiplate	2.7	3.0	+0.3 (+12%)	Market penetration (New indication in Jun 2019)	13.2	23%
Nouriast	1.7	1.5	-0.2 (-9%)		7.1	21%
Haruropi	0.9	1.0	+0.0 (+4%)		5.2	19%

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 product in Japan.

Although the rate of progress appears to be relatively low relative to the plan, Crysvita continues to grow steadily with a 7% increase over the previous year.

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

Durvroq grew steadily with a 37% increase over the previous year and maintained the number one market share within its class.

Phozevel was launched on February 20 and is steadily penetrating the market.

G-Lasta sales decreased by JPY1.3 billion, or 18%, from the previous year due to the impact of a biosimilars launched in November last year.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2023Q1 Results	2024Q1 Results	Changes	Reasons	2024 Plans	Progresses
Crysvita	27.1	35.4	+8.2 (+30%)		175.9	20%
North America	18.8	22.8	+4.0 (+21%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication (Adult/TIO) [APAC] Geographical expansion		
EMEA	8.0	11.9	+3.9 (+49%)			
APAC	0.3	0.6	+0.4 (+144%)			
Poteligeo	5.8	8.2	+2.4 (+41%)		32.5	25%
North America	4.3	6.3	+1.9 (+44%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration	23.3	27%
EMEA	1.5	1.9	+0.4 (+29%)		8.8	22%
APAC	-	0.0	+0.0 (- %)		0.5	4%
Libmeldy / Lenmeldy	-	1.1	+1.1(- %)	New consolidation of Orchard (FDA approval in Mar 2024)	4.5	25%
Nourianz	1.7	1.6	-0.1 (-7%)	Market penetration	8.5	18%
Nesp	2.2	2.9	+0.7 (+32%)		10.7	27%
Gran	1.4	1.8	+0.3 (+24%)		7.2	25%
Tech-licensing	8.9	11.7	+2.8 (+31%)	Upfront revenue from Boehringer Ingelheim and growth of Fasenra	45.0	26%
Benralizumab Royalty[1]	5.7	6.4	+0.7 (+12%)			

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

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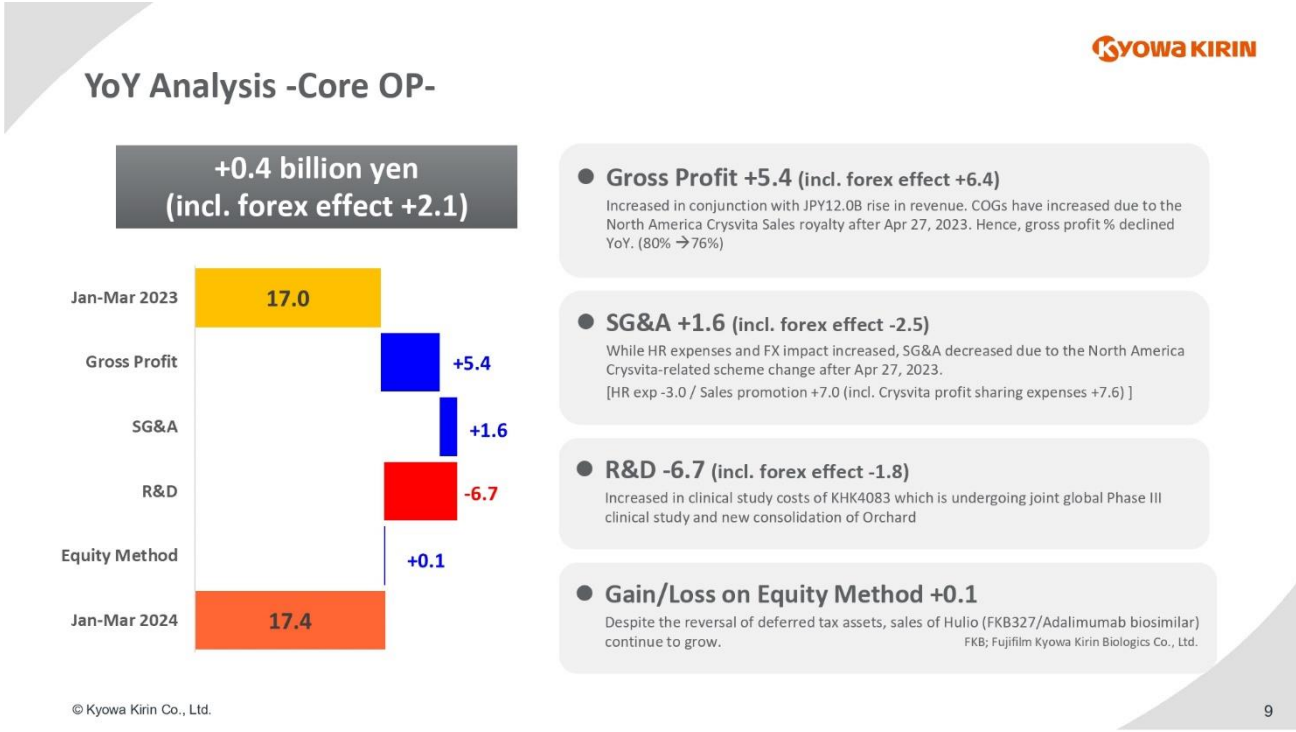
Please see page 8. This is the status of major overseas products.

Crysvita continued to grow in North America, EMEA, and APAC, with a YoY increase of JPY8.2 billion, or 30%.

Poteligeo also continued to grow at 41% YoY. Sales in North America remained strong, and in EMEA, market penetration increased, resulting in higher sales.

For Libmeldy/Lenmeldy, subsequent to the new consolidation of Orchard from January 24, we have recorded JPY1.1 billion of Libmeldy's sales revenue in Europe. In March, we also received approval in the US as Lenmeldy.

Tech-licensing revenue increased by JPY2.8 billion, or 31%, from the previous year 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.



Please see page nine. This is an analysis of core operating profit.

