Kyowa Kirin Co., Ltd.

Financial Results for the Fiscal Year 2020 & Medium Term Business Plan Briefing

February 5, 2021

Event Summary

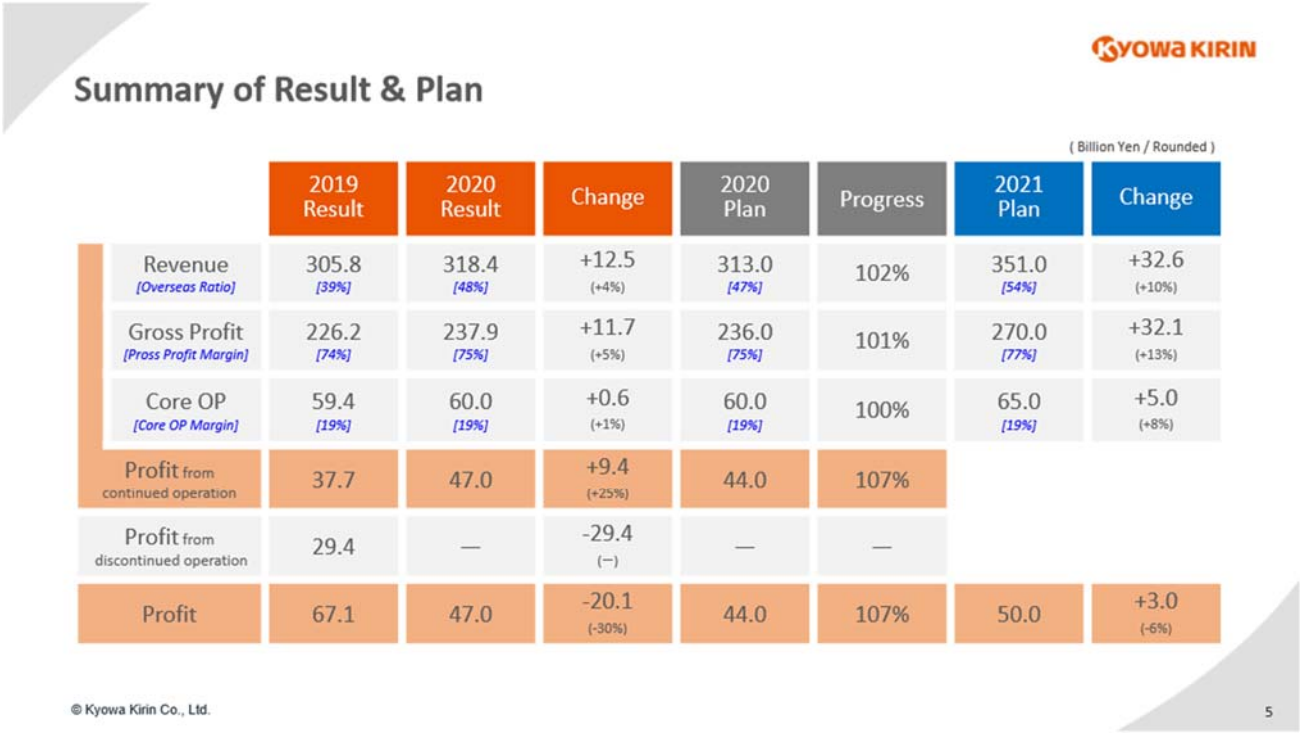
[Event Name]	Financial Results for the Fiscal Year 2020 & Midterm Business Plan Briefing	
[Date]	February 5, 2021	
[Number of Speakers]	4	
	Masashi Miyamoto	President, CEO
	Motohiko Kawaguchi	Executive Officer, Head of Finance
	Yoshifumi Torii	Executive Officer, Vice President, Head of R&D
	Tomohiro Sudo	Executive Officer, Head of Strategic Product Planning

Presentation

Moderator: We will now begin the online briefing meeting for Kyowa Kirin Co., Ltd.'s full-year financial results of the fiscal year ended December 2020 and the 2021-2025 Medium-Term Business Plan, which we announced at 3:30 PM yesterday.

We have four speakers today: Masashi Miyamoto, President & CEO; Motohiko Kawaguchi, Executive Officer and Head of Finance; Yoshifumi Torii, Executive Officer, Vice President, and Head of R&D; and Tomohiro Sudo, Executive Officer and Head of Strategic Product Planning.

Miyamoto will now give the presentation.



Miyamoto: This is Miyamoto. Ladies and gentlemen, thank you for joining us today.

I would now like to present the full-year financial results for the fiscal year ended December 2020.

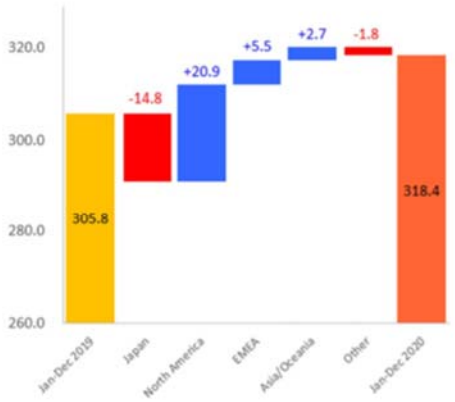
Please turn to page five of the financial results presentation material. In 2020, revenue was JPY318.4 billion and core operating profit was JPY60 billion. Despite the impact of COVID-19, compared to 2019, we were able to achieve growth in revenue and profit. Profit was JPY47 billion, which is a decline from last year, but this is because of the dropout of the gain on the sale of Kyowa Hakko Bio in 2019.

Compared to the revised plan, we achieved 100% or more of all targets. Results were in line with our forecast.

I will explain the 2021 plan again later. We expect 10% growth in revenue and 8% growth in core operating profit.

FY2019 vs FY2020 -Revenue-

+12.5 billion yen (incl. forex effect -2.9)



- **Japan -14.8**
  In addition to newly-launched Crysvita, Romiplate (Additional indication), Rituximab BS (Penetration) and G-Lasta (Expanded market) made strong growth. However, Nesp (Shift to Nesp-AG) and Patanol/Allelock (Lower pollen) were down greatly. In addition, there were negative impact by NHI price-cut applied on Oct 2019 & Apr 2020 and the pandemic.
- **North America +20.9 (incl. forex effect -0.9)**
  Crysvita (launched in 2018) maintained a steady growth. Nourianz (launched in 2019) was also up. Poteligeo was at the same level as 2019 due to the pandemic.
- **EMEA +5.5 (incl. forex effect -1.1)**
  Crysvita (launched in 2018) maintained steady growth (including EAP revenue; label expanded to adolescent & adult in Sep). Poteligeo increased after its launch in Germany etc. On the other hand, Abstral was down due to emergence of generics.
- **Asia/Oceania +2.7 (incl. forex effect -0.5)**
  Regpara kept growing in China.
- **Other -1.8 (incl. forex effect -0.4)**
  - Sales royalties of Fasenra (Benralizumab) made steady growth, but revenue from FKB, contracted manufacturing , and exports etc shrank.

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Please see page six. This is a breakdown of revenue by region. Although the Japan business posted a revenue decline due to the impact of NHI price cut and the patent expiration of NESP, this was offset by the significant revenue growth in North America. In addition, growth was steady in EMEA and Asia.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2019 Result	2020 Result	Change	Reason	2021 Plan	Change	Reason
Nesp + Nesp-AG*	47.6	29.5	-18.1 (-38%)	Nesp-AG launched in Aug 2019 and Biosimilars' penetration	23.2	-6.3 (-21%)	Biosimilars' penetration and NHI price-cut
Nesp	33.6	4.4	-29.3 (-87%)		3.8	-0.6 (-13%)	
Nesp-AG	14.0	25.4	+11.2 (+80%)		19.4	-5.8 (-23%)	
Duvroq	—	0.6	+0.6 (—)	Launched in Aug 2020	4.0	+3.4 (+593%)	Market penetration
Regpara	6.5	3.8	-2.7 (-41%)	Switch to Orkedia	2.0	-1.8 (-48%)	Switch to Orkedia
Orkedia	6.9	9.1	+2.2 (+31%)	Steady market penetration	10.4	+1.3 (+14%)	Switch from Regpara
G-Lasta	24.6	26.7	+2.1 (+8%)	Market expansion	29.8	+3.1 (+12%)	Market expansion
Poteligeo	2.0	2.1	+0.1 (+6%)		2.0	-0.1 (-5%)	
Rituximab BS	9.7	11.8	+2.1 (+22%)	Market penetration	11.5	-0.3 (-2%)	NHI price-cut
Romiplate	4.9	7.6	+2.8 (+57%)	Indication expanded in Jun 2019	8.7	+1.1 (+15%)	Market penetration
Allelock	10.8	8.6	-2.2 (-21%)	Lower pollen and COVID-19	6.8	-1.8 (-21%)	Competitors
Patanol	13.6	10.6	-3.0 (-22%)	Lower pollen and COVID-19	10.9	+0.3 (+3%)	
Nouriast	9.7	9.4	-0.4 (-4%)	COVID-19 and competitors	9.1	-0.3 (-3%)	Competitors
Haruropi	0.1	0.9	+0.8 (+878%)	Launched in Dec 2019	4.6	+3.6 (+402%)	Market penetration
Crysvita	0.1	3.8	+37 (—)	Launched in Dec 2019	5.5	+1.7 (+46%)	Market penetration
Tech-licensing	4.6	2.0	-2.6 (-57%)	FKB	2.5	+0.5 (+23%)	

* 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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I will explain the details for each item, so please see page seven. First, this is the major items in Japan. Nesp and Nesp-AG are down JPY18.1 billion YoY. These two are the biggest factors behind the revenue decline in Japan. It looks like the penetration of biosimilars has slowed at present. However, in the medium term, we believe its penetration will make more progress. In 2021, we brace for a revenue decline of about JPY6 billion, including the impact of the 2021 NHI price cut.

Revenue from Duvroq, which is a HIF-PH inhibitor launched at end-August, came to JPY600 million. This is a new drug in the renal field, which is our strength, so we aim for JPY4 billion in 2021.

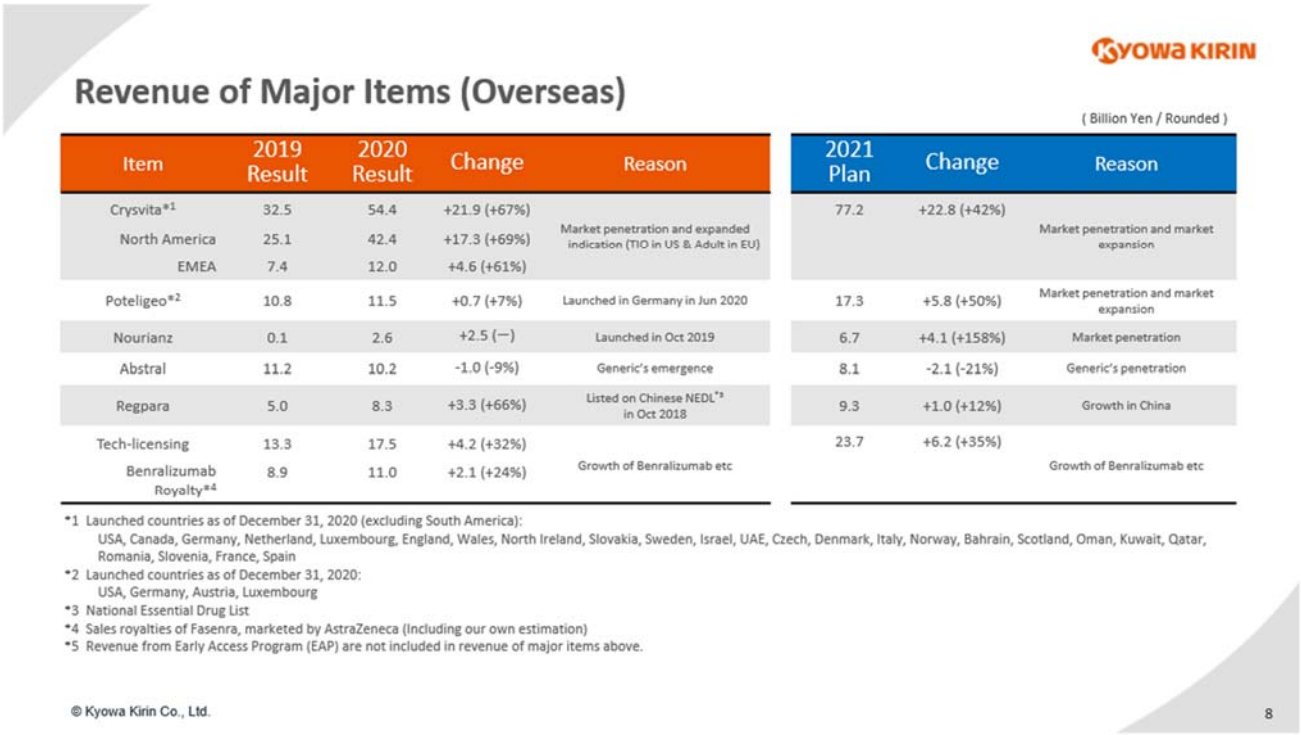
As for G-Lasta, demand is increasing due to the appearance of new anti-cancer drugs. As a result, revenue has increased significantly. Due to COVID-19, cancer examinations are being canceled or postponed, leading to a decrease in patients. Still, we expect ongoing growth in 2021.

Rituximab Biosimilar has been growing very steadily since its launch in January 2018; however, expect a slight revenue decline in 2021 in consideration of NHI price cut.

As for the new drug Haruropi, we think the bottlenecks this year were the restrictions on medical representatives' activities under COVID-19 and the fact it could not be used for long-term prescriptions because it was newly launched. In 2021, we forecast robust growth to JPY4.6 billion.

As for Crysvita, we were a little worried about penetration because of COVID-19, but it has gained steady penetration, and revenue expanded. We will continue to strive for further market penetration in 2021.

Regarding tech-licensing revenue in Japan, the one-time revenue related to FKB in 2019 dropped out, so revenue declined. In 2021, we expect revenue to increase, driven by the growth of Hulio (Adalimumab Biosimilar).



KYOWA KIRIN

Revenue of Major Items (Overseas)

(Billion Yen / Rounded)

Item	2019 Result	2020 Result	Change	Reason	2021 Plan	Change	Reason
Crysvita*1	32.5	54.4	+21.9 (+67%)	Market penetration and expanded indication (TIO in US & Adult in EU)	77.2	+22.8 (+42%)	Market penetration and market expansion
North America	25.1	42.4	+17.3 (+69%)				
EMEA	7.4	12.0	+4.6 (+61%)				
Poteligeo*2	10.8	11.5	+0.7 (+7%)	Launched in Germany in Jun 2020	17.3	+5.8 (+50%)	Market penetration and market expansion
Nourianz	0.1	2.6	+2.5 (—)	Launched in Oct 2019	6.7	+4.1 (+158%)	Market penetration
Abstral	11.2	10.2	-1.0 (-9%)	Generic's emergence	8.1	-2.1 (-21%)	Generic's penetration
Regpara	5.0	8.3	+3.3 (+66%)	Listed on Chinese NEDL*3 in Oct 2018	9.3	+1.0 (+12%)	Growth in China
Tech-licensing	13.3	17.5	+4.2 (+32%)	Growth of Benralizumab etc	23.7	+6.2 (+35%)	Growth of Benralizumab etc
Benralizumab Royalty*4	8.9	11.0	+2.1 (+24%)				

*1 Launched countries as of December 31, 2020 (excluding South America):
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Norway, Bahrain, Scotland, Oman, Kuwait, Qatar, Romania, Slovenia, France, Spain
*2 Launched countries as of December 31, 2020:
USA, Germany, Austria, Luxembourg
*3 National Essential Drug List
*4 Sales royalties of Fasenra, marketed by AstraZeneca (Including our own estimation)
*5 Revenue from Early Access Program (EAP) are not included in revenue of major items above.

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Next, please see page eight. These are the major items in the overseas business. For Crysvita, we did not reach the initial target, but we exceeded the revised target. Newly launched countries include France in October and Spain at the end of the year. Revenue combined with Japan came to JPY58.2 billion.

For Poteligeo, we received a recommendation from NCCN regarding frequency of hospital visits and administrations. Although revenue in the US was flat from last year, revenue in Germany, where the drug was launched in June, contributed significantly to the revenue growth. The launched countries in Europe have not changed from Germany, Austria, and Luxembourg.

