Kyowa Kirin Co., Ltd.

Q3 Financial Results Briefing for the Fiscal Year Ending December 2021

November 1, 2021

Event Summary

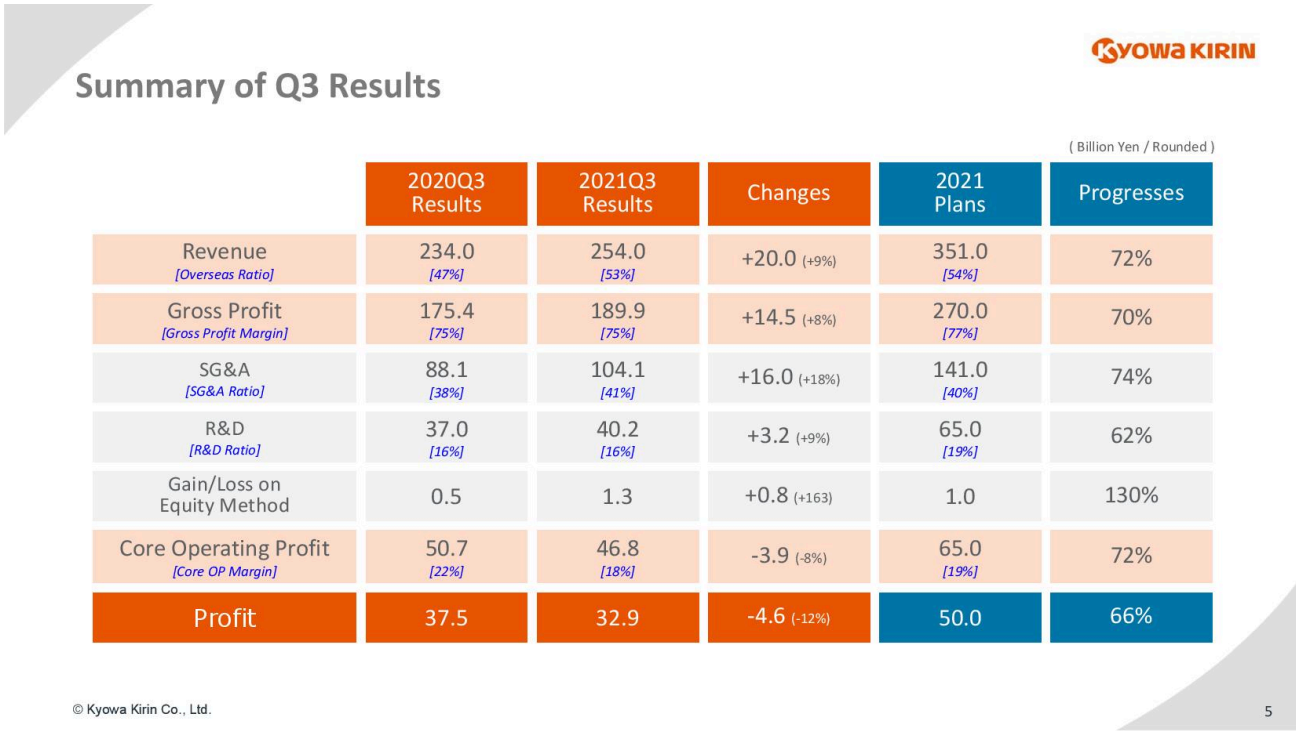
[Event Name]	Q3 Financial Results Briefing for the Fiscal Year Ending December 2021	
[Date]	November 1, 2021	
[Number of Speakers]	4	
	Takeyoshi Yamashita	Managing Executive Officer, Director, Corporate Strategy & Planning Department
	Motohiko Kawaguchi	Executive Officer, Director, Finance Department
	Yoshifumi Torii	Executive Officer, Vice President, Head, R&D Division
	Tomohiro Sudo	Executive Officer, Director, Global Product Strategy Department

Presentation

Moderator: We will now hold a conference call to discuss Kyowa Kirin Co., Ltd.'s financial results for the third quarter of the fiscal year ending December 31, 2021. These results were announced at 3:30 PM today.

Today's participants are as follows: Dr. Takeyoshi Yamashita, Managing Executive Officer and Director of Corporate Strategy & Planning; Motohiko Kawaguchi, Executive Officer and Director of Finance; Dr. Yoshifumi Torii, Vice President and Head of Research & Development; Tomohiro Sudo, Executive Officer and Director of Global Product Strategy.

Mr. Kawaguchi, I'll hand over to you.



Kawaguchi: Thank you.

Please see slide 5. Here is a summary of the cumulative results through to the end of the third quarter.

Compared to the same period of the previous year, revenue increased by 9% to JPY20 billion. Core operating profit, the second line from the bottom, decreased by 8%, or JPY3.9 billion. Quarterly profit decreased by 12%, or JPY4.6 billion.

In the second quarter, sales increased YoY by 5% but in this quarter, we have seen an increase of 9%, so we recognize that we are making good progress in terms of sales.

However, we have not yet been able to cover the increase in expenses necessary for future growth, and core operating profit has continued to be down compared to the previous fiscal year. As for the net income, the impairment loss on the sales rights of Haruropi introduced from Hisamitsu Pharmaceutical was recorded as other expenses. The resulting negative impact is greater than the change seen in the core operating profit.