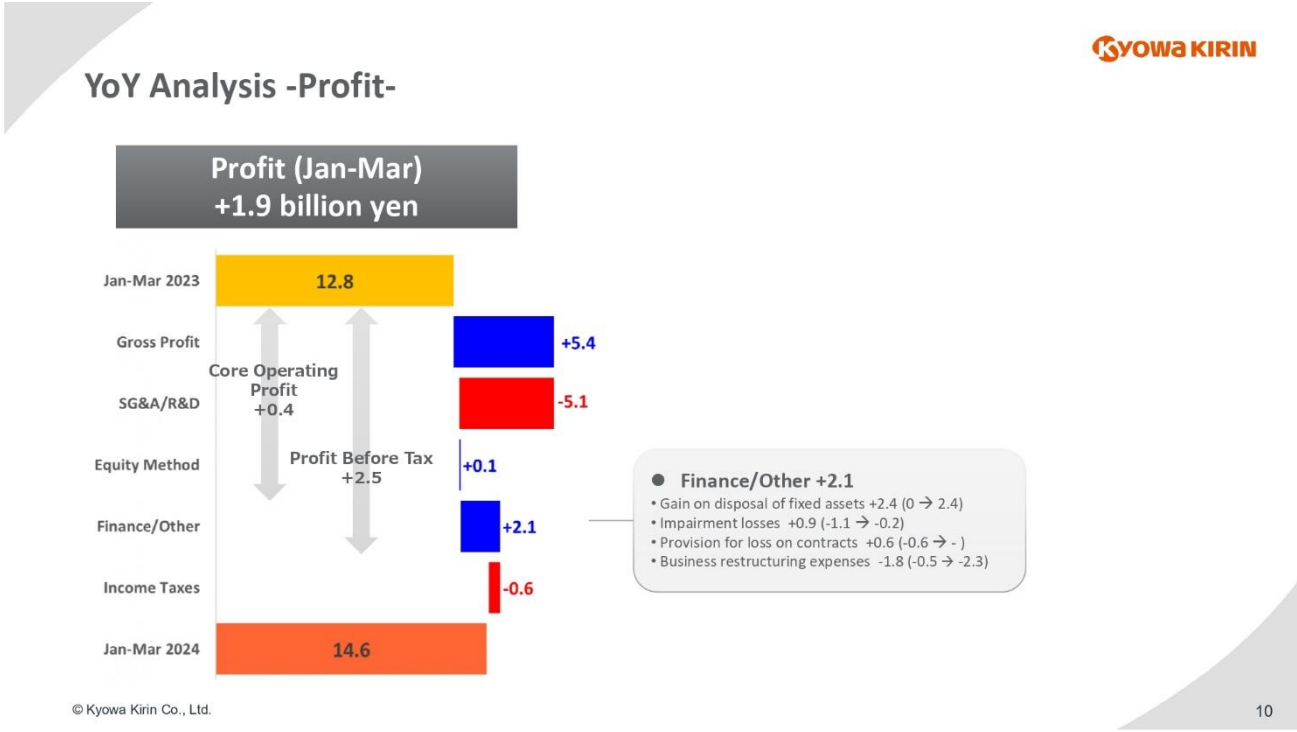
Gross profit increased by JPY5.4 billion, or 7%, in line with the increase in sales revenue. Gross margin declined by 4% to 76% due to an increase in the cost of sales resulting from the recording of sales royalties since Crysvita began its own sales in North America last April.

SG&A expenses decreased by JPY1.6 billion, or 4%, as a result of the absence of profit-sharing expenses recorded after Crysvita's own sales in North America, despite an increase in personnel and other expenses associated with Crysvita's own sales in North America and the effect of foreign exchange rates.

R&D expenses increased significantly by JPY6.7 billion, or 40%, 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 4 percentage points to 22% from 18% in the previous year.

Gain and loss on equity method increased by JPY0.1 billion. The business of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. continues to grow, but this is due to the impact of the reversal of deferred tax assets.

As a result, core operating profit increased by JPY0.4 billion compared with the same period of the previous year.

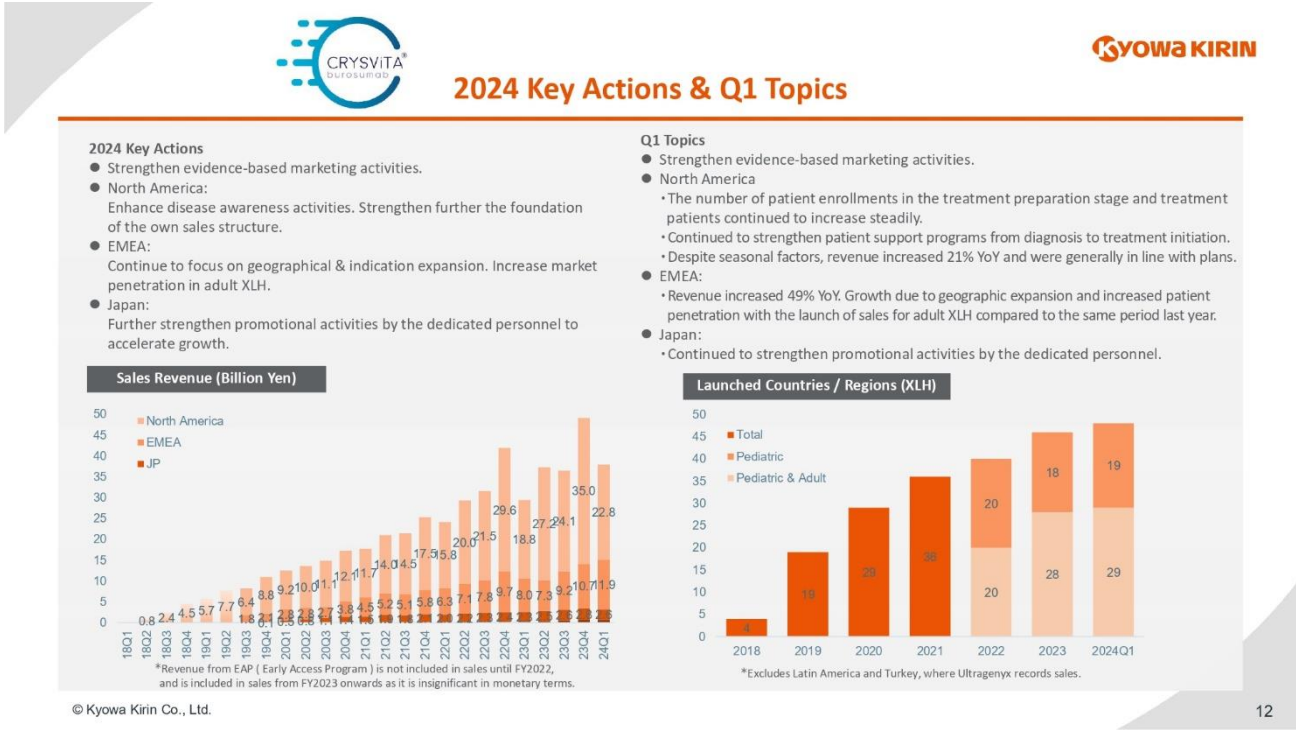


Now, please refer to page 10. In this slide, I would like to show you the part below core operating profit.

Financial and Other increased by JPY2.1 billion. The increase is mainly due to gains on the disposal of fixed assets.

Business restructuring expenses include acquisition-related expenses of JPY0.9 billion related to the Orchard acquisition, as well as changes in the fair value of conditional consideration and other items related to the US approval of Lenmeldy, amounting to JPY1.3 billion.

As a result, profit increased by JPY1.9 billion compared with the same period of the previous year.



Fujii: Next, Fujii will explain about the Commercial Update.