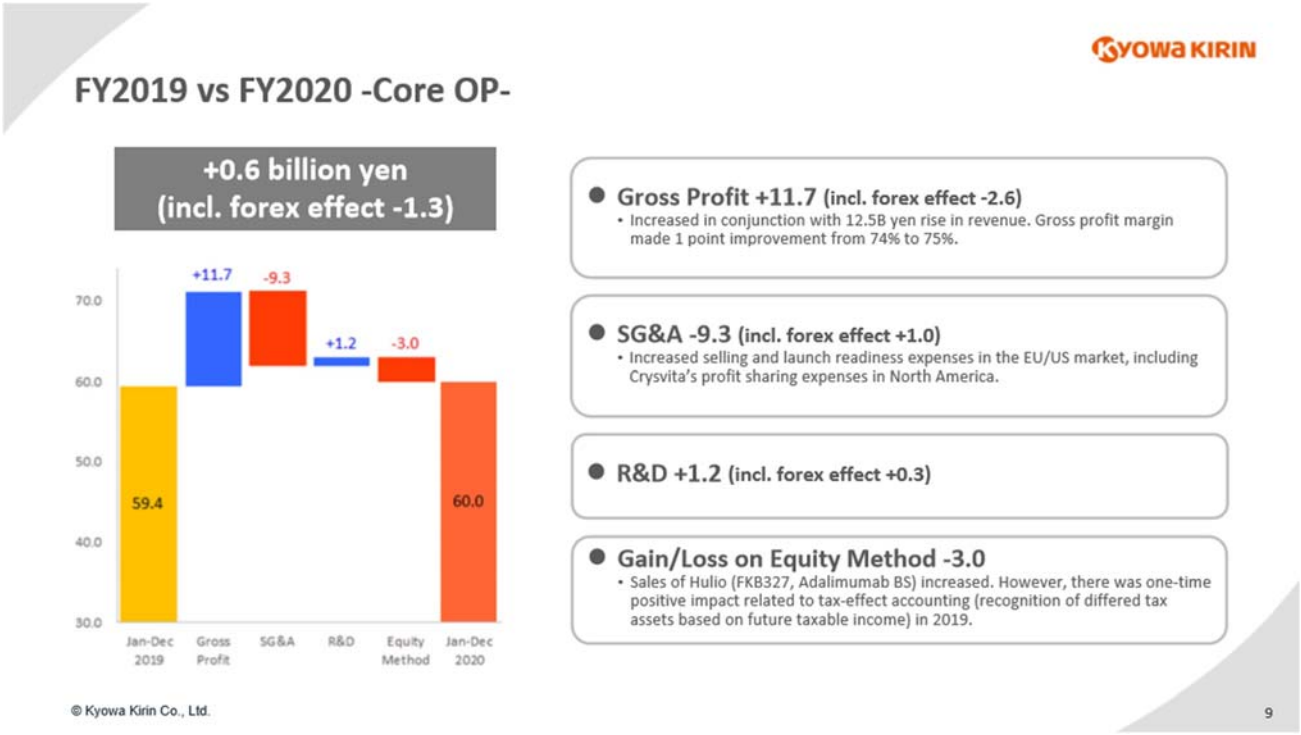
Nourianz was launched in October 2019 in the US, so almost all of the revenue in 2020 has been a revenue growth factor.

As you can see, we expect the sizable growth for these three global strategic drugs to continue in 2021.

Abstral revenue declined due to the launch of generic drugs in Spain in July. We expect the revenue downtrend to continue in 2021.

Regpara revenue continued to be solid in China. We expect revenue growth to continue in 2021.

Overseas tech-licensing revenue expanded, mainly due to an increase in Benralizumab royalty. We expect ongoing revenue growth in 2021, driven by Benralizumab's growth.



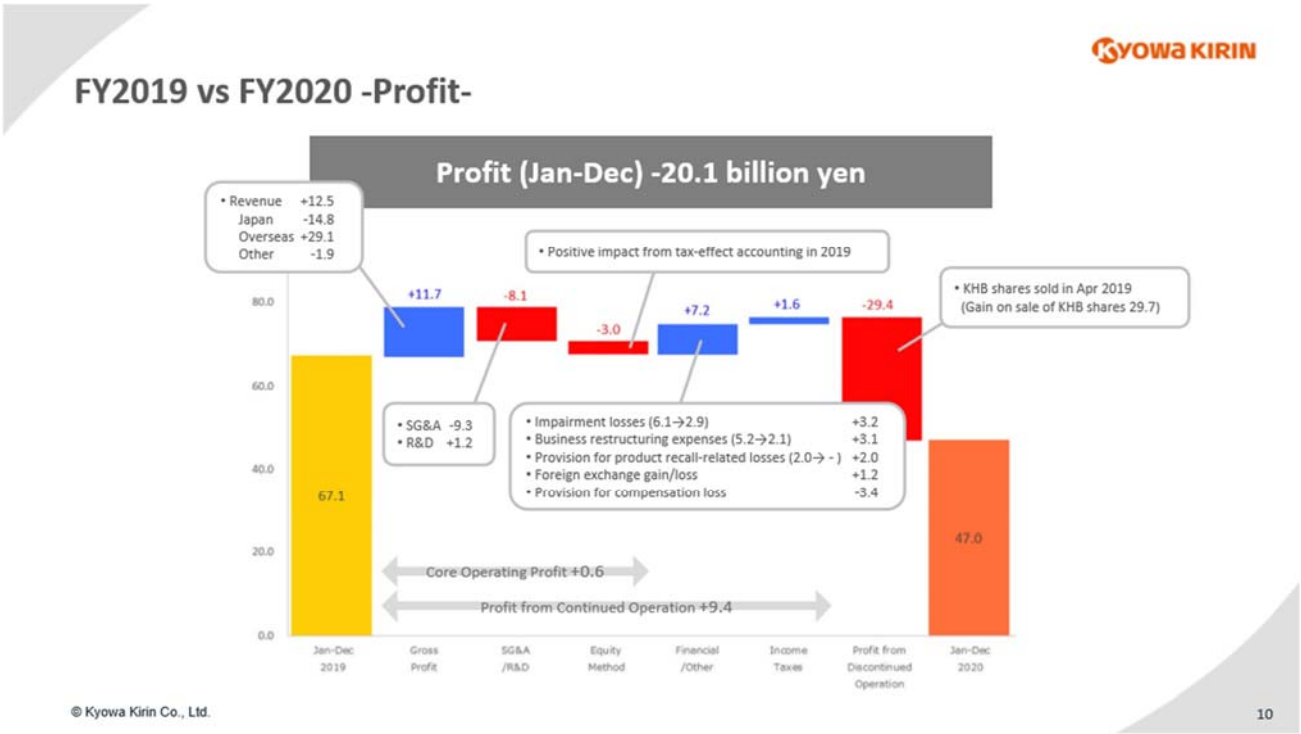
Please see the next page for the chart analyzing the difference between gross profit and core operating profit. Gross profit increased by JPY11.7 billion, thanks to higher revenue. The gross profit margin improved by 1%, owing to the revenue growth of high-margin drugs like Crysvita.

SG&A expenses reduced profit by JPY9.2 billion, as Crysvita's profit sharing expenses in North America increased in parallel with revenue growth and selling-related expenses increased in the EU/US.

R&D expenses were down by JPY1.2 billion, or roughly the same as 2019.

Equity in earnings of affiliates decreased by JPY3 billion. Revenue grew steadily for Hulio, which is a biosimilar of Humira. However, profit declined significantly in 2020 due to the dropout of the tax effect that had a positive effect in 2019.

As a result of the above, core operating profit increased by JPY0.6 billion YoY.



On the next page, I will explain the factors behind the difference in financial and other income and expenses. In the center, you see a large bubble. Inside it are the factors behind the JPY7.2 billion boost to profit.

The first factor is impairment losses. In 2019, we booked impairment losses on the sales rights of Moventig, which we in-licensed from AstraZeneca. On the other hand, in 2020, we recorded impairment losses on in-process R&D expenses for KHK2375. On net, this factor increased profit by JPY3.2 billion.

The second factor is business restructuring expenses. In 2019, we booked special retirement allowance for voluntary retirement in Japan. In 2020, we recorded costs related to business restructuring at a European subsidiary. On net, this factor increased profit by JPY3.1 billion.

The third factor is the provision for product recall-related losses. In 2020, we did not book these losses.

The fourth factor is foreign exchange gain or loss. In 2019, there was a foreign exchange loss, but this reversed in 2020 to a foreign exchange gain, resulting in a significant difference.

The fifth factor is the provision for compensation loss. We have received a compensation claim from Kirin Holdings based on the share transfer agreement of Kyowa Hakko Bio. To prepare for the expenses to be incurred in connection with this claim, we recorded a provision in the third quarter. We are continuing discussions on this matter with the help of outside experts.

FY2021 Plan

(Billion Yen / Rounded)

	2019 Result	2020 Result	2021 Plan	Change
Revenue *[Overseas Ratio]*	305.8 *[39%]*	318.4 *[48%]*	351.0 *[54%]*	+32.6 (+10%)
Gross Profit *[Gross Profit Margin]*	226.2 *[74%]*	237.9 *[75%]*	270.0 *[77%]*	+32.1 (+13%)
SG&A *[S&G Ratio]*	117.3 *[38%]*	126.6 *[40%]*	141.0 *[40%]*	+14.4 (+11%)
R&D *[R&D Ratio]*	53.5 *[17%]*	52.3 *[16%]*	65.0 *[19%]*	+12.7 (+24%)
Gain/Loss on Equity Method	4.0	1.0	1.0	+0.0 (+4%)
Core Operating Profit *[Core OP Margin]*	59.4 *[19%]*	60.0 *[19%]*	65.0 *[19%]*	+5.0 (+8%)
Profit	37.7 (Only Continued Business)	47.0	50.0	+3.0 (+6%)

Next, on page 11, I will explain the financial results forecast for 2021. We forecast revenue of JPY351 billion, an increase of JPY32.6 billion, or 10%, driven by further growth of global strategic products. We forecast gross profit to increase by 13% on a further improvement in the profit margin.

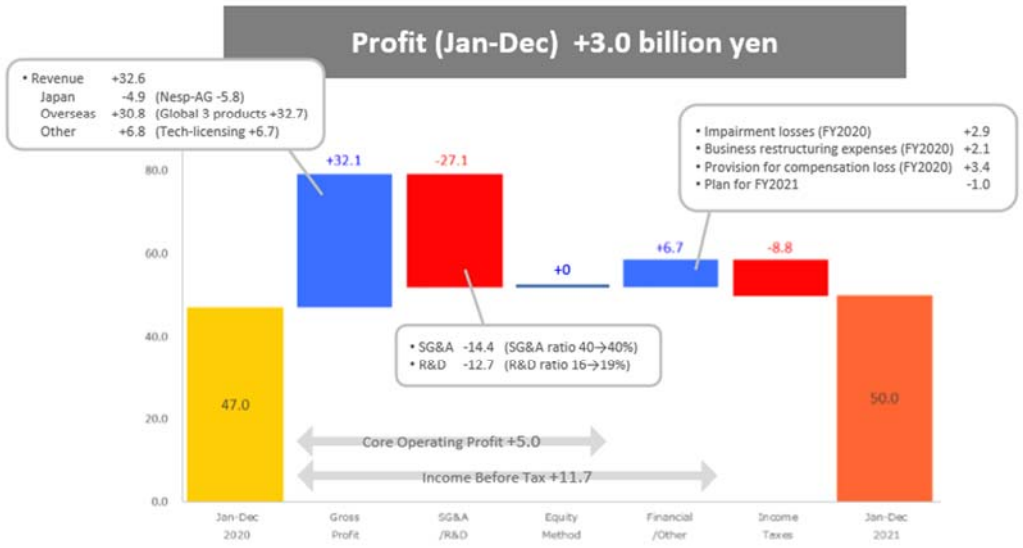
We forecast increases of JPY14.4 billion in SG&A and JPY12.7 billion in R&D compared to 2020. One reason we expect higher SG&A is due to Crysvita's profit sharing expenses. We also anticipate an increase in selling expenses and launch readiness expenses due to expanding sales of Crysvita, Poteligeo, and Nourianz in Europe. Furthermore, we incorporate increased expenses for the quick establishment of global business infrastructure to support our sustainable growth as a global specialty pharmaceutical company, including investments in IT, digital, and personnel.

As a result, the SG&A expenses-to-revenue ratio is unchanged from FY2020 at 40%. But, by investing in these foundational areas of the business, we believe that we can strengthen cost controls down the road. In the five-year medium-term plan, we aim to reduce SG&A expenses to raise profitability even further.

On the other hand, we expect R&D expenses to lower the core operating profit margin in 2021. Development expenses will increase in parallel with advancements in the stages of KW-6356, ME-401, and KHK7791. KHK4083 has not been unblinded yet, so the results are not out yet. We incorporate some readiness expenses for Phase three study. As a result, we expect the R&D expenses-to-revenue ratio to increase by 3% to 19%, from 16%, and this will lower the core operating profit. Please understand this as an investment in innovation for our longer-term growth.

As a result, we forecast core operating profit of JPY65 billion, up 8% YoY. After subtracting income taxes, we forecast a full-year profit of JPY50 billion, up 6% YoY.

FY2020 vs FY2021 (Plan) -Profit-



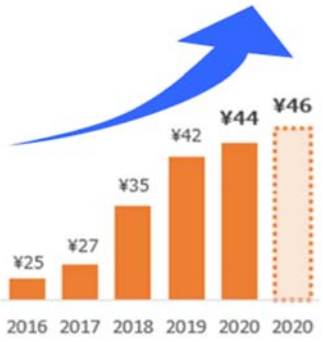
Page 12 illustrates a breakdown of what I just described.

Shareholder Return Plan

- ✓ FY2020 dividend to be **44** yen, and FY2021 planned to be **46** yen
- ✓ **Consecutive up** during FY16-20 term aiming "Leap forward to GSP"
- ✓ 5yr average payout ratio is **39.7%** (against the policy to make it approx. 40%)

Year	Dividend (yen)			Payout Ratio*1	Return on Equity
	Interim	Year-end			
2016	12.50	12.50	25.00	44.9%	5.3%
2017	12.50	14.50	27.00	34.4%	7.2%
2018	15.00	20.00	35.00	35.2%	8.6%
2019*2	20.00	22.00	42.00	33.7%	10.1%
2020	22.00	22.00	44.00	50.3%	6.8%
2021 (Plan)	23.00	23.00	46.00	48.5%	7.0%

*1 Payout ratio for 2021 is the one based on the core earnings (Profit - Other income/loss - Income tax related to the other income/loss)
*2 Repurchase of 10.7M own shares (¥22.6B) executed on February 6, 2019. Total return ratio is 67.3% in 2019.



Next, please see page 14. This is our shareholder return plan. We decided to pay an annual dividend of JPY44 per share in 2020. In 2021, we forecast a JPY2 increase to JPY46 per share, implying a fifth consecutive period of a dividend increase.

As you can see in this chart, we achieved a consecutive dividend increase throughout the previous medium-term plan, and the average payout ratio over the five years was 39.7%. I will explain our future shareholder return policy in the next presentation on the new medium-term plan.

Key Development Updates in 20Q4

- **Initiation of the pivotal phase 2 study of ME-401 for the treatment of indolent B-cell non-Hodgkin's lymphoma in Japan (October)**
- **Announcement of the positive phase 2b results for KW-6356 in patients with Parkinson's disease in Japan (October)**
- **Presentation of phase 2 study data on KHK7791 for the treatment of hemodialysis patients with hyperphosphatemia in Japan at ASN (October)**
- **Marketing authorization application of KRN23 for TIO in China (October)**
- **Approval of marketing authorization of KHK4827 for psoriasis in Malaysia (November) and partial change approval for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis in Japan (November)**
- **Completion of phase 1 study of automated injection device of KRN125 (G-lasta®) in Japan**
  > To be filed during 21Q3 in collaboration with Terumo Corporation
- **Initiation of an innovative collaboration with Axcelead in small-molecule drug development in Japan (October)**
- **Initiation of an AI-powered novel target discovery collaboration with InveniAI (December)**

Next is the section on R&D. Please see page 16. Let me briefly update you on the key development in R&D during the fourth quarter.

I will skip the first three bullet points, because they are the same as what I explained at the third quarter briefing. The fourth point is that we have applied for authorization of KRN23 for treatment of TIO in China. We will continue to work toward expanding the indications in each country.

We are continuing life cycle management for KHK4827 (Lumicef), such as adding countries in the Asia Pacific and expanding indications in Japan.

We completed the phase one study in Japan of KRN125 (G-Lasta) for the safety evaluation of automated injection device, which was started in February last year. We are making preparations aiming for application in the third quarter this year in cooperation with Terumo Corporation, which is in charge of the device.

I will skip the two points on the bottom because we explained those during R&D Day in last December.

Key Development Updates after December

- Initiation of the phase 3 study of RTA 402 for autosomal dominant polycystic kidney disease in Japan (January)
- Approval of marketing authorization of KRN23 for XLH in China (January)
- Marketing authorization application of KRN23 for TIO in Europe (January)

Please see page 17. These are the key development topics after January. We initiated the phase three study of RTA 402 for ADPKD (autosomal dominant polycystic kidney disease) in Japan.

We received approval of marketing authorization of KRN23 for XLH (X-linked hypophosphatemia) in China, and applied KRN23 for TIO in Europe.

Key Business Updates in 20Q4 and in January 2021

- Started construction on the New Quality Building (biopharmaceutical analysis facility) at the Takasaki Plant in Japan (October 2020)
- Approval for Partial Change of Rituximab Biosimilar for the treatment of acquired thrombotic thrombocytopenic purpura in Japan (November 2020)
- Crysvita® has become available to be reimbursed as a self-injection formulation in Japan (December 2020)
- Approval of Dovobet® Foam for Psoriasis Vulgaris in Japan (January 2021)

Next, I will explain the business topics. Please turn to page 19. We have issued a press release for each of these topics, so I will only go over the key points.

In November, we started construction on the New Quality Building at the Takasaki Plant. We will invest about JPY14 billion in the New Quality Building. The completion is slated for July 2022, and we expect it to come online in October of the same year.

In November, we received approval for a partial change of Rituximab Biosimilar.