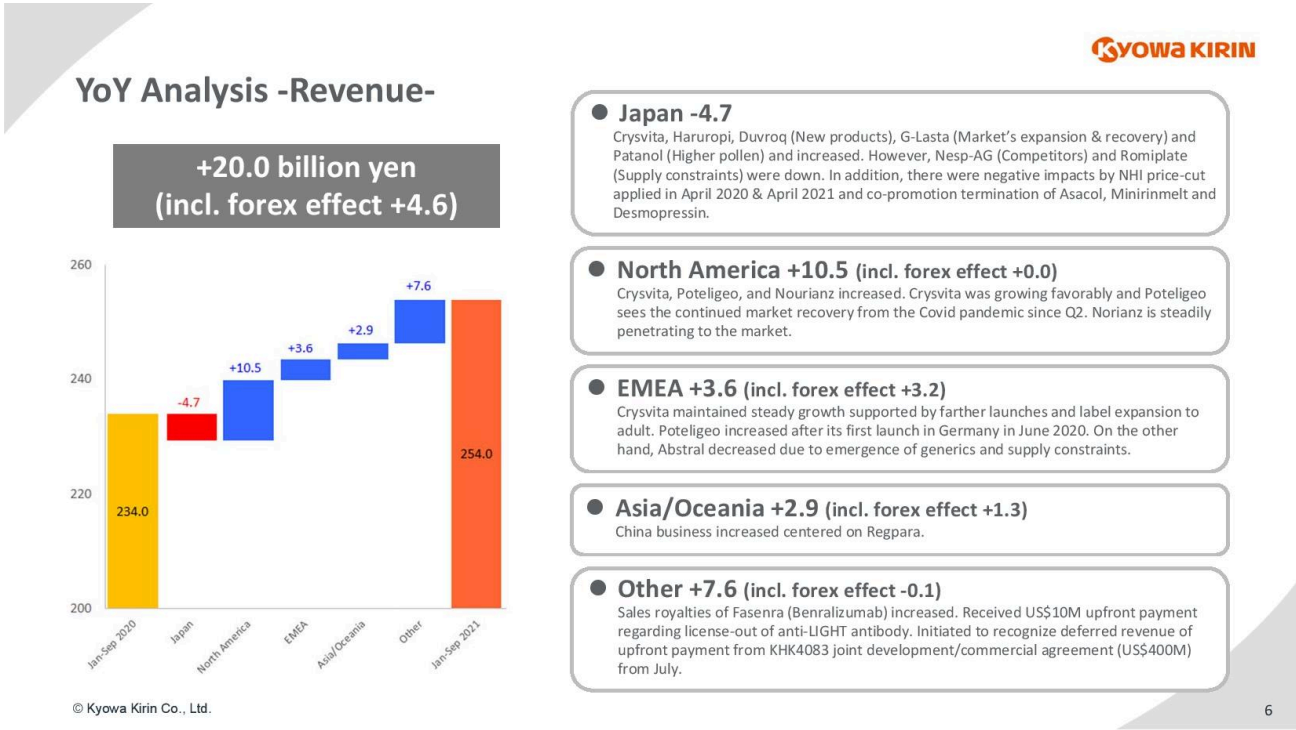
In terms of progress toward the full-year forecast, sales revenue stands at 72%, core operating profit is at 72%, and net income is at 66%.

Sales revenue is generally in line with the plan due to the positive impact of the weaker yen, although some new products have fallen short of the plan.

On the other hand, cost of sales and selling, general, and administrative expenses are slightly high due to the impact of foreign exchange rates and other factors. Most of this is covered by unused R&D expenses and positive equity in earnings of affiliates.

We will aim to achieve our full-year plan of increased sales and profits through sales growth centered on global strategic products and cost control.

From the next slide, I will explain these points in detail.



Please see page 6. Here are the figures for sales revenue broken down on a 4-pole basis under the One Kyowa Kirin system.

Overall trends remain unchanged, with increased domestic sales of G-Lasta and Crysvita. However, in addition to the impact of the NHI drug price revisions in April 2020 and April 2021, there was a significant impact from the end last year of co-promotion of Asacol with Zeria Pharmaceutical, and of Minirinmelt and desmopressin with Ferring.

In the US and Europe, increased sales were recorded for global strategic products Crysvita, Poteligeo, and Nourianz. This contributed to an increase in sales of approximately JPY14 billion.

Sales in Asia also increased by JPY2.9 billion, mainly due to growth in sales of Regpara.

In addition, in the Other segment, in addition to the continued growth of benralizumab, we recorded an upfront payment of USD10 million for anti-LIGHT antibody from Aevi in the US in March. Additionally, we

recorded 3 months' revenue from July to September as part of an upfront payment of USD400 million received from Amgen. Revenue in this segment increased by JPY7.6 billion.

KYOWA KIRIN

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2020Q3 Results	2021Q3 Results	Changes	Reasons	2021 Plans	Progresses
Nesp + Nesp-AG*1	21.9	19.6	-2.3 (-11%)	Biosimilars' penetration & NHI price-cut	23.2	84%
Nesp	3.3	2.9	-0.4 (-12%)		3.8	77%
Nesp-AG	18.6	16.7	-2.0 (-11%)		19.4	86%
Duvroq	0.5	1.4	+0.9 (+187%)	Launched in Aug 2020	4.0	34%
Regpara	2.9	2.1	-0.7 (-25%)		2.0	107%
Orkedia	6.6	7.1	+0.6 (+9%)		10.4	69%
G-Lasta	19.6	21.2	+1.6 (+8%)	Market's expansion & recovery	29.8	71%
Poteligeo	1.5	1.5	-0.0 (-3%)		2.0	74%
Rituximab BS	8.6	8.1	-0.5 (-6%)	Covid-19	11.5	70%
Romiplate	5.8	4.9	-0.9 (-16%)	Supply constraints (2020.6-2021.3)	8.7	56%
Allelock	6.5	6.3	-0.3 (-4%)		6.8	92%
Patanol	8.7	9.2	+0.5 (+6%)	Higher pollen	10.9	84%
Nouriast	6.9	6.4	-0.5 (-8%)	Competitors' penetration	9.1	70%
Haruropi	0.4	2.2	+1.7 (+418%)	Launched in Dec 2019	4.6	47%
Crysvita	2.4	5.1	+2.7 (+113%)	Launched in Dec 2019	5.5	93%
Tech-licensing	1.6	1.5	-0.2 (-10%)		2.5	59%

*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.

7

Let's take a look at page 7 for a product-by-product summary. First, domestic products. I will focus on progress against the full-year forecast.

Nesp AG is performing well, with progress of 86% toward the full-year forecast. Due to restrictions on shipments of biosimilars, which are our competitors, we did not lose as much market share as we had expected.

Duvroq continues to struggle with a progress to full-year forecast of 34%. We have seen a degree of increase in shipments due to the lifting of restrictions on long-term prescriptions from September 1. We will continue to work toward developing the status of this product as a best-in-class HIF-PH inhibitor.

As for Romiplate, the progress to full-year forecast is 56%. It has taken time to recover from the shipment adjustment, but the most recent results have finally returned to the level seen before the shipment adjustment.

Progress to full-year forecast for Haruropi is 47%. As you can see, sales have been steadily growing YoY. However, a difference between conditions on the ground and the initial assumptions made at the agreement, particularly due the coronavirus pandemic, have caused sales to fall short. With the assistance of the auditing firm, we have recorded the impairment loss of the sales right.

