



**Kyowa Kirin Co., Ltd.**

Financial Results Briefing for the Fiscal Year 2023

February 8, 2024

## Event Summary

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<b>[Event Name]</b>	Financial Results Briefing for the Fiscal Year 2023	
<b>[Date]</b>	February 8, 2024	
<b>[Number of Speakers]</b>	4	
	Masashi Miyamoto	Representative Director, President and Chief Executive Officer
	Takeyoshi Yamashita	Director, Senior Managing Executive Officer and Chief Medical Officer
	Motohiko Kawaguchi	Managing Executive Officer, Chief Financial Officer and Global Finance Head
	Tomohiro Sudo	Executive Officer and Global Product Strategy Head

## Presentation

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**Moderator:** Now, we begin the online briefing on Kyowa Kirin Co., Ltd. financial results for the fiscal year ended December 31, 2023, which was announced yesterday at 3:30 PM.

Please note the following prior to the briefing. Please note that we will keep names and company names of all participants for a certain period of time as a list of participants. Please note that the content of this presentation will be available as an on-demand audio stream and transcript on our website. The information presented today contains forward-looking statements. Please note that there is uncertainty due to various risks.

Today's speaker is Masashi Miyamoto, Representative Director, President, and CEO, and he will answer your questions. Director, Senior Managing Executive Officer, and Chief Medical Officer Takeyoshi Yamashita. Motohiko Kawaguchi, Managing Executive Officer, Chief Financial Officer, and Global Finance Head. Tomohiro Sudo, Executive Officer and Global Product Strategy Head.

Today's briefing will last a maximum of 90 minutes. After Miyamoto's presentation, we will be happy to answer your questions. Please download the documents from our IR website.

**Miyamoto:** Good morning, everyone. Thank you for your participation. My name is Miyamoto, Kyowa Kirin.

Since this is the end of the fiscal year and we have many items and materials, I would like to summarize the main points and explain them.

# Qualitative Review for FY2023



## Provide pharmaceuticals for unmet medical needs

- **Maximize the value of global strategic products**
  - ✓ Initiated own sales of Crysvita in North America and keep steady growth
  - ✓ Focused on Crysvita and Poteligeo and accelerated the growth under the new EMEA structure
  - ✓ Further penetration of Crysvita
- **Continue to create groundbreaking new drugs**
  - ✓ Accelerated Global Development of rocatinlimab (over 2,400 patients has registered) and moved forward P2 clinical trial preparation for KHK4951
  - ✓ Started P1 study of KK2260, an antibody with REGULGENT™ (our proprietary bispecific antibody technology)
  - ✓ Received an approval for manufacturing and marketing PHOZEVEL®
  - ✓ Discontinued the development of RTA 402 and KW-3357PE
  - ✓ Had a definitive agreement to acquire Orchard Therapeutics

## Reinforce human resources and structures that support the creation of Life-changing value

- **Cultivate human resources, Strengthen organizations, Build digital platforms, and Others**
  - ✓ Human resources and organization development and: Proceeded succession planning for global key positions, Renewed talent management practices for the managers in Japan, Continued the effort to embed Corporate Culture Transformation "KABEGOE"
  - ✓ DE&I: Reached the ratio of women in key positions under OKK structure to 30%, Rated "Gold" in the PRIDE Index 2023 (JP)
  - ✓ Selected as a 2023 "Health & Productivity Stock" for consecutive two years (JP).
  - ✓ Digital infrastructure improvement: Developed Dx human resource, Launched company-wide use of generated AI in-house environment, Improved efficiency and IT literacy with no-code and low-code tools (RPA, etc.)
  - ✓ Strengthened the leadership structure with expanding CxO structure

## Address patient-centric healthcare needs

- **Patient Advocacy**
  - ✓ Raised disease awareness of XLH and created and expanded opportunities for patient interactions
  - ✓ Conducted disease awareness campaign with centering World Lymphoma Day and initiatives with patient organizations.
  - ✓ Expanded disease awareness activities centered on Rare Disease Month
  - ✓ Hosted an event at "Healthcare Café" organized by four JP pharmaceutical companies (Japan)
- **Provide value that goes beyond pharmaceuticals**
  - ✓ Had an initiative to address patient needs related to XLH/TIO with Ubie.
  - ✓ Planned to address patient needs related to XLH

## Retain the trust of society

- **Ensure stable supplies of high-quality pharmaceuticals**
  - ✓ Proceeded to establish the key products supply system with multiple production sites
  - ✓ Full operation of Takasaki Q-TOWER (quality assurance-related complex)
  - ✓ Addressed human rights issues for all stakeholders through membership in JaCER\*1
- **Help to protect the global environment**
  - ✓ Reduced CO<sub>2</sub> emissions by 54% compared to 2019 with using renewable energy
  - ✓ Disclosed necessary information responding to Assembly Bill No. 1305<sup>\*2</sup> California State Law, USA
  - ✓ Completed construction of Ube Plant office building with ZEB<sup>\*3</sup> certification

\*1: General Incorporated Association, Japan Center for Engagement and Remedy on Business and Human Rights  
\*2: Mandatory Climate Change Disclosure for California-based Companies  
\*3: Abbreviation for Net Zero Energy Building, a building that aims to reduce energy consumption to zero while achieving a comfortable indoor environment.

Could you please skip to page five of the slide presentation? I would like to begin with a qualitative review of our progress in 2023.

With respect to the "Provide pharmaceuticals for unmet medical needs", we have evolved our global sales structure for Crysvita and Poteligeo and have been able to continue steady growth. We have started Crysvita own sales in North America and have started a new structure in EMEA to focus on Crysvita and Poteligeo.

In R&D, global development of rocatinlimab and KHK4951 is progressing steadily, and clinical trials for bispecific antibodies have started as planned. In particular, the ROCKET program for rocatinlimab, which we expect to be the next pillar of growth following Crysvita, is currently comprised of eight clinical studies and is progressing well, with more than 2,400 patients enrolled by the end of 2023.

While the development of RTA 402 and KW-3357PE was discontinued, PHOZEVEL was approved for production and marketing in Japan. As you know, the acquisition process of Orchard announced last year was completed in January. We are moving forward with our efforts to continuously create innovative drugs while adapting to changes in the business environment.

In addition, as you can see, we were able to carry out most of the activities we had planned in terms of responding to "Address patient-centric healthcare needs", "Retain the trust of society", and "Reinforce human resources and structures".

## Quantitative Summary of FY23 Results

(Billion Yen / Rounded)

	FY2022 Results	FY2023 Results	Changes	2023 Revised Plans	Achieved
Revenue <i>[Overseas Ratio]</i>	398.4 <i>[61%]</i>	442.2 <i>[65%]</i>	+43.9 (+11%)	426.0 <i>[64%]</i>	104%
Gross Profit <i>[Gross Profit Margin]</i>	311.5 <i>[78%]</i>	331.0 <i>[75%]</i>	+19.6 (+6%)	326.0 <i>[77%]</i>	102%
SG&A <i>[SG&amp;A Ratio]</i>	166.2 <i>[42%]</i>	163.1 <i>[37%]</i>	-3.1 (-2%)	162.0 <i>[38%]</i>	101%
R&D <i>[R&amp;D Ratio]</i>	62.9 <i>[16%]</i>	72.1 <i>[16%]</i>	+9.2 (+15%)	79.0 <i>[19%]</i>	91%
Gain/Loss on Equity Method	4.3	0.9	-3.4 (-78%)	3.0	31%
Core Operating Profit <i>[Core OP Margin]</i>	86.7 <i>[22%]</i>	96.8 <i>[22%]</i>	+10.1 (+12%)	88.0 <i>[21%]</i>	110%
Profit	53.6	81.2	+27.6 (+52%)	76.0 → 70.0	116%
Return on Equity	7.1%	10.2%			
Dividend Payout Ratio <sup>1</sup>	38.9%	35.5%			

[FOREX]	
FY2022-Actual	JPY130/USD
FY2023-Actual	JPY140/USD
FY2023-Rev. Plan	JPY130/USD

<sup>1</sup> Figures are based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

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Now, please turn to page six, performance summary of FY2023.

Revenue was JPY442.2 billion, up JPY43.9 billion, or 11%, YoY.

Core operating profit was JPY96.8 billion, up JPY10.1 billion, or 12%.

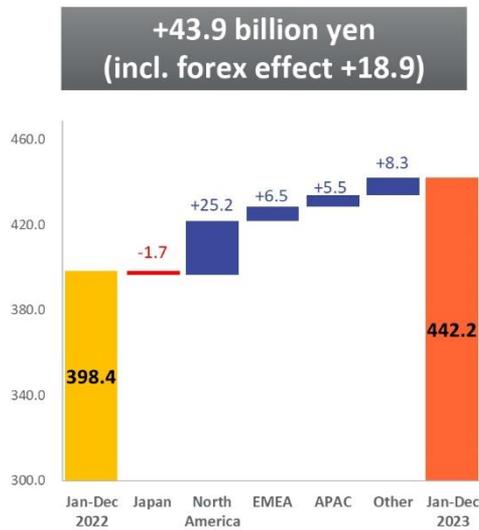
Profit was JPY81.2 billion, an increase of JPY27.6 billion, or 52%, landing with a significant increase in both sales and income. Record high profits have been achieved.

The ROE was 10.2%. We have reached the target level of 10% or more as set forth in the medium-term business plan.

Compared to the revised plan announced in Q1 of last year, revenue and gross profit exceeded the plan by 104% and 102%, respectively. SG&A expenses were slightly higher due to the foreign exchange impact, but R&D expenses were 9% lower than planned.

As a result, core operating profit was JPY8.8 billion, an achievement rate of 110%. An achievement rate for profit was 116%, also JPY11.2 billion higher than the revised plan.

FY22 vs FY23 -Revenue-



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● Japan -1.7

Although Duvroq, Romiplate, and Crysvita increased, revenue in Japan region decreased by 1% due mainly to negative impact by annual NHI price-cut and shrink in Nesp-AG affected by competitive products.

● North America +25.2 (incl. forex effect +9.1)

Revenue in North America region increased by 22% with the growth of Crysvita (+21%), Poteligeo (+25%), and Nourianz (+27%).

● EMEA +6.5 (incl. forex effect +6.3)

Revenue in EMEA region increased by 10% due to the growth of Crysvita (+14%) and Poteligeo (+36%), and transfer of global rights for Tostran to ADVANZ PHARMA by £62.5M (JPY11.5B), although decrease sales of Established medicines, such as Abstral by entered into the Joint Venture Collaboration with Grünenthal on Aug 1.

● APAC +5.5 (incl. forex effect +1.5)

APAC revenue increased by 18% with the growth of Crysvita, and Nesp, while Gran was down due to the Chinese national tender system.

● Other +8.3 (incl. forex effect +2.1)

21% growth in the other revenue was due to the royalties of growing Fasentra (Benralizumab).

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See page seven. This is a YOY analysis of revenue for the four regions.

In Japan, sales of Duvroq, Crysvita, and Romiplate are growing. However, sales of Nesp-AG and other products were affected by the NHI price revision, resulting in a 1% decrease in sales.

In North America, sales increased 22% due to solid growth of global strategic products mainly Crysvita and the yen's depreciation.

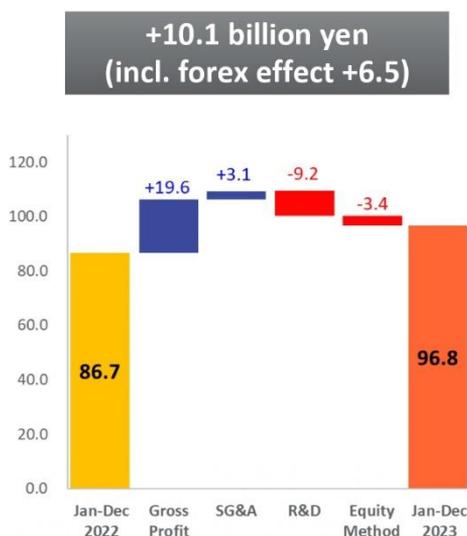
In EMEA, sales revenue from 13 brands, including Abstral, shifted from product sales to royalty income and license fees from August, following the establishment of a joint venture with Grünenthal in the established medicines business. However, sales of global strategic products and the sale of Tostran contributed to a 10% increase in revenues.

In Asia Pacific, sales increased 18% thanks to the growth of Crysvita in Australia.

In other, revenues increased 21% due to an increase in royalties from Fasentra (benralizumab) and other sources.

The trend of revenue from sales of major items on pages 8 and 9 has not changed significantly from Q3, so I will skip this part.

## FY22 vs FY23 -Core OP-



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- **Gross Profit +19.6 (incl. forex effect +16.5)**

Increased in conjunction with the 43.9 rise in revenue. COGs have increased due to the North America Crysvisa Sales royalty after Apr 27, 2023. Hence, gross profit % declined YoY. (78.2% →74.9%) .

- **SG&A +3.1 (incl. forex effect -8.2)**

While the Crysvisa commercial operation expenses are increased in North America, such as HR exp, decreased in Crysvisa profit sharing expenses due to the North America Crysvisa-related scheme change after Apr 27, 2023.  
[Labor -7.3 / Sales promotion -17.5 (incl. Crysvisa profit-share expenses +21.8) ]

- **R&D -9.2 (incl. forex effect -1.8)**

Increased in clinical study costs of KHK4083 which is undergoing joint global Phase III clinical study for Atopic Dermatitis indication.