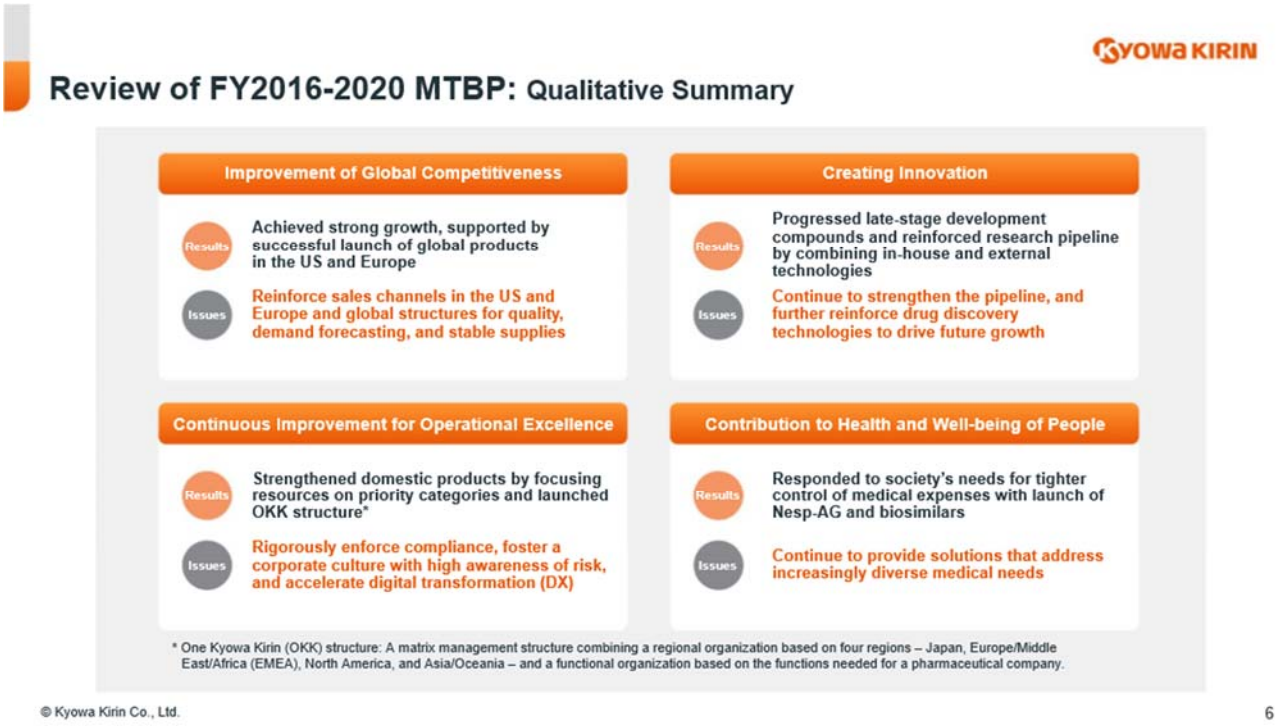
Crysvita has become available for reimbursement as a self-injection formulation. This allows patients to inject the drug on their own at home under the guidance and management of doctors, resulting in a reduced frequency of hospital visits. We believe this will improve convenience and patient QOL.

In January, we received manufacturing and marketing approval for Dovobet Foam. In Japan, we have already released an ointment in 2014 and a gel in 2018. The foam type that was approved this time has superior extensibility and is a dosage that can be easily applied in a relatively short time. We hope that it will further improve convenience for patients.

This concludes my presentation on the financial results.

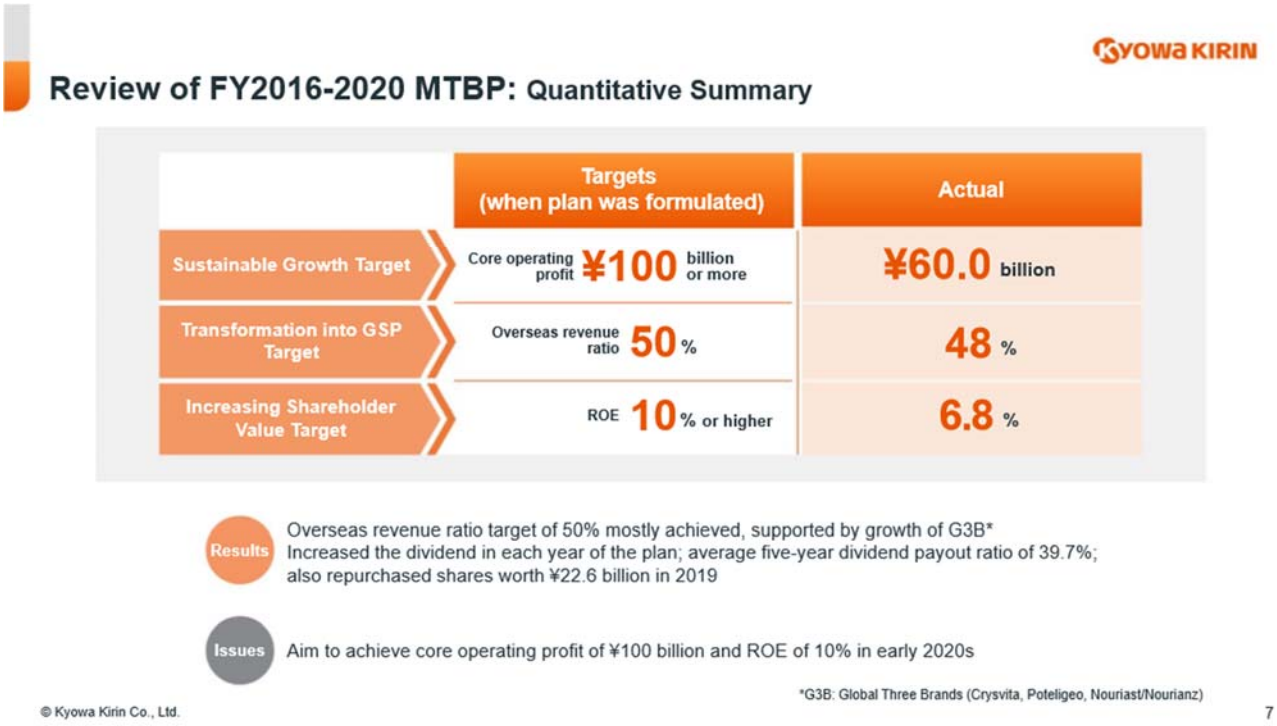
Next, I would like to present the 2021-2025 Medium-Term Business Plan.

First, I will review the previous five-year medium-term plan. In the 2016 medium-term plan, we had these four strategic pillars and three financial KPIs. We had just gotten off to a start aiming to leap forward to become a global specialty pharmaceutical company.



Qualitatively, we believe we have delivered results across all four of these strategic pillars shown here. We successfully launched all three global strategic products overseas. We are making progress on subsequent clinical trials of the next development pipeline. And the research pipeline is also being enhanced.

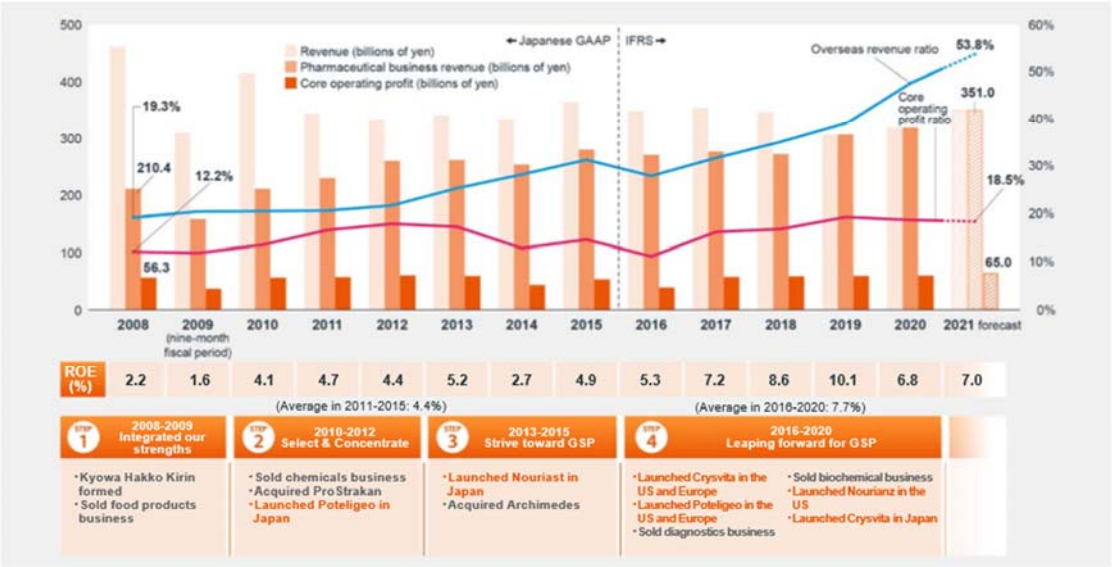
On the other hand, the issues we must tackle to achieve further growth have become clear. To realize sustainable growth over the medium term, we are aware of the need to reflect these issues into the 2021 medium-term plan and work on them.



Quantitatively, we pushed back the achievement schedule of the three KPIs during the medium-term period. The overseas revenue ratio, which is a key indicator for our transformation into a global specialty pharmaceutical company, has increased to 48%, which is significantly higher than 28% in the first year of the medium-term plan.

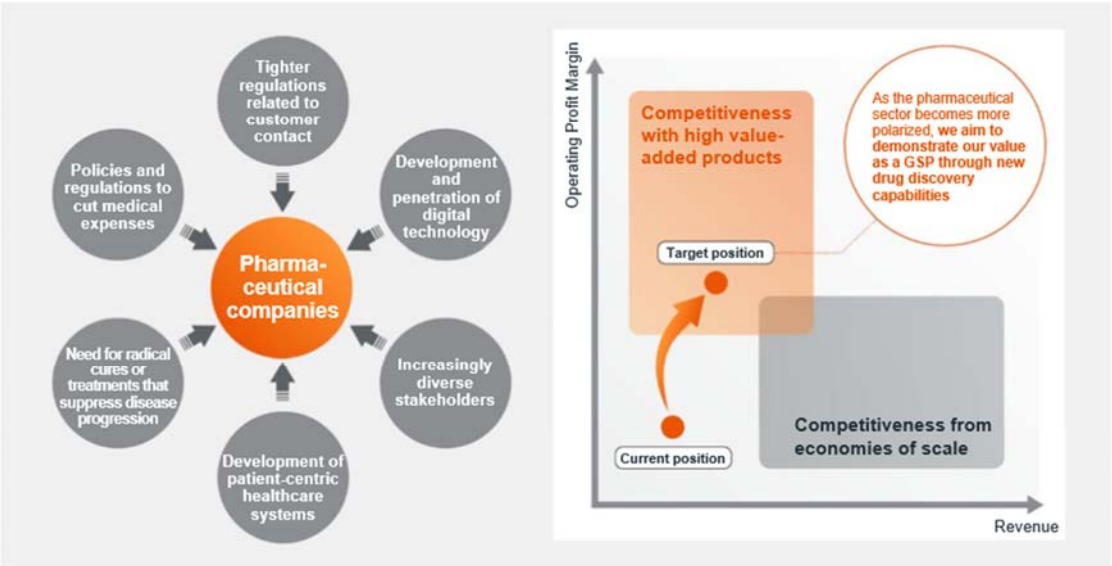
On the other hand, core operating profit and ROE are ongoing issues that will be addressed in our 2021 medium-term plan starting this year. To achieve these targets, we will manage growth investments and cost control in a balanced manner to ensure our growth momentum as a global specialty pharmaceutical company.

Strive and Leap for GSP

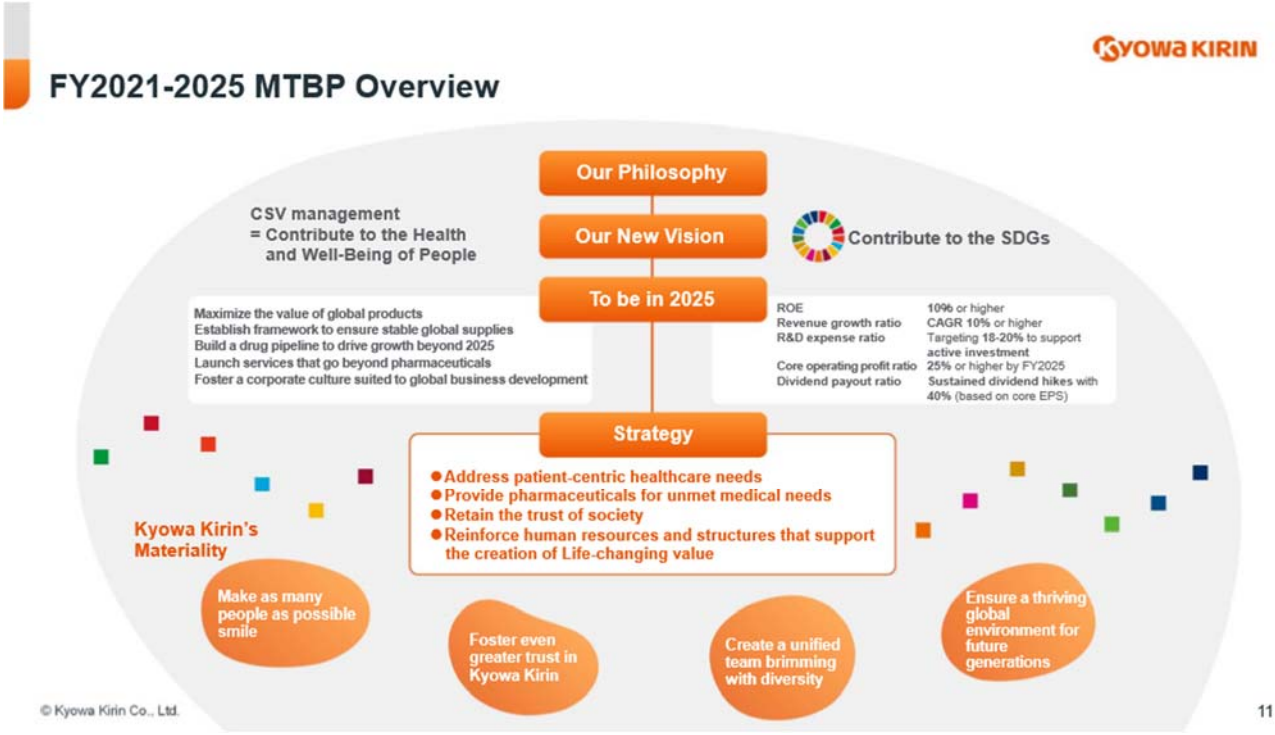


As we have stated before, there are still issues to be addressed, but we believe we have made a certain degree of achievement in our goal of “Strive and Leap for Global Specialty Pharmaceutical Company,” which has been our goal since the company was founded. Toward this end, we have formulated a new vision and strategies for achieving this vision.

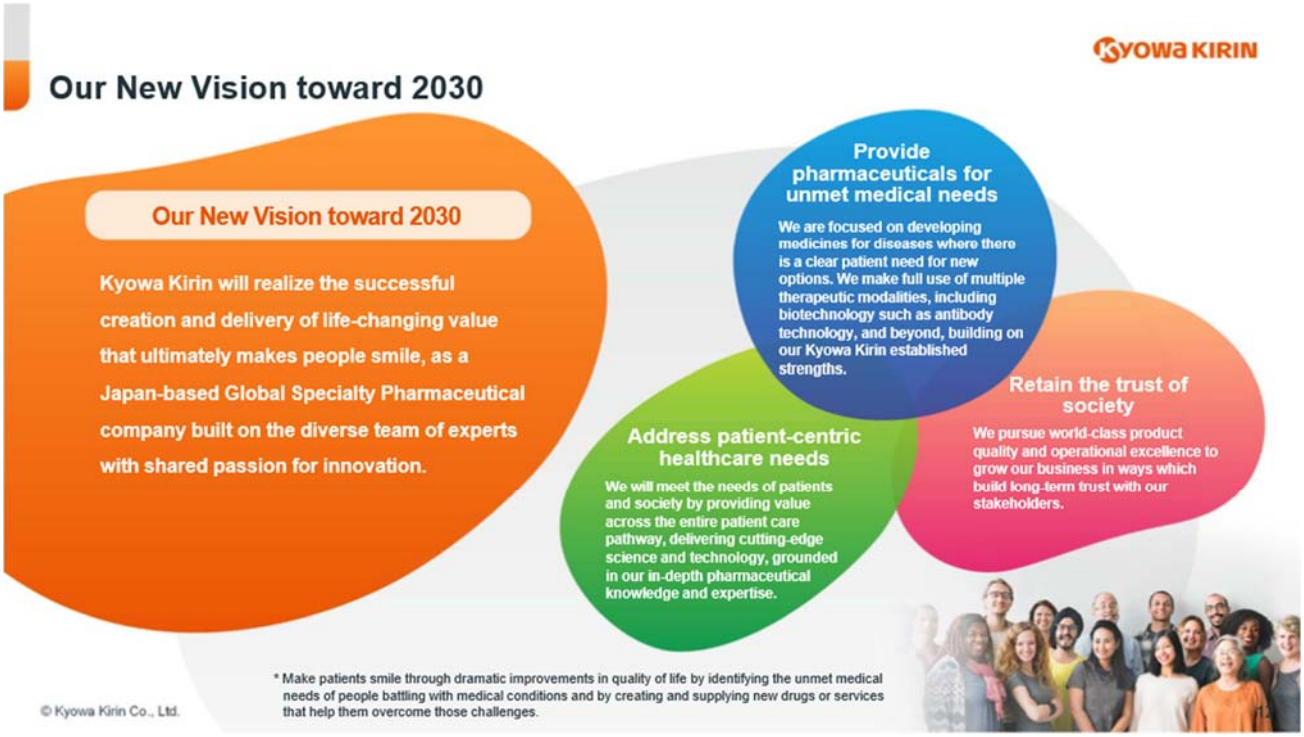
Analysis of Operating Environment and Our Target Position



I will now begin the presentation on the new medium-term plan. This slide will briefly go over the analysis of the operating environment and our target position.