Crysvita continues to grow steadily. The progress rate is 93%.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2020Q3 Results	2021Q3 Results	Changes	Reasons	2021 Plans	Progresses
Crysvita	38.5	55.1	+16.5 (+43%)	[North America] Market penetration & Expanded indication (TIO) [EMEA] Farther launches & Expanded indication (Adult) [Asia/Oceania] Launched in China	77.2	71%
North America	30.3	40.3	+10.0 (+33%)			
EMEA	8.3	14.8	+6.5 (+79%)			
Asia / Oceania	–	0.0	+0.0 (–)			
Poteligeo	8.4	11.0	+2.5 (+30%)	[North America] Signs of market recovery [EMEA] Launched in Germany in Jun 2020 & Farther launches	17.3	63%
North America	8.2	9.2	+1.0 (+12%)			
EMEA	0.2	1.8	+1.6 (+651%)			
Nourianz	1.7	3.1	+1.4 (+80%)	Market penetration	6.7	46%
Abstral	7.6	6.3	-1.4 (-18%)	Generic's penetration & Supply constraints	8.1	78%
Regpara	6.1	6.7	+0.6 (+11%)	Listed on Chinese NEDL*1 in Oct 2018	9.3	72%
Tech-licensing	10.9	16.4	+5.5 (+50%)	Growth of Fasenra & Upfront revenue of anti-LIGHT antibody & Deferred revenue of KHK4083 upfront	23.7	69%
Benralizumab Royalty*2	8.3	11.7	+3.4 (+41%)			

*1 National Essential Drug List
*2 Sales royalties of Fasenra, marketed by AstraZeneca (Including our own estimation)
＊ Revenue from Early Access Program (EAP) are not included in the figures above.

8

Moving on to page 8, we will now touch on the overseas segment.

As for the progress to full-year forecast of our global strategic products, Crysvita is at 71%, Poteligeo is at 63%, and Nourianz is at 46%.

In the US, we continue to see good progress in the identification of new patients and the number of new starting forms for Crysvita. In Europe, the numbers are also steadily increasing, and we are making steady progress as planned.

As for Poteligeo in the US, we explained in Q2 that the market showed signs of recovery. We have continued to see improvement in Q3, and we are making good progress with our plan. On the other hand, in EMEA, the launch schedule continues to be delayed. We will continue to negotiate so that the product can be delivered to patients as soon as possible.

Nourianz in the US has been experiencing sluggish growth relative to the increase in medical reps' activity. We have started to take a proactive approach to the newly targeted medical professionals. The numbers are growing slightly, and we will continue to focus on this product.

As for technology revenue, we started recording revenue from KHK4083 in July. The progress rate is 69%. This is essentially as planned.

YoY Analysis -Core OP-

-3.9 billion yen
(incl. forex effect +1.1)

- **Gross Profit +14.5** (incl. forex effect +3.7)
  - Increased in conjunction with 20.0B yen rise in revenue.
- **SG&A -16.0** (incl. forex effect -2.4)
  Increased for the maximization of "Global Strategic 3 Brands" (G3B) and the early consolidation of global business foundation. [Sales promotion -6.0 (incl. Crysvita's profit sharing expenses in North America) / Labor -4.8 / Other -5.2]
- **R&D -3.2** (incl. forex effect -0.1)
  Development cost of ME-401 and KHK7791 increased.
- **Gain/Loss on Equity Method +0.8**
  Sales of Hulio (FKB327/Adalimumab BS) increased

9

Let's move on to page 9 for an analysis of changes in core operating profit.

Gross profit increased by JPY14.5 billion on the back of a JPY20 billion increase in sales. As for the cost of sales, a few factors have contributed to a deterioration in the gross profit margin compared to the initial plan. Firstly, there has been the impact of foreign exchange rates on the elimination of unrealized gains on inventories, which I explained in Q1. The coronavirus pandemic has resulted in the unplanned retirement of inventories and the occurrence of valuation losses.

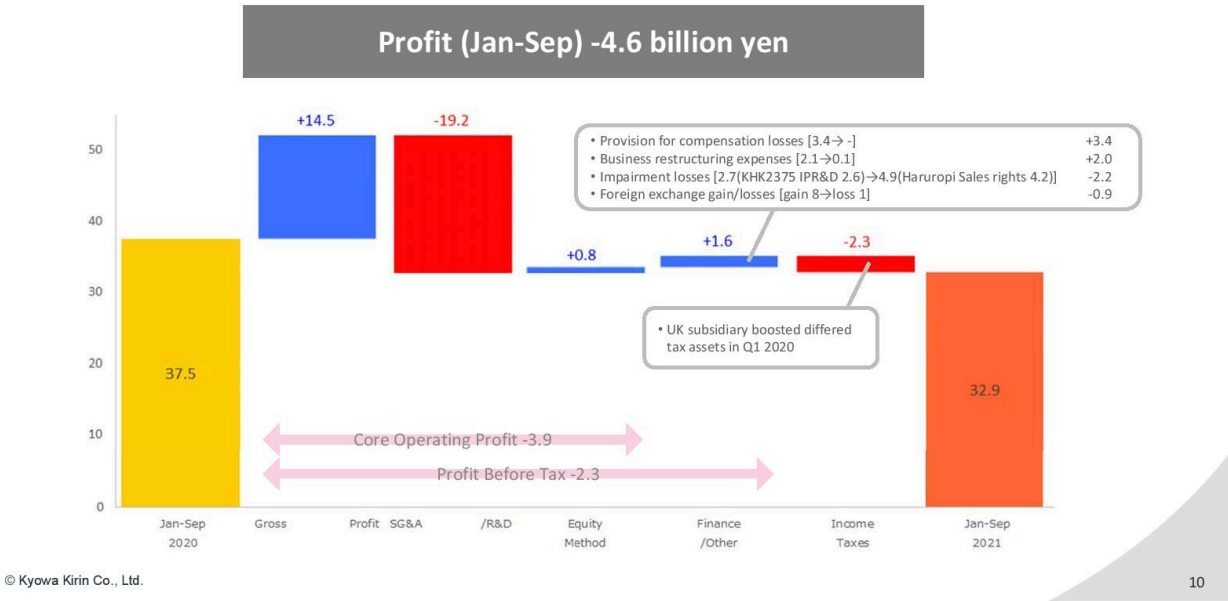
SG&A expenses increased by JPY16 billion, which continues to be a factor in the decrease in profit. As for the breakdown, sales promotion expenses increased by JPY6 billion, as indicated in parentheses. More than half of this is the Crysvita profit share payment. The remainder is due to the recovery of sales activities following the coronavirus pandemic, and an increase in the number of countries where our products are available.

