Innovation all for the patients

CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2024.12 2Q Financial Results

July 25, 2024

Event Summary

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[Participants]	

[Number of Speakers] 6

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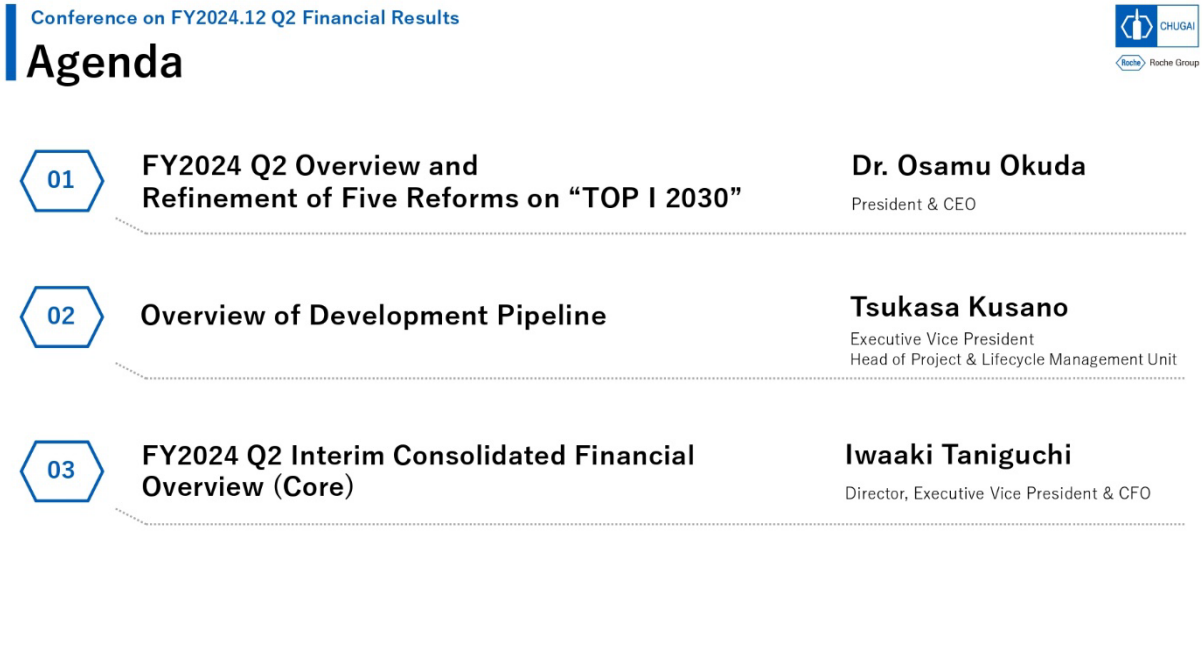
Presentation

Miyata: Thank you for joining CHUGAI PHARMACEUTICAL CO. LTD.'s conference on FY2024 Q2 Financial Results. I am Kae Miyata from Corporate Communications Dept. I would like to serve as your moderator today.



Today, we have an on-site presentation as well as a Zoom webinar. Today's agenda is on the screen in the venue as well as on the screen of the web streaming. Today's conference is going to be held in Japanese, but through the Zoom webinar, you will be able to listen to the simultaneous interpretation in English.

Now Dr. Osamu Okuda is going to present the FY2024 Q2 overview and refinement of Five Reforms on TOP I 2030. If you'd like to capture the screen, this is your time to do so.

FY2024 Q2 Overview

Financial Overview

- **Despite the completion of Ronapreve supply to the government and the NHI drug price revisions etc., strong exports to Roche offset these effects, leading to a slight decrease in revenue**
- **Operating profit significantly exceeded the previous year, resulting in double-digit growth**
- **Earnings forecast remains unchanged for record high operating profit and net income**

Core (billions of JPY)	2023 Jan -Jun actual	2024 Jan -Jun actual	Growth		2024 Jan - Dec forecast	Progress (%)
Revenue	**579.7**	**552.9**	**-26.8**	**-4.6%**	**1,070.0**	**51.7%**
Domestic sales*	313.6	217.2	-96.4	-30.7%	454.9	47.7%
Overseas sales	209.4	268.4	+59.0	+28.2%	467.1	57.5%
Other revenue	56.6	67.3	+10.7	+18.9%	148.0	45.5%
Operating profit	**232.0**	**262.8**	**+30.8**	**+13.3%**	**460.0**	**57.1%**
Operating margin	40.0%	47.5%	+7.5%pts	-	43.0%	-
Net income	**171.4**	**189.5**	**+18.1**	**+10.6%**	**335.5**	**56.5%**
EPS (yen)	**104.19**	**115.15**	**+10.96**	**+10.5%**	**204.00**	**56.4%**

* Recorded sales of ￥81.2 billion for Ronapreve supply to the government in the first quarter of previous year

- Domestic sales declined due to the impact of the decrease in Ronapreve* sales, the NHI drug price revisions, and the market penetration of generic drugs, despite the growth of new and mainstay products. As expected
- Regarding overseas sales, Hemlibra exports to Roche significantly increased. Progress was better than expected
- Other revenue increased mainly due to the increase in Hemlibra related revenue and one-time incomes. Mostly as expected
- With the completion of Ronapreve supply to the government and strong overseas sales, profitability significantly improved, achieving an operating profit margin of 47.5% as a core business.