See page 12. First, we will start with Crysvita.

The graph at the bottom of the page shows sales revenue and the number of countries and regions where the product has been sold since its launch.

Q1 revenue for the entire global market is JPY37.8 billion, an increase of plus JPY8.4 billion or 28% growth compared to the same period last year.

Through evidence-based disease awareness activities, the company has made progress in penetrating patients, particularly adult XLH and TIO, and business growth through expansion of the number of countries and regions where the product is sold, as well as a boost from foreign exchange, has led to solid growth in sales and earnings.

Although the quarterly sales trend may look a little weaker than the previous quarter, Crysvita will grow from Q1 to Q4. Also, in Q1, sales are affected by seasonal factors, such as a reactionary decline from wholesale inventory buildup during the year-end and New Year holidays, and in the US, insurance renewal procedures at the beginning of the year may increase the burden on patients, resulting in a decline in sales. As a result, the progress rate against the plan tends to be low.

In addition to the increase in revenue due to the appropriate buildup of wholesale inventory to meet actual demand, Q4 2023 sales revenue includes an increase in sales in North America due to the recovery from the temporary decline in wholesale inventory at the end of Q3 following the label switch implemented in Q3 2023.

Since these are the reasons for the decline in revenue from the previous quarter, we are not concerned about achieving the fiscal year plan.

Currently, the number of new patients and pre-treatment patient enrollments are also growing steadily, with the number of new starting forms enrolled in the US and in Q1 about 25% over the same period last year.

In addition to continuing our evidence-based disease awareness activities, we will continue to focus on strengthening our patient support programs so that patients diagnosed with the disease can begin treatment more quickly and continue treatment without burden.

Next is about Poteligeo.

Poteligeo's sales revenue also grew by 37%, to JPY8.6 billion globally, an increase of JPY2.4 billion over the same period last year.

The company has continued to grow steadily, supported by regional expansion and exchange rate support, in addition to the effects of policy measures such as increased penetration through marketing activities using evidence from hematology and oncology, and educational activities for early consultation with specialists and implementation of blood tests through disease awareness websites, as well as increased activities in regions with high usage needs based on patient information.

Furthermore, in 2024, we will further advance our evidence-based promotion to further penetrate patients with tumor cells in the blood, and we will also use evidence for patients presenting with skin symptoms to promote access to patients who have lacked reach in the past. We are steadily preparing to start activities for patients presenting skin symptoms well into H2.

Through these activities, we will continue to pursue growth.

That's it for the commercial update.

News Flow of Main Development Pipeline Products

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As of May 7, 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
	Asthma	P2 initiation[1]	Q2 2024
	Prurigo nodularis	P3 initiation	H2 2024
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	Q2 2024
KK8123	XLH	P1 initiation	Q2-Q3 2024
Atidarsagene autotemcel (formerly OTL-200)	**MLD**	**US approval**	Mar. 2024
OTL-203	**MPS-IH (Hurler syndrome)**	**Registrational study[2]**	In progress
OTL-201	**MPS-IIIA (Sanfilippo syndrome type A)**	**PoC study[3] Data - Conference presentation**	Feb. 2024

1. Achieved First Site Activated; 2. Equivalent to P3 study; 3. Equivalent to P1/2 study.

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Yamashita: Next, Yamashita will introduce the R&D update.

See page 15. We will touch on some of the major news items in the main development pipeline.

First, rocatinlimab, a Phase III study in atopic dermatitis, the ROCKET program, is underway. These have enrolled more than 2,800 patients to date, and three trials have now completed patient enrollment.

As for the Phase II trials for asthma, these have started site activation and patient enrollment, and we expect to achieve First Patient In within Q2 as planned.

A Phase III study for prurigo nodularis is also scheduled to begin in H2.

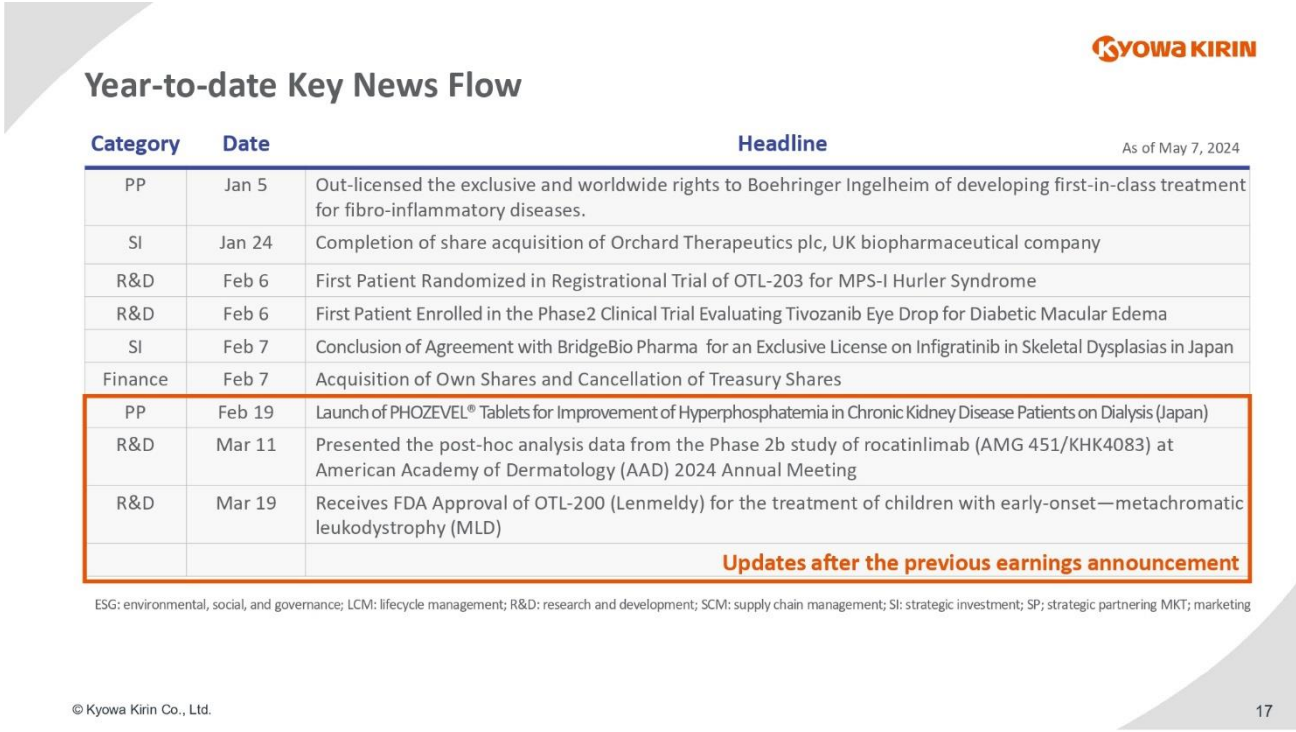
KHK4951 is currently in Phase II trials for nAMD and DME.