- **Gain/Loss on Equity Method -3.4**

While revenue of Hulio (FKB327/Adalimumab biosimilar) increased, FKB's profit decreased due to the impact of reversal of deferred tax assets.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

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See page 10. This is the YoY comparison of core operating profit.

Gross profit increased by JPY19.6 billion due to the increase in sales revenue. The gross margin was 75%, down 3% from the previous year, due to an increase in cost of sales resulting from sales royalties since the start of the own sales of Crysvisa's in North America.

SG&A expenses decreased by JPY3.1 billion due to the absence of profit-sharing and expenses recorded since the start of Crysvisa's own sales in North America, although there was an increase in personnel and other expenses associated with it, as well as the impact of foreign exchange rates.

R&D expenses increased by JPY9.2 billion due to the progress of the rocatinlimab development and other factors.

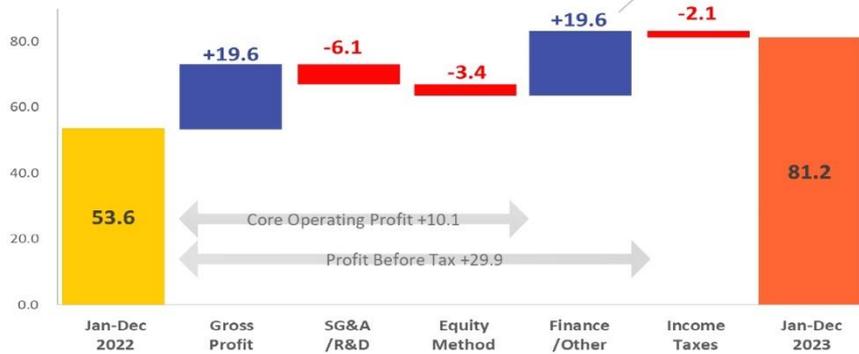
Gain and loss on equity method decreased by JPY3.4 billion. Although the business of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. continues to grow steadily, this is due to the impact of reversal of deferred tax assets at the end of last year.

As a result, core operating profit increased by JPY10.1 billion compared to the previous year.

FY22 vs FY23 -Profit-

Profit (Jan-Dec) +27.6 billion yen

- EMEA established medicines portfolio:
  - Gain on sales of 51% shares plus gain on valuation of remaining 49% shares +14.8
- Impairment losses +7.1 [FY22] ME-401 IPR&D 14.3, irofotase alfa IPR&D 3.2 [FY23] RTA 402 8.3, Ardelyx 1.1
- Foreign exchange gain +1.6 (2.6 → 4.2)
- Business restructuring expenses -3.9 (-2.4 → -6.2)
- Provision for loss on contracts -1.4 [FY23] closing costs: RTA 402 -2.0, ME-401 -0.8



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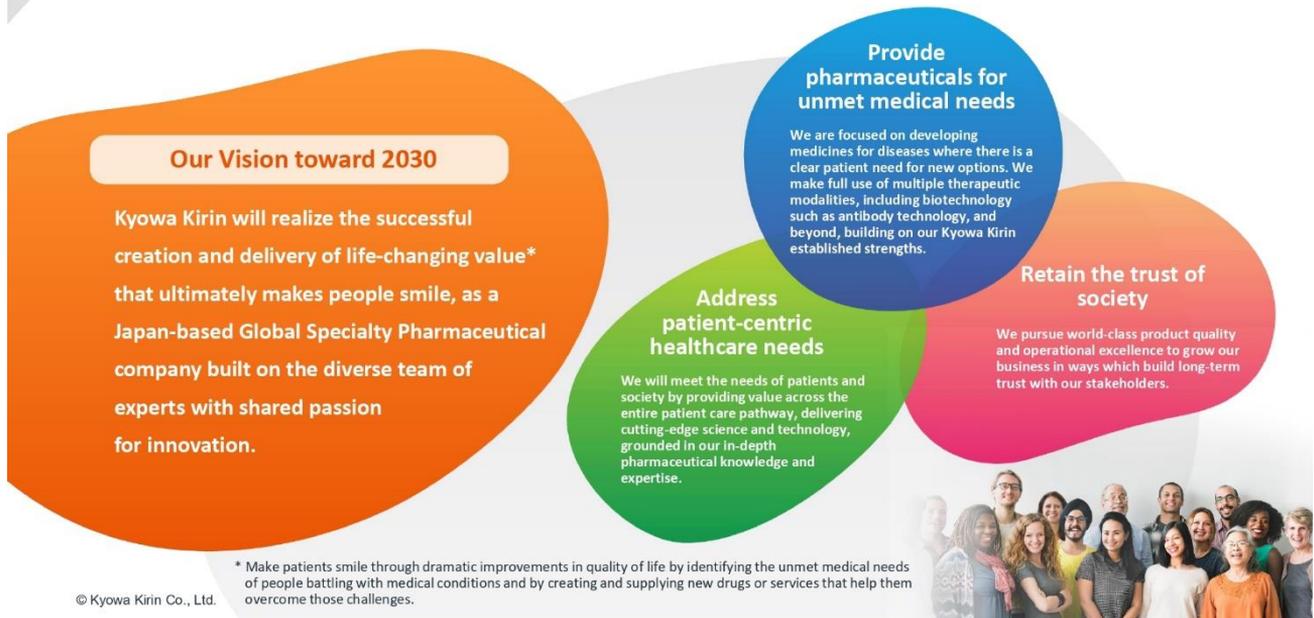
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Now, on page 11. The changes in the portion below of core operating profit, they are the items in the balloon.

Again, there is nothing new from what we have explained up to the Q3 results.

Finally, profit increased by JPY27.6 billion from the previous year to JPY81.2 billion.

## Our Vision toward 2030



Next, I will explain our medium-term business plan. See page 13.

As you know, this is Our Vision toward 2030 we set in 2021.

We have made steady progress toward the realization of this vision as a Japan-based global specialty pharmaceutical company, which we call J-GSP, by evolving our global structure, establishing a global sales structure for Crysvida and Poteligeo, and advancing the global development of rocatinlimab, one of the future growth drivers of the Company.

## Environmental changes since 2021-2025MTBP planning

Internal Change

- Established global our own sales and marketing system for orphan drugs such as Crysvida and Poteligeo.
- Bone & mineral, intractable hematological diseases/hemato oncology, and rare diseases are becoming disease areas of strength.
- Acquired the modality of hematopoietic stem cell gene therapy, which has the potential to eliminate the underlying causes of inherited diseases.
- Portfolio changes due to rocatinlimab value maximization, new asset acquisitions and development discontinuations.
- Through the One Kyowa Kirin structure, an organization that can grow by incorporating diverse skills and structures.

External Change

- Global trend of tighter policies and regulations to reduce health care costs.
- Growing demand for cure or controlled progression and for practical application of new modalities to meet those demand.
- Decrease of druggable targets that can be addressed by monoclonal antibodies or small molecules.
- The entire pharmaceutical industry, including Megapharma, is adopting a strategy of focusing on pharmaceutical business and narrowing their focus disease areas.

See page 14.

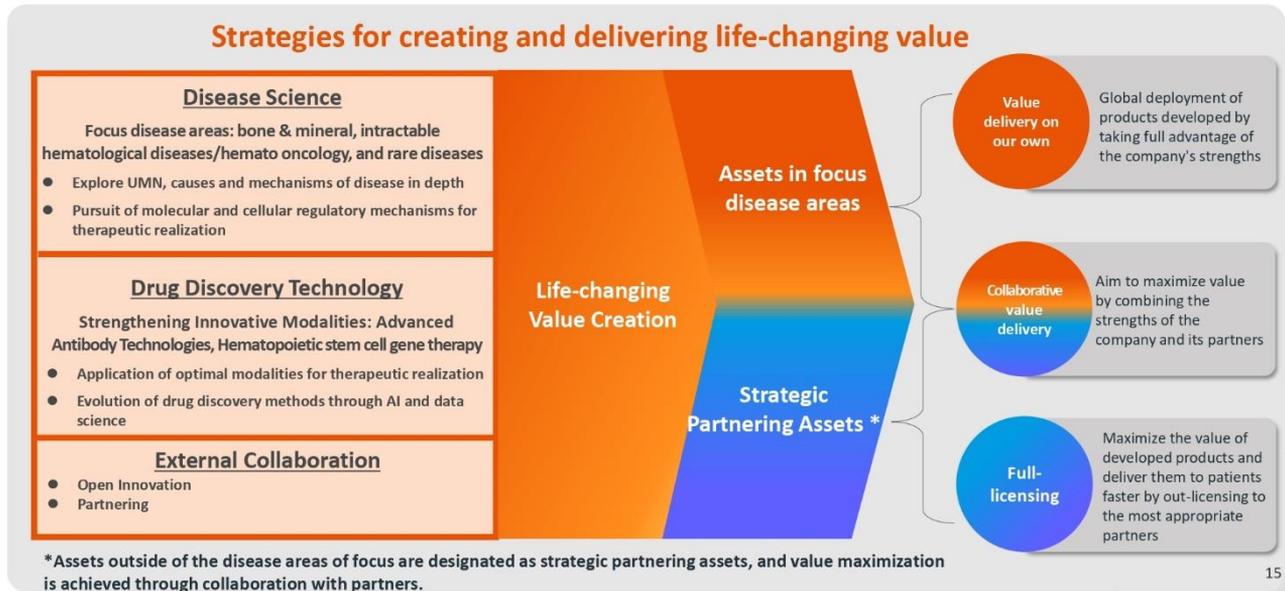
Crysvida and Poteligeo have entered a growth trajectory in the rare disease field on a global basis. We believe that we have entered a phase in which we can pursue a further growth strategy based on our strengths in this field.

On the other hand, in areas where Kyowa Kirin has been strong, there are some difficulties to maximize product value by Kyowa Kirin alone, considering global development and sales structure. In such case, we have chosen a business model that aims to maximize value by obtaining a strategic partner.

In addition, the drug price reductions and the reality that insurance reimbursement is getting difficult are significant challenges. We believe that the pharmaceutical industry is required to provide clearer life-changing value.

In this context, Kyowa Kirin acquired Orchard in order to take on the challenge of creating new life-changing value as a J-GSP. Our hematopoietic stem cell gene therapy, HSC-GT, has the potential to eliminate the underlying causes of inherited diseases.

In order to achieve our vision in the midst of these major changes in the environment, we felt it necessary to increase the resolution of our vision so that we can focus more on our strengths.



This is the strategic story in higher resolution to realize Vision 2030.

What we want to make clear here is that the value we deliver should be life-changing value. In order to continuously create life-changing value, the key to our drug discovery strategy is to more clearly define the disease areas we will focus on and shift our modality to advanced antibody technologies and hematopoietic stem cell gene therapy.

In addition, we will continue to focus on open innovation activities, which we have been doing to date, such as promoting collaboration with partners, funding in venture capitals, and CVC activities.

In terms of maximizing the life-changing value created by these activities, the business model must be appropriately selected. Kyowa Kirin will handle everything from development to marketing on a global basis for the disease areas that we focus on while leveraging external capabilities to maximize value for strategic partnering assets.

In addition to Crysvida and Poteligeo, which we have been maximizing the value of in the first half of the medium-term plan while establishing a global sales structure, we think that KHK2845 is an ADC that is expected to enter the market this year as a product in the hematology and oncology field. Also, products from Orchard, which we acquired in January, will come into the therapeutic areas we are focusing on.

We are also making progress on various early assets that are still in the research phase. We will discuss them again when the right time comes to disclose them.

We expect our strategic partnering assets to maximize their value by building the best possible business model with the right partners, including the fastest delivery to patients.

Although we have stopped the development of some of our pipeline products in 2023, we have some new products entering clinical trials. We will do our best to bring them to patients as soon as possible.

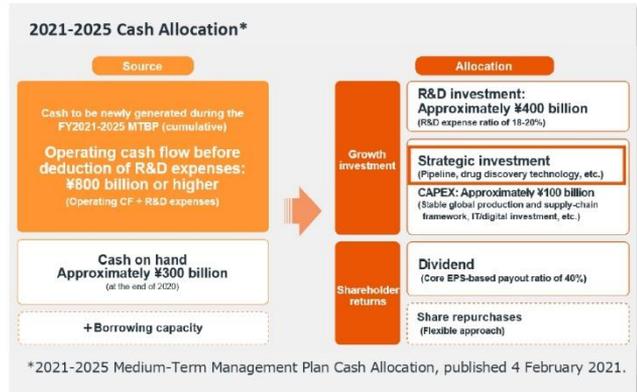
## Strategic Investment ~For successful creation and delivery of life-changing value

### Licensing-in and M&A investments to strengthen the portfolio

- Priority will be given to the focus disease areas
  - bone & mineral
  - intractable hematological diseases/hemato oncology
  - rare diseases

### Investment in science and technology to create new strengths

- Investments aimed at acquiring new drug discovery technologies and early pipelines and accelerating cooperation and collaborations
- VC investment and CVC activities for exploring and accessing information.



See page 17. As for the strategic investments, there has been no major change in our overall approach. We use the wording to fit the current strategy.

Furthermore, it is important to note that the acquisition of Orchard does not mark the end of our strategic investments. We still have some room to invest, so we will continue exploring to strengthen our portfolio, science, and technology.

In terms of the global portfolio, our priority will be on the introduction of products in targeted disease areas. On the other hand, we will consider case by case the products for which we can use the advantage of our sales structure in each region. Of course, we will also continue to enhance our access to and investment in science and technology, including VC and CVC.