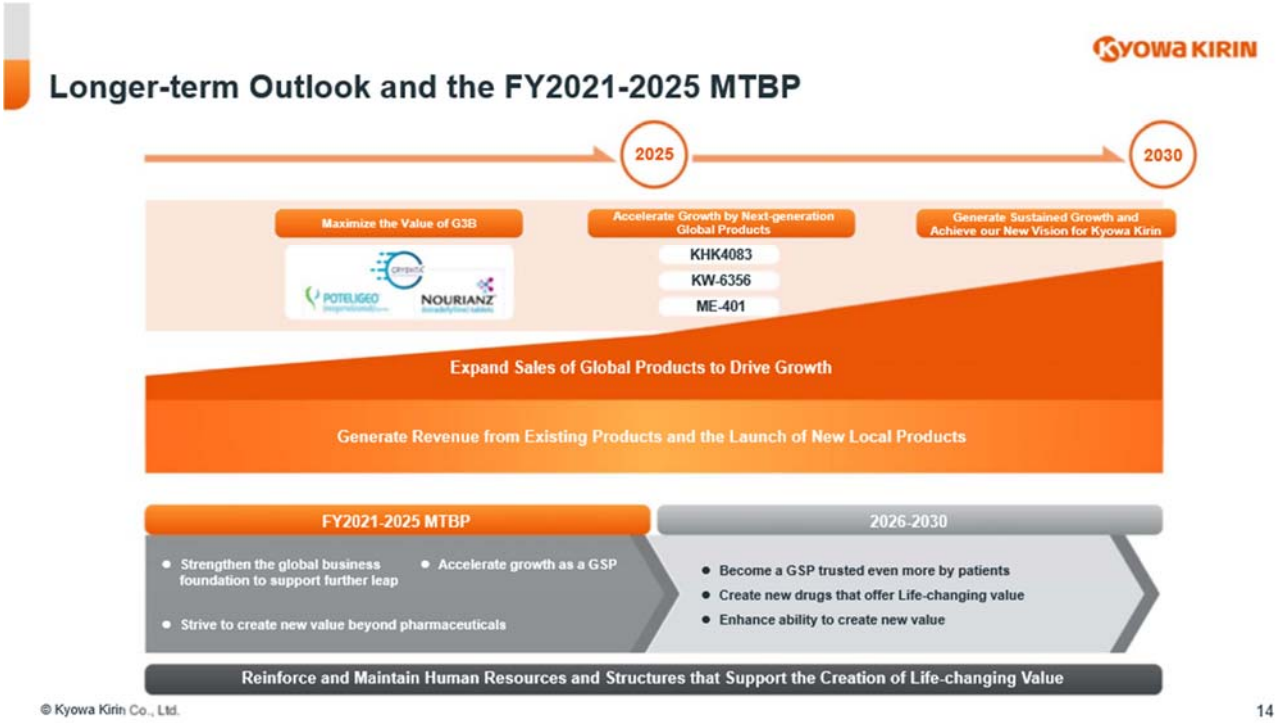


In formulating the 2021 medium-term plan, we reviewed the previous medium-term plan and our materiality. From the standpoint of achieving our own growth while responding to the demand and expectations of society, we set qualitative and quantitative goals as part of our 2025 vision. We incorporated the items that we must work on in the next five years into our strategy to realize our vision.



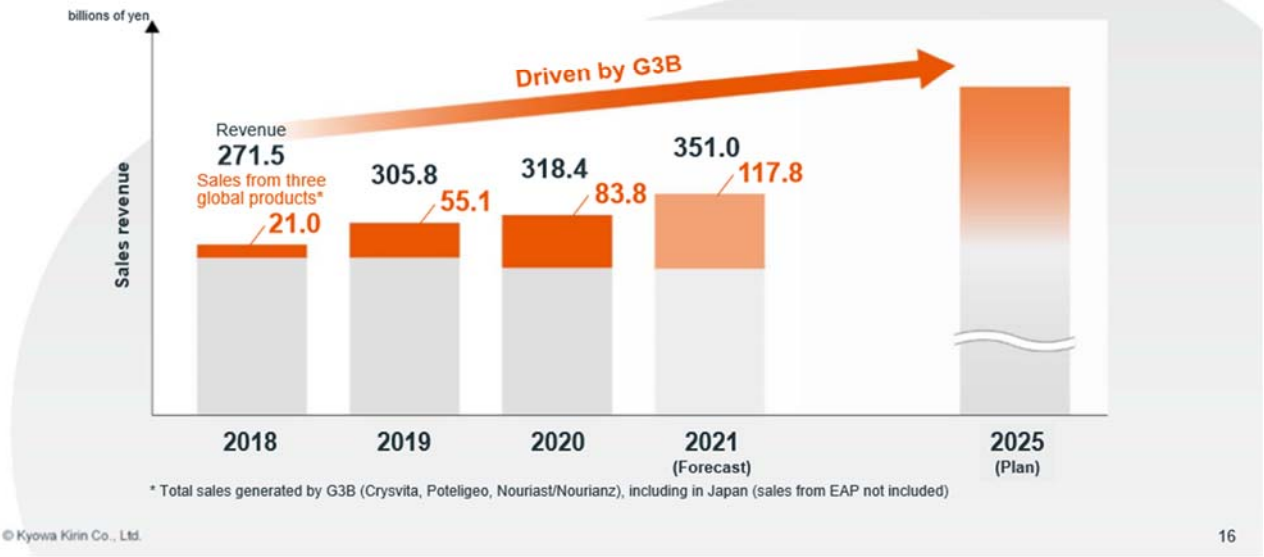
This is the new vision. Our vision toward 2030 is “to realize the successful creation and delivery of life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on a diverse team of experts with a shared passion for innovation.”

Toward the realization of this 2030 vision, we have set three core strategies to achieve these five key targets. We will reinforce human resources and digital structures to implement and realize these strategies.



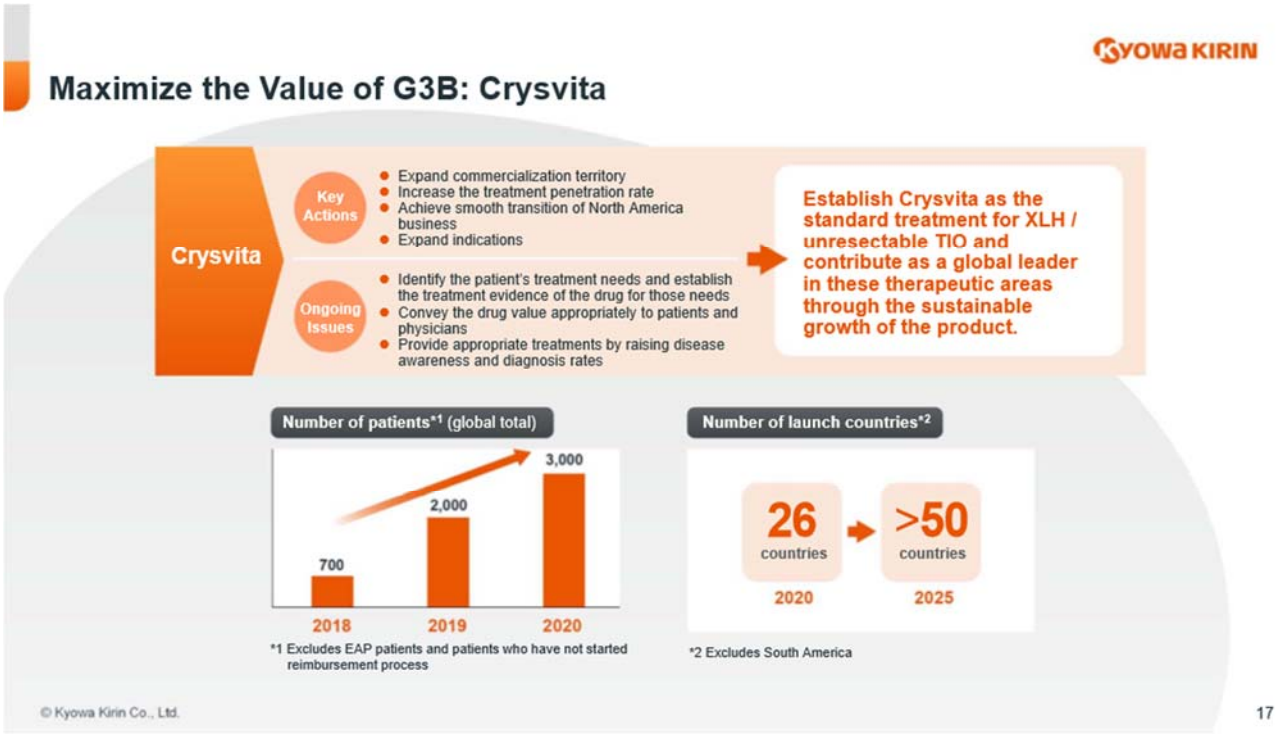
Over the longer term, we will accelerate growth by successfully developing next-generation global strategic products by 2030, in addition to the global strategic products that are currently driving growth. Furthermore, we aim for sustainable growth beyond 2030 by establishing new pipelines and drug discovery technologies.

Maximize the Value of Global Three Brands (G3B)



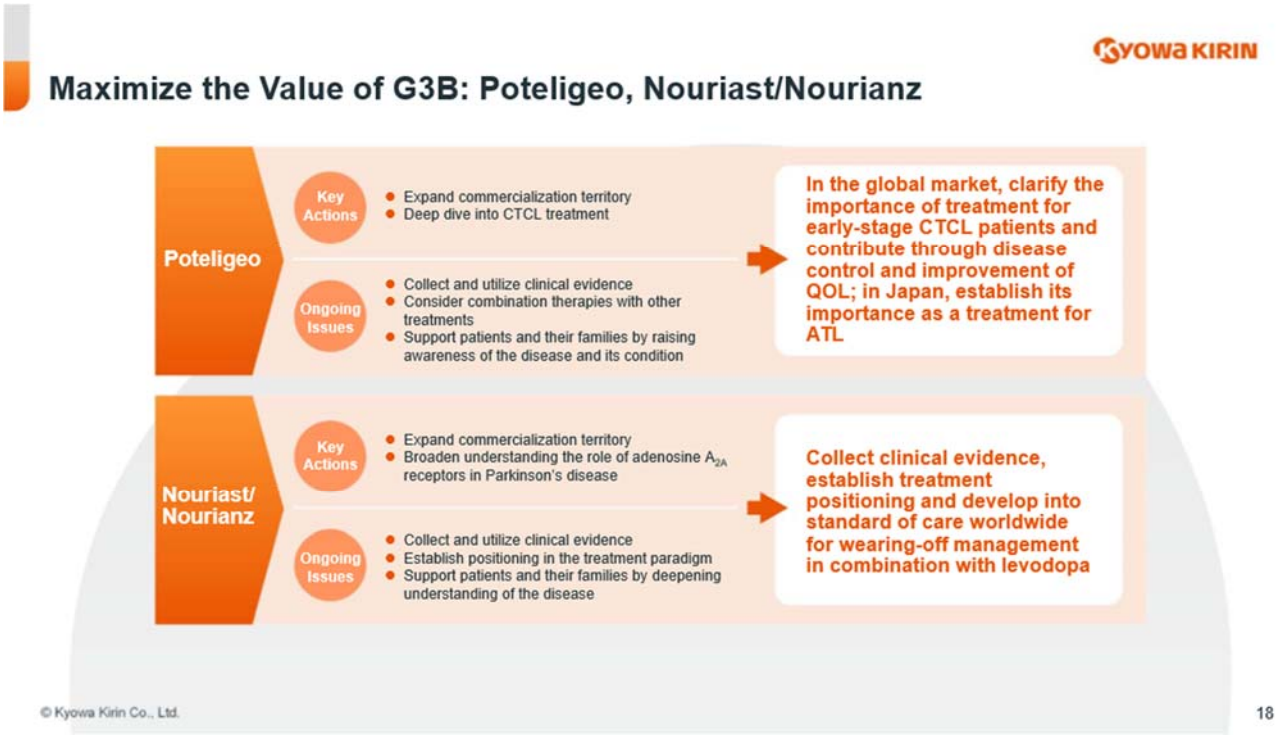
I will explain the three strategies in order. The first strategy is to “provide pharmaceuticals for unmet medical needs.”

During the period of the previous medium-term plan, we succeeded in launching three in-house created drugs—Crysvita, Poteligeo, and Nourianz—in the global market, including North America and Europe. As you can see, sales of the three global strategic products are growing steadily. In the new medium-term business plan, we believe that these three global strategic products will drive the company’s growth. One of the key measures is to steadily maximize the value of each product.



We aim to realize growth by steadily delivering Crysvita to more patients while establishing its position as the standard treatment for XLH and unresectable TIO. Simultaneously, we aim to become a global leader in this field. We will expand our sales area so that we can deliver the drug to patients in more than 50 countries by 2025. At the same time, we will focus on improving the treatment penetration rate and expanding indications.

We will prepare for a smooth transition so that we can start in-house sales from 2023 on behalf of Ultragenyx in the US.



We will clarify the significance of Poteligeo for the CTCL treatment in early phase globally. Simultaneously, we will promote that Poteligeo can improve CTCL disease control and patients' QOL. In Japan, we will clarify the significance of Poteligeo in ATL treatment. We will further expand the sales area.

We will collect clinical evidence for Nouriast and Nourianz and establish their therapeutic positioning. By doing so, we aim to make them the standard treatment for off-time management in combination with Levodopa globally. In addition to expanding the commercialization territory, we will work to broaden people's understanding of the role of adenosine A2A receptors in Parkinson's disease.

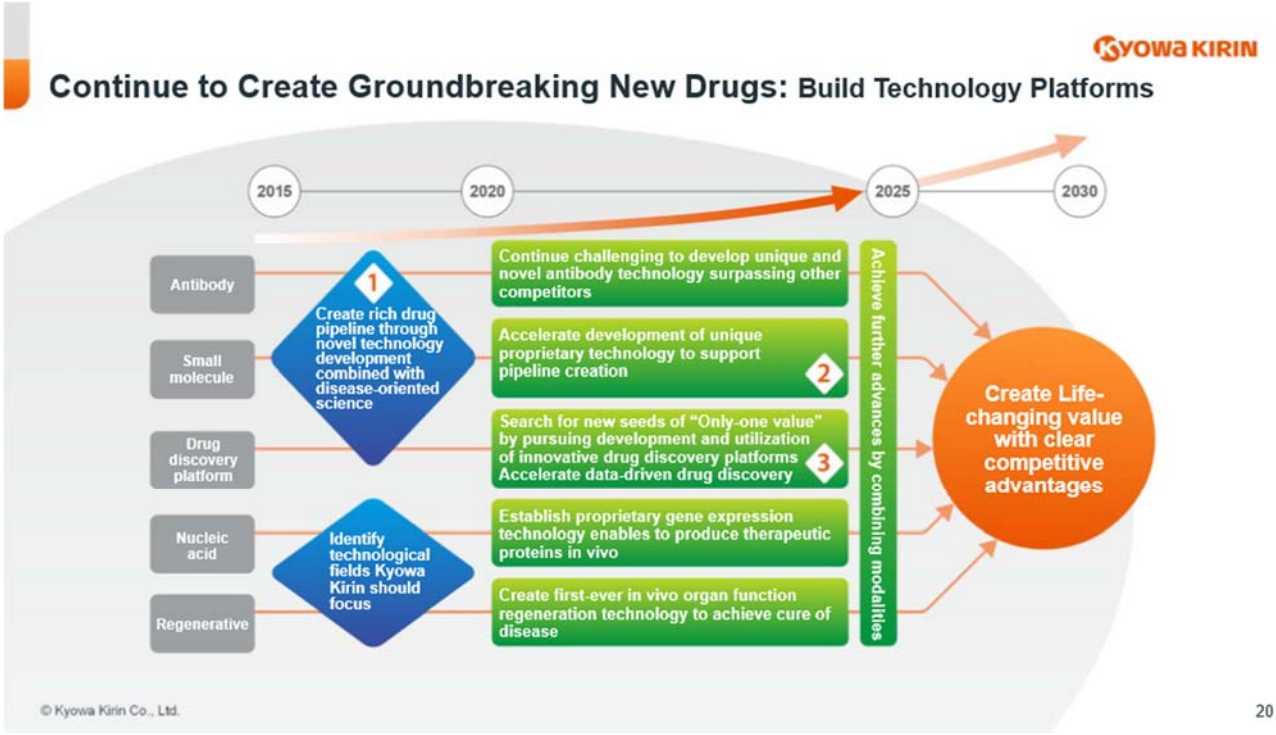
Continue to Create Groundbreaking New Drugs: Next-generation Strategic Products