In addition, personnel expenses increased by JPY4.8 billion. Here, we are increasing the number of personnel to match the launch status of our global strategic products and to strengthen our organizational capabilities. Increase in the others area is JPY5.2 billion. In order to maximize product value and quickly establish a global business foundation, various investments in IT, digital, and other areas are increasing.

Research and development expenses increased by JPY3.2 billion. The largest increase was in development costs for ME-401 and KHK7791, as stated. We see an increase of about JPY4 billion from the previous year with these two items only.

Equity in earnings of affiliates increased by JPY800 million. Sales of Hulio, a biosimilar of Humira, have been steadily increasing.

YoY Analysis -Profit-



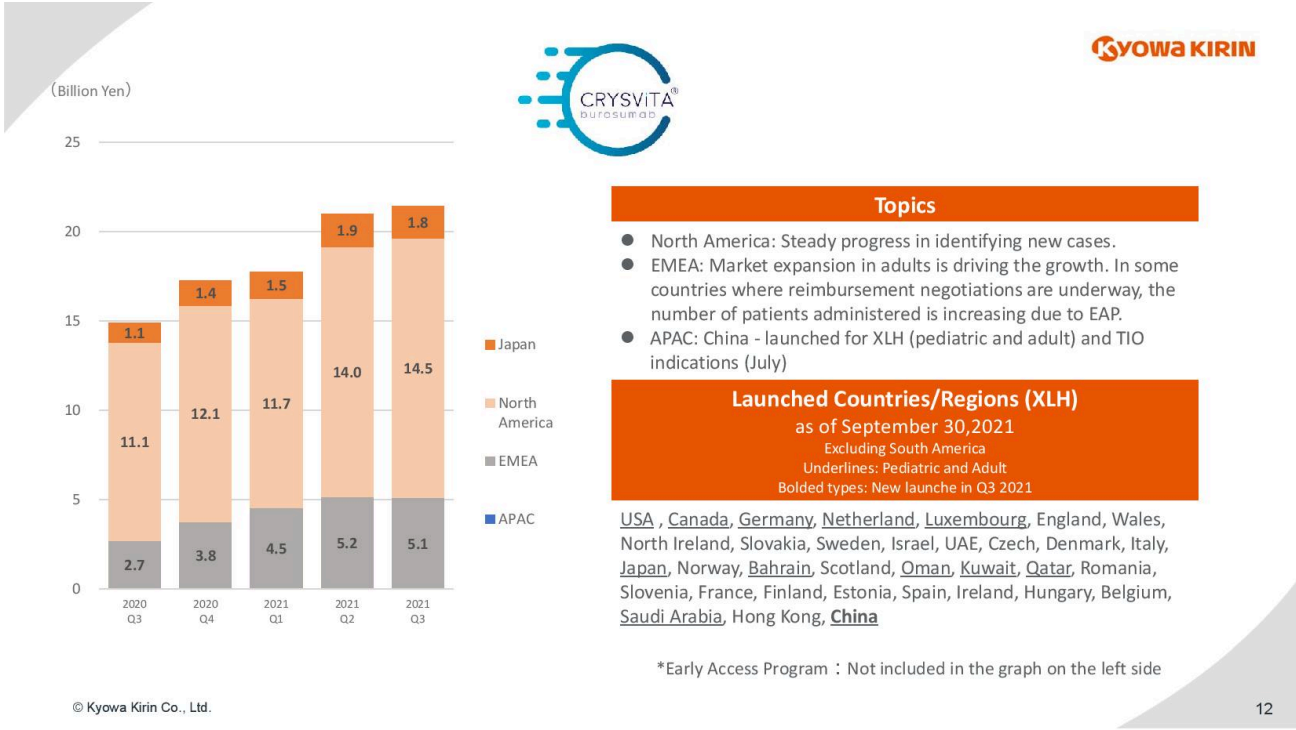
Now, I would like to conclude the financial part with an explanation of the changes in post-core operating profit on page 10.

Following core operating profit, we can see the finance and other section. The total increase in profit here was JPY1.6 billion. As you can see in the annotations, the provision for compensation losses and business structure improvement expenses that were recorded last year were almost non-existent this year, resulting in a combined increase of JPY5.4 billion.

On the other hand, impairment losses totaled JPY2.7 billion last year due to the impairment of compounds including KHK2375, or entinostat. This year, impairment losses totaled JPY4.9 billion, including JPY4.2 billion of Haruropi sales rights newly recorded in the third quarter. The result was a decrease of JPY2.2 billion. In addition to this, foreign exchange loss was about JPY1 billion.

Income tax expenses resulted in a decrease in profit of JPY2.3 billion. Last year, Kyowa Kirin International, our UK subsidiary, had a small income tax expense due to an increase in deferred tax assets, but this year the tax burden has returned to normal.

This concludes the financial review.



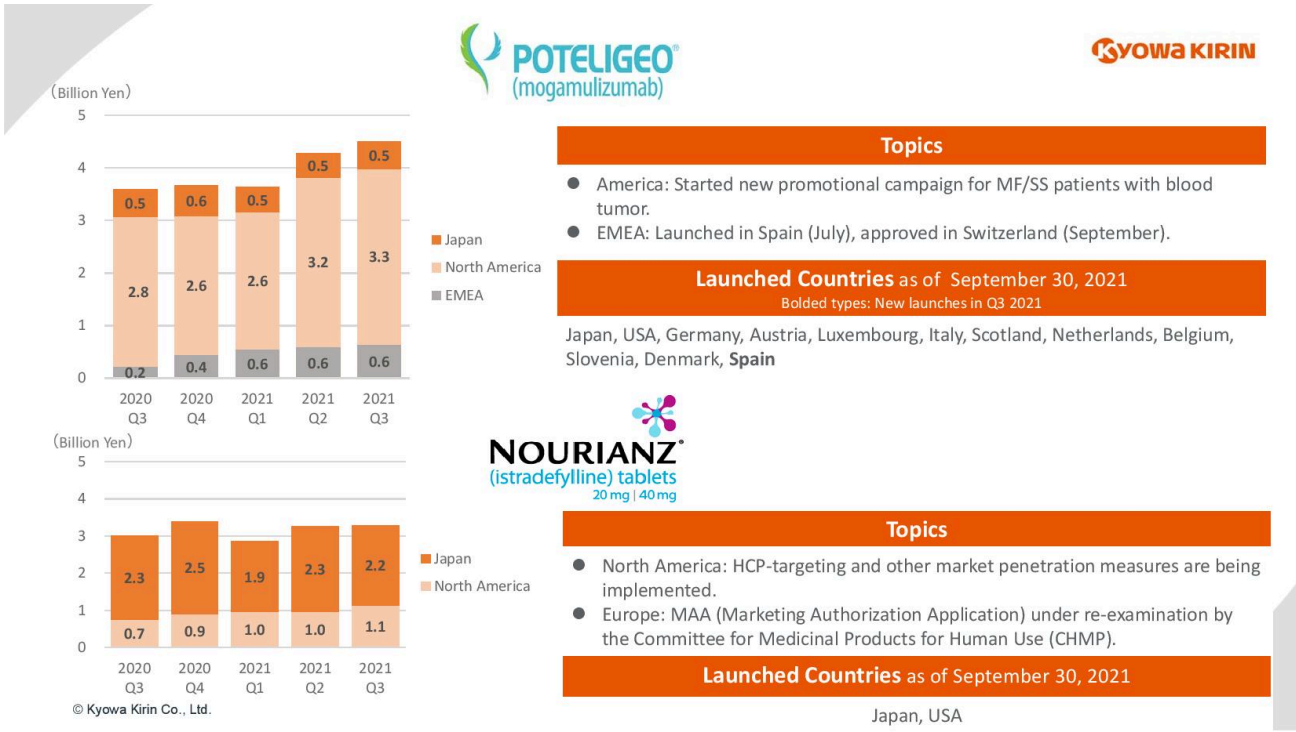
Yamashita: I will now give the commercial update. First of all, Crysvita.