## Qualitative Plans for FY2024



### Provide pharmaceuticals for unmet medical needs

- **Maximize the value of global strategic products**
  - ✓ Conduct evidence-based marketing to penetrate into patients.
  - ✓ Consider LCM to provide further value and strengthen areas of our global product.
- **Continue to create groundbreaking new drugs**
  - ✓ Expand target indications for rocatinlimab (asthma and prurigo nodularis)
  - ✓ Move forward clinical trials for KHK4951, KK4277, KK2260 & KK2269 (an antibody with REGULGENT™, our proprietary bispecific antibody technology), and KK2845 (ADC).
  - ✓ Respond to regulatory requirements for OTL-200 approval in the US and prepare for the market launch.
  - ✓ Explore strategic investment opportunities based on Story for Vision 2030.

### Reinforce human resources and structures that support the creation of Life-changing value

- **Cultivate human resources, Strengthen organizations, Build digital platforms, and Others**
  - ✓ Accelerate human resource development: Support independent career development and learning, expand use of human resource systems.
  - ✓ Continue "KABEGOE" activities for corporate culture reform.
  - ✓ Strengthen digital infrastructure: Dx human resource development, optimize enterprise architecture of IT infrastructure.
  - ✓ Strengthen the leadership structure: Promote leadership with centering CxO.

### Address patient-centric healthcare needs

- **Patient Advocacy**
  - ✓ Develop evidences through XLH real world data.
  - ✓ Expand Shine a Light campaign area to raise XLH disease awareness.
  - ✓ Conducted disease awareness campaign for CTCL with patient organizations.
- **Provide value that goes beyond pharmaceuticals**
  - ✓ Continue to address patient needs related to XLH.
  - ✓ Create additional value by strengthening collaboration with Kirin Group.

### Retain the trust of society

- **Ensure stable supplies of high-quality pharmaceuticals**
  - ✓ Strengthen initiatives to establish steady products supply system globally.
  - ✓ Cooperate with domestic and overseas contract manufacturers for operation management.
  - ✓ Enhance sustainable supply initiatives.
  - ✓ Build a biopharmaceutical API manufacturing building (HB7) (plan to complete in March 2025).
- **Help to protect the global environment**
  - ✓ Reduce CO<sub>2</sub> emissions by 51% compared to 2019.
  - ✓ Take initiatives to reduce greenhouse gas in Scope 3.

I will then explain our plans for FY2024. See page 18.

We will steadily execute our business plan for FY2024 based on our story for Vision 2030, which I explained earlier .

To maximize the value of Crysvida and Poteligeo, we will leverage the evidence accumulated through our activities to date to strengthen disease awareness activities focused on target patients. Additionally, we will enhance our life cycle management efforts.

In R&D, we will advance clinical trials of rocatinlimab and other products which are under development while continuing to search for new strategic investment targets in line with the Story for Vision 2030 that I explained earlier. We will also work to create synergies with Orchard in preparation for the upcoming approval and launch of OTL-200 in the US.

In responding to patient-centered medical needs, earning the trust from society, and strengthening our human resources base, we will make steady progress in the activities we have been diligently pursuing until 2023, and we will engage in all activities to realize our vision to make people facing illness smiles by creating life-changing value.

## Quantitative Summary of FY24 Plans

( Billion Yen / Rounded )

	FY2022 Results	FY2023 Results	FY2024 Plans	Changes	Orchard	FY2024 Plans Excl. Orchard
Revenue <i>[Overseas Ratio]</i>	398.4 <i>[61%]</i>	442.2 <i>[65%]</i>	473.0 <i>[70%]</i>	+30.8 (+7%)	4.5	468.5 <i>[70%]</i>
Gross Profit <i>[Gross Profit Margin]</i>	311.5 <i>[78%]</i>	331.0 <i>[75%]</i>	348.0 <i>[74%]</i>	+17.0 (+5%)	3.0	345.0 <i>[74%]</i>
SG&A <i>[SG&amp;A Ratio]</i>	166.2 <i>[42%]</i>	163.1 <i>[37%]</i>	166.0 <i>[35%]</i>	+2.9 (+2%)	8.0	158.0 <i>[34%]</i>
R&D <i>[R&amp;D Ratio]</i>	62.9 <i>[16%]</i>	72.1 <i>[16%]</i>	100.0 <i>[21%]</i>	+27.9 (+39%)	10.0	90.0 <i>[19%]</i>
Gain/Loss on Equity Method	4.3	0.9	3.0	+2.1 (+218%)	-	3.0
Core Operating Profit <i>[Core OP Margin]</i>	86.7 <i>[22%]</i>	96.8 <i>[22%]</i>	85.0 <i>[18%]</i>	-11.8 (-12%)	-15.0	100.0 <i>[21%]</i>
Profit	53.6	81.2	63.0	-18.2 (-22%)	-11.0	74.0
Return on Equity	7.1%	10.2%	7.6%			
Dividend Payout Ratio <sup>1</sup>	38.9%	35.5%	47.6%			

[FOREX]  
FY2022-Actual JPY130/USD  
FY2023-Actual JPY140/USD  
FY2024-Plan JPY140/USD

<sup>1</sup> Figures are based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

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See page 19. This is the performance outlook for FY2024.

For FY2024, we aim to increase revenue by JPY30.8 billion, or 7%, to JPY473 billion.

R&D expenses are increased by JPY27.9 billion, an increase of 39%, to JPY100 billion. The R&D expense ratio is also expected to increase to 21.1%, up approximately 5% YoY.

Core operating profit fell by JPY11.8 billion, or a decline of 12%, to JPY85 billion.

Profit is expected to decrease by JPY18.2 billion, or 22%, to JPY63 billion.

ROE is projected to be 7.6%.

The plan includes a significant increase in R&D expenses due to the progress in the development of rocatinlimab, which is in global Phase III, as well as R&D and SG&A expenses for Orchard, which has been acquired.

We expect an increase in revenue and a decrease in profit compared to FY2023.

For your reference, the budget related to Orchard is in the second column from the right of the slide. This is a consolidation budget from February, so it is for 11 months. Excluding the impact of Orchard, Core OP plans to increase earnings.

As PMI progresses, it will become very difficult to take out and report Orchard's SG&A and R&D expenses only. So, I am sorry to say, but presenting the overall impact of Orchard's profit gain and loss for the non-consolidated base will be only this time for FY2024 plans. I would appreciate your understanding.

As for the sales forecast of major items on pages 20 and 21, I will only mention newly added products, as I would like to explain about global strategic products as a commercial update later.

## FY24 -Revenue of Major Items in Japan-

( Billion Yen / Rounded )

Item	FY2022 Results	FY2022 Results	FY2024 Plans	Changes	Reasons
Nesp + Nesp-AG <sup>1</sup>	21.1	17.1	14.4	-2.7 (-16%)	
Nesp	3.4	3.2	2.8	-0.4 (-13%)	NHI price-cut & Biosimilars' penetration
Nesp-AG	17.6	14.0	11.7	-2.3 (-17%)	
Duvroq	6.6	9.9	12.2	+2.3 (+23%)	Market penetration (Launched in Aug 2020)
Phozevel	-	-	3.3	+3.3 (-)	Launch in Feb 2024 (Plan)
Orkedia	10.3	10.6	11.7	+1.1 (+10%)	Market penetration
G-Lasta	31.1	31.9	20.5	-11.4 (-36%)	Biosimilars' penetration & NHI price-cut
Poteligeo	2.0	1.9	1.9	-0.0 (-1%)	
Rituximab BS	10.3	9.0	7.9	-1.1 (-12%)	NHI price-cut
Romiplate	10.4	12.0	13.2	+1.2 (+10%)	Market penetration
Nourias	8.0	7.6	7.1	-0.4 (-6%)	Competitors' penetration
Haruropi	4.0	4.5	5.2	+0.7 (+15%)	Market penetration (Launched in Dec 2019)
Crysvita	8.9	10.5	12.9	+2.4 (+23%)	Market penetration (Launched in Dec 2019)

<sup>1</sup> AG stands for Authorized Generic. Official product name is Darbepoetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

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As for the main items in Japan, the trend will not change significantly.

However, one item, PHOZEVEL, which was approved last year, is scheduled to go on sale this month. We are aiming for sales of JPY3.3 billion this year, so we will continue to work hard.

## FY24 -Revenue of Major Items outside Japan-

(Billion Yen / Rounded)

Item	FY2022 Results	FY2023 Results	FY2024 Plans	Changes	Reasons
Crysvita	118.2	142.0	175.9	+33.9 (+24%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication
North America	87.0	105.2			
EMEA	31.0	35.1			
APAC	0.3	1.6			
Poteligeo	22.3	28.4	32.5	+4.1 (+15%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration
North America	17.2	21.5	23.3	+1.8 (+8%)	
EMEA	5.1	6.9	8.8	+1.8 (+26%)	
APAC	-	0.0	0.5	+0.5 (+3,446%)	
Nourianz	6.5	8.2	8.5	+0.2 (+3%)	
Libmeldy (OTL-200)	-	-	4.5	+4.5 (-)	
Nesp	7.6	9.1	10.7	+1.6 (+18%)	Market penetration in China
Gran	8.2	6.9	7.2	+0.2 (+3%)	
Tech-licensing	33.0	40.7	45.0	+4.3 (+11%)	Growth of Fasenna and Fotivda <sup>2</sup>
Benralizumab Royalty <sup>1</sup>	21.6	27.4			

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

<sup>2</sup> tivozanib: Kyowa Kirin has licensed its oncology development/commercial rights to Aveo Oncology Inc (an LG Chem company), and Aveo has sub-licensed the rights outside North America to EUSA Pharma. Being marketed in the US and Europe as Fotivda.

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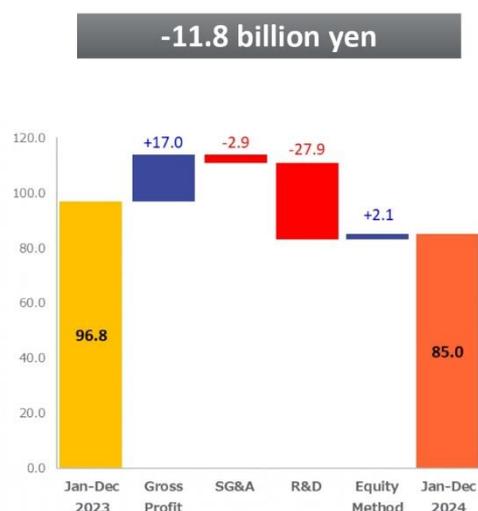
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Page 21.

Regarding the newly added item outside Japan, Orchard's Libmeldy (OTL-200), we aim for sales of JPY4.5 billion yen including the US.

Tech-licensing revenues are expected to increase by JPY4.3 billion from the continued royalty increase from Benralizumab and the steady royalty increase from Fotivda sold by Aveo.

## FY2023 vs FY2024 -Core OP-



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### ● Gross Profit +17.0

While gross profit will grow with the 30.8 rise in revenue (Japan-12.9, North America +27.7, EMEA+1.2, APAC+4.8, Other+9.8 (Orchard+4.5) ), COGs will also increase due to the Crysvita-related scheme change from 'Profit-sharing (SG&A)' to 'Sales royalty (COGs)' after Apr 27, 2023. This is expected to result in lowered gross profit margin by about 1.5% (74.9% → 73.6%)

### ● SG&A -2.9

Although, profit-share expenses on Crysvita (CRV) are no longer being incurred April 27, 2023 onward, 8.0 will be increased for Orchard consolidation.

### ● R&D -27.9

R&D expenses are expected to significantly increase and reach the level of 100 B yen due mainly to full-scale operation of rocatinlimab Ph3 ROCKET program and Orchard consolidation. R&D expense ratio is to increase by approx. 5% (16.3%→21.1%)

### ● Gain/Loss on Equity Method +2.1

Equity method gain is expected to increase by 2.1 due to removal of the impact of reversal of deferred tax assets

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

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Page 22. The following is a breakdown of the changes in core operating profit.

We expect a growth in gross profit by JPY17 billion. Profit-sharing expense payments to Ultragenyx for Crysvita in North America, which had previously been recorded in SG&A expenses, are now recorded in cost of sales, as it will be switched to sales royalties after the start of own operation of the direct sales. In FY2024, this will impact on the cost of sales for the full year, so we expect a decrease in the gross profit margin by 1.5%.

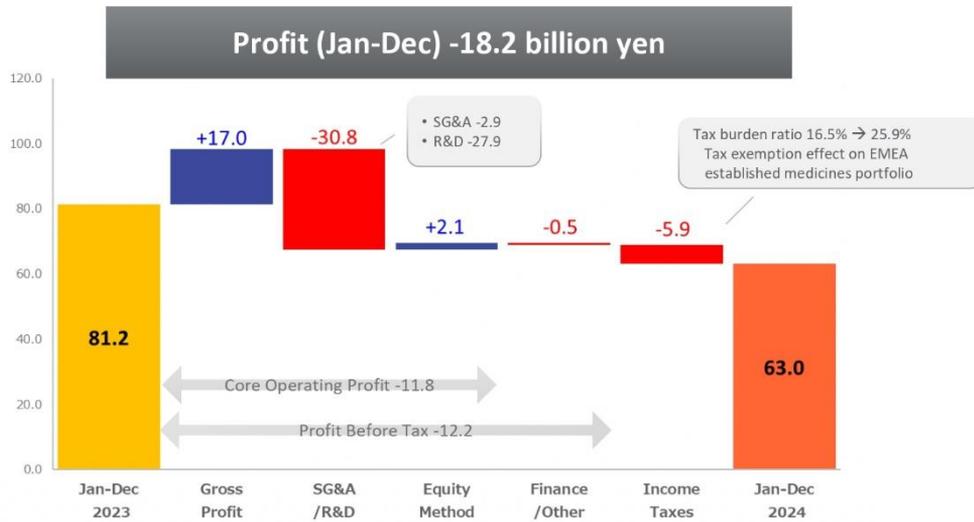
SG&A expenses are expected to increase by JPY2.9 billion. Profit-sharing payments, which had been incurred until April 2023, will be eliminated for the full year. However, the impact from Orchard's new consolidation, etc., will be JPY8 billion, so overall SG&A expenses are expected to increase by JPY2.9 billion.