As for Phase I studies following these products, KK2260 and KK2269 using our bispecific antibody technology, REGULGENT, which we previously announced the start of, are also progressing smoothly.

We also plan to initiate a Phase I study of KK8123 between Q2 and Q3 as a product we expect to be a new treatment option for patients with XLH.

Finally, the pipeline utilizing HSC-GT. As mentioned in the press release and at the recentmeeting, OTL-200 was approved by the FDA in March of this year. The product name in the US is Lenmeldy.

That is all for this quarter's R&D update.



KYOWA KIRIN

Year-to-date Key News Flow

As of May 7, 2024

Category	Date	Headline
PP	Jan 5	Out-licensed the exclusive and worldwide rights to Boehringer Ingelheim of developing first-in-class treatment for fibro-inflammatory diseases.
SI	Jan 24	Completion of share acquisition of Orchard Therapeutics plc, UK biopharmaceutical company
R&D	Feb 6	First Patient Randomized in Registrational Trial of OTL-203 for MPS-I Hurler Syndrome
R&D	Feb 6	First Patient Enrolled in the Phase2 Clinical Trial Evaluating Tivozanib Eye Drop for Diabetic Macular Edema
SI	Feb 7	Conclusion of Agreement with BridgeBio Pharma for an Exclusive License on Infigratinib in Skeletal Dysplasias in Japan
Finance	Feb 7	Acquisition of Own Shares and Cancellation of Treasury Shares
PP	Feb 19	Launch of PHOZEVEL® Tablets for Improvement of Hyperphosphatemia in Chronic Kidney Disease Patients on Dialysis (Japan)
R&D	Mar 11	Presented the post-hoc analysis data from the Phase 2b study of rocatinlimab (AMG 451/KHK4083) at American Academy of Dermatology (AAD) 2024 Annual Meeting
R&D	Mar 19	Receives FDA Approval of OTL-200 (Lenmeldy) for the treatment of children with early-onset—metachromatic leukodystrophy (MLD)
		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

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

See page 17. Here is a list of news releases since the beginning of the year.

Orchard, whose acquisition was completed on January 24, was recently the subject of a presentation by President Miyamoto and Bobby Gaspar, and on March 18 we successfully received approval from the US FDA for OTL-200, which had already been launched in Europe. We will continue our efforts to expand newborn screening to maximize value.

Upon FDA approval, an additional payment of USD1 per ADS will be made to Orchard shareholders in accordance with the CVR agreement.

In Japan, as we explained at the time of the Q4 earnings announcement, we signed an agreement to in-license the development and marketing of infigratinib in Japan from BridgeBio in the US. In addition, we began marketing PHOZEVEL, a hyperphosphatemia treatment, from February.

Thus, based on the strategic story to realize the 2030 Vision, we will strive to firmly achieve the plan for the current fiscal year, while steadily enhancing our assets through in-house drug discovery and collaboration with external parties, and maximizing the value of our assets.

This completes today's presentation.

Question & Answer

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

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

The first question is about KK8123. I have a feeling that you probably won't be able to talk about anything beyond the disclosed information, but I was wondering if you could tell us anything about its relationship with Crysvita, or if there are any advantages in terms of administration, or anything else that you are aiming for, or any differences in positioning with the existing Crysvita.

Yamashita [A]: Since the creation of Crysvita by our Company, we have still been researching the possibility of providing a better treatment for XLH patients. One such candidate was coming up, and we are now moving forward with it.

However, we suspect there are some gaps in Crysvita's research to date, such as the movement of phosphorus or the final outcomes. For this reason, we are now preparing to proceed with the clinical trial to see if we can offer a better treatment option.

Unfortunately, at this time, we would like to refrain from disclosing what this product is compared to Crysvita.

Yamaguchi [Q]: Thank you very much.

Just one confirmation. Regarding the final outcome you mentioned, do you believe that while Crysvita is performing well, but there are some areas that lack power in terms of outcome, and there is room for improvement? Is my understanding correct?

Yamashita [A]: No, it is not that kind of detail. However, phosphorus is only a surrogate marker, and the outcome for the patient will be how good the results are in terms of bone improvement and growth promotion. I wanted to convey to you that we are taking this matter very seriously in terms of these points.

Yamaguchi [Q]: Is that a challenge with a new drug? Or are you challenging as a whole, including Crysvita?

Yamashita [A]: Yes. We are also considering what we can do in terms of Crysvita's own life cycle management, and as I mentioned earlier, we are starting new challenges from the research stage to see if we can create something better.

Yamaguchi [Q]: I understand.

Second, just briefly is fine, there was a comment that the milestone from Boehringer Ingelheim is in Q1. If I count backward, it looks like about JPY2 billion, but will it end in Q1? Or are you planning to get some more this term and a few more over the term?

Kawaguchi [A]: Thank you for your questions, Mr. Yamaguchi. I am Kawaguchi.

As for this fiscal year, it will end in Q1. The income is a lump-sum contractual payment.

Yamaguchi [Q]: You are saying that if it proceeds like a development milestone in the future, it might get in each time in the future?

Kawaguchi [A]: Your understanding is correct.

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

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

I would like a more detailed review of Crysvita's North American and EMEA sales trends. As for North America, I think what was said was that there was a timing discrepancy in Q4 that ended in the portion that was re-labeled from Q3, and even if you consider that back to Q3, Q1 was still growing, so the overall number of quarters is not decreasing that much.

Then Q4 in the first term would be, let's say, purely, or if there is no discrepancy, about USD200 million, and then this Q1 lands at USD155 million, and then it goes up one step from Q2 to Q4, and then from Q2 to Q4, it's flat. Is my understanding correct?

I would like to know more about North America, since it is still difficult to read the trends for this quarter, and there was no particular comment on EMEA this time. Is it simply as planned?

Fujii [A]: Thank you for your question. I'm Fujii.

I believe that the reason for the Q4 bulge is exactly as you understand it now, and we are thinking that if Q3 and Q4 are calculated together, it would be a relatively straight line.

And our experience has shown us that this drug is quite seasonable. Since there is a New Year's vacation in Q4, there is a tendency for wholesale inventories to build up considerably at the end of Q4.

Since it is winter in the northern hemisphere, the stock in Q4 will be thicker because there are concerns about logistics stagnation and such, so there is a desire to keep a little more in stock. On the other hand, Q1 is the opposite, but there will be a reaction to that, and in addition, this will be in the US, but the figures in Q1 will be lower due to insurance switching and other factors.