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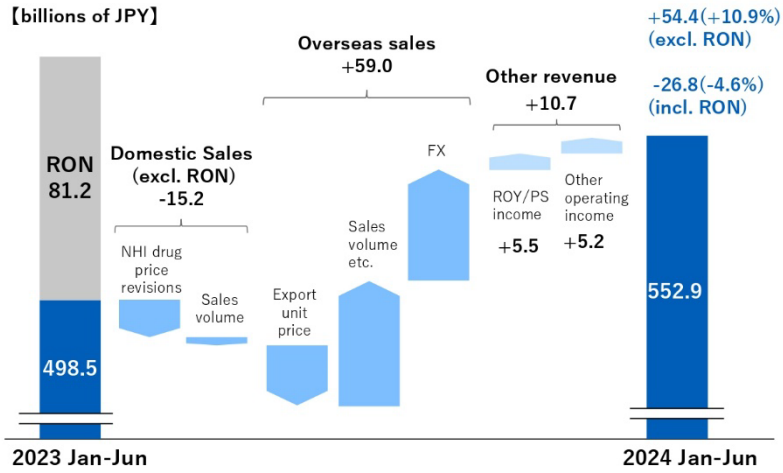
Okuda: I am Okuda. I am President and CEO. First, I would like to look back on the H1 performance of the year. And then, I would like to talk about refinement of Five Reforms on TOP I 2030, our growth strategy. Please turn to page five of your material.

The H1 performance progressed very nicely on track. The revenue compared to the last year was minus 4.6%. This was a marked improvement compared to the big negative impact of Q1 of 24.1%. And it's because of the Ronapreve supply to the government of JPY81.2 billion in Q1 of the last year. Operating profit and net income, despite the declining revenue, increased by more than 10%. This is thanks to the good performance of exports to Roche, especially Hemlibra. Hemlibra exports grew quite dramatically. And because of the product mix change, the operating margin was 47.5%, which is a high profitability. Thus, the progress in H1 was very good. There is no change to the plan to aim for record-high operating profit and net income for the full year.

FY2024 Q2 Overview

Topline Overview



- **Domestic Sales (excl. RON):**

  Declined due to the impact of the NHI drug price revisions, and the market penetration of generic drugs, despite growth in new products such as Phesgo and Vabysmo, and the favorable sales of the mainstay product like Actemra. As expected

- **Overseas sales:**

  Increased significantly by higher sales volume and FX impact, surpassing the decline in export unit price. Progress of Actemra and Hemlibra exports was better than expected.

- **Other revenue:**

  Increased mainly due to the increase in Hemlibra related royalty income as well as one-time income. Mostly as expected

RON: Ronapreve, ROY: Royalty, PS: Profit Share

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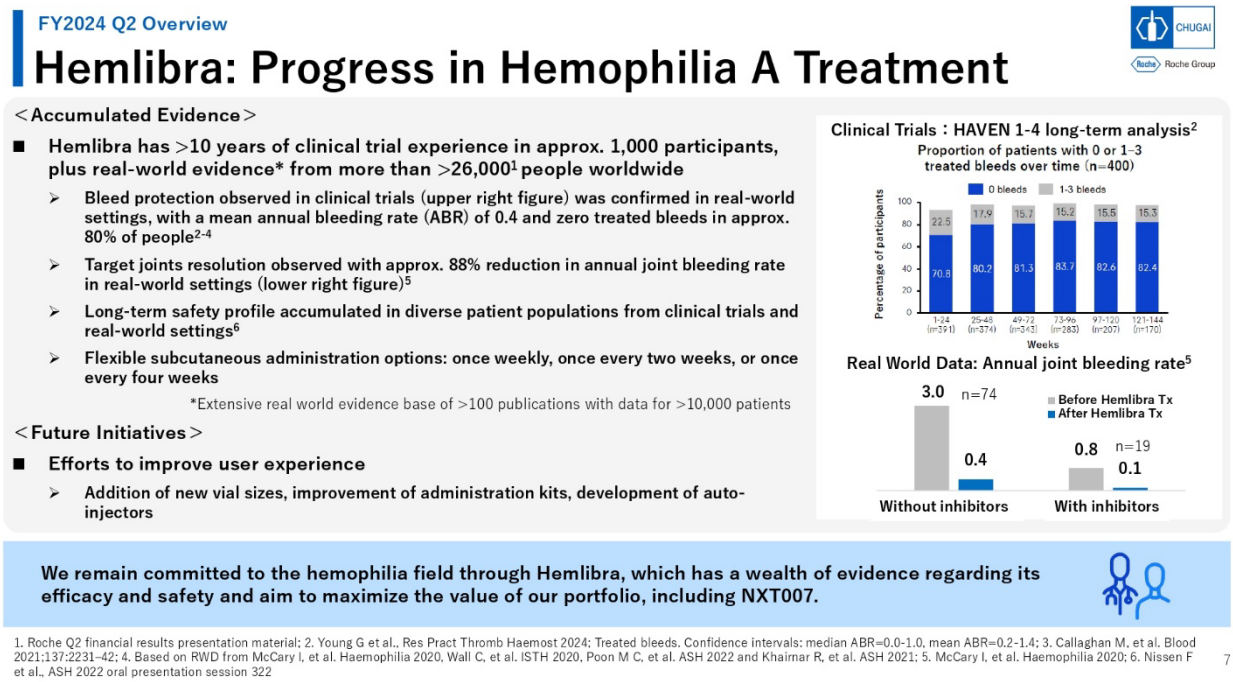
Next slide, page six, please.

