



Kyowa Kirin Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending December 2021

August 4, 2021

Event Summary


[Event Name]	Q2 Financial Results Briefing for the Fiscal Year Ending December 2021	
[Date]	August 4, 2021	
[Number of Speakers]	4	
	Masashi Miyamoto	Representative Director of the Board, President and Chief Executive Officer
	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 the financial results for Q2 of the fiscal year ending December 31, 2021, of Kyowa Kirin Co., Ltd., which were announced at 15:30 yesterday.

I will now introduce today's Company Representatives. Dr. Masashi Miyamoto, President and Chief Executive Officer. Motohiko Kawaguchi, Executive Officer and Director of the Finance Department. Dr. Yoshifumi Torii, Executive Officer, Vice President and Head of the Research and Development Division. Tomohiro Sudo, Executive Officer, Director of the Global Product Strategy Department.

I will now hand over to Dr. Miyamoto.



Summary of Q2 Results

(Billion Yen / Rounded)

	2020Q2 Results	2021Q2 Results	Changes	2021 Plans	Progresses
Revenue <i>(Overseas Ratio)</i>	157.8 <i>[46%]</i>	165.0 <i>[52%]</i>	+7.2 (+5%)	351.0 <i>[54%]</i>	47%
Gross Profit <i>(Gross Profit Margin)</i>	116.9 <i>[74%]</i>	123.8 <i>[75%]</i>	+6.9 (+6%)	270.0 <i>[77%]</i>	46%
SG&A <i>(SG&A Ratio)</i>	58.2 <i>[37%]</i>	67.2 <i>[41%]</i>	+9.0 (+15%)	141.0 <i>[40%]</i>	48%
R&D <i>(R&D Ratio)</i>	24.1 <i>[15%]</i>	26.5 <i>[16%]</i>	+2.4 (+10%)	65.0 <i>[19%]</i>	41%
Gain/Loss on Equity Method	-0.1	0.9	+1.0 (-)	1.0	92%
Core Operating Profit <i>(Core OP Margin)</i>	34.5 <i>[22%]</i>	30.9 <i>[19%]</i>	-3.5 (-10%)	65.0 <i>[19%]</i>	48%
Profit	27.8	25.1	-2.7 (-10%)	50.0	50%

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Miyamoto: Good morning, everyone. I am Masashi Miyamoto. Thank you very much for taking time out of your busy schedule to join us today.

Now, I would like to give a brief overview of our financial results for Q2.

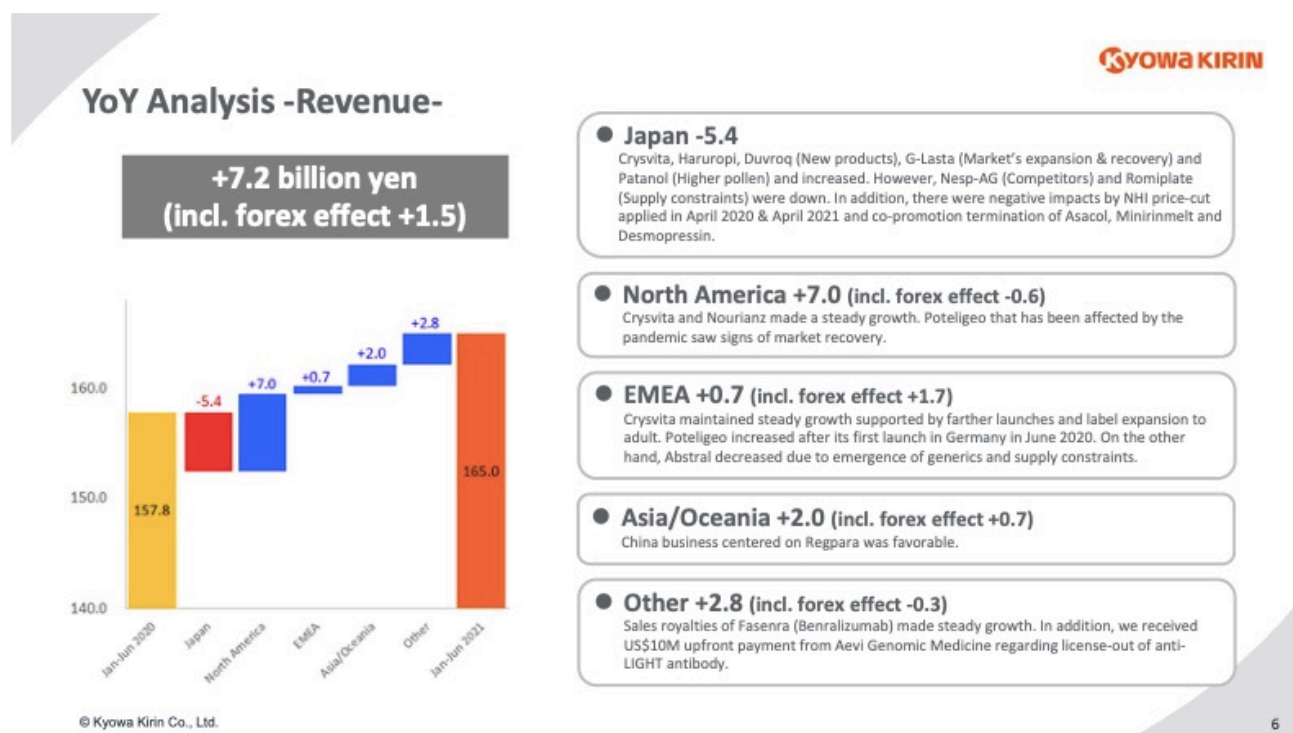
I think you have it at hand, but could you please go to page 5 of the explanatory materials for the financial results.

First, let me review the financial aspect.

Compared to the same period of the previous year, sales revenue was JPY165 billion, an increase of JPY7.2 billion, or 5%. On the other hand, core operating profit was JPY30.9 billion, a decrease of JPY3.5 billion, or 10%. Reflecting this, quarterly profit was JPY25.1 billion, a decrease of JPY2.7 billion, or 10%, from the previous year.

On the other hand, if we look at the rate of progress based on the forecast for the full year, sales revenue, core operating profit, and quarterly profit are 47%, 48%, and 50%, respectively. In that sense, we believe we are making good progress toward the full-year forecasts.

We believe that we have made steady progress toward our full-year plan of 10% increase in net sales and 8% increase in core operating income.



Next, page 6.

I will show you the figures for sales revenue broken down by the 4 global regions.

In Japan, sales of new products are continuing to grow. This growth is led by Crysvita. The results have been impacted by the two NHI price revisions, one in April last year and the other in April this year. Also, due to the impact of the termination of co-marketing of Asacol, Minirinmelt, and Desmopressin last year, sales decreased by JPY5.4 billion.

In Europe and the US, sales increased by approximately JPY8 billion due to growth of Crysvita, Poteligeo and Nourianz, which we have positioned as global strategic products.

Sales in Asia increased by JPY2 billion due to the continued strong performance of Regpara.

Other sales, which mainly include technology licensing revenue, were increased. This was due to the growth of benralizumab, which is licensed to AstraZeneca, and the upfront payment of USD10 million received from Aevi Genomic Medicine for the anti-LIGHT antibody.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2020Q2 Results	2021Q2 Results	Changes	Reasons	2021 Plans	Progresses
Nesp + Nesp-AG ^{*1}	14.6	12.9	-1.7 (-11%)		23.2	56%
Nesp	2.2	1.9	-0.3 (-14%)	Biosimilars' penetration & NHI price-cut	3.8	50%
Nesp-AG	12.4	11.0	-1.4 (-11%)		19.4	57%
Duvroq	—	0.5	+0.5 (—)	Launched in Aug 2020	4.0	14%
Regpara	2.0	1.5	-0.5 (-26%)		2.0	73%
Orkedia	4.3	4.6	+0.4 (+9%)		10.4	45%
G-Lasta	12.8	13.8	+1.0 (+8%)	Market's expansion & recovery	29.8	46%
Poteligeo	1.0	0.9	-0.0 (-4%)		2.0	48%
Rituximab BS	5.4	5.3	-0.1 (-3%)		11.5	46%
Romiplat	4.1	2.8	-1.2 (-31%)	Supply constraints (2020.6-2021.3)	8.7	32%
Allelock	4.9	4.8	-0.0 (-0.0%)		6.8	71%
Patanol	7.1	7.8	+0.6 (+8%)	Higher pollen	10.9	71%
Nouriast	4.6	4.2	-0.4 (-9%)	Competitors' penetration	9.1	46%
Haruropi	0.2	1.3	+1.1 (+457%)	Launched in Dec 2019	4.6	29%
Crysvita	1.3	3.3	+2.0 (+153%)	Launched in Dec 2019	5.5	61%
Tech-licensing	1.0	1.3	+0.3 (+27%)		2.5	54%

*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.