As I mentioned earlier regarding R&D expenses, we will incur an additional JPY10 billion in new R&D expenses due to initiating the consolidation of Orchard. The total increase is expected to be JPY27.9 billion, or a substantial 39% increase, including an increase in the global Phase III study of rocatinlimab.

Gain and loss on equity method is expected to increase by JPY2.1 billion due to the absence of a negative factor from the reversal of deferred tax assets of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. incurred at the end of 2023.

As a result, core operating profit is expected at JPY85 billion, a decrease of JPY11.8 billion YoY.

FY2023 vs FY2024 -Profit-



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Page 23. It shows items below core operating profit.

We forecast that financial and other income will remain almost flat, while income taxes will increase in FY2024.

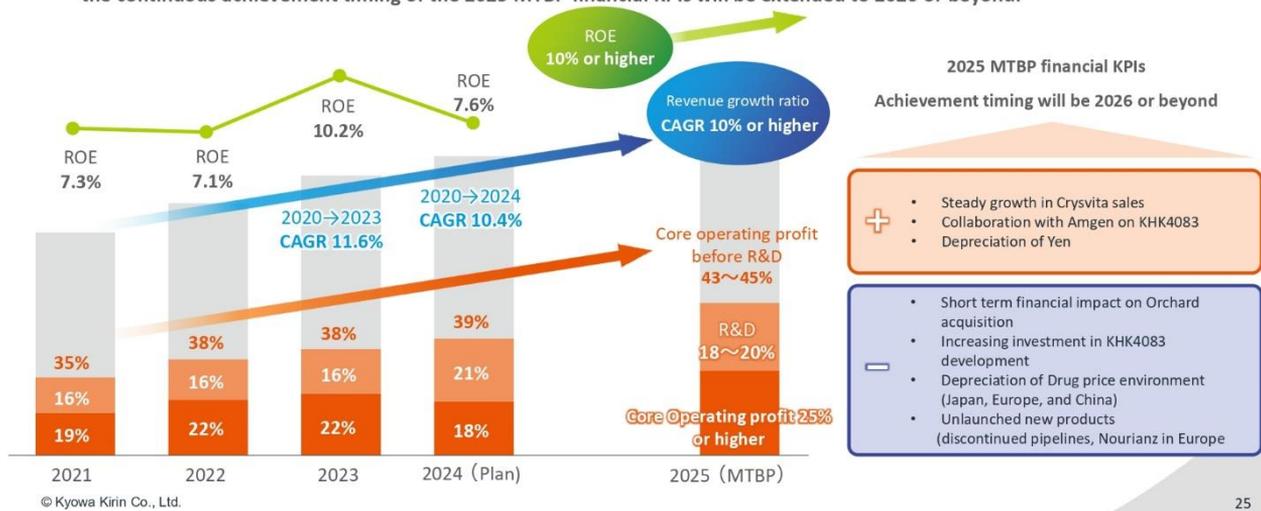
As for the income taxes, they were lower than usual in 2023 because the gain on the sale of shares of a subsidiary associated with a joint venture of the established medicines business in EU in the previous year was treated as tax-free, which had the effect of lowering the tax burden rate.

As a result, profit is projected to be JPY63 billion, down JPY18.2 billion YoY.

## 2021-2025 Medium Term Business Plan

### - Revision of Financial KPI -

- Record high in Core operating profit for FY2023. Achieved KPIs such as “ROE of 10%” and “CAGR of 10% or higher”
- Due to the restructuring of our business model to adapt to environmental changes, the continuous achievement timing of the 2025 MTBP financial KPIs will be extended to 2026 or beyond.



Next, I will explain the progress and review of the financial KPI's in the current mid-term plan, the five-year mid-term management plan that started in 2021. See page 25.

We are proud to announce that we have achieved record profits in FY2023 and have reached our target ROE of 10%. Revenue growth through 2023 was 11.6%, exceeding the benchmark, driven by steady growth in global products.

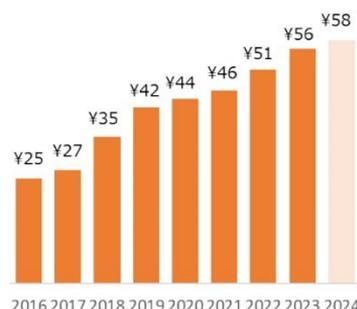
On the other hand, the profit structure deviates from the 2025 target, with the R&D ratio of 16% and the operating margin of 22% in FY2023. Furthermore, as I explained earlier, we have determined that another step into the R&D investment and growth investment is necessary to realize our Vision 2030, as we need to reconfigure our business model.

In light of this, we have decided to revise the continued achievement of financial KPIs, such as an ROE of 10% to a later timeline, specifically after 2026. In order to deliver life-changing value sustainably through sustainable growth, we have decided to make this review as the best way to realize our Vision 2030.

## Shareholders Return

- ✓ FY23 dividend is **56 yen**, and FY24 to be **58 yen** (plan)
- ✓ Plans **8-year consecutive rises** since FY17
- ✓ FY21-24 weighted average payout ratio is **40.8%** (plan)  
(Mid-term guidance for payout ratio “Targeting sustained dividend hikes with 40%”)

Year	Dividend (yen)		Payout Ratio <sup>*1</sup>	Return on Equity
	Interim	Year-end		
2016	12.50	12.50	25.00	44.9%
2017	12.50	14.50	27.00	34.4%
2018	15.00	20.00	35.00	35.2%
2019 <sup>*2</sup>	20.00	22.00	42.00	33.7%
2020	22.00	22.00	44.00	50.3%
2021	23.00	23.00	46.00	43.2%
2022	24.00	27.00	51.00	38.9%
2023 <sup>*3</sup>	27.00	29.00	56.00	35.5%
2024 Plan <sup>*4</sup>	29.00	29.00	58.00	47.6%



\*1 Payout ratio for FY2021/beyond are payout ratios against the Core EPS that is calculated based on the Core Earnings (= Profit - Other income/losses - Related income taxes)

\*2 Repurchase of 10.7M own shares (¥22.6B) executed on February 6, 2019. Total return ratio for FY2019 is 67.3%.

\*3 Year-end dividend of 29 yen/share will be submitted to the 101st Ordinary General Meeting of Shareholders to be held on March 22, 2024.

\*4 Total return ratio for FY2024 will be 109.5% (planned) assuming a share buyback of ¥40billion.

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Next, I will explain shareholder returns. See page 27.

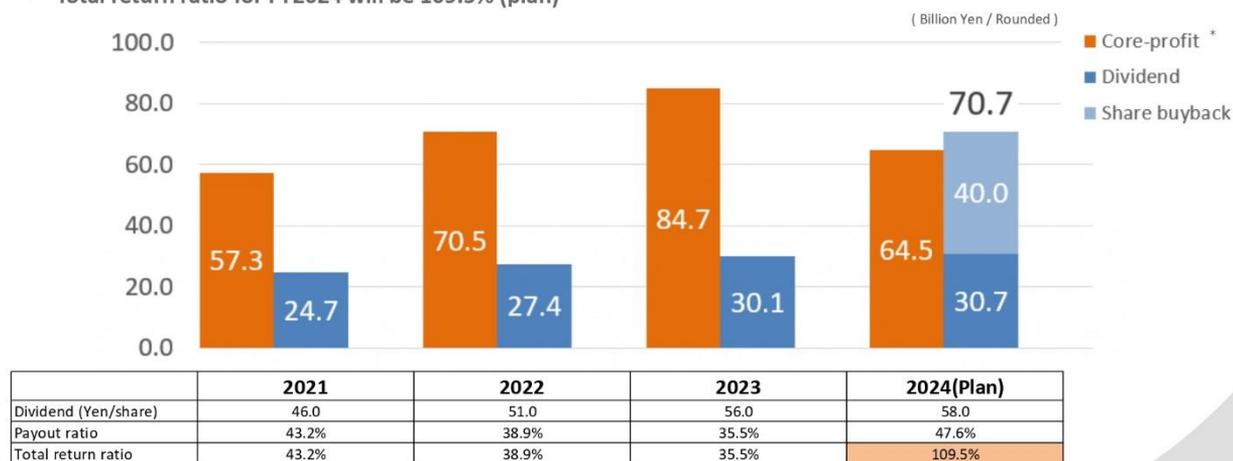
The year-end dividend for FY2023 will be JPY29, up JPY2 from the previously announced forecast of JPY27. The annual dividend will be JPY56, up JPY5 from the previous year.

For the current fiscal year, we plan to increase the annual dividend by JPY2 to JPY58 per share.

In our medium-term plan, we have set a guidance of aiming to continuously increase dividends with a target payout ratio of 40%, and the weighted average dividend payout ratio for the four-year period is 40.8%, calculated based on the FY2024 forecast.

## Share buyback and cancellation of treasury shares

- ✓ To improve capital efficiency and shareholder returns, the company has resolved share buyback and cancellation of treasury shares
- ✓ Up to 40.0 billion JPY, largest ever (Up to 17 million shares)
- ✓ Total return ratio for FY2024 will be 109.5% (plan)



© Kyowa Kirin Co., Ltd. \* "Core profit," profit without other income/losses and related taxes). Payout ratio is payout ratios against the Core EPS that is calculated based on the Core Earnings

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Next, on page 28.

In conjunction with the announcement of the financial results, we announced the share buyback and cancellation of treasury stock yesterday.

The share buyback is aimed at improving capital efficiency and enhancing shareholder returns, with a maximum buyback limit of JPY40 billion and a maximum number up to 17 million shares. Combined with the annual dividend scheduled for FY2024, total shareholder return is expected to be JPY70.7 billion, with a total return ratio of 109.5%.

Our capital policy is to place the highest priority on investment in growth to achieve sustainable growth and maximize corporate value. Since we have more than JPY400 billion in cash reserves at the end of 2023, we expect net cash of JPY250 billion to JPY300 billion after the share buyback and the Orchard acquisition. We believe that we will be able to maintain our capacity to invest in further growth.

Taking into consideration the Company's overall financial situation and stock price level, we have decided to repurchase our shares in order to improve capital efficiency and increase shareholder returns.



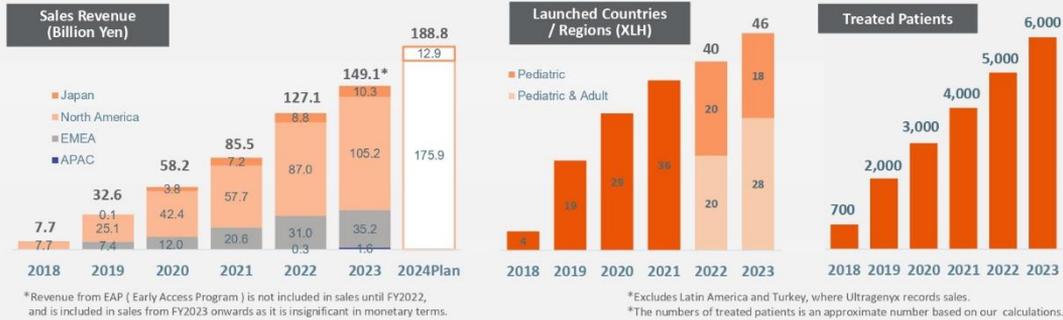
2023 Review & 2024 Key Actions

2023 Review

- North America: Started own sales (Established and started own operation of the direct sales force) Steady growth continued to be achieved through seamless sales transfers.
- EMEA Expanded markets geographically. Started commercialization for adult XLH in Italy and Spain. Maintained growth through patient penetration despite drug price reduction in Germany.
- Japan Strengthened promotional activities by increasing the dedicated personnel.

2024 Key Actions

- Strengthen evidence-based marketing activities.
- North America: Enhance disease awareness activities. Strengthen further the foundation of the own sales structure.
- EMEA: Continue to focus on geographical & indication expansion. Increase market penetration in adult XLH.
- Japan: Further strengthen promotional activities by the dedicated personnel to accelerate growth.



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Next, commercial updates. See page 30. First, Crysvita.

In FY2023, we were able to deliver Crysvita to 6,000 patients. We have made progress in expanding our market area, with the number of countries and regions where we launched our products reaching 46 at the end of last year.

By region, we were able to continue our growth by working closely with Ultragenyx, from the direct selling preparation in North America to the present to facilitate a seamless transfer of the business.

In EMEA, while affected by the German drug price reduction, growth was maintained due to market area expansion, such as the launch of adult XLH in Italy and Spain, and progress in patient penetration.

In Japan, we are working to strengthen our promotional activities by expanding the dedicated staff we have assigned since the end of last year.