Our core business is growing nicely, according to this chart. This is looking at factors affecting the difference of the top line compared to the same period of last year. Excluding Ronapreve, the revenue steadily increased by JPY54.4 billion or 10.9%.

Let's go from the left, domestic sales. New products and mainstay products grew very nicely, but there was a negative impact of NHI drug price revisions. Due to that, domestic sales declined by JPY15.2 billion.

Overseas sales increased significantly by higher sales volume and ForEx impact, surpassing the declining export unit price, and overseas sales increased by JPY59.0 billion. Export of Hemlibra and Actemra especially progressed very well than expected.

Other revenue increased mainly due to the increase in Hemlibra-related royalty income, as well as onetime income. As a result of that, our core business grew very nicely except for Ronapreve factor.



Regarding Hemlibra, which has made a significant contribution to Chugai's business performance in recent years, we have summarized its journey in the treatment of hemophilia A so far.

To summarize Hemlibra's strengths in one word, it is the accumulation of extensive evidence on its efficacy and safety over many years. In particular, having abundant evidence from real-world clinical settings is extremely important in terms of providing reassurance to patients, their families, and medical professionals that it can be used with confidence.

Since the first clinical trial, it's been over 10 years. And overall, across the world, over 26,000 people are using Hemlibra for the treatment of hemophilia A. We now have more than 100 papers published, including the data of more than 10,000 patients. We have real-world clinical evidence, which is very robust in terms of both efficacy and safety.

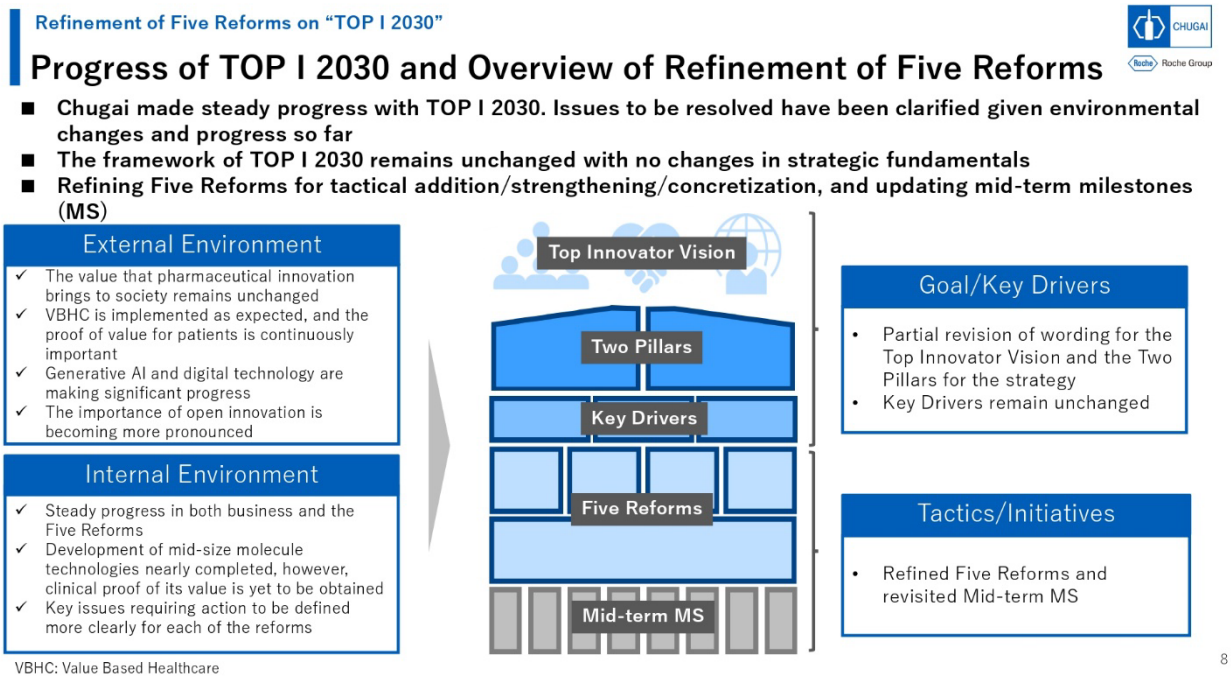
Top right, we are looking at HAVEN 1-4 long-term polled analysis results. More than 80% of the patients had annual bleeding of zero for a long time. And from the real-world data of the advanced nations compared to the previous treatment, Hemlibra increased the zero bleeding rate, meaning that Hemlibra is providing stable prophylaxis of bleeding events in hemophilia patients.

Furthermore, a significant reduction in the number of joint bleeds that cause hemophilic arthropathy has been confirmed, as you can see at the bottom of the slide. And in terms of safety, we have real-world safety data over a long period of time in over 1,000 patients. Just like in clinical trials, we were able to confirm a very favorable safety profile of the product.

We have always listened to the voices of patients and patients' families as well as health care professionals, and worked on improving the convenience of the administration of Hemlibra. Going forward, we would like to work on improving the convenience of the administration even further, and we are now working on the development of auto-injectors for this product.

Thus, Hemlibra has had a lot of real-world evidence for a long time. And based on the experience of the use of this product, we have been able to confirm a high level of satisfaction on the part of the patients as well as the health care professionals. We do believe that this can lead to further competitive advantage.