Please see page 7. I would like to look at some of the results by individual product in Japan.

In terms of progress against the plan, I would like to say a few words. First, about Nesp AG. The progress rate is 57%, which is slightly up on our forecast. This is because there were some restrictions on supplies of competing biosimilars.

Performance of Duvroq is quite weak, with a progress rate of 14%. HIF inhibitors market as a whole are struggling, but on the other hand, as you know, there was news from GSK the other day that the results of the 5 global Phase III trials were very positive. Long-term prescriptions will be available from September, so we are currently stepping up our activities based on these factors. We hope to catch up here in the second half of the year by continuing our steady information activities.

As for Romiplat, the progress rate is 32%, which is also slightly behind schedule. As mentioned in the Reasons column, we had to adjust supplies from June last year to March this year due to a sharp increase in demand, causing a great deal of inconvenience to patients and medical institutions. Since April, there have been no further restrictions on supplies, however the recovery is still a little slow. We have heard from the field that demands are returning to normal, so we also hope to boost in the second half of the year.

Allelock and Patanol have made strong progress because pollen counts increased earlier than expected this year.

Another new product, Haruropi, continued to struggle, with a progress rate of 29%. This is due to the impact of the coronavirus pandemic, which has restricted the activities of MRs to a large extent, as well as the reduced numbers of patients attending clinics. Recently, we have seen a gradual increase in sales, and we hope to continue our efforts to penetrate the market and recover.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2020Q2 Results	2021Q2 Results	Changes	Reasons	2021 Plans	Progresses
Crysvita	24.7	35.4	+10.7 (+43%)	[North America] Market penetration & Expanded indication (TIO)	77.2	46%
North America	19.2	25.7	+6.5 (+34%)	[EMEA] Farther launches & Expanded indication (Adult)		
EMEA	5.6	9.7	+4.1 (+75%)			
Poteligeo	5.4	7.0	+1.6 (+30%)	[North America] Signs of market recovery	17.3	40%
North America	5.4	5.8	+0.5 (+9%)	[EMEA] Launched in Germany in Jun 2020 & Farther launches		
EMEA	0	1.1	+1.1 (-)			
Nourianz	1.0	1.9	+1.0 (+102%)	Market penetration	6.7	29%
Abstral	5.8	4.0	-1.8 (-31%)	Generic's penetration & Supply constraints	8.1	50%
Regpara	3.9	4.6	+0.7 (+18%)	Listed on Chinese NEDL ^{*1} in Oct 2018	9.3	49%
Tech-licensing	7.0	9.1	+2.1 (+31%)	Growth of Fasenra & Upfront revenue of anti-LIGHT antibody license-out	23.7	38%
Benralizumab Royalty ^{*2}	5.2	7.1	+1.9 (+37%)			

^{*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.

Next, page 8.

As for the progress toward full-year forecasts of global strategic products, Crysvita is at 46%, Poteligeo at 40%, and Nourianz at 29% progress.

Crysvita has continued to perform very well following Q1. As I believe Ultragenyx also announced, the number of new patients identified in the US and the number of patients applying to start treatment have been in line with our expectations. We believe that this is progressing as planned.

Poteligeo in the US had a tough time in Q1, but in Q2, the business was back on track and the numbers are growing. We believe that this is partly due to the progress of vaccinations. We will continue to analyze these factors in detail and take action as necessary in the second half of the year as we work toward a market recovery.

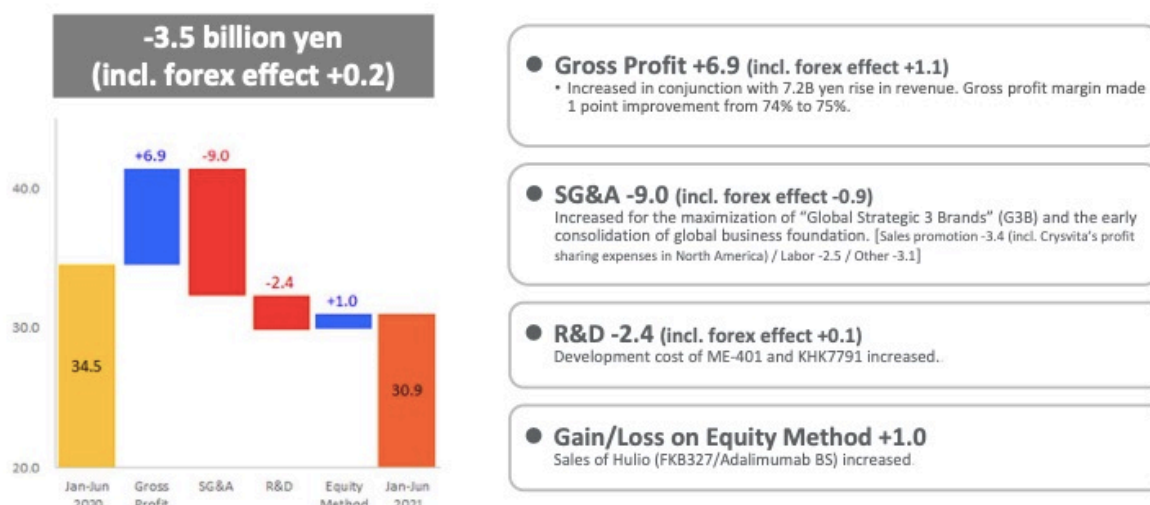
On the other hand, progress of Poteligeo in Europe is still being affected by the coronavirus pandemic. It is taking some time to negotiate the drug reimbursement price with each country. We know that there are patients who are in need of this product, so our task is to negotiate with the authorities so as to both protect the value of the product and bring it to market as soon as possible.

Also, Nourianz in the US is lagging behind in progress. Until about March, activity of medical representatives was very restrained, but since April, the volume of activity has been gradually increasing. This is not yet reflected in the figures.

We are now digging deeper into the causes of this problem and are working on countermeasures to come back to the planned line.

As for technology revenue, Fasenra has made good progress.

YoY Analysis -Core OP-



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This is page 9. This is an analysis of changes in core operating profit.

Gross profit increased by JPY6.9 billion, reflecting the JPY7.2 billion increase in the top line. Gross profit margin also improved by 1%.

Selling, general and administrative expenses increased by JPY9 billion, which is the biggest reason for the decrease in profit.

The breakdown is as follows: sales promotion expenses, JPY3.4 billion. This is mostly due to the increase in Crysvita's profit-sharing payments, and the rest is due to the recovery in sales activities, which has led to the growth in expenses.

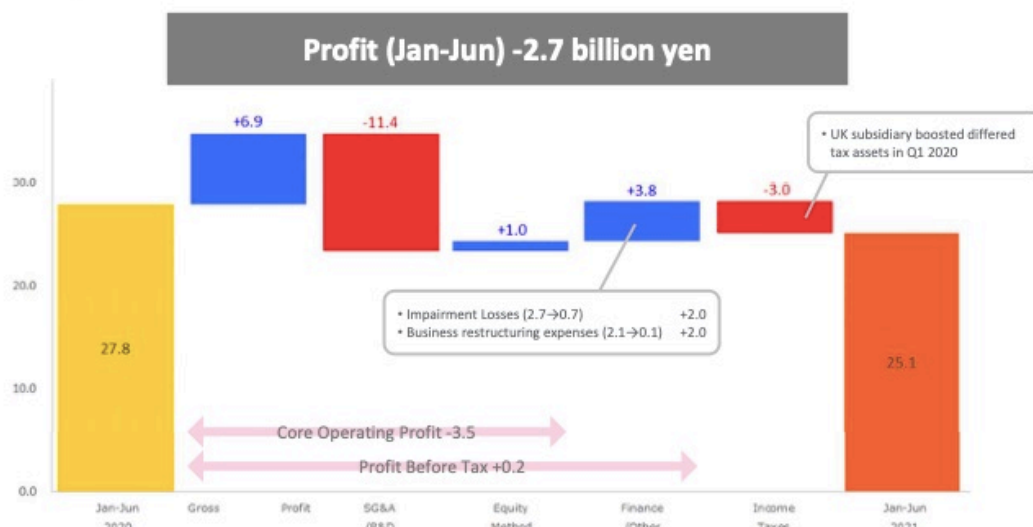
In addition, personnel expenses increased by JPY2.5 billion. This is also due to an increase in the number of personnel to strengthen our organizational capabilities, in line with the launch of global strategic products, and because Kyowa Kirin as a whole is currently making strong efforts for globalization.