Also, this drug, Crysvita, is a drug that is still growing, so we believe it has the seasonality to go up over Q2, Q3 and Q4

Europe is different from the United States. In the US, there is a registration system called "Start Form," which makes it relatively easy to identify each patient one by one, but in Europe, there is no such system, and it is mainly based on interviews, and comparatively speaking, the accuracy of the numbers in Europe is less than in the US; however, based on sales and other factors, as well as the results of our interviews, we are aware that sales in Europe are also trending in line with the plan.

Wakao [Q]: This is, sorry, very detailed. If we assume that the period that ended, Q3 was USD168 million, and if we assume that the dented area was put back about USD20 million to USD30 million from Q4, Q2 to Q4, is that the outlook or the way the sales stand this year as well? I think you just explained that it is like a gradual growth of Q2, Q3 and Q4, but which way should I think of it?

Fujii [A]: We think the pattern so far has been that the numbers grow toward the latter half of the year.

Wakao [Q]: You mean that the movement is a little different from last year. I understand. Thank you.

Please tell one more thing. As for rocatinlimab, for three trials, I suppose, patient recruitment has been completed, and I think ROCKET-Horizon is the data readout by the end of this year, but I would like to know a bit more specifically about the timing of that. According to ClinicalTrials.gov, Primary Completion will be in July and Study Completion will be at the end of September. Does this mean we can expect data readout in a few months after Primary Completion, or in a month or two, or something like that? Or should I assume after Study Completion?

Yamashita [A]: In the meantime, we would like to report only where we have done the analysis as soon as possible. I can only say that it will be in H2.

Wakao [Q]: I understand. As you just explained, if anything, I think Primary Completion will be in July, and from there, the data could be locked, and it is not so wrong to understand that the data could be released in a month or two or something, right?

Yamashita [A]: Yes. We will try to put it together as soon as possible.

Wakao [Q]: I understand.

I think that SHUTTLE and VOYAGER have probably finished recruiting, and I think that Primary Completion will be finished by the end of this year, so we can expect the second and third data readouts from Horizon at an early date, though we don't know if it will be by the end of this year or not.

Yamashita [A]: Yes. We are still in the process of discussing this issue with Amgen. I can say with certainty that we will have the first report by the end of this year, but as you say, we will continue to work on this and hope to have a report soon.

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

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. Thank you.

Please tell us a little more about rocatinlimab, just you mentioned. I think you said that data of Horizon will come out first by the end of the year, and then SHUTTLE and VOYAGER will follow not too long after that. As for the application strategy, I think the first three are about the same timing, but is my understanding correct that if two of these three are good, you proceed for application, although of course you intend to get through all three with good results?

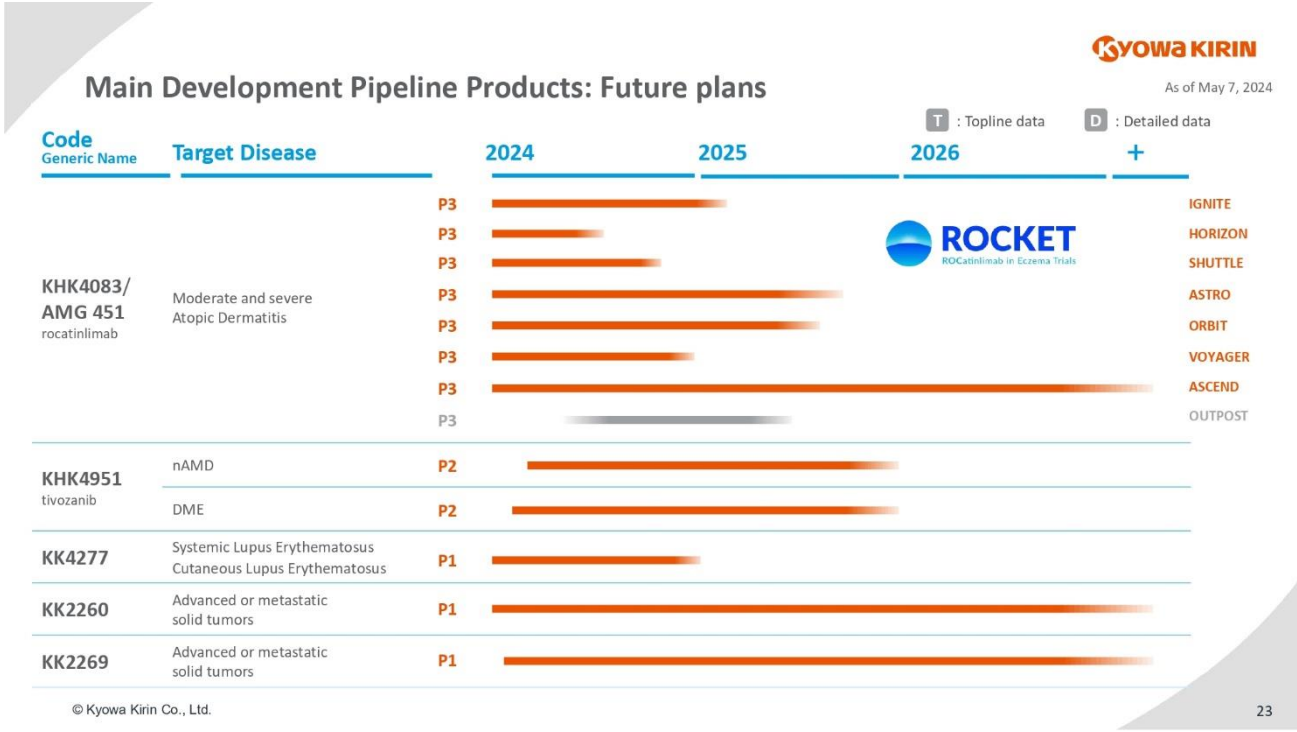
To put it a little more bluntly, when you file an application with these three trials, label-wise, for lack of a better term, it will be filed as a mediocre atopic drug, but is my understanding correct that you will start with a mediocre one, and if successful, file an application with about two or three drugs and wait for ASCEND's results?

Yamashita [A]: For the application, we are now assuming that we will use something other than ASCEND, which comes out after the whole thing, in the application*. Therefore, we would like to proceed in a manner that allows us to claim as much as possible in terms of labels.

*Note: It means that we do not plan to use “all data until the end of the ASCEND study period” for the application. Instead, we plan to use the interim analysis results for the study in the application.

Muraoka [Q]: You are saying that the application is for late 2025 to near 2026, rather than early 2025?

Yamashita [A]: Yes. As you mentioned earlier, there may be a way to start with the prior data and add data in the middle of the process, but for now, we think it would be better to proceed based on the assumption that the data will be ready when the test is completed, as you mentioned, if we are to look at the data in a conservative manner.



Muraoka [Q]: I see.

In the slides you are showing us now, except for ASCEND, there are six*, and it would be desirable to have all six succeed, but it is safe to assume that even if one or two of those results are not good, that will not affect the overall application strategy.

*The correct number is seven.