In North America, we will continue to receive on-site support from Ultragenyx, but we have already shifted to marketing activities by our leads. In order not to slow down our growth rate, we will further strengthen our direct sale marketing structure by promoting evidence-based disease awareness activities, focusing mainly on adult XLH and TIO.

**2023 Review**

- Utilizing evidences including blood compartment
- Raising awareness of importance of blood testing among early-stage patients
- North America: Promotional activities based on medical data
- EMEA/ Asia: Launched countries/regions increased (+15).

**2024 Key Actions**

- Deeper penetration into the existing markets as well as expansion of targets through further progression of evidence-based promotional activities.

\* Revenue from EAP ( Early Access Program ) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

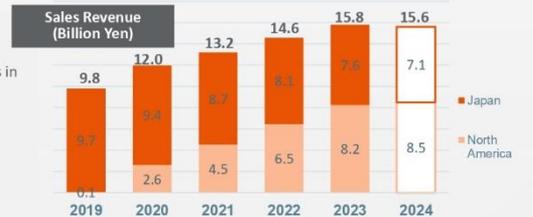


**2023 Review**

- North America: Steadily grew to exceed revenue goal driven by promotional activities resulting in all-time highs in total Rx's and total prescribers.

**2024 Key Actions**

- Accelerate new patient starts by focusing on 1st adjunct to levodopa/carbidopa patient type.
- Communicate the full clinical story of Nourianz through field force activity and updated digital channels.



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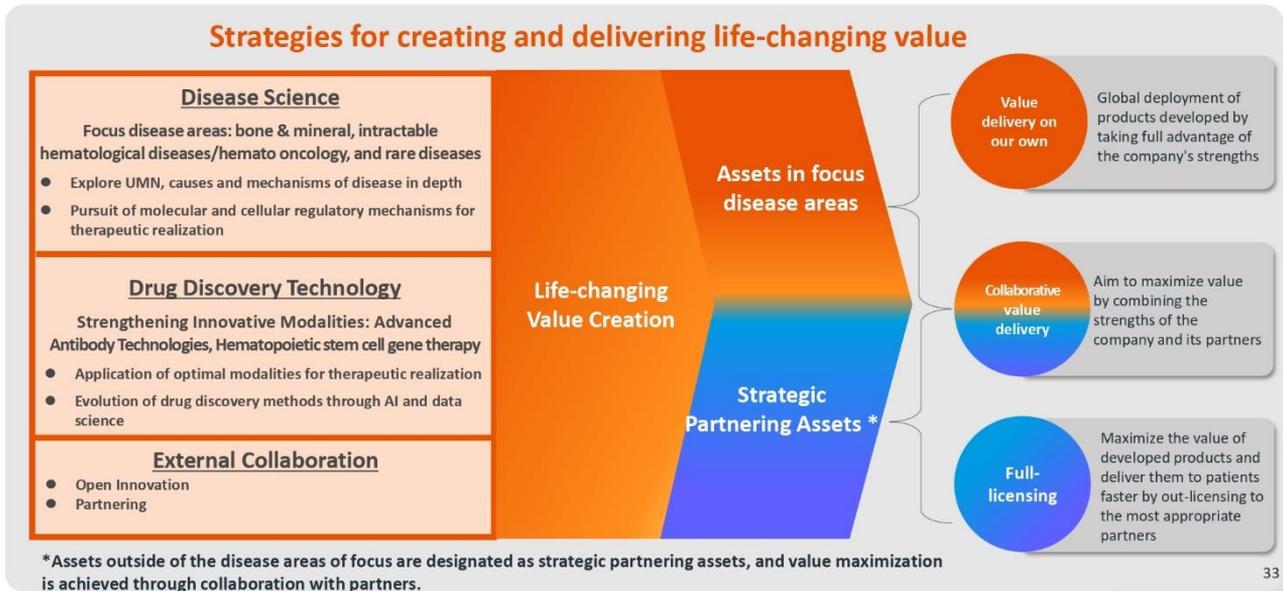
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Next, page 31, Poteligeo.

Sales revenue for Poteligeo also continues to grow steadily.

In 2024, we will further advance our evidence-based promotion to further penetrate to the patients with tumor cells in their blood. We will also use evidence-based approach to promote access for patients experiencing skin symptoms who have previously been underserved.

Lastly, it will be Nourianz. We have made significant growth through promotional activities that emphasize the importance of the drug's distinctive mechanism of action, particularly in the US. In FY2024, we will develop marketing activities focused on positioning the drug in clinical settings. We will also consolidate, reconfigure, and utilize the information accumulated through activities to date to strengthen sales capabilities.



Now, let me introduce to you the R&D updates. Page 33.

Here, I would like to share with you again our strategic story for 2030 for the creation of life-changing value.

## Upcoming Events: Main Development Pipeline Products

As of February 7, 2024

Code Generic Name	Events (Completed are in bold)	Timeline (Completed are in orange)
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis <b>P3 (ROCKET Program)</b>	<b>In progress</b>
	Asthma P2 initiation	H1 2024
	Prurigo nodularis P3 initiation	H2 2024
KHK4951 tivozanib	nAMD P2 initiation	Feb. 2024
	<b>DME P2 initiation</b>	<b>Jan. 2024</b>
KK4277	SLE, CLE <b>P1</b>	<b>In progress</b>
KK2260	Advanced or metastatic solid tumors <b>P1 initiation</b>	<b>Nov. 2023</b>
KK2269	Advanced or metastatic solid tumors <b>P1 initiation</b>	<b>Jan. 2024</b>
KK2845	AML P1 initiation	Q2 2024
OTL-200	MLD <sup>1</sup> FDA decision to be announced	Mar. 2024 <sup>2</sup>
OTL-203	MPS-IH <sup>3</sup> (Hurler syndrome) Registrational study <sup>4</sup> initiation	<b>Jan. 2024</b>
OTL-201	MPS-III <sup>5</sup> (Sanfilippo syndrome type A) PoC study <sup>6</sup> Data - Conference presentation	<b>Feb. 2024</b>

1. Metachromatic Leukodystrophy; 2. PDUFA date: Mar. 18, 2024; 3. Mucopolysaccharidosis type I; 4. Equivalent to P3 study; 5. Mucopolysaccharidosis type IIIA; 6. Equivalent to P1/2 study.

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Please move on to page 34. I would like to touch on some of the major news items in the main development pipeline.

First of all, rocatinlimab. As I mentioned earlier, it is currently undergoing Phase III trial, the ROCKET program. A Phase II study for asthma is scheduled to begin in H1 of this year. In addition, we plan to start a Phase III study for prurigo nodularis, an inflammatory skin disease with severe itchiness, in H2 of this year.

KHK4951 is now in Phase II trials for diabetic macular edema. A Phase II study of neovascular age-related macular degeneration is also planned to begin in Q1.

KK2260 and KK2269, products using our bispecific antibody technology REGULGENT, which we introduced at the R&D presentation at the end of last year, achieved first-patent in November last year and January this year, respectively.

In addition, the ADC named KK2845, which I mentioned earlier on the slide of this year's plan, is scheduled to start clinical trials in Q2 of this year.

Finally, I would like to discuss the pipeline using HSC-GT.

First, OTL-200, which is currently marketed in Europe as Libmeldy, is scheduled to receive the results of the FDA review in March of this year.

OTL-203, which targets Mucopolysaccharidosis type I, has recently started a pivotal trial that is equivalent to Phase III.

OTL-201. We presented the PoC test results at the 20th Annual WORLDSymposium currently being held in San Diego, USA.

## Main Development Pipeline Products (After Ph2)

As of February 7, 2024

	Diseases under development* <sup>1</sup>	Planned Approval Year* <sup>2</sup>	Development status	Total addressable market* <sup>3</sup>	No. of Patients* <sup>4</sup>
KHK4083/AMG 451 rocatinlimab	Moderate and severe Atopic Dermatitis	2026/2027	P3 (Global)	★★★★★	16M
KHK4083/AMG 451 rocatinlimab	Moderate and severe Asthma* <sup>5</sup>	TBD	Preparation underway for P2 (Global)	★★★★★	13.5M
KHK4951 tivozanib	nAMD	TBD	P2 (JP, US)	★★★★	2,600K
KHK4951 tivozanib	DME	TBD	P2 (JP, US)	★★★★	3,400K
OTL-200 libmeldy <sup>7</sup>	MLD	2024 (US)	Filing to FDA	★	(1 in 40K-160K live birth)
OTL-203	MPS-IH (Hurler syndrome)	2029	Registrational study* <sup>5</sup> (US, EU)	★	(1 in 100K live birth)* <sup>6</sup>
OTL-201	MPS-IIIA (Sanfilippo syndrome type A)	TBD	Proof-of-concept* <sup>7</sup>	★	(1 in 100K)

\*1 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities. \*2 Expected year of first approval. \*3 Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in \*1, not projected sales or the Company's targets. Colored areas represent estimates for global, and the rest are for Japan. ★: less than ¥500B. ★★: ¥500B~¥1000B. ★★★: Over ¥1000B~¥5000B. ★★★★: Over ¥5000B~¥1Tn. ★★★★★: Over ¥1Tn. \*4 Total number of estimated patients by Kyowa Kirin. Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan. \*5 Equivalent to P3 study. \*6 "1 in 100k live birth" is estimated incidence for all of MPS-I, of which approximately 70 percent are cases of Hurler syndrome. \*7 Equivalent to P1/2 study.

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Page 35. Based on the above, this slide lists the development pipeline that has advanced beyond Phase II.

In addition to rocatinlimab and KHK4951, we will steadily advance the development of our newly added HSC-GT pipeline and do our utmost to bring smiles to patients as soon as possible.

## Main Development Pipeline Products (nonclinical ~ Ph1)

As of February 7, 2024

	Diseases under development* <sup>1</sup>	Development status	Modality, technology
KK4277	SLE, CLE	P1 (JP, Asia)	Antibody, POTELLIGENT <sup>®</sup>
KK2260	Advanced or metastatic solid tumors	P1 (JP: in progress, US: in preparation)	Antibody, REGULGENT <sup>™</sup>
KK2269* <sup>2</sup>	Advanced or metastatic solid tumors	P1 (JP, US)	Antibody, REGULGENT <sup>™</sup>
KK2845* <sup>2</sup>	AML	Preparation underway for P1 (JP)	Antibody-Drug Conjugate

\*1 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities. \*2 Since the trials had not started yet as of December 31, 2023, they are not currently listed on our company's pipeline table.

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Page 36. Here it shows the development pipeline for the initial stage before Phase I.

In addition to KK4277 shown at the top of the page, we are also working on new initiatives, such as bispecific antibodies and ADCs, to continue creating life-changing value.

We intend to develop each of these products well in order to achieve Kyowa Kirin's vision for 2030.



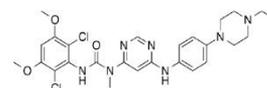
## License agreement for infigratinib

To strengthen our pipeline in the bone and mineral areas, Kyowa Kirin has entered into a license agreement with BridgeBio Pharma for the development and commercialization of infigratinib in Japan.

- Secured exclusive rights for the development and commercialization within Japan, targeting skeletal dysplasias
- The agreement includes an upfront payment of \$100M with royalties up to the high-twenties percent, with additional milestone-based payments to BridgeBio

### Infigratinib

- An oral small molecular FGFR<sup>1-3</sup> inhibitor developed by QED Therapeutics, an affiliate of BridgeBio
- Target Condition: Achondroplasia
  - Genetic condition caused by gain-of-function variants in the FGFR3 gene, leading to reduced long-bone growth and thus shortened limbs and overall stature
  - Designated as an intractable disease (#276) in Japan<sup>2</sup>, with an estimated patient population of 6,000
  - Oral treatment methods are yet to be established
- The P2 trial (PROPEL 2)<sup>3</sup> has demonstrated efficacy, and the global P3 trial (PROPEL 3)<sup>4</sup> is currently underway
- Mechanism of Action: Promotes growth plate development by inhibiting abnormal FGFR3 activity



Kyowa Kirin plans to commence PMDA consultations in 2024 and initiate a registrational study in Japan in 2025

1. Fibroblast growth factor receptor; 2. <https://www.nanbyou.or.jp/entry/4570>; 3. NCT04265651; 4. NCT06164951

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Page 37.

In order to strengthen our bone and mineral area, we have entered into a license agreement with BridgeBio Pharma in the US for the development and marketing of infigratinib in Japan.

Under the terms of the agreement, we have secured exclusive rights for the development and commercialization within Japan, targeting skeletal dysplasia. The agreement includes an upfront payment of USD100 million with royalties up to the upper range of 20%, with additional milestone-based payments to BridgeBio.

Infigratinib is an oral small molecular FGF receptor1-3 inhibitor developed by QED Therapeutics, an affiliate of BridgeBio. The target disease condition is achondroplasia. This disease is a genetic condition caused by gain-of-function variants in the FGF receptor 3 gene, leading to reduced long-bone growth and causing short stature.

In Japan, it is designated as an intractable disease, with an estimated patient population of 6,000. In addition, there is no oral treatment for this disease currently. It has been suggested that this product may promote growth plate development by inhibiting abnormal FGF receptor 3 activity and improve the pathology. The efficacy of the drug has been confirmed in Phase II trials conducted to date and the Phase III global trial is being carried out.

We plan to commence PMDA consultations in FY2024 and initiate a registrational study in Japan in 2025 to start clinical trials.

News releases for FY2023 are listed on the next page.