And the other expenses increase by JPY3.1 billion. As I mentioned earlier, investments for the purpose of quickly establishing a foundation for global business, such as IT, are increasing.

Also, R&D expenses increased by JPY2.4 billion. As you can see here, the development costs for ME-401 and KHK7791 will increase by roughly JPY3 billion.

Equity in earnings of affiliates increased by JPY1 billion due to the steady growth of Fujifilm Kyowa Kirin Biologics' product, a biosimilar of Humira, which is called Hulio.

YoY Analysis -Profit-



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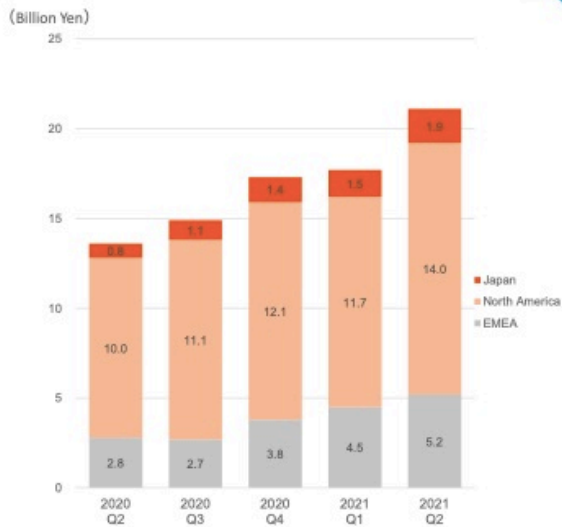
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On the last page, page 10, I would like to discuss the changes in operating income.

Net income increased by JPY3.8 billion in the Financial & Others segment. This was due to a decrease in impairment losses and business structure improvement expenses at Kyowa Kirin International KKI, which oversees the European region, compared to last year.

In terms of income tax expenses, they were very low last year due to the buildup of deferred tax assets by KKI, but this year they have returned to a normal level, which is the reason for the decrease of JPY3 billion.

This concludes the financial review.



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Topics

- North America: Steady progress in the number of newly treated patients.
- EMEA: (EU) Self-injection approved. (Germany) Expansion of indication for adult use contributed.
- AP: (China) Preparation for launch on track. (Singapore) XLH approval.

Launched Countries/Regions (XLH) as of June 30, 2021

Excluding South America
Underlines: Pediatric and Adult
Bolded types: New launches in Q2 2021

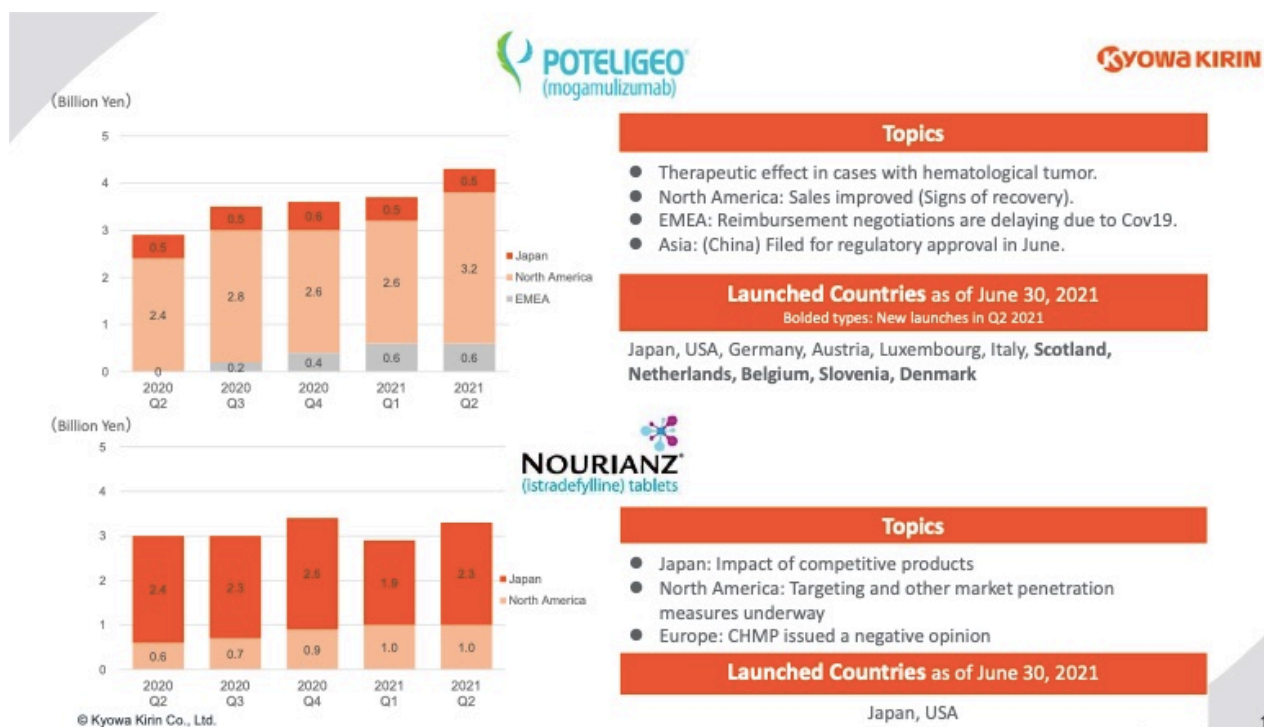
USA , Canada, Germany, Netherlands, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain, Scotland, Oman, Kuwait, Qatar, Romania, Slovenia, France, Finland, Estonia, Spain, **Ireland**, **Hungary**, **Belgium**, **Saudi Arabia**, **Hong Kong**

This is followed by a commercial update. Can you please jump to page 12?

First, Crysvida. In terms of pediatric XLH, the number of countries where it is available has increased to 33 as of the end of June. In Q2, the Company was able to move forward with launches in Ireland, Hungary, Belgium, Saudi Arabia, and Hong Kong. As I mentioned earlier, sales are going well.

For example, the expansion of the indication to adults in Germany is beginning to contribute to sales. Also, in Europe as a whole, self-injection was approved in July. I expect this to be a factor in future growth.

Looking at Asia, preparations are now well underway for the launch of the product in China. In Singapore, the drug was approved for both pediatric and adult use in XLH.



Next, page 13.

First for Poteligeo. As I explained earlier, in EMEA, negotiations for the launch of the product are taking a little longer in some countries for the price negotiations, but we are working persistently here. Although it is not shown on this slide, we achieved launch in Spain in July. Looking at Asia, we submitted an application for approval in China in June.

As for Nourias, we will be conducting activities I mentioned earlier in the future. One issue is that we applied for approval in Europe, but the CHMP gave us a negative opinion, as you all know. This will be addressed by re-examination, which we are currently working on.

Signed an agreement with Amgen for joint development and commercialization of KHK4083, a potent treatment for atopic dermatitis (Disclosed on June 1)

- On June 1, Kyowa Kirin and Amgen entered into an agreement to jointly develop and commercialize KHK4083, an anti-OX40 fully human monoclonal antibody discovered and being developed globally by Kyowa Kirin
 - *This agreement became effective as of July 31, 2021, following the expiration of the waiting period under the U.S. antitrust laws.
- Amgen will make a \$400 million up-front payment to Kyowa Kirin and future contingent milestone payments potentially worth up to an additional \$850 million, as well as significant royalty payments on future global sales.
- KHK4083 has a unique mechanism of action that is expected to become a new therapeutic option for treating atopic dermatitis, with potential in other autoimmune diseases.

Now let's go to page 15, business topics.

As you all know, on June 1, we entered into a co-development and marketing agreement with Amgen for KHK4083. We needed some waiting period in relation with the US antitrust laws but it was completed, then the agreement officially came into effect at the end of last month.