Yamashita [A]: Yes. Whether this project fails or not will depend on the content of the results obtained from the studies, but we have enrolled a sufficient number of patients, and we are proceeding with the project with high expectations that we will be able to obtain sufficient data for the labels we are aiming for.

Also, in terms of effectiveness and safety, we are not currently making many assumptions that certain things will fail, and we are proceeding with the high expectation that if we proceed with this trial properly, it will lead to the expected results.

Muraoka [Q]: I see. Thank you.

Also, about Libmeldy, or Lenmeldy. I'm sorry, in your earlier explanation, are you saying that all of the JPY1.1 billion sales were from Europe and Libmeldy, and Lenmeldy was approved on the 18th of March, so does it mean zero?

If that is the case, then Libmeldy's sales of JPY1.1 billion in Europe seems rather large, but I wonder if there was some transitory factor or if you are talking about the fact that you are beginning to make good progress in finding patients. Please explain the background.

Kawaguchi [A]: Thank you for your question. I am Kawaguchi.

First, there is no doubt that all of the JPY1.1 billion is European sales. In North America, we have high expectations for Q2 and beyond.

Then, this amount, in a dollar base, is USD7.5 million, which was used for three patients. On average, at USD2.5 million, as I have mentioned before, we have had three patients participate at the average unit price of sales in Europe. This does not mean that there was a one-time profit; we have been performing as planned and slightly better than planned.

Muraoka [Q]: I see. Thank you. Because there are three, and it could be the difference between two or three.

If we were to ask you if you think it will be higher this year, is it too early to say that it could be, but that it will be much higher than JPY4.5 billion?

Kawaguchi [A]: That's right. I am expecting it very much, but I feel it is a little too early to tell.

Muraoka [Q]: Is the US responding quite well? Waiting patients, and so on.

Fujii [A]: Newborn screening is still not that widespread in the US, so I expect it to be a gradual start, but there is still a response. It is a little difficult to say at this time, but we do have a response.

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

I would like to confirm the tech-licensing revenue. In your earlier explanation, you mentioned that there was a one-time payment from Boehringer Ingelheim included, but considering the growth of royalties toward H2, I think it is a high rate of progress. But is it correct to assume that this lump sum is the only one-time factor for one quarter here?

I think you also mentioned that you have incorporated some temporary factors into your plan before, but I was wondering if you could tell me if there are any other factors that you have incorporated into your plan for Q2 and beyond.

Kawaguchi [A]: Thank you for your question. Kawaguchi will answer.

As for factors in other category, Boehringer Ingelheim's one-time income is almost the only special factor this time.

And as to your question about whether other temporary items are included in what is classified as other, we have not included any major items in our plan.

And then, on the matter of saying that we are factoring in one-time revenue items into the annual plan, that is included in the EMEA Region.

Ueda [Q]: I understand. Thank you.

Second, can you tell us about the progress of Poteligeo? Although the North American market has increased considerably compared to the same period last year, I think that for the past two years there has been a tendency for Q1 to be relatively low, followed by a large increase in Q2 and thereafter. Will this trend continue this year? Can you please explain if there are no special factors in this Q1 and the market penetration you just explained has resulted in good progress, whether this growth is based on actual performance, or if there are some special factors such as inventory, and so on?

Fujii [A]: Thank you for your question. Fujii would like to answer the question.

As I explained earlier, I believe this is the result of our long PR and steady efforts to educate patients with high tumor cell counts in their blood based on such evidence. We have been able to reach some of the potential

patients that we had not been able to reach in the past, but basically, we understand that our efforts to date have been bearing fruit. We have not been particularly affected by the increase in inventories.

Ueda [Q]: Thank you very much.

If so, considering the very high rate of progress in Q1 and the growing number of items, is it correct to understand that the progress is quite good compared to the plan?

Fujii [A]: I think that is correct.

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

Sakai [Q]: This is Sakai from UBS.

I would like to confirm about Crysvita; I understand that it is highly seasonal and that the number of patients itself is growing. The term "Start Form" is often used, but is it correct to say that almost 100% of the patients who fill out the Start Form, whether adult or pediatric, will enter treatment in the US? This is the first point I would like to confirm.

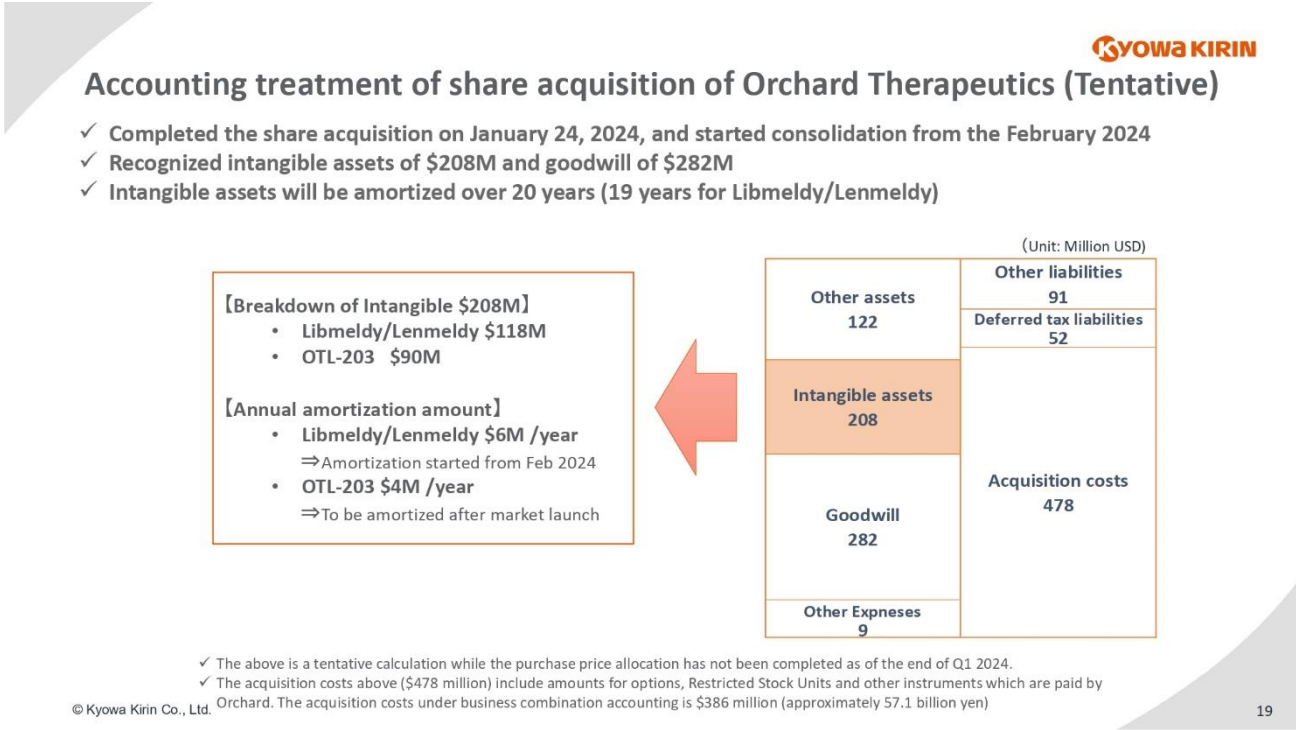
Fujii [A]: Thank you for your question. Fujii will answer this question.