In North America, we are making steady progress in new cases.

In Europe, the expansion of the adult market is providing a tailwind for growth. We are in the process of negotiating for reimbursement in Europe, but in some countries, the number of patients receiving Crysvita is increasing through the Early Access Program. However, the Early Access Program is not included in this bar graph.

In the third quarter, we were able to advance the launch for both pediatric and adult use in XLH as well as for TIO in China.

As a result, in terms of XLH, the number of launch countries as of the end of September is 34.



Next is Poteligeo.

In North America, we have started promotion based on the data of Sézary syndrome and mycosis fungoides patients with confirmed blood tumor. Data show that efficacy of treatment is high in these patient groups.

In Europe, we made progress with the launch of the product in Spain in July and the approval in Switzerland in September.

Next is Nourianz. As mentioned earlier in the finance section, in the US, the focus for Nourianz is penetration through a proactive approach to target doctors. We are aiming to achieve solid results with this initiative.

In addition, in Europe, as has been announced, the CHMP is currently re-examining the application for approval.

That's it for the commercial update.

Upcoming Events: Next-generation Strategic Products

✓ : Completed events from Jan 1 to Aug 3, 2021
✓ : Completed events from Aug 4 to Nov 1, 2021

Code generic name	Target disease	H1 2021	H2 2021	H1 2022
KHK4083/AMG 451	Atopic dermatitis	P2b topline data ✓	P2b detailed data ✓	P3 FPI
KW-6356	Parkinson's disease			P2b detailed data P3 FPI
ME-401 Zandelisib	FL (3L, mono)	P2 LPI ✓	P2 topline data	
	MZL (3L, mono)	P2 FPI ✓		
	FL/MZL (2L, combo)		P3 FPI ✓	
RTA 402 Bardoxolone methyl	Alport syndrome DKD		MA (JP) ✓	* (JP)
	ADPKD	P3 FPI (JP) ✓		
KHK7791 Tenapanor	Hyperphosphatemia under maintenance dialysis	P3 FPI (JP) ✓		

* Anticipated timing of regulatory decision; FPI: first patient in; LPI: last patient in; FL: follicular lymphoma; MZL: marginal zone lymphoma; ADPKD: autosomal dominant polycystic kidney disease; DKD: diabetic kidney disease; MA: marketing application

15

Torii: Please see page 15. I will give an R&D updates.

This is a list of events related to next-generation strategic products that are expected to be achieved in the next 6 months or so, starting from the beginning of the year. Today, I would like to give you a brief overview of the events that we accomplished between August 4 and today.

On August 17, we started the second-line Phase 3 study of zandelisib, or ME-401. This is called the COASTAL study. This study will evaluate the efficacy of zandelisib in combination with rituximab in patients with relapsed or refractory follicular lymphoma and marginal zone lymphoma who have received at least 1 prior therapy.

In addition, on October 2, we presented detailed efficacy and safety data of the Phase 2 study of KHK4083 in atopic dermatitis at the late-breaking session of the EADV. All current public data was presented at our October 4 briefing session, so I will skip that today.

Biomarker data will be presented at the Inflammatory Skin Disease Summit, the ISDS, on November 4. We are currently in discussions with the regulatory authorities for the start of Phase 3 trials, which are scheduled for the first half of next year.

That concludes my presentation.

Question & Answer

Moderator: I would now like to move on to the Q&A session. Please limit your questions to 2 at a time. Thank you for your cooperation.

Yamaguchi: This is Yamaguchi from Citi. Thank you.

1st thing, as Mr. Kawaguchi mentioned at the beginning of this presentation, the difference between the progress made up to Q3 and the full-year forecast. Considering that R&D and other activities will probably be completed and the progress of some products has been somewhat weak, I felt that it is slightly tough to achieve the full-year forecast. Is it correct to assume that this is the case?

Kawaguchi: Thank you for your question, Mr. Yamaguchi.

As you mentioned, sales are struggling a little in a few areas, but fortunately, the yen has weakened more than our forecast at the beginning of the year, which will probably have a positive impact of about JPY9 billion. We believe that including this, we will be able to exceed the initial sales forecast.

On the other hand, in the cost of sales, there is a foreign exchange difference related to unrealized gains on inventories of about JPY2 billion. We have been aware of this from Q1. Additionally, there has been a small write-down and retirement of inventories, which has caused a slight downward revision to the plan.

However, we have been able to control our SG&A expenses in line with the Company's plan so far.

In terms of research and development expenses, to be honest, there might be a small degree of unused expenses throughout the year. As for KHK4083 and KHK6356, when we planned at the beginning of this year, we assumed that we would start Phase 3 within the year. However, as you know, we have revised the plan a little bit so that we will start Phase 3 in the first half of next year.

As for 4083, through the partnership with Amgen, half of the cost will be paid by them. These 2 factors mean that there are likely to be some unused R&D expenses. Another point is that although it is not a large amount, the equity in earnings of affiliates has already exceeded the plan at the beginning of the year, so this is a positive result.