Upcoming Events: Next-generation Strategic Products

✓ : Completed events from Jan 1 to May 6, 2021
 ✓ : Completed events from May 7 to Aug 3, 2021

Code generic name	Target disease	H1 2021	H2 2021	H1 2022
KHK4083	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		MA (JP) ✓	* (JP)
	DKD			
	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

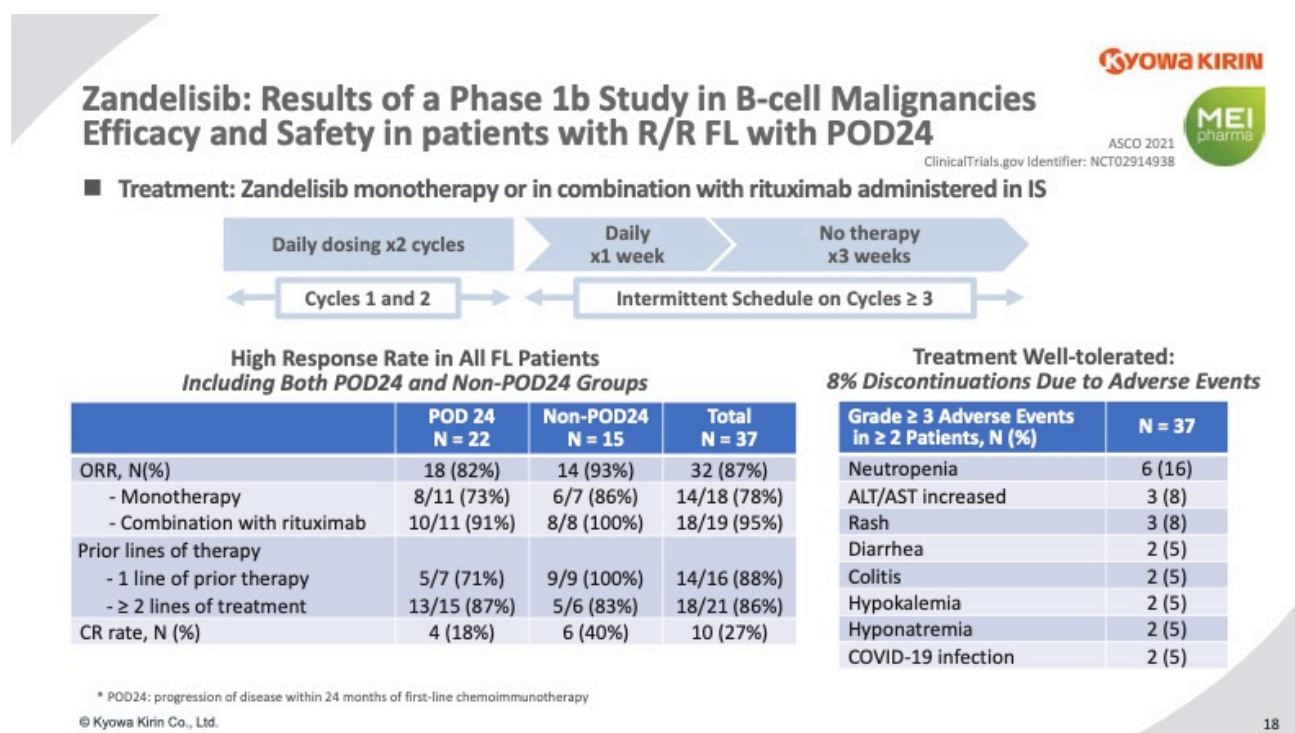
Next, I will briefly introduce the R&D update. Please see page 17.

This table is a summary of the events that may occur between the beginning of this year and the first half of next year. Today, I'd like to share with you an event that we accomplished between May 7 and today.

On June 7, we started an additional cohort targeting relapsed or refractory marginal-zone lymphoma in Phase II TIDAL study of zandelisib, ME-401.

Also, we presented 3 abstracts on zandelisib at ASCO in June. I will explain a little bit about these data later on.

In July, on the 28th, we filed an application for manufacturing and marketing approval in Japan for bardoxolone methyl for the treatment of Alport syndrome. For this indication, the drug has been designated as an orphan disease drug, so we believe that it will be reviewed as a priority review item.



Please see the next slide. This is a Phase Ib study of zandelisib as a single agent. It targets relapsed or refractory follicular lymphoma.

I believe you can see “POD24” in the lower left table. This refers to patients whose disease progressed within 24 months after the start of the first-line treatment. These patients are known to have a very poor prognosis.

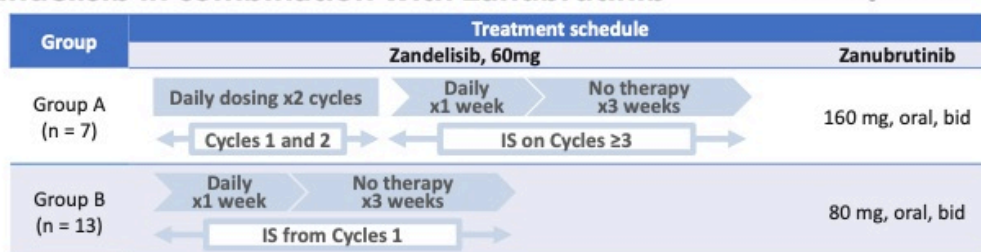
As you can see in the table, the response rate in the overall population was 87%, which is very good, and the response rate in the POD24 patients was 82%, which is also very good. As you can see in the table on the right, the tolerability of the drug was also good.

Zandelisib: Results of a Phase 1b Study in B-cell Malignancies

Zandelisib in combination with Zanubrutinib

KYOWA KIRIN

ASCO 2021
ClinicalTrials.gov Identifier: NCT02914938



Combination of zandelisib 60 mg on an IS from Cycle 1 and zanubrutinib 80 mg twice daily is well tolerated

Grade 3-4 AESI, N (%)	Group A N = 7 (%)	Group B N = 13 (%)
ALT / AST increased	2 (29%)	2 (15%)
Rash	1 (14%)	0
CMV colitis	1 (14%)	0
Pneumonia	1 (14%)	0
Diarrhea	0	0
Atrial fibrillation	0	0

Disease Response in 100% of Patients with iNHL and CLL

Evaluable N = 18	FL N = 8	CLL/SLL N = 5	MZL N = 2	MCL N = 1	DLBCL/HGBCL N = 2
ORR, N (%)	8 (100%)	5 (100%)	2 (100%)	1 (100%)	0
Group A	1 (100%)	3 (100%)	1 (100%)	1 (100%)	0
Group B	7 (100%)	2 (100%)	1 (100%)	0	0

Currently enrolling in expansion cohorts for FL and MCL with Regimen B

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The next page is page 19, which shows new Phase 1b data on the combination of zandelisib and zanubrutinib, a BTK inhibitor, in patients with relapsed or refractory B-cell malignancies.

The combination therapy was generally well tolerated in the entire cohort of 20 patients, and there were no new or increased incidences of toxicity in the patients treated with the combination therapy compared to monotherapy studies, as shown in the table on the left side of this slide.

In addition, the response rate for relapsed and refractory indolent B-cell malignancies and CLL was 100%.

Based on these results, we are now conducting an expanded cohort of patients with relapsed or refractory FL and MCL, and we are evaluating the efficacy of the Group B regimen shown in the slide.

Expanding Zandelisib Development Activities to Explore Full Potential

Zandelisib Single Agent	Zandelisib + Rituximab	Other Zandelisib Combinations
<ul style="list-style-type: none"> Ph 2 Study TIDAL in 3L+ FL and MZL Ph 2 Study K02 in 3L+ in iNHL (Japan) 	<ul style="list-style-type: none"> Ph 3 Study COASTAL in 2L+ FL and MZL 	<ul style="list-style-type: none"> + Zanubrutinib in FL and MCL in 2L+ + R-CHOP in DLBCL in 1L + Ven-R in CLL

* CLL: chronic lymphocytic lymphoma; DLBCL: diffuse large B-cell lymphoma; FL: follicular lymphoma; iNHL: indolent B-cell non-Hodgkin lymphoma; MCL: mantle cell lymphoma; MZL: marginal zone lymphoma; R-CHOP: rituximab-cyclophosphamide/doxorubicin/prednisone/vincristine; Ven-R: venetoclax-rituximab

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The next slide is our development strategy, showing how we will increase the value of zandelisib in the future.

For monotherapy, the Phase II TIDAL study is ongoing for FL and MZL for third-line therapy and beyond. In Japan, we are conducting a Phase II study with the same design as the TIDAL study.