## Year-to-date Key News Flow

Category	Date	Headline	As of November 1, 2023
LCM	Nov 22	Launched Calcimimetics Agent ORKEDIA® TABLETS 4mg (Japan)	
LCM	Jan 5	Out-licensed the exclusive and worldwide rights to Boehringer Ingelheim of developing first-in-class treatment for fibro-inflammatory diseases.	
SI	Jan 24	Completion of share acquisition of Orchard Therapeutics plc, UK biopharmaceutical company	
R&D	Feb 6	First Patient Randomized in Registrational Trial of OTL-203 for MPS-I Hurler Syndrome	
R&D	Feb 6	First Patient Enrolled in the Phase2 Clinical Trial Evaluating Tivozanib Eye Drop for Diabetic Macular Edema	
SI	Feb 7	Conclusion of Agreement with BridgeBio Pharma for an Exclusive License on Infigratinib in Skeletal Dysplasias in Japan	
Finance	Feb 7	Acquisition of Own Shares and Cancellation of Treasury Shares	

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment  
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Please go to page 41 for a list of news released after the Q3 results.

As announced on January 5, we have submitted an agreement to out-license to Boehringer Ingelheim of the compounds we have been generating from our research.

The Orchard acquisition closed on January 24.

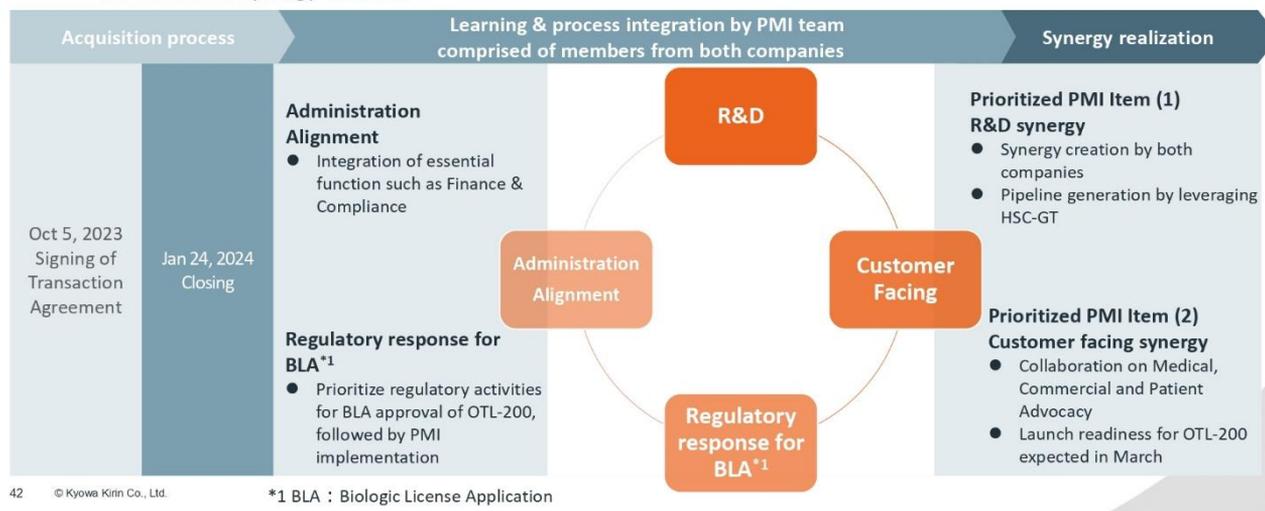
As I explained earlier, we have concluded an agreement with BridgeBio to license the development and marketing of infigratinib in Japan.

Based on this strategic story to realize Vision 2030, we will enhance our assets through in-house drug discovery as well as through collaborations with external parties and select the optimal process to maximize value.

There are the two more slides remaining, but I will explain the post-merger integration plan of Orchard and the acquisition combination accounting.

## Plans for Orchard Therapeutics Post Merger Integration

- Completed acquisition of Orchard Therapeutics on January 24<sup>th</sup>, 2024.
- Build PMI (post-merger integration) team comprised of members from both companies, and initiate activities for successful synergy creation.



First, the integrated plan.

Upon closing on January 24, we promptly set up PMI and post-merger integration teams. Then, we have already begun activities to realize synergies sooner.

The PMI team has begun discussions on the integration of the foundational functions, such as finance and compliance, as well as the response to the approval of OTL-200 in the US, which is scheduled for next month. After these efforts progress, we will proceed to the full-fledged PMI phase.

At PMI, our top priority is to create synergies in R&D and customer facing. In R&D, we will work to realize synergies through research and drug discovery using the platform of hematopoietic stem cell gene therapy.

As for customer facing, we will promote cooperation in medical, commercial, and patient advocacy activities, and we will prepare for the launch in anticipation of OTL-200's approval. Reimbursement for OTL-200 is newly available in Ireland, Belgium, and the Netherlands on January 25, and regional expansion is underway in Europe.

Other products under development are also making steady progress, and we will work to maximize their value as assets in the disease areas we are focusing on.

## Accounting treatment of share acquisition of Orchard Therapeutics (Tentative)

- ✓ Completed the share acquisition on January 24, 2024, and will be consolidated starting from the February 2024
- ✓ Recognized intangible assets of \$201M and goodwill of \$254M
- ✓ Intangible assets will be amortized over 20 years (19 years for OTL-200 (Libmeldy))

(Unit Million USD)	
<b>Other assets</b> 172	<b>Other liabilities</b> 108
	Deferred tax liabilities 50
<b>Intangible assets</b> 201	<b>Acquisition costs</b> 478
<b>Goodwill</b> 254	
<b>Other Expenses</b> 9	

**【Breakdown of Intangible \$201M】**

- OTL-200 \$159M (incl. US)
- OTL-203 \$42M

**【Annual amortization amount】**

- OTL-200 \$8M /year  
⇒ Amortization will start from Feb 2024
- OTL-203 \$2M /year  
⇒ To be amortized after market launch

The above is a tentative calculation based on assumptions using Orchard balance sheet as of December 31, 2023 (preliminary figures based on US GAAP). Going forward, we will discuss with KPMG to finalize the amounts and accounting treatment.

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This will be the last slide.

Regarding accounting treatment of share acquisition, I would like to explain it, although it will be a tentative estimate of values based on preliminary figures as of the end of December based on US GAAP.

The acquisition of shares was completed on January 24. We will essentially be consolidating 11 months of profit and loss starting in February for FY2024.

The consideration to be paid to the owner, including the conditional consideration if OTL-200 is approved for marketing in the US, will be USD478 million, or approximately JPY70.7 billion.

As for intangible assets, we are evaluating two pipelines, OTL-200 and OTL-203, totaling USD201 million.

The remaining USD254 million, excluding assets and liabilities held by Orchard, is goodwill.

The amortization period for intangible assets is planned to be 20 years. Since OTL-200 is already on the market as Libmeldy, the amortization period will be 19 years, one year less.

Orchard's products and other developed products are anticipated to pose high barriers to entry for follow-on and competitive products. Furthermore, the absence of so-called patent cliffs is projected to enhance earnings over an extended duration.

Libmeldy is an intangible asset valued at USD159 million in Europe and the US combined. It is scheduled to begin amortization in February following the start of consolidation. OTL-203 is valued at USD42 million as an intangible. It is scheduled to undergo depreciation from the date of market launch.

These accounting treatments are tentative, and the amounts and accounting treatments will be finalized upon discussion with the auditing firm.

It gets pretty long, but that is all from me.

## Question & Answer

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**Moderator [M]:** I would now like to move on to the question-answer session.

**Yamaguchi [Q]:** Thank you. Good morning. I am Yamaguchi from Citi.

My first question is a bit vague, sorry. As for the overall picture of your company's forecast for this fiscal year, there are Orchard, generics and biosimilars in Japan. In addition, there are negative factors in Europe, or the sale of subsidiaries and various other negative factors, but overall, the numbers are quite strong. You will expect an increase in profit when excluding Orchard.

There are various individual components to consider, but I'm curious about whether the overall design leans towards being aggressive, reasonable, or conservative. I think you are always on the reasonable side, but I thought at first that it seems a bit more aggressive than I anticipated. What is your view on that, Mr. Kawaguchi?

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

From my standpoint, I believe that we always budget reasonably.

Just the year before last, when I announced our forecast, Yamaguchi-san mentioned that it seemed quite a challenging forecast. I also thought it was challenging, but we were able to land much bigger than the forecast this fiscal year. There was a tailwind of the yen's depreciation in FY2023, but we were able to meet our target slightly higher than planned still, even without the tailwind.

I hope you will understand that we have set similar goals for 2024 that we can firmly achieve.

**Yamaguchi [Q]:** Thank you. The second question is a bit more detailed.

You mentioned KK2845 and ADC. I am sorry for my lack of knowledge about blood cancer, but could you tell me if you know the payload, DAR, etc.? I would also appreciate a description of the components, including what you are trying to achieve, if any.

**Yamashita [A]:** Chief Medical Officer Yamashita will answer.

At this time, we are not yet able to disclose the details of this ADC. We hope to be able to provide such information when we are able to report.

**Yamaguchi [Q]:** I understand. One brief. I think that ADC can be easily platformed. Your company entered from the blood cancer, but I think it is a popular platform for solid tumors. Is it likely to be a modality that you plan to develop as a platform afterwards?

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

Our company has always been in the antibody drug business, and we have a large pipeline of antibodies in our pipeline. As an advanced form, we introduced bispecific this time, and we are also considering the development of ADC, which we believe will create new value in the field of antibody-based drug discovery. We are also making efforts to have such a lineup.

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

**Muraoka [Q]:** Hello. This is Muraoka of Morgan Stanley.

The first is a confirmation, just to be sure, Crysvita in this fiscal. Mr. Yamaguchi mentioned earlier that the plan for this term looks aggressive overall, and I agree with it. I know it seems silly to ask detailed questions every three months in terms of Crysvita, but there were tremendous sales in October to December. Then, when I asked the IR person yesterday, he mentioned that there was no particular buildup of wholesale inventory. I would like to confirm if it is accurate.

On the flip side, I'm wondering if my assumption is correct: that there is no risk of experiencing any unexpected disappointments from January to March, unlike the situation we faced a year ago. Please advise me on this first.

**Sudo [A]:** Thank you very much, Muraoka-san. I, Sudo of the Global Product Strategy, will answer your question.

The simple answer is that rather than a particular buildup of wholesale inventory, the wholesale inventory that decreased once in Q3 has returned in Q4. We had quite a bit of wholesale inventory buildup in December of the year before last, but we did not do that last year. So, I am assuming that we will not have to worry about that in this Q1.

**Muraoka [Q]:** I understand. In other words, there are no factors to worry about right now, is that correct? Last year, there were actually some factors, but you didn't tell us much about them at the time of the financial briefing, so we were surprised when the Q1 period ended. Am I okay to assume that you don't have any in particular issues that you are having now?

**Sudo [A]:** Yes. It is safe to say we don't have those.

**Muraoka [Q]:** Okay, thank you.

The other question is about rocatinlimab, KHK4083. I think the result will become available from H2, and I think it comes from Horizon. My question is, in what way will you disclose this information to us?

There is a big conference for respiratory around September or October, and I don't know if you can make it there in time. However, in the press release, I'm not saying that you need to release all eight items individually, but can you at least provide the first one or two important studies individually? Or it will not be disclosed until a certain extent?

Since it is a matter of six months or so at the earliest, can you tell us how to think about it and how do you announce to us?

**Yamashita [A]:** Yamashita will answer.

I understand that you are very interested in it, so we also think it is very important to think about how to present the rocatinlimab's result.

Currently, we are working with Amgen on this project, so we are still considering such aspects. Therefore, we have not yet decided on a form we are going to take to answer your question. We will provide updates once we make progress.

**Muraoka [M]:** I understand. I would strongly encourage you to provide updates as frequently as possible. That is all.

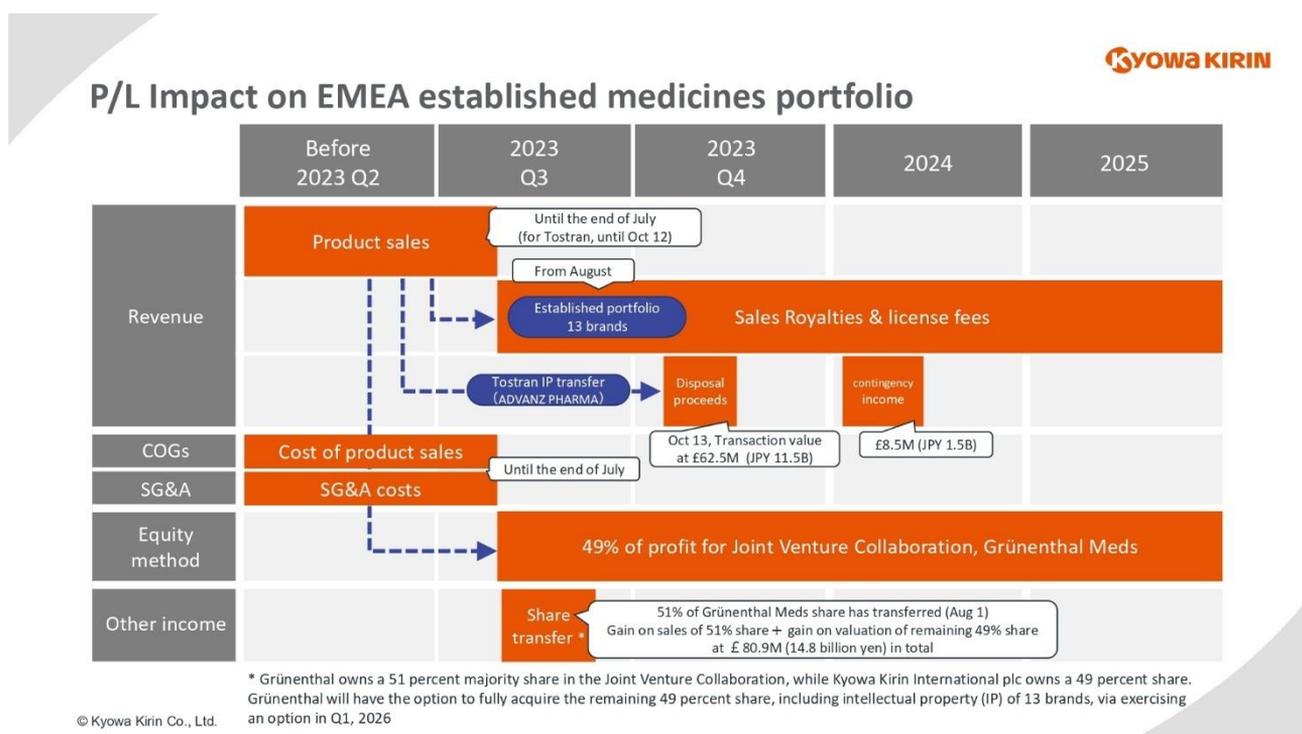
**Wakao [Q]:** My name is Wakao from JPMorgan. Thank you. I have two questions.