We will continue to commit to hemophilia field, including NXT007, an investigational project. We would like to continue to increase the value of our portfolio in hemophilia.



From the next slide, page eight, I would like to talk about the refinement of Five Reforms of TOP I 2030.

Top I 2030 is a 10-year strategy through the back casting from the 2030 VISION. This is a long-term strategy, and it has been three years since the start of the strategy, so we thought we should stop here to review the progress so far: what kind of external environment shifts are taking place; and what kind of execution progress is being confirmed in the internal environment? Given such a review, for the remainder of the seven years, what do we have to do; and how do we have to do things; and at what speed in order to achieve the vision of 2030?

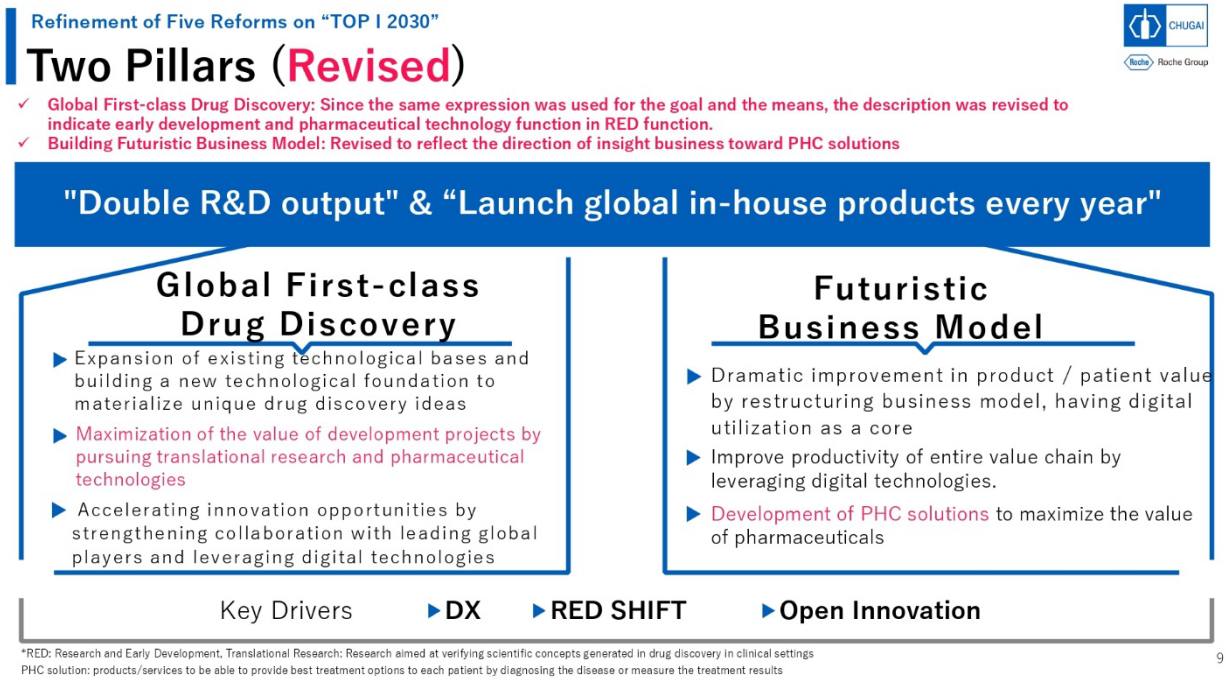
First, on the external environment at the top left. The value that pharmaceutical innovation brings to society remains unchanged. This assumption has not changed. But on the other hand, regarding drug discovery and generative AI and digital technologies, we have seen a lot of advancement in those technologies. And due to that, the importance of open innovation has risen even further.

Next, regarding the execution of Chugai's strategy, we have been steadily advancing many projects without compromising quality, aiming towards the goals of doubling R&D output and launching our own global products every year as set forth in TOP I 2030.

The five reforms have also been making steady progress. Of course, we have faced difficulties, and challenges have become apparent. Looking back on these three and a half years, we have reaffirmed that there is no need to change the fundamental core of our strategy, the goals of TOP I 2030, or its framework. In other words, it is an extremely robust strategy.

At the same time, we have reaffirmed how challenging these goals are. However, while we felt that we could not achieve them by simply following our previous methods, paradoxically, this has also given us confidence that we can achieve them.

This is because our review has revealed the tactics that need to be changed in order to achieve these high goals. In other words, we have been able to refine the reforms necessary for achieving our goals. Today, I will explain the refinement of the RED function reform, which plays an extremely important role in achieving the goals set forth in TOP I, focusing on drug discovery, development, and pharmaceutical operations.



There are no major changes to the two main pillars of our strategy.