We plan to initiate a Phase III COASTAL study in combination with rituximab for FL and MZL for second-line treatment and beyond later this year.

Regarding other combination therapies, as I mentioned today, we are looking at combination with zanubrutinib in a Phase I study in FL and MCL for second-line therapy and beyond and enrolling patients in an expanded cohort, so that we can maximize the power that this compound has. We plan to conduct a variety of trials.

This concludes my brief explanation.

Question & Answer

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

Yamaguchi: This is Yamaguchi from Citigroup Securities. Thank you very much. I have two questions.

The first is about the balance between technology income in the first and second half of the fiscal year. This seems to be weighted toward the second half of the year.

In relation to that, could you give us a comment on the balance of some of the accounting milestones from the recent Amgen collaboration, including those that are pro-rated for the period, and the likelihood of achieving the technology revenue in the second half of this fiscal year? Or is it the case that the Amgen revenue is already included?

Kawaguchi: Thank you for your question, Mr. Yamaguchi. I will answer.

As you mentioned, technical income is higher in the second half of the year.

One reason for this is that Fasenra's technology income has been steadily increasing, but a bigger factor is that we budgeted for this one-time income in our forecast at the beginning of the year, although we did not anticipate this partnership with Amgen. This will fall in the second half of the fiscal year, so that is contributing to the balance.

This is what happens in terms of the upfront payments from Amgen. For the accounting treatment of this project, the contract became effective at the end of July, so it will be recorded after that.

We are in the process of confirming with the audit firm what accounting treatment will be applied in Q3, so we cannot say anything definite, but we expect to book a certain amount of income. If we could apply the company's expected accounting method, there should not be a large gap between that amount and the amount we have factored in as our target. I hope you understand that this does not mean that there is a large upside.

Yamaguchi: I understand. Thank you.

The second thing is the status of Nourianz in Europe. In the current fiscal year, I don't think sales expectations were very high, but in the medium-term plan, I think Nourianz is forecast to have quite significant sales in Europe.

I know that some delays are unavoidable, but from the standpoint of an outside observer, I would like to know how long it will take to respond to the re-examination, or what the odds are, and at what point we will know.

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

First, let's talk about re-examination. In terms of time, we expect it to take about 4 to 5 months. Therefore, it will be evaluated again in that period, and the results will become available.

As for the probability of success, it is difficult to make a concrete evaluation, but since we have come this far, the company fully understands that it is a challenging situation.

On the other hand, if you look at the average results outside the company so far, it seems that about 20% to 25% of the results have turned out to be positive. We will do our best to prepare and deliver the product to patients. Thank you.

Yamaguchi: Thank you very much.

Kohtani: I'm Kohtani from Nomura Securities.

The more I look at zandelisib, the more I think it is a very interesting drug. It's not just a matter of devising a regimen of one week of administration and 3 weeks of rest, but also its feature to penetrate all tissues in the body due to over 100 liters of the steady-state volume of distribution, and it is different from other drugs that are just staying in the bloodstream. Because of this, the side effects are quite low, apparently.

I would like to ask why this is an investigator-initiated trial, not a company-sponsored trial.

There is a competitor called copanlisib, and in the CHRONOS-3 trial of relapsed and refractory diffuse non-Hodgkin's lymphoma, it also showed prolonged PFS with combination therapy. This drug is an intravenous drug, and there were many side effects such as high blood sugar and high blood pressure. Your company's zandelisib is an oral drug, and the side effects are quite mild, so I thought it would have an advantage.

As Roche mentioned, the treatment for DLBCL has not changed for more than 17 years, and the market is quite large, so I think this could be conducted as a corporate trial. This is the first question.

Torii: Thank you for your question. I will reply.

As you mentioned, the intermittent administration of the drug can be supported by the feature characterized by its high distribution into blood cells and its long half-life in the blood.

As Dr. Miyamoto explained earlier, there are several projects and programs in progress, but it is difficult for MEI Pharma and us to carry out all of them by ourselves. This is where we can cooperate with the investigators, and we are now considering the overall priorities in this way.

As for DLBCL, as you said, it is a very difficult disease to treat. This is also quite a challenge, but we are now considering it in the hope that it will have a promising effect. Thank you.

Kohtani: Copanlisib, which has exactly the same mechanism, has been shown to be effective in combination therapy in relapsed and refractory patients in the CHRONOS-3 trial, so I guess it's not such an implausible trial?

Torii: This is the way we are proceeding as a result of discussions with MEI Pharma.

Kohtani: I understand. Secondly, this is a bit of a specific question.

I have been looking at the protocol for the Phase III KOUNO-TORI study of KW-3357 for gestational hypertension. It seems the PRESERVE1 trial of goat-derived antithrombin in the US failed due to patients' severity. So only severe patients with low antithrombin activity in their blood are recruited this time. This was probably not the case with PRESERVE, so I was thinking that this could be expected to be quite successful.

In Europe and the US, goat-derived products are already sold, but as you know, considering the risk of parvovirus infection, your product is better.

Also, your company can administer this in one hour, and the other product is a 24-hour continuous injection, so that is something that is quite beneficial. The number of patients with serious disease is quite large worldwide.

So, why is this only in Japan? What do you think about the idea of adding Western patients or Western foreign countries? That's my second question.

Miyamoto: Thank you very much, Mr. Kohtani. I'm grateful that you've paid attention to the details here.

In fact, we think that this has the potential to become a very interesting drug.

The reason why we started in Japan is that there are more doctors in Japan who think that antithrombin itself is effective in treating pregnancy hypertension. American doctors were very skeptical because of the failure of the goat-derived product.

Therefore, our strategy is to motivate health professionals in the US by providing solid data in Japan first.

Does that make sense?

Kohtani: How about Europe? After all, if you look at the data disclosed by a certain company in the past, there are probably 20,000 to 30,000 people in developed countries alone. Moreover, this is a very serious condition for which there is no cure, and both the mother and child may die. Isn't it possible to do something more in Europe?

Miyamoto: We also have to consider the mindset of the doctors and the price situation.

As you said, eventually, if all goes well, we would like to expand this to the global market. As you said, it is a very serious disease, and just delaying the delivery for a week or two, for example, can be very beneficial for both the mother and the baby, so I think it is a very important point.

So, as a company, we would like to aim for that as well, but first we would like to focus on whether we can really get that kind of data in Japan, and if we get good data, I myself think that the basic strategy is to consider this on a global scale.

Kohtani: I have high hopes. Thank you very much.

Miyamoto: Thank you very much.

Muraoka: Hello. Morgan Stanley, this is Muraoka. Thank you.

Eli Lilly's Phase III results of lebrikizumab, an IL-13 antibody for atopic dermatitis will come out in the second half of this fiscal year.

I think we have already discussed the comparison with Dupixent, but what are the differentiating factors and advantages of KHK4083 in terms of the possible mechanism of comparison with the IL-13 antibody?

Probably because both Dupixent and lebrikizumab are injected every two weeks, and this one probably has a longer dosing interval, so I think that's the best place to start, but that's my guess. Please let me know how I should consider that area. That's the first question.

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

In terms of the mechanism of action, atopic dermatitis has been reported to involve not only Th2 but also Th1 and Th17 cells, and most biologics, including Dupixent, target molecules downstream of Th2.

Since this KHK4083 acts on a wide range of cells, including OX40-positive Th2, Th1, and Th17 cells, we are currently developing it with the expectation that it will be a useful option for patients who have had insufficient response to other drugs.

Muraoka: This is the point, but in the Amgen call this morning, when asked about the expectations for Amgen, it was said that it would be used in areas where other drugs are ineffective.

In other words, will Phase III, which will start next year, focus on Dupi-resistant patients? If that were the case, how much would the patient population shrink?

Torii: Thank you for your question. We are now working with Amgen on this, and we will be negotiating with the FDA and other regulatory authorities.

We are currently working on a development plan to bring this drug to a wide range of patients who need it, rather than focusing only on those who are resistant to existing drugs.

Muraoka: Okay, thank you very much. There's one more question.

I guess G-Lasta will reach its LOE in Japan next year. If you are thinking about a biosimilar strategy like you did with Nesp, I think you may have already submitted an application. Please let me know as much as you can about that.

Miyamoto: Thank you, Mr. Muraoka. This is Miyamoto. I'm sorry, but that's a very important strategic area, so I'm not able to give any detailed answers.