The first question is where it will take you after having a strong performance this fiscal year. My biggest concern is about sales in the areas undisclosed for individual products. I would like to know why that area is growing.

If we accumulate the sales of individual products and look at the other parts of the business, it is about JPY40.5 billion for the current fiscal year. I think it was JPY37.3 billion in the previous fiscal year. There was a gain of about JPY11 billion from the transfer in the previous fiscal year, and there will be another JPY1 billion in this fiscal year. Based on that, I feel that there will be a growth of about JPY10 billion or more for this fiscal year in the portion which is not disclosed.

I am not sure why this area is growing. Could you explain if there is a temporary factor in this area or if it is simply the growth of individual products and such?

**Kawaguchi [A]:** Thank you for your question, Mr. Wakao. I think the numbers align with your analysis.



For factors other than individual product sales, there was a transfer of Tostran in this fiscal year that amounted to JPY11.5 billion, as you can see on page 48. The conditional consideration for this has not yet been finalized, but we incorporated JPY1.5 billion in our budget.

In addition, the one-time revenue from Boehringer Ingelheim, which was mentioned earlier, is also included, although the amount is not disclosed.

Other one-time revenues not yet determined at this time have also been factored in. I wonder if those portions show as difference.

**Wakao [Q]:** I understand. If so, you meant that there is about JPY10 billion in other areas, most of which cannot be disclosed at this time, but is it correct to understand that the out-licensing portions include Boehringer Ingelheim?

**Kawaguchi [A]:** Yes, that's right. We will refrain from giving specific details, as they have not been finalized at this time, but we hope you will understand that we have incorporated such items into the budget, not limited to out-licensing.

**Wakao [Q]:** Very well understood, thank you. One more thing, please tell me about the revision of the medium-term plan.

The core OP margin of 25%, which is one of the KPIs for FY2025, has moved beyond 2026 onward. I understand the factors as written here. What I would like to know is whether it would have been possible to achieve 25% or more of core OP without the acquisition of Orchard. Since the mid-term plan runs until 2025, it may not be possible to say at this time, but is there any definite timing for the achievement of 25% or more of core OP?

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

As you can see in the chart on page 25, one of the major reasons for the decline in the ratio of core OP is the ratio of R&D expenses, especially in 2024 and 2025. Now, we are in a phase to make more aggressive investment than we had originally anticipated and putting pressure on core OP. Therefore, the core operating profit margin before deductions, excluding R&D expenses, has steadily risen to 39%.

However, in order to achieve the mid-term plan, we need at least 43% before R&D expenses. Even excluding R&D expenses, we will not be able to reach this level, so we have moved a sustainable achievement to beyond 2026.

The factors of the negative impact are on the right side. We will probably not be able to reach 25% without Orchard, and this is our actual ability as of now. We would like to achieve this goal as soon as possible after 2026, but there are various changes in the environment, so we are currently discussing how we should plan for the future. I cannot say when at this time, but we will as soon as possible.

Another thing is that I am more particular about ROE than operating margin. We believe that the most important KPI is to achieve 10% above the cost of capital as soon as possible and to maintain and improve this level on a stable basis. So, the main to improve it is to enhance profit growth in the numerator, as outlined in the main goal of this medium-term plan. By doing so, we managed to achieve 10% by profit growth for FY2023.

However, as I mentioned earlier, there has been a series of discontinuations on developments, so we have made the acquisition of Orchard to achieve future sustainable growth and also invested in R&D, especially in KHK4083. This will be our major source of earnings, so we will invest aggressively in this area, including the expansion of indications. Profit growth will stand still a bit for FY2024, as we have decided to give priority to these investments. Therefore, we have chosen to improve the denominator by share buyback, as we believe that we should take measures to improve the denominator when we cannot improve the numerator.

As you can see on page 28, the total shareholder return will be 109%, which is above profit. It means we took a measure that the denominator will not increase, or will slightly decrease, in order to improve capital efficiency. Our goal is to achieve an ROE of 10% or more in 2026 and beyond and to make the Company capable of continuously maintaining and improving the target ROE.

This is a bit of a long explanation, but I hope I answered to your question.

**Wakao [Q]:** I understand very well. However, should I understand that a share buyback is not a card that can use that often?

**Kawaguchi [A]:** Yes. Our policy is to buy back shares in a flexible manner. As Miyamoto explained earlier, our capital policy prioritizes growth investment for sustainable growth in the future. We do not intend to do share buyback in a way that would deplete the funds.

In this fiscal year, we have increased cash by JPY60 billion, bringing us to JPY400 billion in cash reserves. We spent JPY80 billion for strategic investments out of the reserves, which are JPY70 billion for the acquisition of Orchard and JPY10 billion for the infigratinib milestone. Still, it is at the level of JPY320 billion. Even if we buy back JPY40 billion of our own shares, the amount would still be JPY280 billion. Therefore, we should be able to maintain the level of over JPY250 billion in the future.

Given this and the fact that the Company has ample capacity to invest in growth, as well as stock price level, we decided to proceed with share buybacks in a flexible manner at this time to improve capital efficiency.

**Wakao [M]:** I understand very well. Thank you very much.

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

The first question is about the differentiation strategy of rocatinlimab. I believe that some of the Phase III trials are conducted with once every eight week dosing after the maintenance phase, but the protocol is basically once every four weeks.

I think a very similar mechanism is Sanofi's amlitelimab in Phase III, which has a protocol in place to actively consider a dose of once every 12 weeks. Since Sanofi is a bit behind in the development compared to rocatinlimab, I think they might be taking on some risks. If they achieve success in their trials, it could potentially pose a threat to rocatinlimab.

I wonder how you see the necessity of considering different ways of dosage or usage. I believe that they are ahead of us in the development of asthma, but are there any differentiation strategies that you are considering to catch up with them? If so, could you please share with us?

**Yamashita [A]:**

First of all, rocatinlimab is currently being developed with a view to Q8W. As you mentioned, the competing products are running behind us, which inhibits OX40 ligand. It is Q12W this time, and we have an impression that they have set a challenging trial, which is as you have said.

We, of course, have no idea what will happen to this Q12W at this point. First, we must complete our trials, including this Q8W, and get them to patients as soon as possible. I think that is the first thing we should do.

We believe that rocatinlimab is superior in its ability to reduce the number of target cells and to work for a longer period of time. We will consider the possibility of further extending the duration of treatment while considering the future situation.

As for asthma, although we are running behind them, I believe securing the indication for asthma treatment is crucial. Considering there are patients who suffer from both asthma and atopic dermatitis and taking into account the issues related to the relevant medical departments, I believe that having an indication is an extremely important first step for rocatinlimab. Therefore, we would like to proceed with the study with a firm focus on there.

That is all.

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

The second question is about guidance for this fiscal year. I saw an article in a media briefing in which Mr. Kawaguchi called the plan for the new fiscal year just started quite challenging. I felt a little different nuance from what you explained today, so I would like to confirm if you made such a statement. If so, could you please comment on what it meant?

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

I recall that the plan has always posed challenges, but in my judgment, it is reasonably challenging. I don't remember the exact statement, so I can't say for sure, but I hope you understand that my purpose is to always include a healthy challenge that is reasonable. We will make sure to achieve this goal.

**Hashiguchi [M]:** Thank you very much. That is all.

**Ueda [Q]:** My name is Ueda from Goldman Sachs. I would like to ask you about the targets in the mid-term plan to start with.

I am looking at the table graph on page 25, and I would appreciate it if you could share your review of the reasons why it did not reach the target, even when excluding Orchard.

Regarding the target of achieving a sales growth rate of at least 10%, it seems that your company has been maintaining a level that exceeded 10%. And you also mentioned earlier that you are investing aggressively in R&D, but considering the pace of JPY400 billion during the period, I think you are controlling the R&D expenses within a certain range.

Can you tell us your analysis of what is causing the current margin compression and when, if ever, you will set a new target?

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

As shown in the lower right corner of page 25, except for Orchard and the expansion of development investment, the top line has exceeded 10% due to the progress of the yen depreciation. However, in reality, drug price revisions have worsened compared to the assumptions made in the mid-term plan. The environments are getting severe than our assumption in both Japan and Europe and China. These factors are working as body blows.

Then, another factor is the inability to launch several new products in the market. We have been explaining that the impact of each product was not so significant because we included the probability in the new product under development in the sales amount, but several development projects were cancelled.

Also, for Nourianz. We had put in a certain number of sales in anticipation of approval in Europe, as this product is highly profitable. These factors have reduced the overall profitability. Therefore, the reality is that we are seeing a situation where we are a little out of reach for 2025 even excluding Orchard.

In response to these changes in the environment, as I mentioned earlier, we will narrow our focus, develop a more efficient organizational and operational structure, and aim for significant growth in the areas that has narrowed down.

We also need to consider how we can partner well in the areas outside of our focus where we have not narrowed down and how we can partner in ways that will contribute to increasing our business value. By putting strategies in place in these areas, we will become a company that can achieve this goal in a sustainable manner as soon as possible.

Speaking about our current situation, we would like to focus on those transformations, and we would like to delay the achievement of the initial KPI for 2024 and 2025.

**Ueda [Q]:** Thank you very much. Then, at present, for example, you have not set a specific timeframe to set new goals at this moment, have you?

**Kawaguchi [A]:** Yes, that's right. I mentioned that there are some KPIs that we will not reach in this current mid-term plan for 2025. However, first of all, we will make firm progress toward the 2025 mid-term plan. In the meantime, I hope you will allow us to think carefully about our next goals.

**Ueda [Q]:** Yes, I understand, thank you.

The second question is about the R&D policy you presented on page 33. You have explained some of the areas where you will promote in-house development. I would like to know in what areas you will promote partnering or full out-licensing. I would appreciate it if you can add a comment on that.

The next page shows the main pipelines, including tivozanib for ophthalmology and bispecific antibodies for solid tumors. In your development strategy, do these areas correspond to partnering or out-licensing, or do you have any supplementary information on how you will use your own R&D assets?

**Miyamoto [A]:** Thank you, Mr. Ueda. I, Miyamoto, would like to answer.

It is exactly what you just mentioned, and I think it is on page 35 or page 36, the pipeline table.

Regarding KHK4951, as you rightly pointed out, for example, we lack expertise in the field of ophthalmology, and there is also no commercial activity on a global scale. Of course, we will proceed with Phase II. I believe that partnering will be necessary to maximize value, including finding a good partner if the results are good, and delivering the product to patients as soon as possible, although it will depend on results.

When I look at something early, especially in the area of solid cancers, I think the data so far is very interesting and exciting. Though, as you mentioned, covering all solid cancers requires a very large R&D investment, and competition can be very tough even after the product is launched on the market. So, I think we will probably look for a partner for this as well. We believe that this will maximize the value of our products and from the standpoint of our own stamina.

I think that is roughly the explanation that we can give for the visible pipelines.

**Ueda [M]:** Yes, I understand, thank you very much. That is all from me.

**Sakai [Q]:** Thank you very much. This is Sakai of UBS.

I have been wanting to ask President Miyamoto about this for some time. With the Orchard acquisition, I don't mean to rehash the story, but you have stepped into a whole new area of the so-called rare disease, hunter syndrome, and gene-cell therapeutics by this merger.

I would like to ask about the background, why did you choose this company and why did you decide to enter this area? Although you mentioned about numbers in terms of the medium-term plan, I think that this was a very big decision in terms of strategy. I have the impression that we have not received a direct explanation from the President, so I would like to ask you about it.

You may not be able to answer this, but how did you assess the amount of this acquisition? I believe this is autologous cells, so we don't really know how far this technology can be developed. I would be grateful if you could give me some kind of answer on the President's evaluation of this value, including areas that I mentioned.

This is the first question.

**Miyamoto [A]:** Thank you, Mr. Sakai.

It was certainly a big decision. The most important thing is, after all, that we recognize the value in the potential of this treatment method.