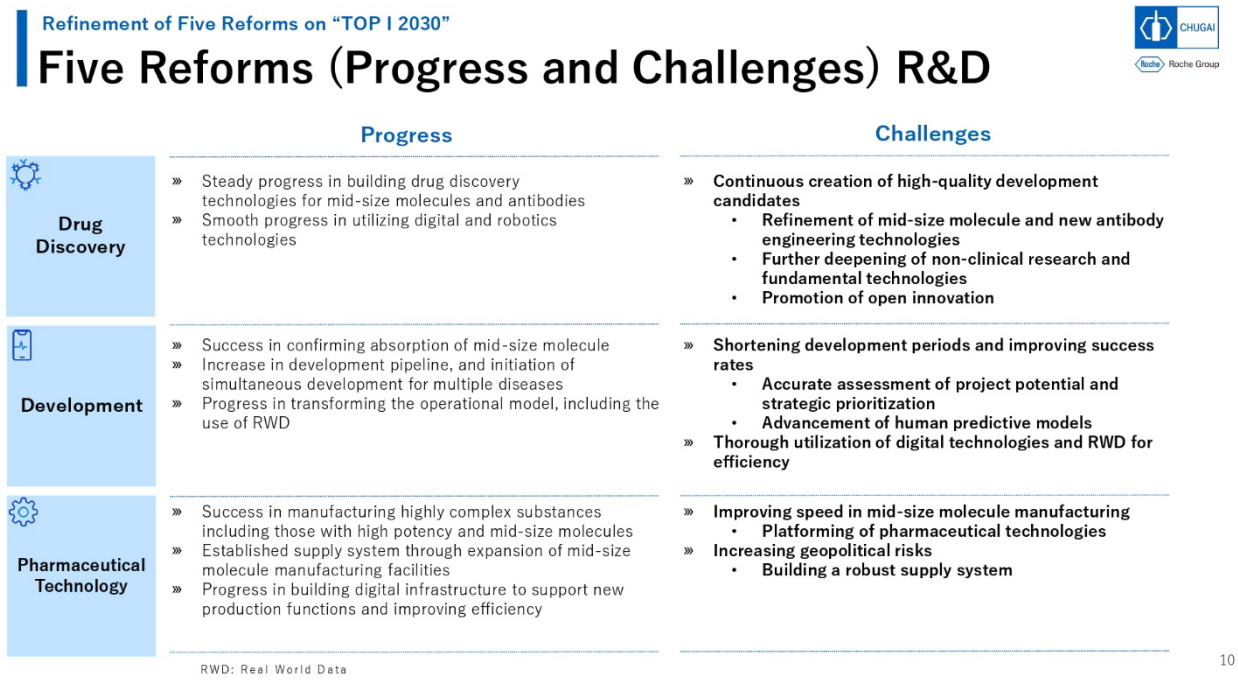
The parts in red indicate minor revisions. On the left side, for achieving Global first-class drug discovery, we have clearly stated the strategy for development and pharmaceutical functions consisting of RED. On the right side, for building futuristic business model, we have redefined the direction of our insight business as PHC solutions.

Looking back on the R&D progress, we have defined what kind of challenges need to be overcome. Drug discovery, development, pharmaceutical technology. I would like to look into each modality.

First, about the antibody. The new technologies have been advanced. We now have proprietary antibody engineering technologies based on which a lot of projects have moved on to the clinical stage, and we are now simultaneously developing different indications. We are using digital and robotics, and we have been able to improve the efficiency of drug discovery to a certain extent. But we do believe that in terms of the progress of many of the projects, which are in the early clinical stage, we still have some room for improvement.

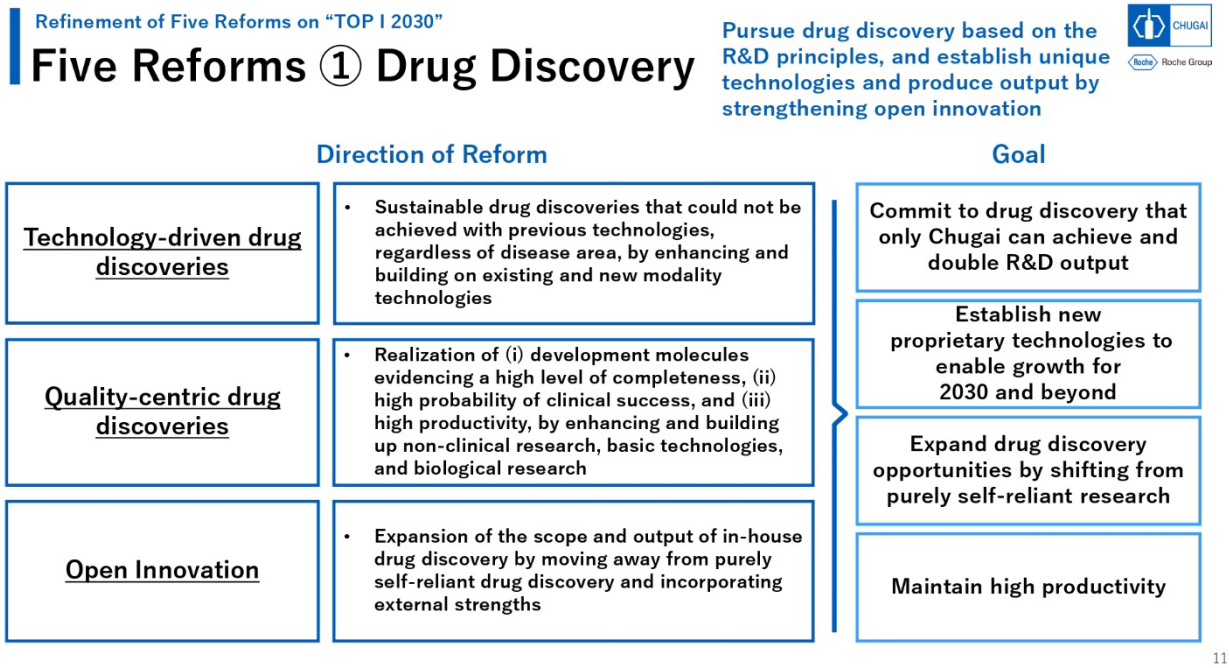
Next is mid-size molecule. LUNA18 oral absorption has been confirmed. As modality, mid-size molecules now have better probabilities of success. But at the same time, on the other hand, PoC has not been achieved yet. For mid-size molecule, a lot of nonclinical projects have made advancement. They are close to portfolio in. And in terms of the pharmaceutical technology, there has been a lot of progress in terms of mid-size molecule with high potency and high difficulty. But compared to antibody, the speed is slower for pharmaceutical technology of mid-size molecules. We need to develop a platform and accelerate the development.