Muraoka: Am I correct in assuming that you have already taken steps?

Miyamoto: For example, as you know, there is an on-body injector, which Amgen is also working on, but the very important point of this G-Lasta is that it can be administered only once. But unfortunately, that means patients returning to clinic the day after chemotherapy.

As you know, they have to come to the hospital the day after the chemotherapy, and it is a very difficult situation. If the patient returns home attached to his or her body on the day of the chemo, G-Lasta can be injected the next day, which I think is quite beneficial, especially for outpatients.

We are already working on this kind of thing, so we are considering various options as we go forward.

Muraoka: I understand. Thank you. Thank you very much.

Wakao: This is Wakao from JP Morgan. Thank you.

The first question is about the results of Q2. I think that the SG&A expenses in Q2 were in line with the plan, but I think that the use and the investment of Q2 expenses was slightly larger or earlier than the previous two fiscal years.

I would like to know a little more about how Q2 performed in relation to the full-year plan, and I would also like to know if there is basically no possibility of an upward swing.

From the next fiscal year onward, should we assume that SG&A expenses will continue to increase and that investments will increase to further structure the Global 3 products? Can you tell us if we should expect to see a certain level of completion in this fiscal year? This is the first question.

Kawaguchi: Thank you for your question, Mr. Wakao. I will answer.

First of all, regarding your words that you feel like expenses are being made earlier than usual, it is true that there was a tendency of expenses unused in the first half of a year, but this time, we are using it as planned. It is not that we are exceeding our internal plan, but that we are using the funds appropriately and in a controlled manner.

In the second half of the fiscal year, we will continue to use the funds as planned. We are trying to save what we can, but we don't think much that there will be large unused budget.

One more thing to note is that the expenses that we control are based on foreign currencies, and our annual forecast is based on the assumption of JPY105, so there will be a certain amount of foreign exchange impact on SG&A expenses overseas. I think that there is a possibility that such impact will go up, even if we use it as planned.

As for expenses for the next fiscal year and beyond, as I mentioned in the explanation of the medium-term management plan, we will establish a global business foundation as early as possible in the first half of the plan, as we are currently doing this year. In order to achieve this, we will continue to invest in IT and digital investments in the first half of the plan. For 2022, we will try as much as possible not to increase the ratio of SG&A to total sales, but at this stage, we assume that the amounts will increase to a certain degree.

Wakao: Thank you very much. How much was the impact of the exchange rate in Q2 and the first half?

Kawaguchi: Q2 is also affected by the exchange rate to a certain extent. However, even including the impact of foreign exchange rates, we believe that Q2 portion will be within our budget. For the second half of the fiscal year, if the exchange rate remains near the current JPY110 level, there is a possibility that this portion will exceed the budget.

Wakao: Thank you very much.

Secondly, I would like to know about the publication of the results of the Phase IIb study of KHK4083. I understand that you will be making a presentation at EADV, but I would like you to summarize your points.

First of all, regarding efficacy, the EASI value seen in the Phase I study was 74% at 22 weeks, so we should keep an eye on the EASI value of 74% and see if it is close to that value.

Also, regarding the regimen, I think it was Q2W in Phase I, but I think we will be able to see how the drug is administered at what intervals, so that is to be confirmed.

As for the safety of the drug, in the text base, it was mentioned that there were patients with advanced atopic dermatitis or fever, so how much impact would this have on the safety of the drug? I think you have already told us that there is not much impact on this area, but I think we will have to confirm this with the actual data, and I would like to know the key points again.

Do you have any plans to hold a conference call or other event at your company after this conference? If so, please let me know. Thank you very much.

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

As for the last question, there will be an opportunity to give an explanation after the conference presentation, and we are preparing for that now. We will keep you posted on the date and time.

As you mentioned, I would like you to check the frequency of administration, the strength of the drug effect, and the persistence of the drug effect because we monitored for a certain period of time after the administration is completed. I hope you will also look from the perspective of safety.

Wakao: I understand. Incidentally, at the previous briefing, you commented that you did not have a big concern with patients whose symptom got worse, and I understand that there is no particular problem with fever.

Torii: Yes. Both KOLs and investigators have been carefully examining the safety of the product, and we have confirmed that it is not a serious concern.

Wakao: I understand. Thank you. Thank you very much.

Ueda: I am Ueda from Goldman Sachs. I would like to ask you if you could tell us about the current status of the impact of COVID-19.

It was mentioned in the presentation, but I would like to know if there has been any impact on the market penetration of main products such as Crysvita, Poteligeo, and Nourianz. I think there are some differences in this area depending on the region, so I would appreciate your explanation.

Also, if COVID-19 were to re-expand in the future, I would like to know what the risks are. Thank you.

Sudo: Thank you very much, Mr. Ueda. I will answer.

This is a bit of a broad question, so I'm not sure if I'm on target. The situation is a little different for each drug, so I would like to talk briefly about it.

First of all, Crysvita in the US, especially in Q2, has shown that it has a solid footing. As Dr. Miyamoto mentioned earlier, the identification of patients is also progressing well, so our sales activities have returned to normal.

For the US, we don't see it as a big problem, nor do we see it as a problem in the future. Of course, if the situation of COVID-19 changes significantly, then the situation may change, but at present, we are aware of no major problems based on the information we currently have.

As for Crysvita in Europe, we are making progress with the price negotiation following the approval of adult indications, but there are still some delays. Obviously, compared to the US, sales activities are also more limited.

I'm glad to see that there was almost no negative impact on actual sales this time, but the activities themselves are considerably lower than in the US. I think that we need to be careful in the future.

However, the drug itself has become very popular among patients, and we believe that it is growing steadily.

Next is Poteligeo, and as Dr. Miyamoto mentioned earlier, Poteligeo in the US has been improving a lot in Q2. I have a feeling that patients are coming back quite a bit.

On the other hand, for large hospitals in the oncology field, sales activities are still limited, and we are not able to do enough.

However, I wonder if there is a change in the movement of patients and also the characteristics of the treatment field. The severity of COVID-19 is now much better understood than in the past, and the number of patients has been increasing.

In Europe, as mentioned earlier with Crysvita, sales activities are quite limited, so we are struggling in some areas. I have heard that there are some difficult aspects, including the price negotiations as mentioned earlier.

As for istradefylline, first of all, field activities for istradefylline in the US have been returning to normal. Although we have not reached the same level as before COVID-19, compared to Q4 of last year, we have seen a gradual return of business activities in the first and Q2s.

On the other hand, as Dr. Miyamoto mentioned earlier, we are facing a difficult situation in terms of numbers.

We were able to warm up the engine and get a good start, but the engine stopped with COVID-19 and is now starting up again, so we are in the middle of warming up.

In terms of recovery from the impact of COVID-19, we are seeing an increase in activity.

Thank you.

Ueda: Thank you very much for your explanation. The second question is about Nourianz in Europe, as mentioned in your previous question.

What is the difference in interpretation between the US and other regions compared with Europe, where this negative view has been taken? I am aware that the data itself was not very clear to begin with, but could you please explain to the extent that you can tell us what the points of contention are?

Sudo: I will take this question too.

First of all, the data used for the entire project was from the same database, which had 8 different tests. 4 of the 8 trials have positive results and 4 have negative results.

One of the biggest concerns of the EMA was that the data itself might not be sufficiently consistent. One of the reasons for this is that of the trials, only two are on European populations. These two trials were two of the 4 negative trials.

Therefore, the EMA is considering based on these two tests, and I think that was one of the factors that made the discussion a little difficult.

I think that is the biggest difference with the situation in the US. Thank you very much.

Ueda: I understand. Thank you very much. That is all.

Sakai: This is Sakai from Credit Suisse. I'd like to follow on from the previous Poteligeo question.

I think there was an understanding that the extension of the dosing interval was a temporary measure under COVID-19. Can you give us an update on that?

Since the current situation is that patients are returning, I guess the point would be the dosing interval. This is the first question.

Sudo: Mr. Sakai, thank you very much for your question.

This is a bit of conjecture, but first of all, there are no changes to the guidelines themselves. However, as I mentioned earlier, vaccination against COVID-19 has progressed, and as I also mentioned earlier about severe cases, I think we now know much more about the situation than before. I can imagine that one of the biggest factors is that patients are returning to treatment in this environment.