It was actually the research that brought us to make contact with Orchard in the first place. We have an idea, and when we want to implement it in patients, we thought which technology is best to use. After looking at the various studies, we found what Orchard is doing very interesting.

Moreover, Orchard was still in the process of obtaining approval or not at that time, but it was very close to the market. Then, we discussed the possibility of working together on the research side.

Then, I saw so much potential in them. As you probably know, we have a very long history—hematopoietic stem cells, erythropoietin, G-CSF, darbepoetin, and pegylated G-CSF, of which we were the first company in the world to clone. Now, there is romiplostim based on that technology. As you can see, we have a very long history of research on hematopoietic stem cells, and we are quite compatible with them.

We also entered into cellular medicine in the early 2000s, though it did not work out. We also collaborated with a venture, but we quit it. So, to some extent, we have a pretty good understanding of the potential and limitation to cellular medicine.

With that base in place, the potential for treating genetic rare diseases, which Orchard is focusing on, was very interesting. This is the base we became aware of and understand the potential of Orchard.

So, there are things that we want to do, and then we put ideas together. There is a way that we would do together in research, but then, we wouldn't get it as a platform, right? Then, we were asked if we would go for an acquisition, and here we are.

As I explained in the very last slide, there is quite a bit of valuation on the goodwill side. It is a future potential. The key point is how we can create a new pipeline by applying our ideas to this platform, and we see tremendous potential here.

It is not simply that we saw the pipeline that Orchard had, and we thought it was very attractive from a business perspective. We would like to put our bets on future potential. Since this is research and development, we may be talking about probability, but we will take a certain amount of risk.

However, from our point of view, it is a risk worth taking, given the tremendous potential. We hope to provide solutions for diseases that currently lack effective treatments, thus creating a new pipeline moving forward. This was the reason behind my decision to proceed.

**Sakai [Q]:** I understand. So, you would like Orchard to maintain what is commonly referred to as autonomy, and you wish to continue with the management style you have entrusted to Orchard.

**Miyamoto [A]:** We will be busy for a while, especially around the time when Libmeldy/OTL-200 get approvals in the US, so we are not planning to take PMI all of sudden. However, as I mentioned earlier, the major value is how we will generate the pipeline in the future.

Of course, we plan to have them have a certain degree of autonomy. In terms of research and development, we are strongly motivated to integrate at an early stage to create a new platform from which we can build on our strengths. We both have agreed to enter into this area with a strong commitment, and we have already begun discussions.

**Sakai [Q]:** I understand, and one more thing, briefly.

As for the share buyback you mentioned earlier. This means that if this share buyback is completed and if all the shares are purchased, the parent company will have a 56% stake of the Company.

I asked the IR representative yesterday, and he said that the parent company has stated that they have no intention of making it a 100% subsidiary. In any case, you can buy up to 2/3 of the share, until the TOB is mandated to be automatically triggered. So, I am wondering if this leads to the statement that you will consider a flexible share buyback in the future again. Please let me check this area. I think that is probably why the stock price is so high today.

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

To be precise, the ratio of voting rights is currently 53.8%, but if we are able to acquire all 17 million shares this time, the ratio will be 55.6%, which means that the ratio of voting rights will increase by 1.8 percentage points. I believe that we still have a lot of room in terms of the ratio of voting rights, putting aside if we can reach 66% or not for now.

On the other hand, since we are listed on the prime market, the ratio of shares in the market is still over 40% even after the share buyback, and we are keeping a close eye on this. However, please understand that we are at a level where we can do this a few more times and with enough resources.

However, this does not mean that we will execute it on a regular and continuous basis. Rather, we would like to do so in a flexible manner while carefully watching the environment, as I mentioned earlier.

**Sakai [Q]:** I understand. It seems to come with various conditions. 55.6% of the voting rights?

**Kawaguchi [A]:** No, after the share buyback is completed.

**Sakai [M]:** After completion, I understand. Thank you very much.

**Wada [Q]:** This is Wada of SMBC Nikko Securities. Thank you very much. I have two questions.

First, I would like to ask about the infigratinib license agreement. The description is for skeletal dysplasia. I am wondering if infigratinib is being developed in oncology, and am I correct in understanding that the development rights for this in Japan are not taken yet?

This is my first question.

**Miyamoto [A]:** Miyamoto will answer.

As I explained earlier, we are licensed only for skeletal dysplasia.

**Wada [Q]:** Am I correct in understanding that, currently, you do not have a plan to obtain optional contract or add-on?

**Miyamoto [A]:** I can't give you the details of the agreement, but we are focusing on skeletal dysplasia, and that is why we obtained the license.

**Wada [Q]:** Okay, thank you. Second point.

As for the landing in 2023, I think the profit is higher than expected because you were not able to use as much R&D expenses as planned. I wanted to ask you about the strategic investment. I was wondering if you were active in anticipation of a large acquisition in 2024.

In the end, I wonder if perhaps the main reason that R&D funds were not being spent was the lack of a pipeline that would be invested in the later stages of development. So, I would like to ask how high a priority you are giving now to buying products in the late-stage development, say Phases II or Phase III.

**Miyamoto [A]:** Miyamoto will answer.

It is true that there is a large portion of unspent R&D funds in the landed fiscal year, but this does not mean that the funds were not used up because there were no late-stage products. Rather, there was a considerable number of projects running, each of which was a little off from the plan. So, the first point is that it is not because there were major delays or delayed major clinical studies.

Based on that, your question was about if we were thinking a large-scale M&A in the future. Licensing or acquisitions are always possibilities, as there is always an element of chance involved. We are not ruling them out, and we are constantly on the lookout for opportunities, although it should be within our capabilities. As for whether or not we have concrete plans, the answer is, as always, that we cannot answer.

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

You are saying that the JPY100 billion for this fiscal year is a reasonable level that can be used mainly for Phase III of rocatinlimab.

**Miyamoto [A]:** Yes, that's right. As I explained earlier, Phase III is now underway with Amgen, and there is talk an expansion of indications will begin.

The Orchard pipelines are coming in, so including the incremental investment from that, we are planning to make a much larger investment than in 2023, which I think is a perfectly reasonable plan.

**Wada [M]:** I understand. Thank you very much.

**Mamegano [Q]:** Thank you. My name is Mamegano from BofA. Thank you for taking my questions.

I have one question for you. Orchard's P&L for this fiscal year is JPY3 billion for gross profit, JPY8 billion for SG&A, and JPY10 billion for R&D. The impact on profit is a negative JPY15 billion for core OP. I would like to ask about the timing for Orchard to break even in the future.

I think these figures are for this fiscal year, but I wonder what will happen to R&D and SG&A expenses in the next fiscal year and beyond as sales grow. I would like to know more about that.

I think the plan for this fiscal year includes the approval of Libmeldy in the US, so expenses will not increase much, especially for SG&A expenses. Can you tell me if the plan for the future is made based on this fiscal year? Thank you.

**Miyamoto [A]:** Thank you, Mamegano-san. I, Miyamoto, would like to answer.

I may have spoken too fast in my presentation, but as I explained in the presentation, it will be extremely difficult to analyze Orchard's portion separately when we proceed with PMI in the future. So, we will not show this type of information in the future anymore.

To answer your question about when Orchard will break even, we are not making plans for each item, but rather, we will proceed to PMI. So, I think it is quite difficult to talk about the details separately.

Based on your understanding on this matter, Orchard had announced their outlook before merging with us. According to it, I believe Orchard was planning to break even in the next few years, if they were operating independently without our involvement, although this is speculative.

Sorry, this is all I can say, but I hope you don't mind.

**Mamegano [Q]:** Thank you very much. I'm sorry to be persistent, but since you are evaluating Orchard's assets and potential, I think R&D expenses will increase in the future. Is it correct to understand that SG&A expenses will not grow from here? I would appreciate it if you can comment on that part.

**Kawaguchi [A]:** I will answer, Kawaguchi.

It is my understanding that there will be no significant increase. Conversely, we would like to pursue cost synergies in here as well.

**Mamegano [M]:** I understand. Thank you very much.

**Akahane [Q]:** Since there is not so much time left, I would like to ask you a simple question, or rather, confirm how you will perform this fiscal year.

In the period just ended, core operating income increased by double digits. However, this fiscal year will see a double-digit decrease in operating profit, which is on pages 19 and 22. First of all, revenues are up 7%, and the overseas ratio will increase by 5%, which is the same as Poteligeo. In terms of value, Crysvita will also increase.

As you explained on page 22, the gross margin ratio will decrease by 1.5%. Can this be mostly explained by the change in the scheme associated with the shift to direct sales, as you explained, although there is also the issue of drug price reduction and co-payments for long-term listed products?

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

**Akahane [Q]:** So, everything else is neutral, I understand. On the other hand, the reason for this double-digit decrease in profit is that, as various people have mentioned many times, R&D expenses that are JPY100 billion for this fiscal year is dragging, which is an increase of JPY27.9 billion. As you mentioned earlier, there is also the cases of Orchard and rocatinlimab Phase III.

However, the achievement rate of the previous fiscal year was 91%, as has been mentioned many times. However, since this has been postponed for the current fiscal year, should we consider this JPY100 billion as a fairly high accuracy or certainty, including Orchard?

If so, would you say that your earnings forecast announced should be considered reasonable? Is my understanding correct that there is not much room for an upswing or anything like that at this point?

**Kawaguchi [A]:** We have a reasonable budget that is as achievable as possible, with a healthy stretch at this point, so there are no upside factors at this time. However, we would like to make efforts during the term to see an upward swing here.

**Akahane [Q]:** So, this JPY100 billion R&D should be looked at as highly accurate and precise?

**Kawaguchi [A]:** Regarding the JPY100 billion in R&D expenses, there are various reasons for this year's forecast, but we have included a certain amount of unused expenses in the forecast, which is based on the accumulated base.

In other words, the accumulated amount could surpass JPY100 billion, but we have factored in the probability of funds remaining unused in the JPY100 billion figure. So, at this point we are trying to avoid large unused funds like those in 2023.

However, since various circumstances will change during the period, we hope you will understand that we have incorporated our best estimate at this time.

**Akahane [M]:** I understand very well, thank you very much. That is all.

**Yamaguchi [Q]:** Sorry, just confirming. I'm afraid this is the second time.

One thing, Orchard's selling. Did the US include the 45? Also, I don't know where I might be able to find the results of the previous year, but if you have the results of the previous year, although you might not have it as you didn't buy them, could you please share them with us?

**Miyamoto [A]:** Thank you, Mr. Yamaguchi.

I have set the 45 on the assumption that it can be released in the US as well.

About the previous term, the disclosed amount is up to Q3, which is for nine months, and was USD14.8 million.

**Yamaguchi [Q]:** I understand. Thank you very much. One more thing, briefly.

About infigratinib, this is the first oral medicine for 6,000 patients. I think that existing products are being used for various purposes, such as growth hormone and surgical bone stretching and such.

What image do you have in terms of the degree of penetration of this drug and also the period of use. I was wondering if it is for a certain period of time since it is probably for children. Can you give me an image about that?

**Miyamoto [A]:** Thank you, Mr. Yamaguchi.

In fact, BioMarin has already launched the drug called VOXZOGO in the form of subcutaneous injections in Japan. We are making predictions based on the penetration of that product.

VOXZOGO is injected subcutaneously every day, but infigratinib can be taken orally. We made this deal with the projection that we would be able to capture a certain market share.

**Yamaguchi [Q]:** So, it will be the same positioning.

**Miyamoto [A]:** Yes. The target patients are exactly the same, so in that sense, I think we are in the same market.

**Yamaguchi [M]:** I understand. Thank you very much.

**Hyogo [Q]:** My name is Hyogo from Mitsubishi UFJ Trust and Banking Corporation. Let me ask you one last question.

About your approach to improve capital efficiency, I understand that you are making efforts to improve capital efficiency, such as share buybacks. However, what other measures are you taking to improve capital efficiency, other than share buybacks and dividend increases, given that R&D expenses tend to increase in the future? I am afraid that simply investing in R&D with the goal of expanding the pipeline may not enable you to surpass an ROE of 10% indefinitely.

So, my question is what kind of internal initiatives and projects to improve capital efficiency are running now? Please give us your comment on that, which I assume will be Mr. Kawaguchi.

That is all.

**Kawaguchi [M]:** Thank you for your question.

The purpose of your question is to talk about improving the denominator rather than the numerator to enhance profitability.

**Hyogo [Q]:** Yes. Even if the top line does not change.

**Kawaguchi [A]:** This is exactly in the Story for Vision 2030 introduced on page 15, which is a strategy to focus on our vision, to be efficient, and to increase future value. We believe that this will help us improve profitability.

We will have an opportunity to introduce things more specifically as we develop strategies and tactics. Broadly speaking, we hope that you will understand that this Story for Vision 2030 will lead to improved capital efficiency.

**Hyogo [Q]:** Because there is quite a qualitative way of saying, it is difficult for external people to understand how effective they are. So, I would like to know how much this will lead to such efficiency at an appropriate timing. In addition, I am hoping that you will slim down the balance sheet a bit, so that you can generate a bit more cash. I would appreciate it if you could explain these points as well.

I feel that it is difficult to understand things with your qualitative explanation unless you give us figures.

That is all. Thank you very much.

**Moderator [M]:** Thank you very much. We are sorry, but this concludes the online presentation on the financial results for the fiscal year ended December 31, 2023.