A Start Form is issued for people who have not yet been diagnosed but are suspected of having the disease. Based on that, we will find out what kind of insurance plan the patient has, and we will identify what is necessary to be covered by this insurance, for example, genetic testing must be done, and what are the requirements.

Therefore, not 100% of the patients who receive a Start Form are transferred to treatment, but a fairly high percentage of them do.

Sakai [Q]: So, a patient fills out a Start Form, or rather, based on the decision to make a definitive diagnosis, the patient enters treatment about three months after that, is this interval or window period, or is this roughly how it works? Or has this interval been shortened?

Fujii [A]: I cannot disclose the specific number of days today, but we consider this to be one of our important initiatives, and we are making great efforts in this area. The actual period between the issuance of the Start Form and the actual on-treatment of patients is gradually shortened.



Sakai [Q]: I see, I understand.

Another question is about Orchard's business combination accounting figures that you have disclosed on page 19 this time. The figures disclosed at the time of Q4, which are also provisional, and this time are also provisional, but I think the amount of OTL-203 as intangible assets has increased compared to the last time. I think it's almost doubled.

I understand that Libmeldy is still decreasing, and is that correct? I don't know how much you can tell us about why this adjustment was made, probably because of the relationship with the auditing firm, but I was just curious about the numbers, so please tell us as much as you can.

Kawaguchi [A]: Thank you for your question. Kawaguchi will answer.

When we showed you the last time, it was still a tentative PPA, and then it was further re-examined by the advisor who is doing the PPA, although it has not yet been confirmed by the audit firm. This is the latest information.

We basically haven't changed our assumptions about sales projections, etc. However, in contrast to this, for example, the direct research expenses of each are not changed to this extent. In contrast, we have been told that the allocation ratio for indirect costs, indirect research costs, and sales costs have changed as a result of a little more elaboration in how they are allocated to these two products. So, would it be fine with you to explain that the total has not changed, but it is due to the change in the allocation ratio of indirect costs for both products?

Incidentally, this is also a tentative amount right now because we have not yet received the final confirmation from the auditing firm, but I think we will probably be able to tell you the finalized amount in the next Q2.

Sakai [Q]: If we are talking about a change in the way indirect costs are spent, does that mean that the assumption is now that expenses spent on OTL have increased?

Kawaguchi [A]: Yes, that would be true. OTL, or rather in Libmeldy.

Sakai [M]: Excuse me, 203, right?

Kawaguchi [A]: An increase in the amount of 203 means a decrease in cost.

Sakai [M]: I see, it means that profits have increased.

Kawaguchi [A]: Yes, that's right.

Sakai [Q]: The profit forecast has increased, right? I understand. In any case, this means that you will have almost a definite value in Q2.

Kawaguchi [A]: That's right. We do not expect that to deviate significantly from this value.

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

Akahane [Q]: Thank you.

The previous person asked a lot of questions, and I'll ask you similar questions, but looking at this so-called Q1, you said that this quarter is going very well, so there is no problem at all in achieving the full year goal, but when I was looking at page five, research expenses are also increasing very much. Orchard is as expected, but is 4083 also almost as expected? And then, is my understanding correct that Boehringer also entirely anticipated and the figures have not deviated from the estimation at all?

Kawaguchi [A]: Thank you for your question.

First of all, in terms of R&D expenses, if you look at page five, we are at JPY100 billion for the year, and JPY23.3 billion against that, so we are 23% of the way there. As you have seen, this is progressing as planned against the plan. As for 4083 and Orchard, I cannot show you the actual results, but we spent about two months worth of R&D expenses in Q1 against our annual R&D expenses of JPY10 billion, and everything is progressing as planned so far.

Akahane [Q]: So, 4083 is also as expected, right?

Kawaguchi [A]: Yes, that's right.

Akahane [M]: I understand very well.

Kawaguchi [A]: We have already included the amount of Boehringer's lump-sum income in the plan, and it is in line with the plan on the foreign currency base, although there is a slight upward movement due to the exchange rate.

Akahane [Q]: I understand very well.

Since we are allowed to ask two questions, just one more point. On page 15, in the development section, if you simply look at the table, I think there is a great deal of anticipation for rocatinlimab, but as was mentioned in the newspaper earlier, there have been various drugs for atopic dermatitis recently, and the doctors have commented on how the options are expanding. There are also Japanese companies, such as Torii and Otsuka.

In the case of your company, the patients are in the middle or severe stage, but I don't know if it's a good idea to ask this at the clinical stage, but I have the impression that the market is larger than expected. What do you envision the market environment, or sales, to be like when your company comes out with its application?

Yamashita [A]: Okay, Yamashita will answer this question.

As you say, there are more and more drugs for atopic dermatitis now, and I think there may be some talk of good results with oral JAK kinase inhibitors and the like.

In fact, the market is expanding rapidly, although new discovery of atopic dermatitis patients may also be occurring. Patients who have been affected for a long time are continuing their treatment, but they will become nonresponsive to the therapeutic agents they are using and will move on to the next drug.

Among them, we target patients with moderate to severe symptoms, those who have progressed to quite severe conditions. Biologics are used in this area, and as is also said in the case of rheumatoid arthritis, after a certain period of use, the biologics may become ineffective and be switched to a different drug.

Our 4083, rocatinlimab, has a new mode of action, and we believe that there is a great business opportunity in that it has a different approach than the drugs patients have used in the past. Even with the increase in the number of drugs in various stages of development, we have the impression that the number of patients in the target areas we are aiming for is increasing rapidly, and I hope that we can continue to promote our business there.

Akahane [Q]: Looking at this table, in terms of development, for the time being it's just these two or three, rocatinlimab, so does that mean that most of the development will be concentrated here?

Yamashita [A]: Right now, in our company, rocatinlimab is at a high stage, and I think it will be one of the first global products to be released as a new drug in the future. We intend to proceed with those that follow as soon as possible.

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

Yamaguchi [Q]: Thank you very much. I am Yamaguchi from Citi.

Regarding G-Lasta, I imagine it is in a competitive situation, where if a biosimilar comes in and turns over the use of drugs at a few hospitals because it is hospital-based, the sales will gradually disappear. There is also the NHI price cut.

On the other hand, there is also the matter of Bodypods, but the NHI price is different in three months, and I think it is difficult to see the situation in various ways, but how will the situation develop in the remaining nine months? I think expectations are naturally high, especially for Bodypods, but can you comment on the situation in this context?