As for the dosing intervals of 4 weeks or two weeks, we do not have specific information at the moment, but considering the COVID situation that I mentioned earlier, I think it is possible that the administration method will return to two weeks.

The situation is currently being analyzed. Thank you very much.

Sakai: I understand. Thank you.

Also, I'm not sure if this counts as a question, but it's about the financial results for this Q2.

Personally, I was very surprised at a lot of things. Since Dr. Miyamoto became president, there has been a strong commitment to the numbers, and I think you have been able to stack up a good number of achievements.

This time, even though the trend of Q1 has been carried over, the cost is still coming out ahead of the top line. This includes upfront investment, as well as Crysvita's profit-sharing, which is a good investment. I think this balance is not very good. I imagine that this is probably the reason for today's stock price.

When I listened to the President's opening comments that he was not concerned about this result, I got the impression, but I was under the impression that it could be cleared up, although it may be a bit extreme expression. However, I still feel uncomfortable about it. Can you give us some comments?

Miyamoto: Thank you, Mr. Sakai. This is Miyamoto.

As for the cost, as Mr. Kawaguchi explained earlier, we feel that we are using it as planned. When we explained the medium-term business plan, we told you that costs would be higher in the first half compared to the growth of the top line.

Basically, I think we are working within that plan, and of course, the COVID situation is still in place in some areas, and on the other hand, we are cutting costs considerably in some areas, so personally, I think that we are controlling the costs very well.

On the other hand, as explained earlier in the top line and sales section, there are still some areas that have not quite reached the level of the plan due to the impact of COVID etc. That's an area that we're working hard on remedying. We can't continue to blame the coronavirus pandemic forever, and we need to get the figures in line with the plan. That's the message I'm communicating to my team.

Overall, I feel that the costs are in line with the plan. On the other hand, the top line has not been achieved yet, so we need to do something about that. At the moment, when looking at the full year, we are not lowering our targets at this time, but we are working to achieve them.

I'm sorry, I hope that answers your question.

Sakai: Yes, thank you. Thank you very much.

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

I have a question regarding the CKD indication, RTA 402. As I recall, we were expecting that the Phase III trial would be completed around January to March next year, and we thought that the results would be available in the first half of 2022, but on page 17 of this slide, there is no specific comment on the first half of 2022 in the area of CKD.

Is there currently any delay in the development of this, or when the results will be disclosed? A little more information would be helpful.

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

The DKD trial is progressing well. On the other hand, in terms of long-term data, it is not up to us to decide how much data we need. There it needs to be decided in consultation with the PMDA. At the moment, we don't have a definite timeframe for this part of the project.

So, once we have reached an agreement with the PMDA and we know roughly when the top-line data will be available, we would like to report back on the timing. Thank you very much.

Arai: Thank you very much. I have another question about development in this CKD area.

In Japan, Forxiga was approved for a similar indication, but what is the current status of the competitiveness of RTA 402? With the approval of Forxiga, how much direct competition will there be, and how should we think about the existence of that competition in terms of commercial opportunities? Any comments would be greatly appreciated.

Torii: Thank you for your question. The positioning of each drug will also depend on the label and indication of our RTA 402. We will continue to discuss and clarify these positioning issues with KOLs. Thank you very much.

Arai: I understand. Thank you. Thank you very much.

Miura: I'm Miura with Jefferies Securities. First of all, Crysvita was approved for self-injection in Europe in July, but what is the potential of this approval?

I wonder if self-injection will drive growth in Europe in the future. Also, what is your opinion on the possibility of self-injection affecting in other areas, such as in the US and Japan?

Sudo: Thank you very much, Mr. Miura. I will answer.

First of all, in the EU, one of the major triggers behind this push for self-injection is the influence of COVID-19.

The current situation is that most European countries are sending nurses to treat patients. In some cases, self-injection was used when the nurse could not visit the patient due to COVID. Therefore, we do not believe that the market will grow significantly because self-injection is now possible.

In Japan, self-injection has already been approved, so it can be used in some situations.

In the US, when the drug was first approved, we considered self-injection, but there are quite a few steps before the patient can take the drug from the vial to the syringe and administer it. There were some difficult situations, so the US has not taken the indication for self-injection.

This time, following the discussion between the FDA and Ultragenyx, we are allowed to be used for self-injection in the special circumstances of being in the coronavirus pandemic. However, we are not thinking of changing the label itself at the moment. That's all.

Miura: Secondly, I think you mentioned earlier that Duvroq, and HIF inhibitors as a whole are struggling in Japan.

What are your company's views on the factors that have caused HIF inhibitors to struggle in the first place, and how do you plan to increase the sales of Duvroq in light of the fact that long-term prescription of Duvroq will be possible in the future? Can you please confirm the situation here? Thank you very much.

Miyamoto: Thank you, Mr. Miura. I will answer this question.

I think that there are many factors, but one of the things that we are struggling with is the safety concerns of HIF-PH inhibitors. There are reports of blood clots and hemoglobin overshoot, so I think that is a factor.

On the other hand, we launched erythropoietin in 1990, and since then we have accumulated a very strong base of knowledge on hemoglobin control. We have a great deal of knowledge about how and under what circumstances hemoglobin changes, and what side effects occur. We have built this knowledge together with doctors. That is the basis of our activities.

In particular, as I have already explained about Duvroq, it is also a drug that can control dosage from very low volume, so we have been developing it from the outset while paying close attention to its safety.

The data from GSK looks very positive. I haven't had a chance to look at the details yet, but I have heard about the top line, and I have also heard that the safety data is very good.

If this is true, then we will develop based on that, paying attention to safety first. Also, I would like to develop this product while emphasizing that it has power that is comparable to erythropoietin drugs.

I believe that the fact to administer the drug orally is a great advantage, and I believe that it is our mission to deliver this advantage to patients. We are working in this way to develop the drug.

Miura: Thank you very much.

Tanaka: This is Tanaka from Mizuho Securities. The first question is about tenapanor, which was not granted approval in the US last week. I don't think we should depend on the US, but it seems to me that the FDA is saying that it is not very effective. What is the Company's position on this? Thank you.

Torii: Thank you for your question, Mr. Tanaka. I will answer.

We would like to know what the FDA is concerned about. I believe that we need to understand the details of the intention behind the decision to issue a CRL.

On the other hand, in Japan, we are currently conducting Phase II and later trials in consultation with the PMDA. The results of Phase II have already been reported at ASN and other conferences, and there is a clinically meaningful effect of phosphorus reduction compared to placebo. In addition to the effects of phosphorus in patients who are poorly controlled with existing phosphorus adsorbents, the results of Phase IIb also showed a reduction in the pill burden, the number of tablets taken.

If the results of Phase III, which we are currently conducting, are in line with our expectations, we will submit an application in Japan as planned.

Tanaka: Okay, thank you very much. The second question is about development of China, although I am not sure how it was incorporated in the medium-term plan.

Crysvita will be released in the future, and I think China was also included in your territories for RTA 402 after that. Could you tell us how China features in the management plan?

Miyamoto: Thank you very much, Mr. Tanaka. This is Miyamoto.

I believe that China has great potential in the medium- to long-term. In this sense, we are determined to do our best in China.

As you know, the regulations change very often. In terms of both approval applications and drug prices, things are changing very frequently, and it is difficult to factor in. I can't give you specific figures on how much we have included in our medium-term plan, but we have not yet factored in the fact that Crysvita, for example, will have a very large contribution from China.

I'm sorry for the somewhat vague answer.

Tanaka: I heard that for Crysvita, although it may not happen by 2025, the goal is for 10 billion.

Miyamoto: There was a person in charge who said that, yes.

Tanaka: I understand. If RTA 402 is successful in Japan, when do you think it will be ready for deployment in China?

Miyamoto: China is also unique in this respect, so of course we need to consult with the authorities, but if we are requested, for example, to do Phase I, II and III, I think it will take a relatively long time.

Tanaka: I understand. Thank you very much.

Akahane: Thank you very much. This is Akahane from Tokai Tokyo Research Center. Since I have two questions, I have questions about individual products and overall performance.

First of all, in individual cases, I am looking at pages 3 and 7 of the appendix materials. Regarding Nesp and AG, as you explained, generic manufacturers have been experiencing various problems and the supply of biosimilars has been stopped. Is it correct to understand that the demand moved to our side because other products were not available?

Miyamoto: Thank you, Mr. Akahane.