In the past 3.5 years, we have been able to identify common challenges for modalities. We have a lot of projects which are in the early-stage clinical development, but they are still taking too much time. We need to accelerate the early-stage clinical development even further. We need to reduce the time of development and improve the probability of success even further and identify the potential of the value as early as possible and concentrate our resources, meaning that the strategic prioritization is required.



If you think about the long-term growth of Chugai, we need to further enhance new modality in drug discovery, and we should be able to generate molecules at the stage of drug discovery, which are close to the perfection as much as possible.

Like this, while we have had a number of achievements, the challenges that we have to overcome have become visible. Based on this, we have refined respective reforms.



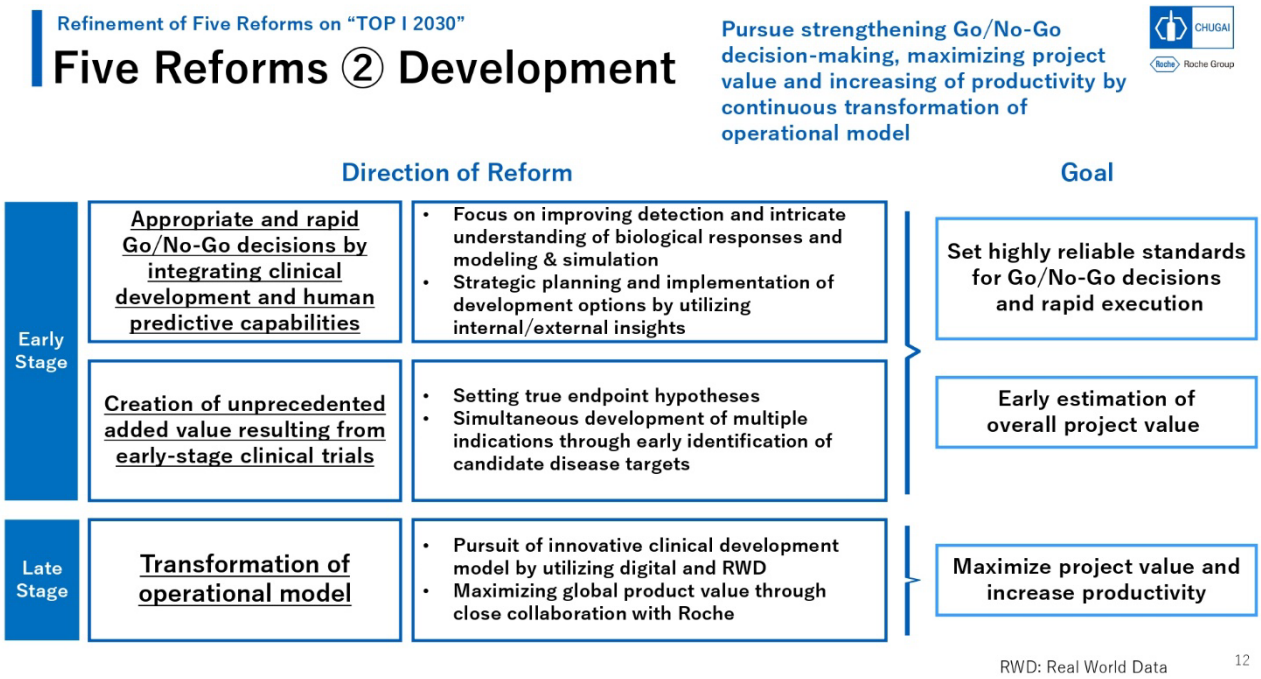
In drug discovery, to clarify the direction of reforms, we have revised the descriptions based on our R&D principles. However, our basic strategy remains unchanged, that is to pursue the multimodality drug discovery.

R&D principle is what articulates the success factors that led to the development of competitive products such as Hemlibra and Alecensa. This includes technology-driven drug discovery and quality-centric drug discovery. With these two as the pillars, we set open innovation as the third pillar.

The box at the center shows the direction of each specific initiative and their goals are shown to the right. As we have always done so, we will commit to the drug discovery, which nobody else but we are able to do, more than ever. We will target the molecule, which nobody else could target. We will conduct drug discoveries, which will realize the MoA, which nobody could ever think of.