We certainly can't be overly optimistic, but we are working hard to achieve the plan for the first year of the medium-term business plan, especially focusing on cost control.

That was a slightly long answer. I'm sorry.

Yamaguchi: Understood. Thank you. That's all from me.

Operator: The next question is from Mr. Wakao, JPMorgan Securities Japan.

Please go ahead.

Wakao: This is JPMorgan, Wakao here. Thank you.

First, as Mr. Yamaguchi just asked, I think you mentioned that some R&D expenses may not be used. On the other hand, the forecast for this fiscal year is JPY65 billion, and the cumulative total results through to the third quarter is JPY40.2 billion, so there is a little less than JPY25 billion remaining. I thought that the portion planned for Q4 was quite large, and that if it were unused, that might have quite a big impact.

I was wondering how much of the remaining portion will go unused for in Q4? Would you be able to give more of a breakdown of the elements involved?

Also, if the clinical trial for KHK4083 will start next year, should I assume that the R&D expenses in the next fiscal year will be higher than what your company had previously expected?

In the medium-term management plan, you are going to aggressively invest in research and development, and I understand that, but if you take out the next fiscal year alone and add the unused figures of the current fiscal year on the ones of the next fiscal year, is it fair to say that the next fiscal year will be at a high level a bit?

Kawaguchi: Thank you for your question.

As you said, we will not be able to reach the JPY65 billion level of R&D expenses at the end of the fourth quarter.

In Q4, R&D expenses as a whole will increase by several billion yen compared to a normal quarter, since there will be the year-end settlements. Also, for the KW-6356 and KHK4083 that were mentioned earlier, a certain amount of expenses will be incurred prior to the start of Phase 3. So, the R&D expenses will be incurred more than the third quarter.

Even with these factors, I do not disagree with your view that there will be a certain amount of unused expenses.

The budget for next year is currently being prepared, and while we are considering the impact of this, we are not anticipating a large impact. Regarding next year's budget, the details of the development plan with Amgen for KHK4083 have not yet been finalized, so there could be a certain impact. Regarding 6356, when Phase 3 starts, there will of course be a degree of expenses.

Additionally, we will also have to spend a lot of money on development for ME-401. We are not in a situation where we have enough leeway towards the R&D guidance of 20% of sales, so will have to make efficient and effective investments on R&D. For that, we are currently working hard to prepare the budget.

Wakao: Understood.

Secondly, regarding the progress of Crysvita, you explained that it is in line with the plan and that the number of patients in the US is growing. However, if you look at the bar graph on page 12, you can see that Japan is doing better than expected, qualitatively. From the graphs, North America seems flat and EMEA has also decreased slightly, so I'm having trouble seeing the link between today's explanation and the current progress, so how should I understand this?

Is the situation like this because the timing of sales, the growth in the number of patients, and the timing of recording those sales are out of sync, or is there some other factor that is causing the graph to be flat?

Sudo: I will take this question.

Although we are following the trends of the number of patients in general and new patients in particular, we do not currently believe that the overall market trend is going to flatten out. Therefore, we feel that we will be able to grow our business in Q4 and in 2022 also.

Incidentally, as you mentioned, in Europe, if you look at Q2 and Q3, the figure looks a little flat. However, the drug prices have been fixed in a country where we had implemented the Early Access Program. In the second

quarter, sales did increase slightly due to that. In essence, we are seeing a solid growth in the number of patients. We don't have any particular concerns about this.

Thank you.

Wakao: Understood. I think it is correct to say that North America and Europe are expected to grow steadily in the fourth quarter.

Incidentally, in Japan, I believe that sales are progressing better than planned, although they are down a little compared to Q2. Could you comment on the situation in Japan?

Sudo: As Mr. Kawaguchi mentioned earlier, the situation in Japan has been quite steady in terms of budget. The market itself is developing in a manner similar to the pattern of the US market launch, and to be honest, the market moved better than I expected.

Likewise, it has just begun in the Japanese market, so I think there is plenty of room for growth in the future. We don't have any major concerns based on these results from Q2 or Q3.

Wakao: Understood. I understand that we could expect a little more sales growth in all regions in Q4. Thank you.

Muraoka: Hello. This is Muraoka of Morgan Stanley. Thank you.

I would like to follow up on the previous question regarding business performance. Assuming you can achieve the core operating profit of JPY65 billion as expected, you'd basically need to see an average annual increase in profit of about JPY15 billion until 2025.

I believe that the Company is capable of that, but when I look at the numbers, I am getting worried. Costs will be high in the next fiscal year, or the rate of profit increase will accelerate considerably from the next fiscal year? When you explained the medium-term business plan, I think you said that the first half of the plan would be investment-led, but since this year's situation will continue next year, it seems like a potentially difficult situation. Could you please comment on that?

Kawaguchi: Thank you for your question.

As for the status for the next fiscal year, as I mentioned earlier, we are currently working on the plan for the next fiscal year. Therefore, of course, I cannot say anything definite, but as I explained at the time of the medium-term business plan, in the first half of the medium-term business plan, the pace of improvement in profitability will be slow because investment expenses will take precedence. Therefore, we do not expect linear profit growth, but rather a slight delay in profit growth from the top line growth and then a sharp increase.

For the next fiscal year, we have not planned for such large profit growth even in the medium-term plan, and the situation remains unchanged that medium- to long-term growth will be fragile unless we make solid investments, including a certain level of risk response, to strengthen our global infrastructure. Therefore, it is very difficult to exceed your expectations in terms of profits, but I hope you understand that making solid investments in this area is important for the enhancement of our corporate value in the medium to long term.

Of course, we will continue to strengthen our control of expenses, recognizing it as an important issue.

This is a bit of a qualitative answer, but I hope it is enough.

Muraoka: Thank you very much. It was very helpful. As for the prior investments that need to be made even in the next fiscal year, I think there are various investment items as you mentioned today. However, are there any other items that you are still planning to invest in, or will you continue to incur expenses for the investments that you made this year? Do you have any additional items in mind?

Kawaguchi: Thank you very much.

Basically, we will not be able to finish strengthening our infrastructure in 1 year, so we will need to invest firmly and continuously over the next 2 to 3 years. For example, IT investments will not be completed in 1 year, so those investments will continue in the next fiscal year. In addition, as you know, there will be a transition of Crysvita sales activities in North America from Ultragenyx to us in April 2023.