	Country / region*1	Indication*2	Approval year*3	Total addressable market*4	No. of patients*5
KHK4083	NA/EU/JP	Atopic dermatitis	2025/2026	★★★	16,000K
KW-6356	NA/EU/JP	Parkinson's disease	2025	★★★	3,500K
ME-401	NA/EU/JP	Follicular lymphoma Marginal zone lymphoma	2023	★★★	~800K
RTA 402	JP/Asia	Alport syndrome Diabetic kidney disease Autosomal dominant polycystic kidney disease (ADPKD)	2022 2023 2025	★★★	2,500K~
KHK7791	JP	Hyperphosphatemia under maintenance dialysis	2023	★☆☆	250K

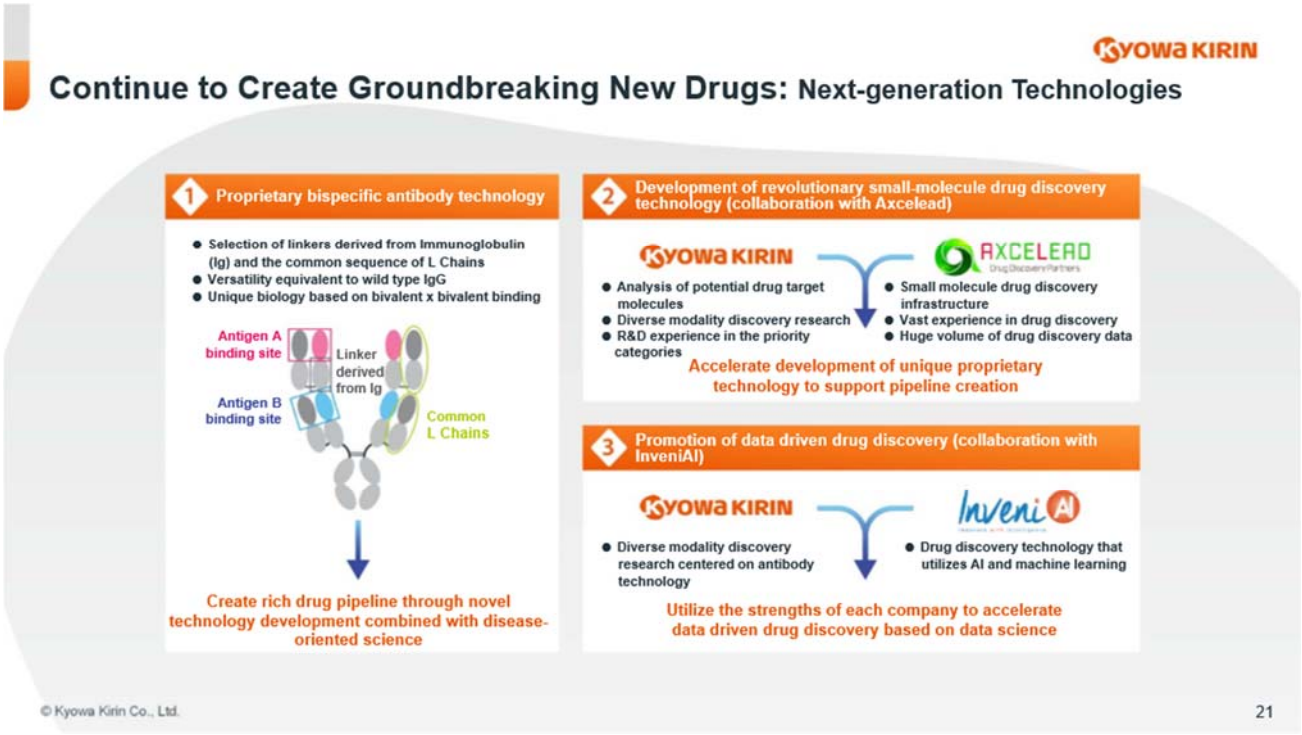
*1 Countries or regions where Kyowa Kirin currently has marketing rights and will launch products (or will conduct marketing activities); products may not be launched in all countries or regions shown in the table
*2 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities
*3 Expected year of first approval
*4 Expected total addressable market, which is the sum of all products for the indications shown in *2, in all countries or regions defined in *1, not projected sales or the Company's targets; ★ = less than ¥50bn, ★★ = ¥50-100bn, ★★★ = Over ¥100bn
*5 Total number of estimated patients in all countries or regions defined in *1.
*6 The size of the total addressable market and patient numbers are based on our estimates

Next, we show here the late-stage pipeline drugs that may be launched during the 2021 medium-term period among the strategic products that are expected to accelerate our growth as the next generation of the three global strategic products.

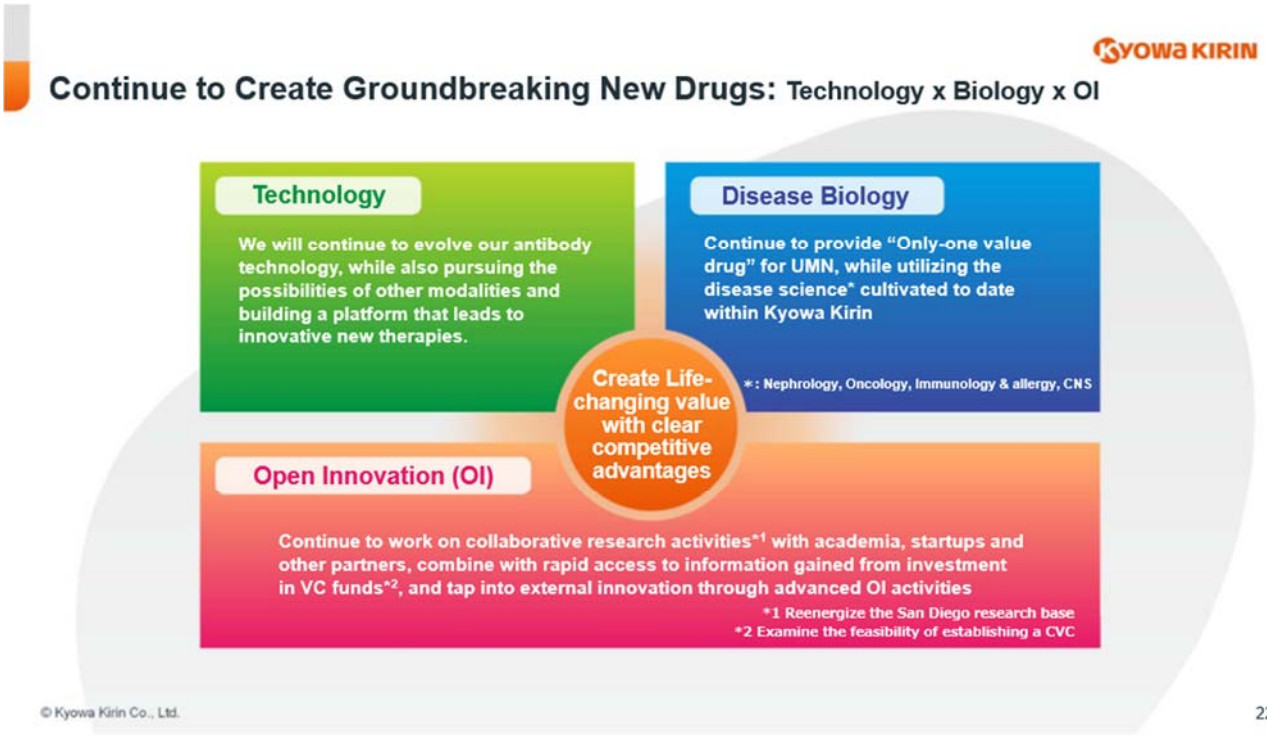
Please note that the stars indicating total addressable market indicate the size of the entire market and do not represent the potential of each product individually. We will proceed with careful and rapid development under a meticulous strategy so that we can maximize the potential of these candidate drugs.



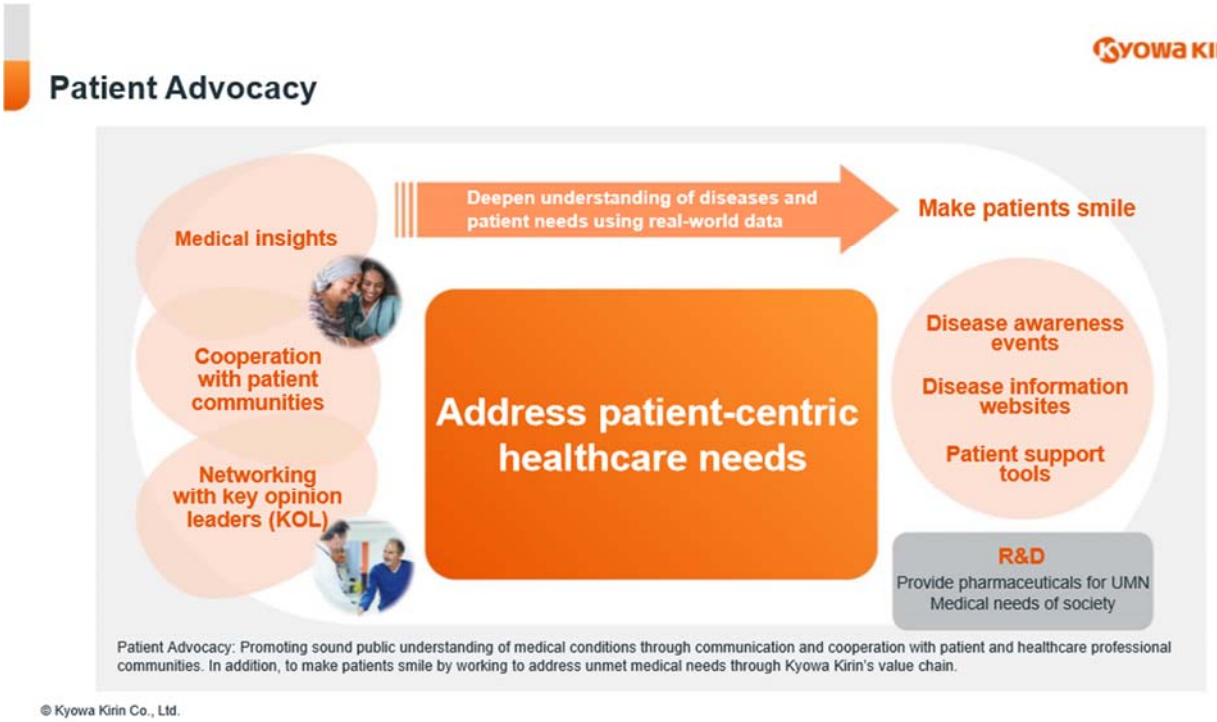
During the 2021 medium-term business plan, we will refine the technologies that form the basis of drug discovery and each of the four modalities that have been carried on from the previous medium-term plan. On top of that, we aim to build a technology platform with an overwhelming competitive advantage by striving to combine these modalities.



Specifically, during the 2021 medium-term plan, we aim to enter clinical trials of candidate drugs that apply next-generation antibody technology, including our unique bispecific antibody technology. Furthermore, with a view to the future, we will build completely new technologies and select efficient targets by utilizing open innovation with partners who have distinctive strengths.



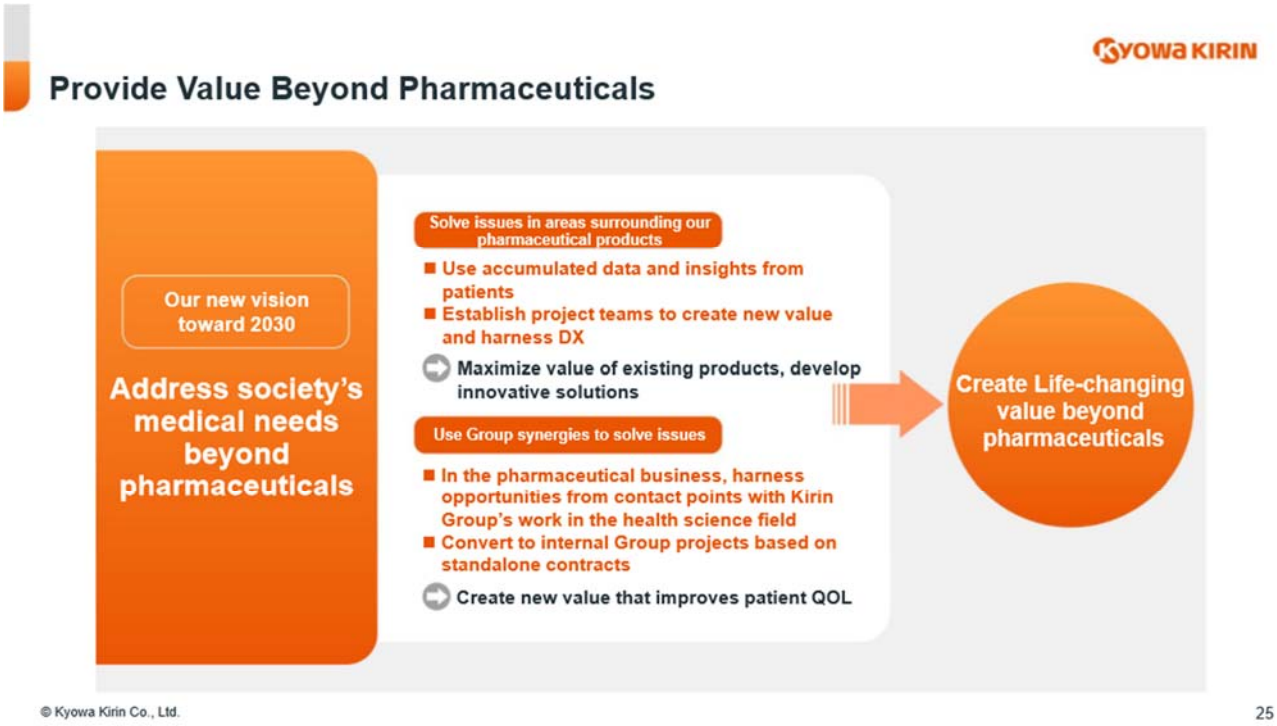
We have shown here the overall R&D concept for continuously creating groundbreaking new drugs. We aim to create life-changing value by advancing technology, deepening our understanding of diseases, and actively drawing on external resources.



The second core is to address patient-centric healthcare needs.

To bring smiles to those facing illness, as described in the new vision, we will be putting even more effort into patient advocacy activities. While developing and marketing drugs for rare diseases, such as Crysvita, we were convinced that strengthening patient advocacy will ensure that our business activities are aligned with the wishes of patients and healthcare professionals. By extension, we feel this will help us embody our corporate philosophy.

We aim to evolve these activities into globally-linked patient advocacy activities.



Providing value beyond pharmaceuticals is a new challenge for the future. To do so, we must search for solutions, not only for pharmaceutical drugs, but also in related areas. We will strive to explore and address this issue by setting up a project team to create new value, including digital technology, so that we can envision ourselves as a global specialty pharmaceutical company from a long-term perspective.

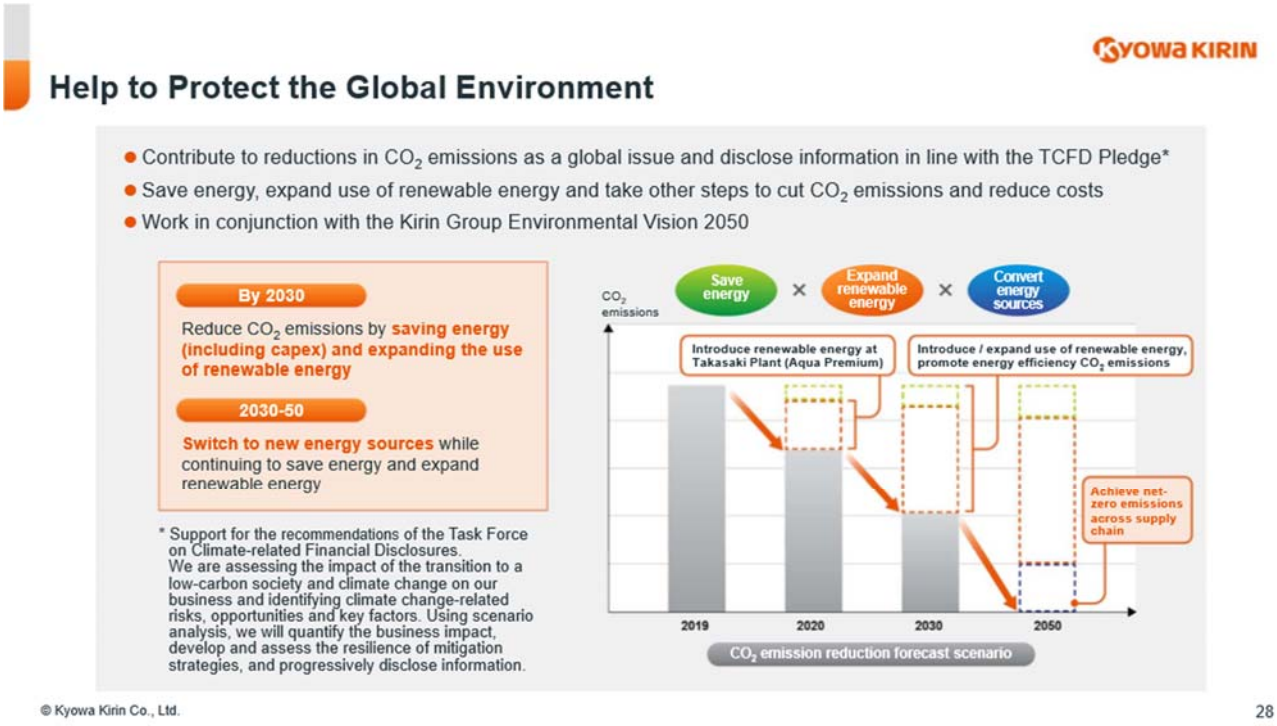
To bring smiles to patients, we will also continue to take on the challenge of creating new value through the confluence of Health Science Business, which is one of their focus areas, and our Pharmaceutical Business. We will address social issues in combination with the perspective of seeing patients as consumers and the knowledge and technology of the Health Science Business. By doing so, we look forward to the possibility of creating unique solutions that can only be achieved by the Kirin Group.