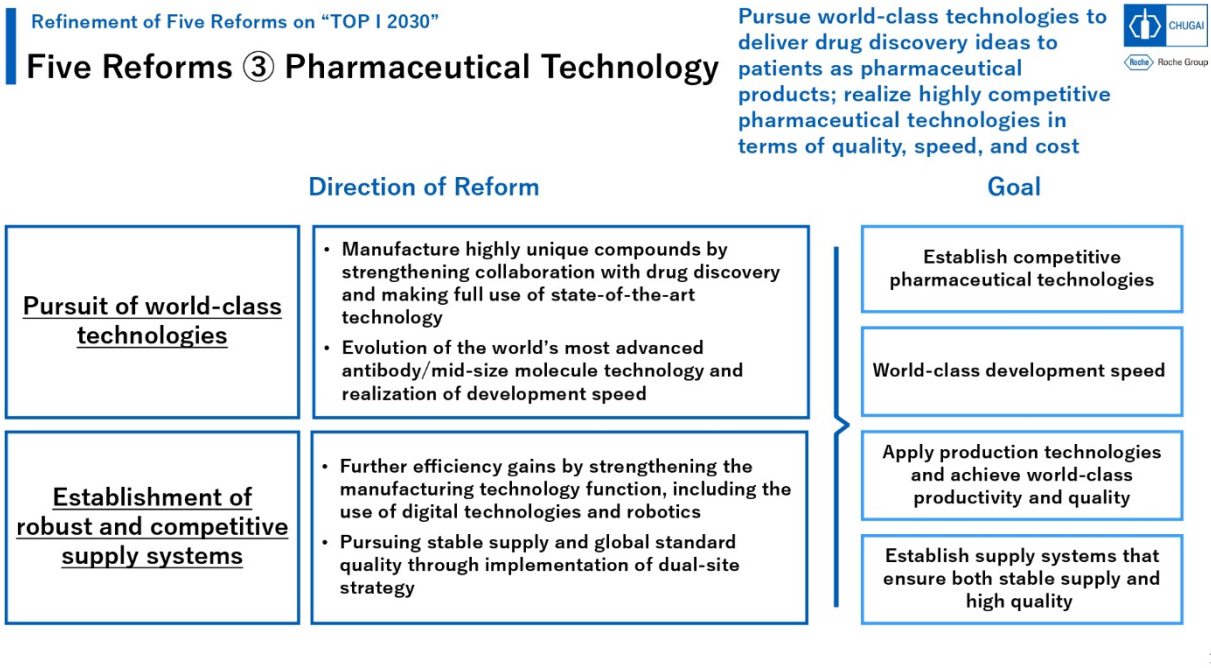
One of the examples is mid-size molecule. To keep our competitive advantages, we will further our technological development. To double the output, we will select the molecule with high level of completeness as a development candidate. Combined with human predictive models, we will aim to achieve high clinical success probabilities. At the same time, we will leverage external innovations and drive Chugai's unique technological development and drug discoveries.

These reforms will not only contribute to doubling the R&D outputs up to 2030, they will also form the foundation for growth beyond 2030.



As you can see, we have refined the reforms and targets for each of the early-stage and late-stage developments. In order us to be able to make the decisions about project values at the early stage, we will create the science-based appropriate clinical development options and execute.

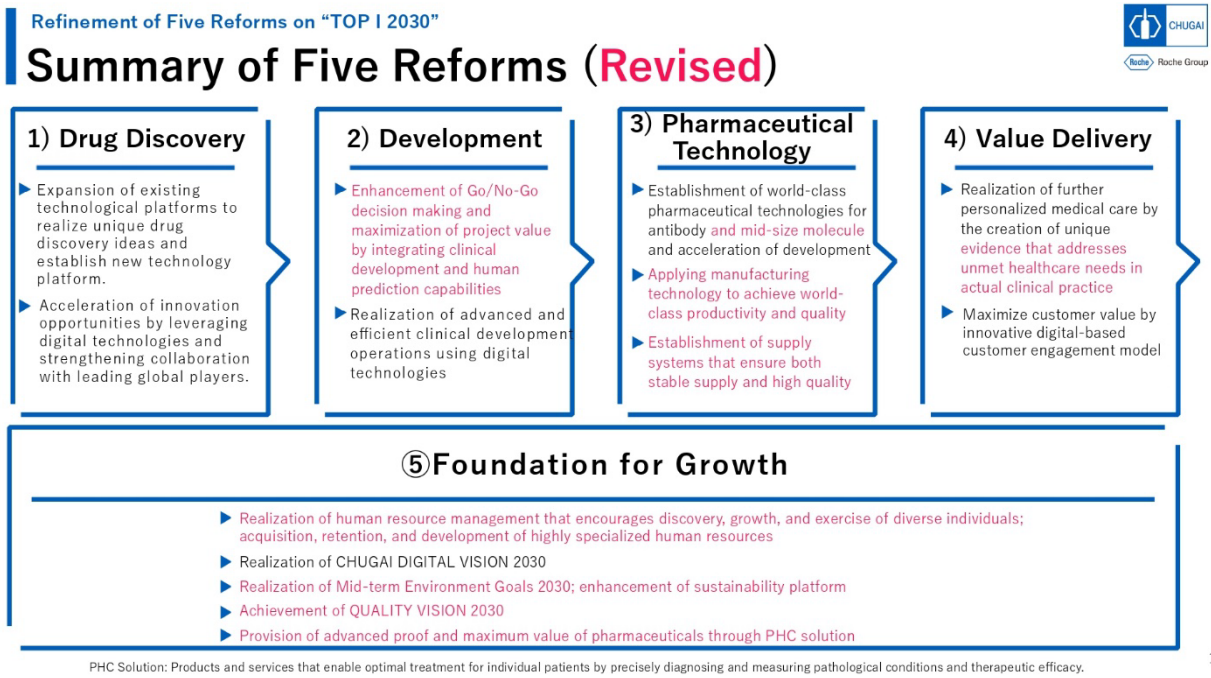
As was explained earlier, in the past, it was too time consuming for us to estimate the values of the projects in the early clinical, so we will set the highly probable go and no-go criteria so as to make agile decisions and we will focus resources in the promising projects. And by running this challenge cycle, quickly, we'd like to double the output while keeping the quality. This is critical in order for us to achieve the TOP I goals.