In preparation for this, we need to start preparations a year in advance, and we need to make a solid investment in this area. It is an important investment for the linear growth of Crysvita, which is a major priority for us. Other than that, it is basically a continuation of this year's program, with no major changes from this year.

Muraoka: I understand. Thank you.

1 more thing, you mentioned that the effect of the Early Access Program for Crysvita makes the figures for Europe look a little smaller. If we assume that the unit price in the Early Access Program, which is not recorded as sales, is about the same as that of the UK or Germany, can you give us a rough idea of whether the third quarter sales of JPY5.1 billion will reach nearly JPY6 billion or not?

Sudo: Thank you very much, Mr. Muraoka.

Due in part to COVID-19, there was actually a general delay in the discussion of drug prices for adults. This has been a factor in the Early Access Program having more adult patients than expected.

Although I would like to refrain from giving specific figures today, I believe that the adult market is developing in a way that is almost comparable to the Japanese or US markets, so basically the amount is not that small. However, it is still difficult to say whether it is a large amount of money or not, so I think it would be better if you understand it as such.

In the US market, in terms of the number of patients, the ratio of adults to children and adolescents has become about 1:1. If you would forecast of that, imaging such things I mentioned, it would be appreciated.

Muraoka: I understand. So it is safe to assume that the impact of EAP will diminish considerably in the next fiscal year?

Sudo: I'm sorry. Could you repeat that?

Muraoka: I'm sorry. I think it is safe to say that the negative impact of the EAP in Europe will diminish considerably in the next fiscal year, right?

Sudo: That's right. In this sense, as you say, I expect that the expanded label of the drug will have a solid impact on sales.

Muraoka: I understand. That's all. Thank you.

Arai: This is Arai of BofA Securities. Thank you.

I apologize for the repetition, but in terms of the rate of progress against the full-year plan for this fiscal year, in the cost of sales section, in addition to the unrealized profit of JPY2 billion, there is a 1-time valuation loss. I think you explained that this was due to the impact of the coronavirus pandemic. Could you comment on figures and background of that, please?

Kawaguchi: Thank you for your question.

The write-down and disposal of inventories is a certain amount that occurs every year, although some of it is transient. However, in the plan, we have already factored in only the minimum amount.

I mentioned earlier that it was due to the coronavirus pandemic. To be specific, for example, when we launch a new product, we usually purchase adequate amount to never occur the stock-out. However, if we fall far short of our sales plan, we end up retiring a larger number of expired products than expected. We actually saw such cases more than normal years due to the pandemic.

In addition, I can't go into specifics, but I can say that there were some transient occurrences, and these factors have generated losses of about JPY2 billion more than planned up to the third quarter. As a result, cost factors have caused a decrease of about JPY4 billion from the plan.

Therefore, unfortunately, the gross profit margin for the year is expected to be 77%, which is a 2% improvement over the previous year, but since it is JPY4 billion loss, we will have to settle for about 1% lower.

Thank you.

Arai: Thank you very much. Doesn't that kind of activity usually happen in, say, the October-December period?

Kawaguchi: That is what I am hoping for. For the time being, we are making a firm allowance for possible write-downs in Q3, so unless there is some kind of trouble, I don't think there will be another large amount in Q4.

Arai: Thank you very much.

My second question is about 4083. Do you have any plans to obtain a breakthrough therapy designation in the US, for example, after the Phase 2 trial?

Torii: Thank you very much.

We are currently working with Amgen to make preparations, including negotiations with the authorities. Although no such plans have been raised at this time, we are not denying the possibility of such a project in the future.

Arai: I understand. Thank you. That's all.

Ueda: I am Ueda from Goldman Sachs.

I would like to know the impact of the coronavirus pandemic on the market for the 3 global products, Crysvita, Poteligeo, and Nourianz.

As mentioned earlier, Crysvita has remained a little weak in Q2 and Q3, even in the US. I feel that the momentum is a little weak. Poteligeo also looks as if there was not much growth in Q2 and Q3, while there was some improvement from Q1. Nourianz, and in particular, the domestic product, seems to be a bit negative in some areas.

I believe that coronavirus had an impact on patient trends for each of the growth products, so I would like to know if this re-expansion has had any impact and how things are going at the moment.

Sudo: Thank you for your question.

In terms of sales, the impact of COVID-19 itself is still being felt in Europe for Poteligeo and in the US for istradefylline. I think this is where the big difference is. However, looking at the overall picture, I think that excluding these, we are making good progress.

Incidentally, Poteligeo in Europe and istradefylline in the US were launched just before the COVID-19 pandemic, so I think one of the main reasons was that they were heavily influenced by that.

As for Crysvita, frankly speaking, looking at the current market trends, as mentioned earlier, there has not been much change between Q2 and Q3. Our sales activities are just now starting to pick up again, so we feel that there is a lot of headway to be made yet. We are in a situation where we are not particularly concerned about sales being relatively flat due to COVID-19.

Other than that, I have heard that sales activities in general are quite limited for large hospitals, both in Europe and the US. I wonder if the impact is particularly hard to see in Europe. I've also heard that sales activities for istradefylline have returned to about 50% of their former level, so I'm hoping that we will be able to deliver the product to patients through these activities.

Thank you.

Ueda: Thank you very much.

My second question is if you could tell me about the impairment loss on Haruropi that has been recorded. In your explanation, you mentioned that the figure at the start of the fiscal year was a little lower than expected due to the impact of COVID-19. If that is the case, what discussions led to the decision to record an impairment loss at this point in time? To what extent do you still have intangible assets remaining for this drug?

Also, since this was not incorporated in the plan, is it correct to say that this will have a negative impact on the plan of income before income taxes and net income? Thank you.

Kawaguchi: Thank you for your question. I will answer.

The reason for the timing of the impairment of Haruropi is that it was launched in December 2019, just before the start of the coronavirus pandemic. Last year's results also fell short of the plan, but in general, it is a little early to determine the signs of impairment in the first year after the release of a product. It is usually determined after 2 to 3 years.

In addition, the budget for the next fiscal year and the rolling forecast for the year ahead will be developed at this time, although it is a temporary plan. We looked over the numbers with the audit firm and reached our conclusion. In that sense, the impairment loss was recorded at this time as a result of the appropriate accounting treatment at the fastest possible time.

Unfortunately, the economic conditions at the time of introduction are not disclosed, so I cannot discuss it in detail. There is a certain amount of intangible assets remaining. On this occasion, we have calculated the amount of impairment loss for accounting purposes based on a conservative forecast, so we do not think there is much chance of a large negative impact after this.