The third core is to retain the trust of society.

As set forth in ”To be in 2025,” we aim to expand the business and our commercialization territory as a global specialty pharmaceutical company. To do so, it is important to build a stable supply system in line with the business expansion, and further investments are necessary to achieve this. We will also pursue efficiency improvements through production technology innovation.

In advancing these, what we need to firmly establish in the company is the quality-first culture. We will demand the same quality, not only to the production team, but also across all group operations, including subcontractors.

We will strengthen the foundation that supports our growth as a global specialty pharmaceutical company by working on the stable supply of safe and high-quality products as the foremost issue.

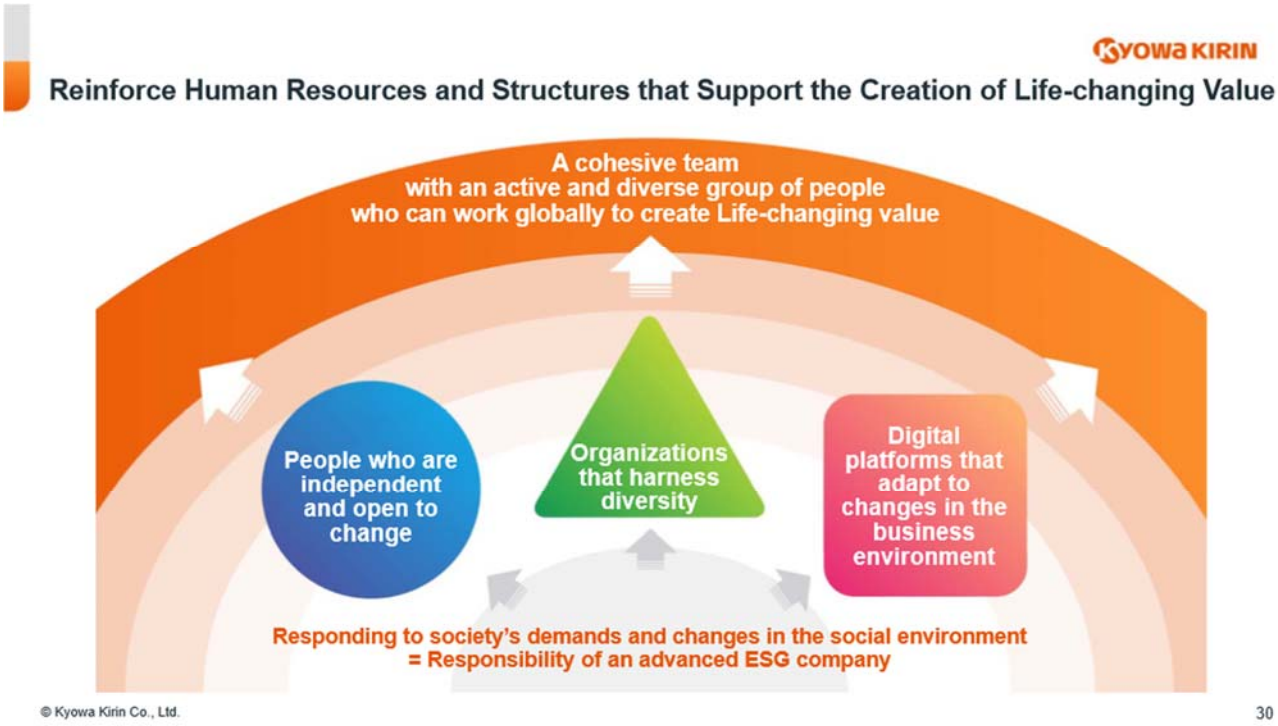


In formulating the new medium-term business plan, what we have focused on even more than the previous medium-term business plan was “creating shared value” or CSV. We have studied the materiality of how the company, which upholds CSV management, should tackle business issues, while at the same time meeting the demands and expectations of society.

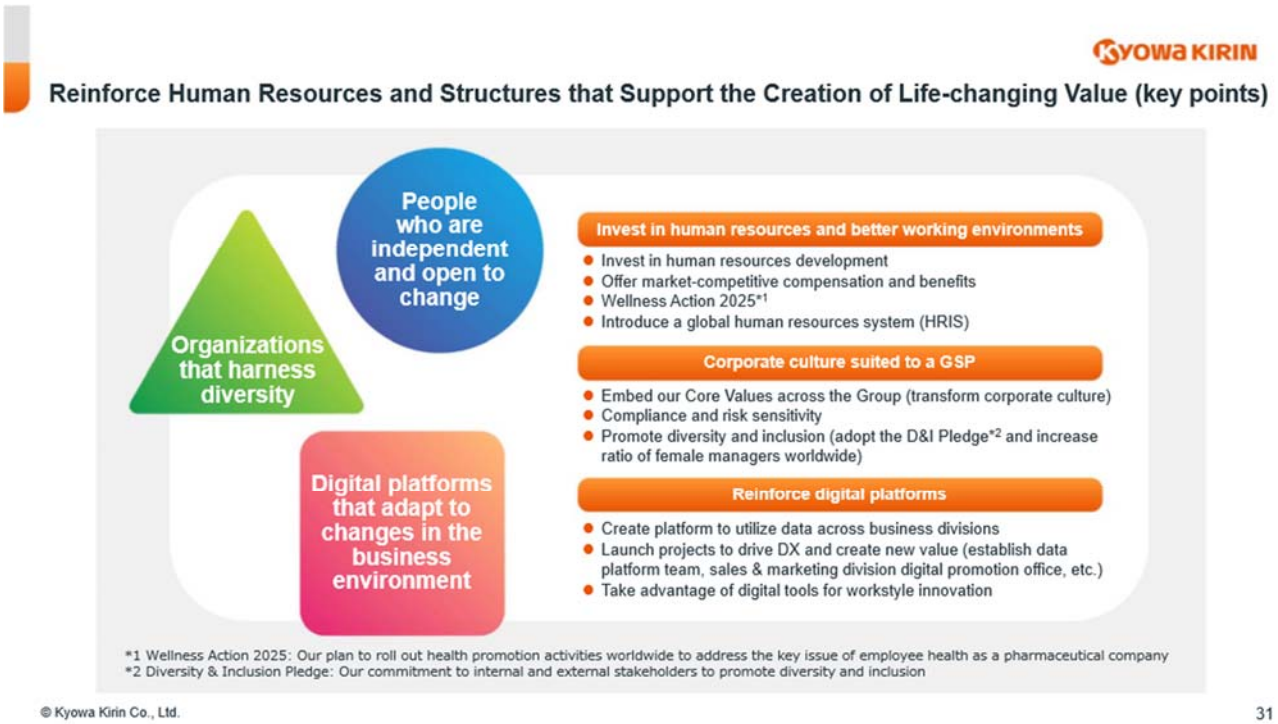
Global environmental conservation, especially climate change initiatives, have been taken up as a global social issue. As a member of society fulfilling our responsibilities for the future, we position these as issues to be addressed continuously.

Specifically, the Kirin Group has set the following as targets. By 2030, the Group will balance the reduction of cost and CO2 by promoting the reduction of CO2, centered on the expansion of energy-saving and renewable energy, including capital investments.

Furthermore, the Group will promote energy conversion in addition to the expansion of energy-saving and renewable energy up to 2050. Simultaneously, the Group aims for net-zero emissions in the entire value chain by 2050. In these ways, we will address these global issues as a member of the Kirin Group.



I will explain about reinforcing the foundation for implementing these strategies. As stated in our new vision, we believe the foundation for all of our efforts in implementing the three strategies explained up to now will be a passion for innovation and a cohesive team with an active and diverse group of people. Throughout the new medium-term management plan, we will work on improving human resource engagement, creating an organization and culture that facilitates their work, and responding to the rapidly changing business environment, especially investments in the reinforcement of digital platforms.

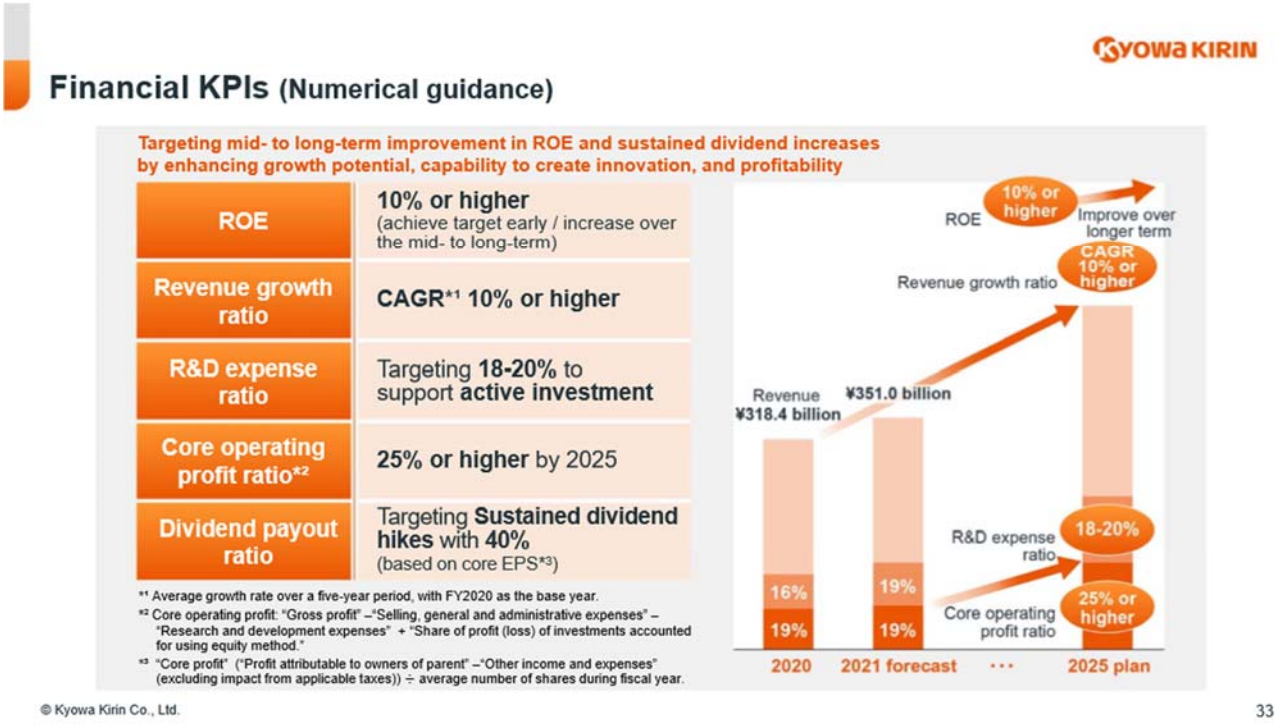


The first key point is an investment in people who are independent and open to change. The key actions are investment in global human resource development and implementation of talent management.

The second key point is to foster a corporate culture suited to a GSP.

The third key point is to reinforce digital platforms. We will promote business reform through digital transformation. We have also announced organizational changes this time. We will promote digitalization at the domestic sales &

marketing division even more strongly. In addition, we will utilize digital technology in the entire value chain from drug discovery to post-sales. Furthermore, we will invest in platforms for the utilization of data across all supporting departments. By actively investing in these fields, we hope to ensure that we do not fall behind.



Finally, I will explain the financial strategy. The KPIs that we would like to achieve in the five years up to 2025 by implementing the various strategies we introduced today are as follows.

The first KPI is ROE. We target 10% or higher, which is above the shareholders' cost of capital. By achieving this level as soon as possible and maintaining and improving this level over the longer term, we aim to continuously improve enterprise value. To achieve an ROE of 10% or higher, it is important to simultaneously enhance our growth potential, the capability to create innovation, and profitability. For that purpose, we have set revenue growth ratio, R&D expense ratio, and core operating profit ratio as KPIs.

Regarding the revenue growth rate, we will further promote efforts to expand profits and maximize the value of the three global strategic products, and steadily advance next-generation strategic products toward market launch. By doing so, we aim to achieve dramatic growth, with a five-year CAGR of 10% or higher.

On top of that, to enhance the pipeline that will drive growth after 2025, we will aggressively invest in R&D with a target of 18% to 20% of revenue. Once again, we have made it clear that we will invest firmly in R&D over the next five years for future growth.

By growing revenue, investing in R&D, and controlling SG&A expenses, we aim to achieve the fourth KPI, which is a core operating profit ratio of 25% or more by 2025.

We aim for a dividend payout ratio of 40%. This is the payout ratio using core EPS, which is based on core profit after subtracting other income and expenses and related tax effects from profit. We aim to continuously increase dividends throughout the medium-term period by steadily growing profit in parallel with the revenue expansion and core operating profit ratio improvement.

Capital Policy

This slide shows our capital policy for the next five years. We will give top priority to growth investments. We plan to use a considerable amount of the current cash on hand of approximately JPY300 billion and the cash inflow that will be provided in the next five years for growth investments.

As indicated in the note, our investment policy is to sustain a net cash position in principle, while maintaining sufficient financial flexibility by securing borrowing capacity and fundraising methods, like commercial paper and commitment line.

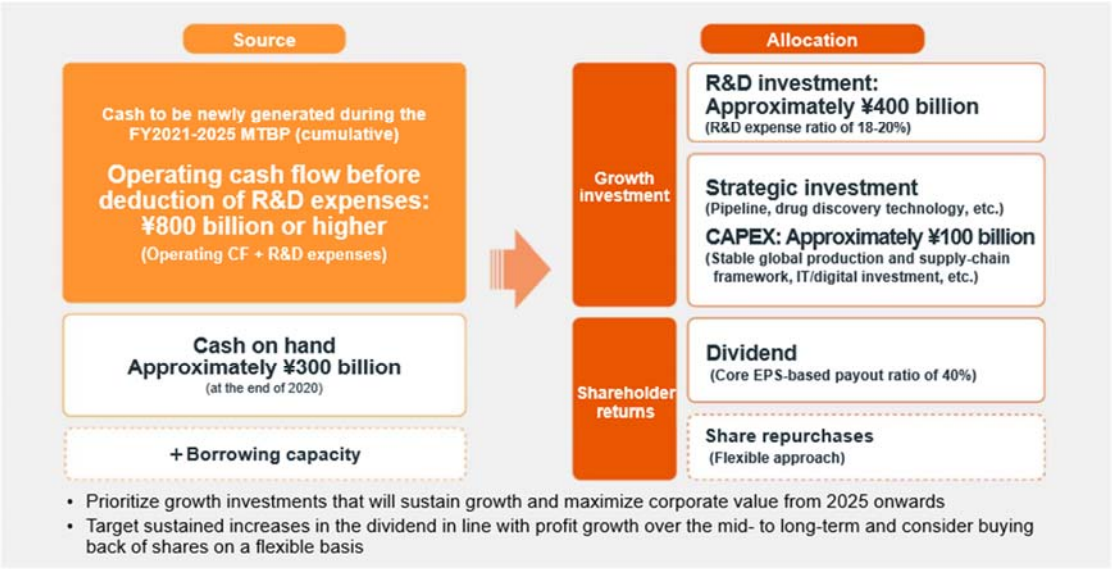
To return profits to shareholders while making solid investments in growth, we aim to continue increasing dividends with a target of 40% of core EPS, as explained earlier.

Growth investments can be broadly divided into the three areas shown here. R&D investment should be considered synonymous with R&D expenses. We will invest aggressively in R&D, targeting an R&D expense ratio of 18% to 20%, to continuously create pipeline drugs and maximize value of those, and develop drug discovery technology unique to Kyowa Kirin.

The second area is strategic investment. This is an investment for utilizing external resources. We aim to acquire pipelines and drug discovery technologies by making use of the knowledge and discernment we have cultivated until now.

The third area is capex. The investment will be for establishing a system for stable production and supply of high-quality pharmaceuticals, maximizing the value of global strategic products, and developing a business infrastructure, such as digital platforms.

Cash Allocation



I would like to introduce the rough idea of cash allocation under this capital policy. On the left side, we indicate that the source of capital will be the expected operating cash flow before deduction of R&D expenses, amounting to JPY800 billion or more over the next five years, in addition to approximately JPY300 billion of cash on hand.

On the right side, we show the capital allocation plan. We expect to invest about JPY400 billion in R&D and JPY100 billion in capex. We will not set a quantitative target for strategic investment, but we can use a considerable amount. Our policy is to aggressively invest if there are good investment targets that would contribute to our future growth.

This concludes my explanation of Kyowa Kirin's 2021-2025 Medium-Term Business Plan. We will steadily implement these strategies as the first step toward the realization of the new vision for 2030.