Progress is 57%, so it's a little better, but it is broadly in line with our expectations. However, we have heard that the companies that are developing Nesp biosimilars have had some restrictions to their shipments, so the penetration has been delayed. I expect that the delay in the penetration of biosimilars has had a positive effect on our Nesp AG.

Akahane: I understand. Also, considering vaccination and the reduction in medical visit under coronavirus, if you look at Poteligeo, you can see that there is a clear distinction between countries, especially the US and Japan. Is this the reason why sales of Poteligeo are as they are in response to the coronavirus pandemic? Should I assume that the others are also affected by this?

Miyamoto: Thank you, Mr. Akahane. Your question seems to be getting at whether sales of Poteligeo can be explained by COVID.

Akahane: The overseas countries are experiencing tremendous growth, and Japan is not doing so well. So, since the vaccine has progressed in the US and sales have increased, is it safe to assume that we will see even more of these effects in Q3 and beyond?

Miyamoto: This is referring to Poteligeo?

Akahane: Yes, that's right. I was hoping to find out, if I could, how this affects other products as a whole.

Miyamoto: Thank you very much. Potelligio is certainly back on track in Q2 in the US, and we are still trying to figure out what the real reason is for the growth. If I knew that, I would be able to say something more clearly, but basically, the situation is as Mr. Sudo explained earlier.

I think there is a good possibility that the growth is due to the effect of vaccination in the US and various regulatory issues.

As for other drugs, the market, the situation of use, and how doctors and patients are working with COVID are different in each area. It's hard to say in general, but one thing is clear, and for new drugs in particular. As a commercial activity, the first thing we need to do is to provide the information and explain it to the medical professionals. Then, after that, when we start procedures, for example, how do we handle insurance reimbursement?

In addition, it is difficult for us to follow the procedures for signing up new drugs into the hospital's account when activities are suppressed. Therefore, although this is not limited to us, if our MRs activities are restricted due to the impact of COVID, we tend to struggle, especially with new drugs. I believe that this will be affected considerably by how hospitals will regulate our visits.

However, it is useless to say that there is nothing we can do about it, so we are now working on various ways to introduce new drugs and provide information to the doctors. It is not assumed that the impact of COVID will disappear in the near future, but rather that it will continue for a while, and we need to think about what to do.

Akahane: Understood. I would like to conclude by asking that, in terms of the total business performance, the progress rate of core operating income is 47.6%, but the royalty and technology usage income is estimated to be JPY9.1 billion in the first half and JPY14.6 billion in the second half, which is not bad. There is also the cost aspect. Considering these royalties, I got the impression that it is not so bad, is this wrong?

Kawaguchi: I will answer.

That is a major factor. Another point is that Crysvida and other global products are now steadily increasing, so sales in the second half of the fiscal year are larger than the first half in our plan.

On the other hand, SG&A expenses and R&D expenses are also slightly tilted toward the second half, so it is expected to be balanced.

Akahane: Understood. Thank you.

Hashiguchi: This is Hashiguchi from Daiwa Securities. Thank you.

I think Dr. Miyamoto mentioned earlier about the future of Duvroq and his expectations for the data from the trials conducted by GSK.

I think this trial is a non-inferiority trial, but the first question is whether the results suggest a benefit in terms of CV events, et cetera, over ESAs.

Another thing about this disease, or renal anemia, is that there is a lot of racial variation. Also, the way doctors think about iron control may differ between Europe and the United States and Japan.

I understand that Japanese doctors tend to put a lot of emphasis on Japanese data, especially in this area, but is this global study done by GSK a study that includes Japanese data?

Of course, we can expect this test to have a positive impact, but to what extent is it likely to be a tailwind for sales of Duvroq?

Miyamoto: Thank you very much, Mr. Hashiguchi.

As you said, it is a non-inferiority trial, and I have not looked at all the details, I have just been informed that the results are good.

I think that the data showed that it was very safe and with strong results in comparison to conventional erythropoietin drugs. This needs to be reviewed, of course. I don't know if data for Japanese people is included, because I don't have the data right now.

I've just gotten confirmation on that. Japanese people were not included in the trial. On the other hand, GSK has already conducted a study in Japan and obtained approval, so the data is fully usable.

Also, although Japanese data is certainly emphasized by doctors, we are often asked what kind of data has been obtained in actual practice in Japan, and how other doctors are using it.

For us, this is the basis of our activities to date. In addition, as I have said before, I believe that we can use our historical know-how to provide information. That is one of our strengths.

Hashiguchi: Thank you very much, that's all.

Yamaguchi: Excuse me, this is the second time, if I may. This is Yamaguchi from Citi. Thank you very much. This is not directly related to the financial results, but your company is developing an anti-amyloid beta antibody called KHK6640.

I understand that there has been no specific update from your company in the recent past, but I believe that expectations for the efficacy of this drug have been rising for various reasons. If you have any update on this drug, please let me know.

Miyamoto: Thank you very much, Mr. Yamaguchi. It's a topic I've been asked about rather often lately.

Unfortunately, the answer is that there is no update that I can give you.

Yamaguchi: You are developing it, right?

Miyamoto: We haven't stopped the development yet.

Yamaguchi: Phase I was completed and there has been no change since, is that right?

Miyamoto: Indeed. That's pretty much it. We have to look at the overall situation and make decisions about whether or not we can go ahead or not.

It is true that Eisai is moving in a very positive direction, but I think that the situation is not yet settled. I think we will be looking at those things and making decisions in the future.

Yamaguchi: I understand. You are at the stage where you are considering the next step.

Miyamoto: Yes, indeed. That sums it up quite well.

Yamaguchi: Thank you very much. Also, a brief answer is fine, but I was told that preparations are underway for Crysvita in China.

I appreciate that it won't be possible to get any specific figures at this time. Please tell us about the timing of the launch, the target cities, the scale, and the extent to which this is possible with your company's current coverage in China.

Sudo: Thank you very much, Mr. Yamaguchi. I will answer.

As you know, we have been able to get both XLH and TIO and indications in Q1 in China. Currently, we have completed the packaging application and the import acceptance tests, and although there are still some issues to be resolved, we are moving toward commencing sales.

We are still negotiating the price with provinces, so as we announced last time, we will launch during Q3, or at the latest during Q4. I expect the number to be much smaller, maybe in the single digits, though.

As for the NRDL, as you know, it will take a long time, maybe two or three years onward. So, we will continue to monitor the situation and develop it in China in addition to the Patient Assistance Program.

Yamaguchi: Thank you very much. When you said single digits, did you mean the number of patients? Or in units of JPY100 million? Or the number of cities?

Sudo: This is unfortunately the number of patients.

Yamaguchi: So, the initial goal is administration to such numbers?

Sudo: That's right. I'm hoping that if we can start small, we can start with a few cases before the end of the year. That is the situation.

Yamaguchi: Thank you very much.

Muraoka: It's Muraoka from Morgan Stanley MUFG Securities. Sorry, this is my second time too, but I'll be brief.

I'd like to ask about what was and was not included in the initial plan for this fiscal year. Although I understood that the deferred recognition of the Amgen upfront payment will be under royalties, was decrease in R&D due to cost burden by Amgen also included in the annual R&D budget of 650? Or did it not contain it? Please tell me about that.

Kawaguchi: Thank you for your question. As for the development cost of KHK4083, this fiscal year was originally positioned as the preparatory stage for its Phase III, so it does not constitute a large amount of money to begin with. In addition, at the beginning of this year's plan, we did not have the assumption of co-development with Amgen, so detailed adjustments as such the development cost burden was not included in the initial plan.

As I mentioned earlier, I hope you can understand that we have incorporated the upfront from the partnering for KHK4083 as a vague major goal.

Muraoka: I understand. Thank you. And one more thing, though it's not an essential issue.

Regarding Crysvita, there is a vitamin D deficiency in Japan, but is there any indication that this is having a positive effect on uptake and new starts in Japan?

Miyamoto: Thank you, Mr. Muraoka. This is Miyamoto.

It probably isn't strongly correlated. From a medicinal point of view, it is true that there is data that vitamin D returns to a level close to the normal level when Crysvita is administered.

Then is it possible that Crysvita would be used in XLH patients because alternative treatment requires a normal vitamin D level? We haven't particularly observed such trend as of yet.

Muraoka: I understand. Thank you. Thank you very much.

Moderator: Thank you for your questions.

This concludes the conference call regarding the financial results for Q2 of the fiscal year ending December 31, 2021.

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

[END]