Fujii [A]: Thank you for your question.

As you are aware, biosimilars have been introduced in case of G-Lasta, but Bodypods are still marketed independently by Kyowa Kirin.

Therefore, we expect sales of these Bodypods to remain at the planned level in 2024.

Yamaguchi [Q]: Do you disclose how much Bodypods sales are now?

Fujii [A]: We have not disclosed it yet.

Yamaguchi [Q]: I understand.

Also, I often hear about the promotion measures of the biosimilars, but what is the speed of the erosion between your company's view and the actual, since it was last November, I think there are many cases where the figures of a hospital could be turned over entirely in about four months' account.

Kawaguchi [A]: Kawaguchi will answer.

As for penetration, we felt that the initial start was a little earlier than we had expected, but as you know, biosimilar manufacturers announced limited shipments on March 13, which we had not anticipated. We are hoping that this will have some positive impact on our plan. We don't see this situation here well yet.

Yamaguchi [Q]: I understand. You thought it would be a bit early if it keeps going, but those particular factors came to appear, so it is a bit of a halt, right?

Kawaguchi [A]: That's right.

Yamaguchi [Q]: I understand. Thank you.

Also, I think you are doing another clinical trial called 4083 pre-filled syringes, Phase I, right? I'm sorry, I'm afraid this is diverging, but as a result, are you going to ask Terumo, who has always been a good friend of yours? Sorry, this is a strange question, but what do you think?

Yamashita [A]: Yamashita will answer the question.

In fact, it has not yet been decided. We will let you know when we have more clarity on such matters.

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

Wada [Q]: I am Wada from SMBC Nikko Securities. Thank you. I have two questions.

First, I would like to ask about the difference from the plan with regard to the cost ratio you described on page five. The gross profit margin is 74% in the plan, but the actual results for Q1 are 76%, which is higher, which I think means that the cost ratio is lower. Is it correct to assume that the gross profit margin will continue to increase in the same manner from Q2 to Q4?

Kawaguchi [A]: Thank you for your question.

I think that Q1 has some positive factors in terms of cost compared to the plan, and it still looks good, maybe 1%, but if you add it up over the year, I don't think it will be that big a positive, but it's not negative, or at the moment it's on the plan line. I hope you can understand this. Q1 covers for three months, so the impact looks to be a bit large.

Wada [Q]: Thank you very much.

Also, another question is, I would like to ask about the competition for rocatinlimab. Sanofi released Phase IIB data of amlitelimab, which is your competitor, in March, and I think the data is pretty good, but are there any points of differentiation in the formulation with them? I'm wondering if you would be willing to get OX40 for both, and I would like to ask you about the point of differentiation there.

Yamashita [A]: Yamashita will answer the question.

First of all, as you pointed out, Sanofi announced the results of the study of antibodies to the ligand of OX40, and we were interested in the results and wondered what the outcome would be, but the fact that the results suggest that the antibodies show long-term effects, and we think that it has become clear that the antibodies to this target are very promising, and we are very positive about that.

rocatinlimab is working on antibodies against the receptors, and we will have to see how much difference there is when the data becomes available.

The data presented by Sanofi is written in such a way that it is difficult to directly compare it with our own data, and we are currently examining various aspects of it. We hope to clear this up with more data in the future.

Wada [Q]: Thank you very much.

In addition, as for the timing of market launch, Sanofi's data will be available in 2026 and the application will be filed in 2027, but in the case of your company, I am aware that it is about one year earlier. Is it correct that as a first in class, your company's rocatinlimab is earlier?

Yamashita [A]: Yes, I think that is generally correct. Thank you.

Wada [M]: Thank you very much. That's all.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. Excuse me, but this is the second time to ask questions. Thank you.

As for 8123, I'm not sure if I can call it the second generation of Crysvita, but if this goes well and successfully, this will naturally be a stand-alone development on a global scale, right? Perhaps there is something like first refusal rights for Ultragenyx? I know this is a bit farfetched, but if there is anything like that, please let me know.

Yamashita [A]: Yamashita will answer the question.

I don't think there is any particular arrangement for such a thing. We will be discussing what options are available to us as we move forward in these areas.

As I mentioned earlier, I think we should try to move forward with this first, so of course, as I mentioned earlier, this is something that came out of our research at our institute. I hope you understand that this is the situation.

Muraoka [Q]: I see. Thank you.

One more thing, Orchard, is going quite well and the recent meeting was also impressive, in my opinion.

On the other hand, when you announced the acquisition of Orchard, I think you said something to the effect that this was still not enough, and I think you can still add more in terms of the balance sheet at all, but is my understanding correct that you are still actively considering purchases?

Fujii [A]: Thank you for your question. I'm Fujii.

As you can imagine, we are always looking for opportunities to introduce assets or acquire companies, and if there is a good fit with our strategy and financial discipline, we will continue to actively introduce and acquire companies.

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

Wakao [Q]: I'm Wakao from JPMorgan. Excuse me for my additional question.

Sorry to overlap with Mr. Muraoka's current question, but I would like to know a little more about the 8123 post-Crysvita kind of thing. The business positioning here is post-Crysvita, and Crysvita is, its LOE is about 32 years, so hopefully, you'll launch it after or around that, and you'll leverage the current franchise and aim to double the sales as an XLH indication. Can we think of it in that kind of positioning?

Yamashita [A]: Yamashita will answer the question.

The time frame is as you just mentioned, and we are definitely considering what we can do within that time frame. That is something for sure.

However, as I mentioned earlier, we are still just starting out with the research, and at this point we have no way of determining what will happen in the future, or what form of proceeding would be best in the future business environment. First of all, we would like to proceed with testing so that we can quickly clarify whether or not this is a good idea. That's about it.

Wakao [Q]: I understand.

Regarding the development period, you did not specifically answer the question earlier, but based on your experience with Crysvita, I think Crysvita itself took about six to seven years for clinical development, is it very difficult to shorten this period? Do you have such know-how?

Yamashita [A]: We would like to discuss this and other issues with the development team as we move forward.

There may be a trade-off between having enough data and taking the time to get it quickly, but we are working on this with the goal of proceeding as firmly as possible.

Wakao [Q]: I'm sorry to be persistent, but in this supplementary material, there is no mention of any particular technology being used, so is my understanding correct that it is a pure humanized antibody with a different sequence from Crysvita, not that any particular proprietary technology of your company is used? Do you use some kind of technology, something special?

Yamashita [A]: No, we are not talking about putting something new in here. Rather, we think it would be better to use the experience we have accumulated so far and the research we have done on the subject.

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

Moderator [M]: Thank you.

There being no further questions, this concludes the online meeting on the financial results for Q1 of the fiscal year ending December 31, 2024.

Thank you for your continued support of Kyowa Kirin.

[END]