This will have a negative impact on the plan of net income for this fiscal year.

Thank you.

Ueda: Thank you very much for your kind attention. That's all from me. Thank you.

Kohtani: I'm Kohtani from Nomura Securities.

I would like to make 2 points. First, I would like to know about the situation with Nesp. Nesp has maintained a progress rate to full year forecast of 86%, while competitor products have not penetrated as much as expected.

Many of Nesp's users are sensitive to product price, so I would like to ask why our competitors' biosimilars are not gaining traction. Is this simply related to the curtailment of sales activities by biosimilar makers in the coronavirus pandemic, or is there another factor? What is the impression for next year? Will you be able to maintain a certain level of market share in the future because there are more customers who appreciate AG than your company had expected? Can you please comment on this? This is my first question.

Yamashita: I will answer.

This time, we had anticipated that sales of Nesp would gradually decline, but the figures are now exceeding that plan. I believe that the manufacturer of the so-called generic product, which produces the competing Nesp BS, has restricted shipments, probably because they cannot supply enough.

As a result, I have heard that some facilities that once used Nesp BS are now switching back to our Nesp AG.

Also, when BS first entered the market, there was a lot of focus on price differentiation in order to gain market share at a rapid pace, so market share moved significantly. However, the situation has now settled down.

However, we believe that the price difference will remain at a certain level for a long time, so as you mentioned earlier, we expect that some price-sensitive facilities now using Nesp AG will return to BS.

Thank you.

Kohtani: I understand.

The second point is about the biomarker data for KHK4083. The biomarkers presented in Phase 1 were measured in the peripheral blood of OX40-positive helper T cells, TARC, IL-22, LDH, and the percentage of eosinophils. Are you measuring basically the same things?

Also, I would like to confirm that TARC is the only marker for atopic severity in Japan, and it is not used in other countries. Because of that, I think LDH could be important in the future. Is my understanding correct? This is my second question.

Torii: Thank you for your question, Mr. Kohtani.

Since the data haven't been announced yet, I can't go into details, but I hope you understand that basically the same things that we saw in Phase 1 are included.

Kohtani: Do you have any comments on the relationship between TARC and LDH? Sorry, I'm not very knowledgeable about this myself.

Torii: That is also something that will be brought up in our presentation of results at ISDS. Thank you.

Kohtani: I understand. Thank you very much.

Tanaka: This is Tanaka from Mizuho Securities. Thank you.

As for the first question, the AYAME trial for RTA 402 is scheduled to be completed in May of next year, I believe. What is the status of the trial at present?

Torii: Thank you for your question, Mr. Tanaka.

As you mentioned, regarding the data necessary for the application, the data cutoff will be in May of next year. There are no major changes, and we are making good progress now.

Tanaka: With regard to Alport syndrome, the application has been filed in Japan, but I think there was an advisory committee in the US at the beginning of December. I think there was a time when your partner discontinued due to side effects or other problems. I wonder if there are any safety issues. Could you comment on this?

Torii: Thank you for your question.

So far, we have not had any information suggesting that the FDA is starting this advisory board because of any specific concern.

Tanaka: I understand.

The second question is about Crysvita in China. I understand that it's already on the market, is that right? I think the list price has not been decided yet, but what is the situation now? I would like to know if the price is a fixed fraction of what it is in Japan, or if you have any rough idea what it is.

Sudo: Thank you very much.

First of all, the product was launched at the end of July, and 1 patient has already started receiving the drug. At the moment, the NRDL designation is being prepared for next year, and this 1 person is not being reimbursed, but is paying for and using the drug privately.

As you know, the situation in China is changing in many ways, so it is difficult for us to predict a specific time frame, but our first priority is to obtain prices at the NRDL, or national level, as soon as possible, and then launch the product. First of all, we are doing our best to prepare for this.

Tanaka: Is there any particular bottleneck in terms of identifying patients, or diagnosis?

Sudo: It has now been about 3.5 years since we launched the product in the United States and Europe. We have a variety of knowledge, and we are now in the process of sharing this information with the Chinese company to identify patients.

However, there is also the current situation where the patients can be found differ greatly from country to country, so we will continue to monitor this situation carefully as we conduct our activities.

I understand that China tends to have many patients in large facilities, but I hope that we can continue to look closely at patient distribution patterns in order to identify more patients eligible to benefit from this treatment.

Tanaka: I understand. Thank you very much.

Sakai: This is Sakai, Credit Suisse. I'm very sorry, but I wasn't able to listen to Mr. Kawaguchi's part and the commercial update part because of a poor connection.

I'm sorry if my question overlaps with that, but I see that selling, general, and administrative expenses have increased considerably, including personnel expenses. I think that IT expenses are also a factor, but could you give a breakdown of where these personnel expenses are being used?

Kawaguchi: Thank you for your question.

Among SG&A expenses, personnel expenses increased by about JPY4.8 billion in Q3. This increase is not due to a huge increase in any particular department, but basically to strengthen our global functions. This is the most important issue for us right now.

For example, in all functions such as MA, QA, SCM, and PV departments, we are planning to increase the number of global staff to a certain extent, both in Japan and in each region.

Sakai: Do you have any data at hand about the actual increase in headcount in Q3?

Kawaguchi: I don't have the materials at hand right now, so please let me considerif we could provide you with that in the following opportunity.

Sakai: Yes, I understand. Thank you.

And 1 more thing, you may have already answered this, but I think the ban on long-term prescription of Duvroq was lifted in September.

I don't think it will affect the sales up to Q3, but after that, can you tell us how the situation is going or if there are any changes?

Yamashita: I will answer.

The ban on long-term prescriptions of Duvroq has been lifted, and we are still seeing moreand more use in these areas. Our competitors also received their approval at the same time, and the results are similar, but in terms of market share, we are seeing a very good trend.

As for Duvroq itself, I think the penetration of this drug as a new drug in this class has been a little weak overall due to the impact of COVID. However, Duvroq is doing quite well, and sales are increasing.

Thank you.

Sakai: Since you haven't changed your full-year forecast, to some extent, does this include a statement of intent?

Yamashita: Indeed. In terms of the overall trend, results up to now have not been so strong. While there are areas we are reviewing, we feel that the future forecasts are good.

Sakai: I understand. Thank you very much.

Moderator: Thank you very much.

As we are almost out of time, I will now conclude the conference call of the financial results for the third quarter of the fiscal year ending December 31, 2021.

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

[END]