We ask for your continued support and understanding.

Question & Answer

Moderator: We will now move on to the Q&A session.

We would like to answer the questions of as many participants as possible, so we would like you to keep your questions to up to two per person. Now, if you have any questions, please go ahead.

Hashiguchi: This is Hashiguchi from Daiwa Securities. Thanks.

My first question is about your plan for R&D expenses in the current period. You mentioned in your presentation that part of the expenses for Phase Three trials of KHK4083 is included in the plan. Does that assume that you will continue to develop the drug on your own, or does it also take into consideration the possibility of collaborations with other companies? Please tell me the underlying assumptions behind the plan, as well as the options you are currently weighing and their probability.

Miyamoto: Thank you, Mr. Hashiguchi. Regarding KHK4083, and what options we are considering for the future, we are, of course, considering various options, including continuous development on our own and partnerships with others. Competition is fierce in the market. So, we will have to keep an eye on that as we advance our efforts.

Regarding R&D expenses, the results of the Phase Two trials have not come out yet. So, as I explained earlier, various options are incorporated into the assumptions. Sorry, we cannot share the detailed numbers today.

Hashiguchi: Thank you. Second, please tell me about your R&D strategy in the current medium-term plan. I understand that, in the previous plan, you had four major modalities focusing on four key categories. On page 20, there is a description of the four major modalities. On page 22, there is also a description of the four categories. However, you have not used the expression “four major” or “four” this time.

Is this the same strategy in substance, or is there a difference in nuance? How much progress have you made, especially in reinforcing the infrastructure for the modalities?

On page 22, there is only a description of two of the four major modalities, and progress cannot be seen in the other two modalities. Please tell me the importance of each modality to the company at present.

Miyamoto: Thank you. Regarding your question about the four categories, or four major modalities, first of all, those were concepts centered on Japan. The four categories were implemented in the previous medium-term plan under that context.

However, we are currently expanding globally. Thus, we are undertaking a dramatic transformation from a Japan-centered way of thinking to globally oriented approaches. We are toning down the focus on categories compared to before. Naturally, we have accumulated expertise and understanding of diseases, which we will carry on. But the tone of the plan is to have a global focus.

Regarding modalities, Torii will give you further explanation later, but as you stated, we have faced some roadblocks in terms of nucleic acid and regenerative medicine, as touched on in the presentation. Active efforts are being made in our labs to change the target or move research in a different direction. But we are still not at the stage of giving you concrete information.

Torii will also comment on this.

Torii: Thank you for your question. As a point in retrospect of the previous medium-term plan, we have achieved some results in bispecific antibodies, as shared in the R&D Day the other day.

Regarding nucleic acid and regenerative medicine, honestly speaking, we could not achieve the anticipated results, as many issues arose while advancing research. But this experience has also clarified how to solve these issues. By drawing on this experience, we will work to move research to the development phase at an early stage.

Going forward, it will be increasingly difficult to identify drug discovery targets. Hence, we will need to look beyond those four modalities, including combinations of those modalities and leveraging new modalities. Out of those diverse modalities, we will select the appropriate modality and conduct drug discovery. As announced yesterday, we will change the organization of the R&D headquarters starting in April. We will make even more active efforts than before to advance inter-modality and inter-category research and the combination of modality and category.

Hashiguchi: Thank you. I would like to ask an additional question about your thoughts on categories. What are your global plans when setting sights on the long-term trajectory, even beyond 2025?

At present, the key categories are focused on existing drugs. But that gives me the impression that there is a possibility these key categories could change over time. Perhaps there is not anything set in stone at this stage. But, eventually, wouldn't it be better to have key categories like you do in Japan and focus your efforts on building those categories for the future? Do you have aims to develop global operations through in-licensing or portfolio enhancement, as you are doing now in Japan? Or are your plans for global operations slightly different?

Miyamoto: Thank you. This is probably an issue that is far down the road and dependent on what kind of products we can launch from the pipeline. Using common sense, it would be extremely inefficient to haphazardly jump onto new stages of the competition. It is natural to target the domains close to the current products and focus on efforts undertaken.

Naturally, we are looking for attractive opportunities in the periphery of our three global products as part of our growth investments. As you say, we will not handle everything on our own just because an opportunity emerges. If there are opportunities that do not match our focus, then we would weigh options, such as partnerships or out-licensing. In such ways, we intend to manage the business efficiently.

Hashiguchi: Thank you. That is all.

Wakao: This is Wakao of JPMorgan. Thanks. My first question is about Crysvita. You already touched on this earlier, but could you explain the impact of COVID-19 on the fourth quarter and how you have incorporated that impact into your plan for the current period? Could you please explain the impact, especially in Europe? That is my first question.

Miyamoto: Thank you. This is Miyamoto. The impact was not large; albeit there has obviously been some impact. Our plan for the current year incorporates the same level of impact for the first half. Especially in Europe, there were some delays in drug price negotiations, which may have partly been due to COVID-19. Sudo will give the details.

Sudo: Thank you for your question. I will go over one at a time. First, in the US, there was an impact from COVID-19, but the overall market was strong. The market was roughly in line with the plan. There would be concerns if the impact of COVID-19 were to aggravate this year. But, otherwise, we should be able to achieve the target issued this time.

In Europe, there was a delay in launched countries due to COVID-19. On the other hand, we acquired indication for adult (XLH) in September last year, and Germany has gotten off to a very good start. We have made quite a good start even under the restrictions on commercial activities under COVID-19. Thus, we have high expectations for the European market. We think the momentum of the three global products will be relatively strong, including in 2021.

Wakao: Excuse me. Regarding your point about the delays in drug price negotiations last year, have those negotiations been finalized? Is it fair to say that those delays will not present any particular risks this year?

Sudo: Correct. As you say, a large portion of negotiations have been finalized in the fourth quarter. We were not able to completely meet the target for launched countries, but we achieved product launches in many countries. I have great expectations of the growth in pediatric XLH indication this year.

However, a separate round of drug price negotiations will start for indications in adults. We may see some impact on these negotiations again, but I am hoping the growth in pediatric XLH indication will move forward powerfully this year.

Wakao: That is clear. Thanks. Second, please tell me about KHK4083 for atopic dermatitis. When is the data readout? Also, you explained earlier that the competitive environment is getting tougher. Recently, Sanofi in-licensed KY1005, a drug by Kymab that targets OX40-Ligand. Please comment on this.

It is clear from the contract between Sanofi and Kymab that OX40 is an excellent target. On the other hand, Kyowa Kirin targets the receptor. Are there any differences in targeting OX40-Ligand versus its receptor? Also, please tell me your thoughts on KY1005. That is all.

Torii: Thank you for your question. Regarding your first question about the data readout, as we have been saying, the top-line results will be out during the first quarter. We will issue a press release once those results come in. We will publish the detailed data at an academic conference sometime during this year. We are currently in discussion with our KOL doctors.

Regarding your question about Kymab, to begin with, there are several predecessors for treating atopic dermatitis, such as IL-4 and IL-13. OX40 is effective more upstream by suppressing targeted T cells. Compared to antibodies for OX40-Ligand, KHK4083 directly targets OX40 expressed on the target cell membrane. Furthermore, KHK4083 is embedded with our proprietary POTELLIGENT technology, and ADCC can remove the target cells. Of course, we will need to follow the clinical results carefully. Still, theoretically, we expect that targeting OX40 and removing cells with ADCC would help obtain a strong and long-lasting medicinal effect, and development activities are currently underway.

Wakao: Thank you. I understand. By the way, I was wondering if you conducted some kind of basic research regarding the suppression of the ligand when deciding on targeting OX40. In other words, have you decided to target OX40 after conducting such research?

Torii: Yes. We made various considerations in the early stages to determine which process to target. We selected the current development candidate based on such research.

Wakao: That is clear. Thanks. That is all.

Yamaguchi: This is Yamaguchi from Citigroup Global Markets Japan. Thanks. I have two questions.

My first question is about SG&A expenses. This year, you expect SG&A expenses to increase considerably and other than the profit-share payment for Crysvita. In your medium-term plan, the ratio is not written out clearly, but I assume that the ratio will fall. I understand that you will begin in-house sales of Crysvita during the medium-term period. On top of that, you expect infrastructure investments to build up in the current fiscal year and partly in the next fiscal year. But, thereafter, you expect the SG&A expense ratio to fall, and it would ultimately have a positive impact on achieving the core operating profit ratio of 25%. Is that correct?

Miyamoto: Thank you, Mr. Yamaguchi. This is Miyamoto. Yes, it is as you say. We have discovered through our global expansion that there are still many areas where we fall short in basic strength. By putting up with a higher SG&A cost right now, we think it would lead to better cost control in the future. For example, building that basic strength would lead to faster and higher-quality management globally, leading to the elimination of redundant costs.

Thus, we intend to move in the direction you pointed out. We will particularly need to spend more SG&A expenses this year.

Kawaguchi, would you like to comment?

Kawaguchi: It is as you say, Mr. Yamaguchi. The biggest part contributing to profitability in 2025, from a core operating profit ratio of 19% to 25%, is the enhancement of our ability to control the SG&A expense ratio, so that we can lower the ratio. Your understanding is exactly correct. Thanks.

Yamaguchi: Thank you. Just to clarify, you will begin in-house sales of Crysvita in the US from 2023, correct?

Miyamoto: Yes.

Yamaguchi: Right. That is, of course, included in the new medium-term plan, right?

Miyamoto: Yes. That is included in our calculations.

Yamaguchi: Okay. Second, when looking at the R&D list, there is a description in the notes about TAM. Essentially, you have listed out the first four drugs as having a potential market size of over JPY100 billion.

I understand that part. But the profile of each product is not clear yet. The size of each market multiplied by the potential of each product would equal the peak annual revenue of each product. Could you comment on a rough estimate of the peak annual revenue of each product? A qualitative answer is fine.

Miyamoto: Miyamoto. I will ask Sudo to give a more detailed answer later. Sorry if the table was a little confusing. Obviously, we cannot give you the exact numbers we are looking at. Just to give a rough image, the market for KHK4083 is extremely large. The competition will be tough, but we hope to turn KHK4083 into a blockbuster.

As for ME-401, development may take some more time, but if development proceeds as we anticipate, then we expect it to become a major product.

As for KW-6356, the Phase Three trials will be started, and the product potential will depend on the results thereafter. We hope the drug will grow bigger than the current Istradefylline.

RTA 402 has a chance of becoming a major product from a global perspective. The area we have rights now, as you see, however, are Japan and Asia, so it will be difficult to turn them into blockbusters. Still, there are many patients, and they are in our specialty domains, so we hope to make them fairly successful products. Sorry for the vague answer.

Sudo, would you like to add to that?

Sudo: I will give my brief comments on the three drugs on the top. As Torii touched on earlier regarding KHK4083, we have high expectations for it as Kyowa Kirin's unique product. As stated, it will hinge on how much potential can be drawn out in the Phase Three studies. This atopic dermatitis domain will grow very large in the future. As you know, rival drugs include JAK inhibitors, such as IL-13 and IL-4 mentioned by Torii earlier. There are a host of such rival drugs.

An external party has announced an estimate of the TAM in 2028 of around JPY2 trillion. Against this backdrop, KHK4083 will be the eighth or ninth drug to be marketed, so it will depend on how much of the market share we can capture. Naturally, our goal at Kyowa Kirin is to develop this drug into a blockbuster. This is the image we have for KHK4083.

As for KW-6356, we hope to launch this product as a drug that fully leverages A2A rather than second-generation agents, as commented by Miyamoto earlier. In that sense, we will make solid investments in challenging studies to probe the possibility of turning it into a blockbuster. That is our aim.

As for ME-401, we consider this drug to be highly unique among PI3K delta inhibitors. I think MEI Pharma will release some data on this from time to time. The third-line data will be released in the fourth quarter this year. We are looking forward to these results. ME-401 will likely be released as a drug that is effective and safe among such PI3K. It says here that current indications include treatment for FL and MZL, but a large market can be expected through the expansion of indications, including CLL. There are still various risks as we go through Phase Three studies soon, but the company's expectation for this drug is high. That is all.

Yamaguchi: Thank you.

Sakai: This is Sakai from Credit Suisse. Thanks. I would like to ask about the numbers. In the section where you give guidance for financial indicators, a simple calculation would derive a FY2025 sales figure of slightly above JPY500 billion. Multiplying that figure with a core operating margin of 25% would imply a core operating profit of around JPY125 billion. In a note somewhere, it said that the issue would be to achieve a core operating profit of JPY100 billion at an early stage of the 2020s.

If that is so, given that the core operating profit forecast for the current period is JPY65 billion, it would mean the profit growth would accelerate rapidly and then slow down a little thereafter. This growth trajectory would not be possible unless there is a significant contribution from the three global products.

The questions asked earlier by others were about the four new drugs, but their contributions will only be from 2025 or later. In that case, the level of profit contribution from the three global products would need to be high, especially for Crysvita, which would switch to in-house sales in the US starting in 2023.

The reason why I ask this is because, when you announced the medium-term plan last time, operating profit slipped sharply. I would like to know if there are grounds on which you can guarantee the likelihood of achieving the new medium-term target.

Miyamoto: Thank you, Mr. Sakai. The issue of JPY100 billion in core operating profit and ROE is an ongoing theme from the previous medium-term plan, and we understand this must be reviewed properly.

Regarding your question about achieving JPY100 billion in core operating profit in the early 2020s as stated in the previous medium-term plan—it is true that various assumptions in the previous medium-term plan were overturned. The point is that we aim to achieve a core operating profit of JPY100 billion during the current medium-term period.

On the other hand, regarding your question about the degree of involvement of the three global products, which is the point of your question, we indeed think that the contribution will be high. As I explained, the key point of the current medium-term plan is the growth of the three global products. We think the involvement rate will also be very high. We will especially drive growth with a focus on Crysvita to achieve the financial guidance that you mentioned. We will make solid efforts to achieve the targets.

On the other hand, we will increase profits by expanding the top line. As explained in response to the question by Mr. Yamaguchi, we will create a structure to firmly control SG&A expenses. By firmly controlling costs, we plan to translate that into solid profits.

Sakai: Okay. Sorry, let me ask one more thing about Crysvita. You commented that the market size for TIO is of a considerable amount. Do you actually incorporate that to a large extent in your forecast?

Miyamoto: Thank you. Yes, it can be said that the market size is large, and there are more patients than we initially expected. I think it is factored into the numbers. Sudo will comment on the details.

Sudo: Thank you, Mr. Sakai. Regarding TIO, the image is that the market size is large, in the sense that there are more patients than we initially expected. As a rough estimate, our expectation is for revenue to reach around, say, 10% or so of the overall XLH value as a starting point.

The product was launched in December 2019 in Japan and June 2020 in the US. There are some differences depending on the country, but our aim is to capture about 10% of the market, as I just stated.

Sakai: Thank you. I am not sure if this is a question, and you might not answer it—I think there will be various discussions at least during the next five years of this medium-term period regarding the parent-subsidiary listing from the perspective of governance and reorganization of TSE.

I would like to ask this once again. President Miyamoto, in your view, what is the advantage of being a part of the Kirin Group? How would you explain it to investors and the investment community?

Miyamoto: Thank you. First of all, as I have stated many times, there is no sign of Kirin Holdings having some kind of a major negative impact on the decision-making to advance our pharmaceutical business. I would like to underscore, first and foremost, that governance is being carried out in a sound manner as a listed company, and the business is advanced effectively through independent governance.

Furthermore, as I explained in the new medium-term plan, many pharmaceutical companies are currently expanding activities into realms beyond medicine. We think these new realms will be extremely important in terms of supporting customers. From this standpoint, Kirin Holdings is mainly propelling the initiatives around Health Science. We are not at the stage of showing everyone some concrete plans. But we think there is significant room for coordinated measures as a Group. This is something that other Groups or companies cannot do, so we hope to show solid advantages on this front.

Sakai: Okay. Thank you very much.

Ueda: This is Ueda from Goldman Sachs. First, I would also like to ask about the medium-term targets, specifically the assumptions behind the revenue forecast.

The forecast implies that revenue would increase by roughly JPY200 billion. What kind of items will drive that growth? Earlier, you mentioned that it will mainly be the global three products, but how much of the JPY200 billion growth will be accounted for by Crysvita? I believe the next-generation strategic products will not contribute much, because the market launch will be in 2023 or later. Please tell me if your forecast includes uncertain factors like in-licensed products or products under development.

Miyamoto: Thank you, Mr. Ueda. As you said, the key point will be the growth of the three global strategic products. Obviously, the lion's share will be from Crysvita. But it will not just be Crysvita. We will also grow Poteligeo and Nourianz.

We will also develop and launch new products domestically. We aim for an increase of JPY200 billion, including contributions from domestic products. We also factor in the expansion of commercialization territory. All of those factors are included in the JPY200 billion increase. Again, to repeat, we will be aiming for an increase of around JPY200 billion, and the key point will be the three global products.

Ueda: Let me confirm. This does not include in-licensed products or acquisitions, correct?

Miyamoto: No, we do not have any plans for that right now, and we also do not intend to fill the target by including in-licensed product x or y.

Ueda: Okay. Thanks. My second question is about the numerical guidance provided on page 33. Is there an item in this guidance that you particularly emphasize?

Also, even though you indicated the revenue target based on CAGR, you indicate the profit target as a ratio. You also mentioned making aggressive investments in R&D. Will you be giving greater priority to the JPY400 billion R&D budget or the profit ratio? Please tell me your thoughts on these points.

Miyamoto: Thank you. All of the targets are important, but we think we especially need to focus on ROE. We need to make solid progress across the other indicators to achieve the ROE target. ROE is the product of the other targets, and we consider it to be our mission to maintain ROE above the cost of capital. As such, we will give priority to ROE.

Kawaguchi will answer your other questions.

Kawaguchi: We aim to steadily increase ROE until 2025, and we aim to continue to raise ROE beyond that. To do so, we will continue to aim for a revenue growth rate of 10% or higher. If we were to indicate that as a number, then the number would take on its own life. You will all know the target amount if you do the calculation. But the intention behind it is to continue to grow at 10%.

To do so, it is important to make solid investments in long-term innovation rather than emphasizing short-term profits. In this context, we target an R&D expense ratio of 18% to 20%. If we do so, then the amount of R&D investment should roughly double, or reach the JPY100 billion level, in FY2025. If this were to include strategic investments outside of our current pipeline to add new drugs, then we would need the R&D budget to conduct development. That would be included in the allocation of the roughly 20% R&D expense ratio in 2025 so that the company can grow even further.

This means that the operating profit ratio would be slightly lower than everyone's calculation. We will steadily improve this ratio by even 1% each year from the current level of 19% to 25%. The key point here is the reduction of the SG&A ratio. We think it is important to create a structure capable of global cost controls, including IT investments, partly in reflection of our shortfalls in the previous medium-term plan.

In the previous medium-term plan, we still did not have a clear understanding of what it means to have a global structure. We are now in the process of creating this global structure and view it as a crucial issue to tighten our grips over cost control as a global headquarters.

In any case, we envision becoming a company capable of raising ROE to 10% or higher over the longer term, as a result of those efforts, by FY2025. By doing so, we also aim to continuously increase the dividend.

Ueda: Thank you. I would like to confirm one point. So, in terms of that R&D expense, while it is important to make growth investments, you would also consider increasing it further depending on revenue in light of what you said just now about ROE or profit margin, correct?

Kawaguchi: That is correct. Therefore, JPY400 billion is not a limit. It is a benchmark for cash allocation, and we are just showing that this is the rough estimate. But we will also need to balance the R&D ratio to revenue with profit growth, so we will increase the investment in parallel with revenue growth at around 18% to 20% of revenue.

That said, this target level of 18% to 20% is reflective of our aggressive stance compared to the current level of 16% to 17%.

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

Tanaka: This is Tanaka from Mizuho Securities. Thanks. First, I would like to ask about the outlook for the current fiscal year shown on slide seven of the financial results presentation.

Overall, you expect revenue to decline by a little more than JPY4 billion. How did you factor in the impact of drug price revisions? Furthermore, how did you factor in the drug price revisions every year in the medium-term plan?

Miyamoto: Thank you, Mr. Tanaka. This is Miyamoto. Frankly, the 2021 NHI price revisions are extremely harsh. We formulated the plan for this year and the overall medium-term plan while keeping a close eye on discussions in the Central Social Insurance Medical Council. However, the table was turned at the very end, making the conditions very tough. Revisions were made at the last end.

We have factored in the price revisions to some extent for the current year. The conditions are harsh. I cannot say the volume yet, but there is a considerable amount. We still do not know what will happen over the medium-term period. But, in that sense, if you were to ask us if we made exact predictions of what would happen if the next regular revision or the following annual revisions were to take place following the 2021 revision, we have not incorporated the revisions to that extent.

In any case, the impact would be negligible if it is a new drug, so it is a crucial point for us to continuously roll out new drugs in Japan. We need to finalize the development of drugs like KHK7791 and RTA 402 so that we can steadily advance them to market launch. This will be a vital point in Japan.

Tanaka: I would like to check one point about the part on slide seven where it explains the impact of the NHI price cuts on the right side. Does it mean that you saw a larger-than-expected impact on Nesp-AG, biosimilars, and other new drugs? Regarding Crysvita, the revenue last year was JPY3.8 billion, and this year you expect JPY5.5 billion. It looks like revenue growth is slowing, no?

Miyamoto: Regarding new drugs, as you know, there are various price cuts for new drugs, too, but there is also a new drug price hike that is applied at the end, so part of the price is maintained. All of those factors are taken into consideration in these numbers.

As you say, the revenue growth is JPY1.7 billion. We estimated this number partly in consideration of the ongoing impact of COVID-19. Sudo, do you have anything to add about Crysvita in Japan?

Sudo: Thank you for your question. As you said, my honest opinion is that we can probably go a little higher than JPY5.5 billion. However, the difficulty is that when we analyze the market, we find that the medical institutions using Crysvita are fixed. As you know, this is an orphan drug, so the number of patients is limited. We made a slightly conservative estimate, given the impact of COVID-19, in slowing our efforts to horizontally expand usage. If we cannot even reach this number, then it would be quite troubling. We will work hard to achieve this target.

Tanaka: Okay. Thanks. My other question is about atopic dermatitis. There are still options, and decisions are not finalized, but when looking at other companies, I get a strong impression that these types of drugs are handled either by a dermatology specialist company or a major foreign pharmaceutical company. When deciding on whether to market the drug on your own, or partner with other companies, what would be the decisive factor? Would it be the ability to obtain high-quality or differentiated data?

Miyamoto: Thank you. Obviously, data is all-important, so that would be a major factor. But we will also be looking at the prevailing circumstances and speed, including the competitive situation, as stated earlier. We will also be looking at the ability to expand sales after obtaining marketing approval. All of those factors will be considered to reach a decision.

Tanaka: Okay. Thank you.

Arai: This is Arai of BofA Securities Japan. Thank you. I would like to ask about your thoughts on expanding the market share of Crysvita in adults.

In past medium-term plans and industry papers, there have been references of Crysvita's global market potential being over JPY100 billion. Based on what I see in the new medium-term plan, I think Crysvita probably has the potential of generating JPY150 billion or more in revenue globally. I think part of that is because of the larger-than-anticipated market opportunity for TIO treatment. But an important factor behind this growth driver will be the expansion of market share in adults.

Please tell me your current thoughts on the strategy to expand the market share in adults, considering the solid expansion in Europe, starting with Germany, as stated earlier, and the current conditions in the US.

Miyamoto: Thank you, Mr. Arai. Your question strikes at the essence. We also believe that the crucial point for Crysvita's growth is how we can raise the penetration rate in adults.

Sudo will explain this in more detail later. The key point, however, is how to raise awareness about this disease and the hardships faced by patients of XLH and TIO. Even doctors who are key opinion leaders involved in clinical trials in Europe said they were surprised after administering Crysvita in adults. In fact, there were some doctors who did not know that the situation was so dire for these patients, and even these patients were also not aware of own severe conditions they had had. They were stunned by how much they got better.

The key point will be how much we can raise awareness about the disease, backed up by proper evidence. It will be important to focus on raising awareness about the disease while simultaneously searching for people with the disease.

Sudo will give more details.

Sudo: Thank you for your question. This is the most important area where we will need to implement strategic measures. It has been about two years and eight months since we launched the product in the US. An analysis of the launch shows that the drug gained penetration in adults from an earlier stage than we thought. The rough estimate is about a 6-to-4 ratio. After two years, the usage ratio in adult patients is actually rising. Obviously, the adult population is about four times as much as pediatric patients, so it is a question of penetration rate or whatnot, and there is still more room to improve.

But what I am trying to get across is that this process takes some time. That is one of the factors. Another factor, as Miyamoto touched on, is that we need to acquire the data and put in solid effort to communicate the benefits to many patients. Patients with the disease, including mild XLH, experience a worsening of symptoms over the medium- to long-term. Thus, we want the drug to be involved in their treatment at the earliest stage possible. We will make continuous efforts to provide value to such patients, as described in our vision to provide "life-changing value."

Arai: Thank you. Second, I would like to ask about overseas royalty income. The forecast for this year is around JPY6 billion above the previous year's result. Can this be explained mainly by royalty income from Fasenra, or is there a significant one-time milestone or one-time revenue that will be recorded?

Kawaguchi: The increase is mainly attributable to royalty income from Benralizumab (Fasenra). But it also includes some one-time revenue, as you pointed out. We cannot share the details today, but it does include a one-time revenue.

Arai: Okay. Thanks.

Muraoka: Hello. This is Muraoka of Morgan Stanley. Thanks.

First, I would like to ask about Crysvita in the new medium-term plan. You said that approval in China was obtained in January. How much potential in China do you expect? Or what are the assumptions underlying your China strategy? It will be best if you could give an explanation with numbers. That is my first question.

Miyamoto: Thank you, Mr. Muraoka. China is a country with many potential patients given the huge population. In particular, in the cities of provinces where the income level is high, there tend to be many patients concentrated at large hospitals, making it easier to expand sales. In that sense, China is a country where expanding sales is relatively easy. But, as you know, the insurance policy changes frequently and is quite unpredictable. Therefore, sales are considered based on such background. Sorry, we cannot provide numerical data at this point.

Sudo, would you like to comment?

Sudo: Thank you. We obtained approval in China on January 5. Going forward, there will be a packaging application, and a certification test called an import acceptance test. We are aiming for market launch around the third quarter.

The insurance policy is unpredictable, as Miyamoto just explained. There are policies on a national level and a provincial level, and they change rapidly at various timings. Our Chinese subsidiary is paying especially close attention to the provincial policy, and we intend to launch the product at the best possible timing.

One crucial point is that we are considering starting the market launch in the third quarter as a patient assistance program. It is hard to say anything about the numbers, but personally speaking, I have told our Chinese subsidiary that I need them to reach the double digits in billions of yen of revenue. I asked them to aim for that as the minimum, and that this is the kind of business I would like them to implement. I also want to support them on that front at a strategic level.

Muraoka: Excuse me. When you say a minimum of double-digit billions of yen in revenue, do you mean that this minimum is included in the medium-term plan?

Sudo: No, that is not what I said. I said that this is my personal hopes for the drug. The number that is incorporated in the medium-term plan is lower than that.

Muraoka: Okay. Thanks. My other question is about new drugs, particularly related to KHK4083. My question is in two parts. Earlier, you were mentioning about peak revenue. Let me first confirm whether the definition of a blockbuster drug is a billion-dollar in revenue. Based on that, my question is about the hypothetical scenario if positive results are obtained from the Phase Two trial of KHK4083. If the drug were to advance to Phase Three trials, I think there would be a good chance that the study design would be similar to its Phase 2b. Please tell me how different the test design will be for the Phase Three trial compared to the Phase Two trial if the results for the Phase 2b trial were good.

Miyamoto: Thank you, Mr. Muraoka. As you said, the probability of success will likely increase significantly if the data for the Phase Two trial is good. However, as we have been explaining, we expect that competition will intensify. Thus, designing the Phase Three trial to make the distinctiveness of this drug stand out will be the key to lead to the market launch success. We intend to design the Phase Three trial after examining the data from the Phase Two trial.

I think Torii has some comments about this.

Torii: As Miyamoto just stated, the basic stance is to decide after seeing the results for the Phase 2b trial. If the results are good, then we will start negotiations with the regulatory authorities in each country, such as the FDA, EMA, and PMDA. For example, in Europe, we might be required to conduct a comparator study. Each country has different requirements. Hence, those situations will be taken into consideration as we decide on the Phase Three development plan.

Muraoka: Excuse me. The definition of a blockbuster drug is USD1 billion in revenue, correct?

Miyamoto: Yes, that is correct.

Muraoka: Okay. That is all. Thanks.

Miura: This is Miura from Jefferies Japan. I would also like to confirm one point about Crysvita.

I am looking at page 17 of the medium-term plan. It says here that the drug has been used to treat 3,000 patients so far in Japan, the US, and Europe, meaning that it has been used to treat around 8% of the market potential, which you have indicated.

Earlier, you mentioned that KOL doctors were surprised by the effects. I understand that this is a wonderful drug that you would like to increase penetration among even more patients. Are there any bottlenecks in the short-term or longer-term acceleration of the drug's penetration rate in patients?

If the penetration rate were to accelerate, do you think it would be possible that the drug would, for instance, be used by 50% or 40% of all patients in the future?

Miyamoto: Thank you, Mr. Miura. This is Miyamoto. As I said earlier, it is necessary to raise awareness and understanding of the disease among doctors and patients. That will likely be the bottleneck.

Patients with XLH have been living with those conditions since they were born, so many think that the conditions are normal. They have never had conditions the same as others, so they are not aware of how much inconvenience they are going through. Obviously, there are symptoms like pain and fatigue, but there are also conditions that even patients themselves do not know much about.

Therefore, the crucial point will be to raise the level of our accumulated knowledge into what can be called evidence, and to use that evidence to raise awareness.

Sudo, would you like to add anything?

Sudo: Our biggest concern is whether there are really that many patients. The number of patients is estimated based on the assumption that one in every 20,000 people have this disease. But we are not sure if there are really that many patients.

On the other hand, we also have a tangible feeling that the drug is gradually reaching the patients in need as evident in the market response. Roughly speaking, we have only been able to deliver the drug to one-third of the patients in the European market who we want to reach with this drug in the future. This is because the drug has only been used for pediatric patients, and even for usage in pediatric patients, the drug has only been launched in 23 countries. In this way, the scope of reach is still limited. Numerically, we think the number of patients will likely grow even further.

The same can be said of the US. It has been a little less than three years since the market launch. We expect the penetration rate to increase by around two-fold or three-fold. We especially think so because it is a genetic disease. That is our feeling based on our analysis of the market, and activities are currently underway.

Miura: I would like to confirm one point regarding what you said about establishing the knowledge you have about the drug as evidence. Does it mean you have plans to publish papers or provide strong data on the drug in the future?

Miyamoto: Thank you. Yes, in regard to establishing evidence, we think it will be necessary to publish papers that clarify what the disease is and how it can be treated with Crysvita. We will need to solidify that evidence through a certain amount of investments, including in observational studies.

Miura: Thanks. My second question is about royalty income in connection with Fasenra. You might not be able to answer this question, due to considerations about your partner. The other day, in a conference called AAAAI, Amgen and AstraZeneca said they are developing the drug Tezepelumab and successfully completed Phase Three trials. They announced data indicating efficacy in patients with low eosinophils.

On the other hand, they were unable to produce results in Phase Three studies showing with statistical significance that the drug reduces the dosage of oral steroid. Thus, there is a drug with mixed data that has passed the Phase Three trials and is in the stage before application. Could you comment on the competitive situation of Fasenra in the future, given this competitive environment?

Miyamoto: Sorry. I can only tell you to ask AstraZeneca about this.

Miura: Yes. Okay. Thanks. That is all.

Akahane: This is Akahane of Tokai Tokyo Research Institute Thank you. I have one question about the major items on pages seven and eight and another question regarding cost.

As for the major items, my question is about Nesp and AG. In the fiscal period ended, AG grew robustly, but you expect AG to fall in the current period's forecast. I believe this is attributable to the impact of biosimilar and the NHI price cut. Could you tell me the competitive situation right now with biosimilar manufacturers and how much of an impact you expect quantitatively from the NHI price cut?

Also, in section three of the supplementary material, it shows that the quarterly results for AG is growing from JPY6.1 billion to JPY6.2 billion and JPY6.6 billion. Please tell me the reason for lowering your forecast this fiscal year, despite this growth.

Also, section three of the supplementary material does not include Crysvita revenue in North America and EMEA. Is this something you do not want to disclose for strategic reasons? Or is it difficult to know because the drug will be launched in many different countries?

Miyamoto: Thank you, Mr. Akahane. Regarding Nesp-AG, it is exactly as written here. We expect further growth in biosimilars and also incorporate the impact of the NHI price cut into our forecast for the current fiscal year. As for your question about the numerical figure of this impact, we are sorry, but we cannot share that. The forecast reflects the further growth of biosimilars and the result of the 2021 NHI price cut.

Regarding your question about why we do not have the Crysvita revenue broken down to Europe and the US, one reason is that it is difficult to make a forecast. The drug is being rolled out in partnership with Ultragenyx in the US, and we decided not to break down this number after discussions with Ultragenyx.

Akahane: I understand. This is my last question. On page 11, the SG&A ratio in the period ended was 38%, implying a reduction of JPY7.3 billion. I believe part of this reflects the limitations on sales activities due to COVID-19. On the other hand, some online medical-related companies have doubled their profits on the back of a shift from traditional MRs to medical networks, medical advertisements, and web conferences. What is the content of the cost reduction? On the contrary, in the current fiscal year, you expect to raise the ratio back up to 40%, implying an increase of JPY14.4 billion. Does this mean that the content of costs will change considerably?

Miyamoto: Thank you. The reason we were able to suppress costs so much in the current period was due to COVID-19. It is not just the items related to sales, but costs were suppressed across the entire SG&A expenses. For example, travel expenses dropped significantly. Rental fees for large conference rooms also fell. Those kinds of items were accumulated and led to this result. So, the first point is that the cost reduction does not just apply to sales.

Next, regarding the reason why the cost will increase this year, this is as I already explained. We expect increased investments, including in digital and IT, as we make solid preparations for global infrastructure. Especially in Europe, there are still preparations that need to be made toward launching new products. There will be increased costs for those preparations.

Akahane: I understand. Thank you.

Moderator: Thank you very much for joining us in our briefing meeting today. We look forward to your continued support of Kyowa Kirin.

[END]