These are the pharmaceutical technology reforms that have been refined.

In the pursuit of the global standard, we'd like to refine the antibody and the mid-size molecule as well/ For that, we will have to pursue global technology. As for production, we will have to consider not only the cost competitiveness, but also the factors of the robust supply system that is the stable supply factor. And these are the four goals shown on the righthand side.

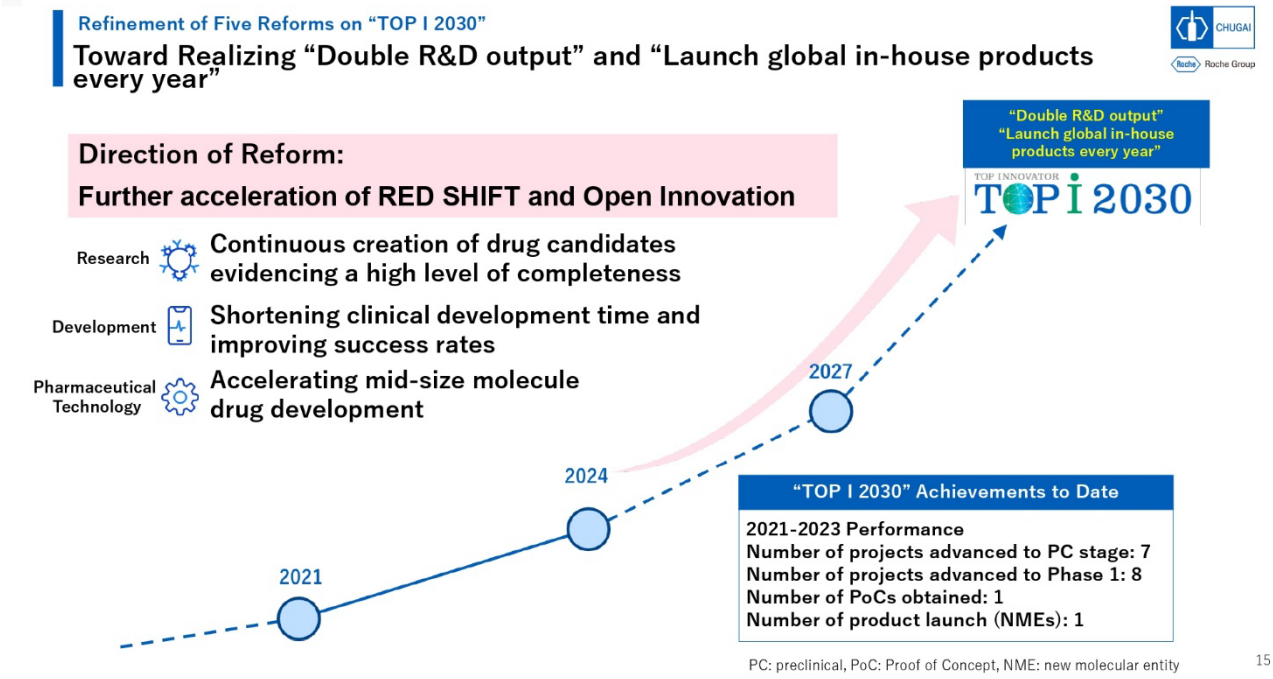
The second development period is that this is the period from the selection of the candidate compounds up to the submission of the clinical trials. We'd like to benchmark against the top-level companies in the world. And for each antibody and mid-size molecule, we have set these targets up to 2030. We will pursue enhancing our competitiveness in all of the quality, speed, cost, and pharmaceutical technology fronts. I have explained about the refinement of the reforms and as for the RED functions.



The next slide shows the Five Reforms summaries, including the functions other than RED.

The portions shown in red are the changes that we have made this time. I will skip the explanations about the functions other than RED. As for the progress and challenge of each reform and about the refinements, we have attached additional slides, so please refer to the slides as necessary.

Based on the refinements, we have revisited the mid-term milestones, and I have added some slides at the end. I will skip the explanations, but we have made the disclosures limited to the following three. First is towards the achievement of the TOP I 2030, the one that has the strategic importance; the second one is the one with which the clear endpoints of valuation metrics have been identified; the third is the one that the investors have high interest in.



This is the last slide.

When we reflect on the first three years of TOP I 2030, we have started to make focused investments into R&D under RED SHIFT. Compared to the past 10 years, the number of PC transitions and P1 transitions has increased. We have started to see the signs of change. But on the other hand, as for the originally anticipated initiatives, we have started to see the gap against the target. We will have to accelerate further the RED SHIFT.

As for pharmaceutical development, this is a long-term effort, so we may not see the outcomes immediately. But with the acceleration of initiatives, we believe that the outcomes will be expanded further.

And this slide shows the curve. As you can see, the curve becomes steeper and that reflects the image that I just explained. With the size of our business, it is a very high target to launch the global product every year, but we will not only pursue the numbers, we would like to work towards the realization of sustainable medicine with high levels and focused on patients. We'd like to overcome the unmet medical needs one by one. We'd like to keep producing the values that are truly sought out by patients.

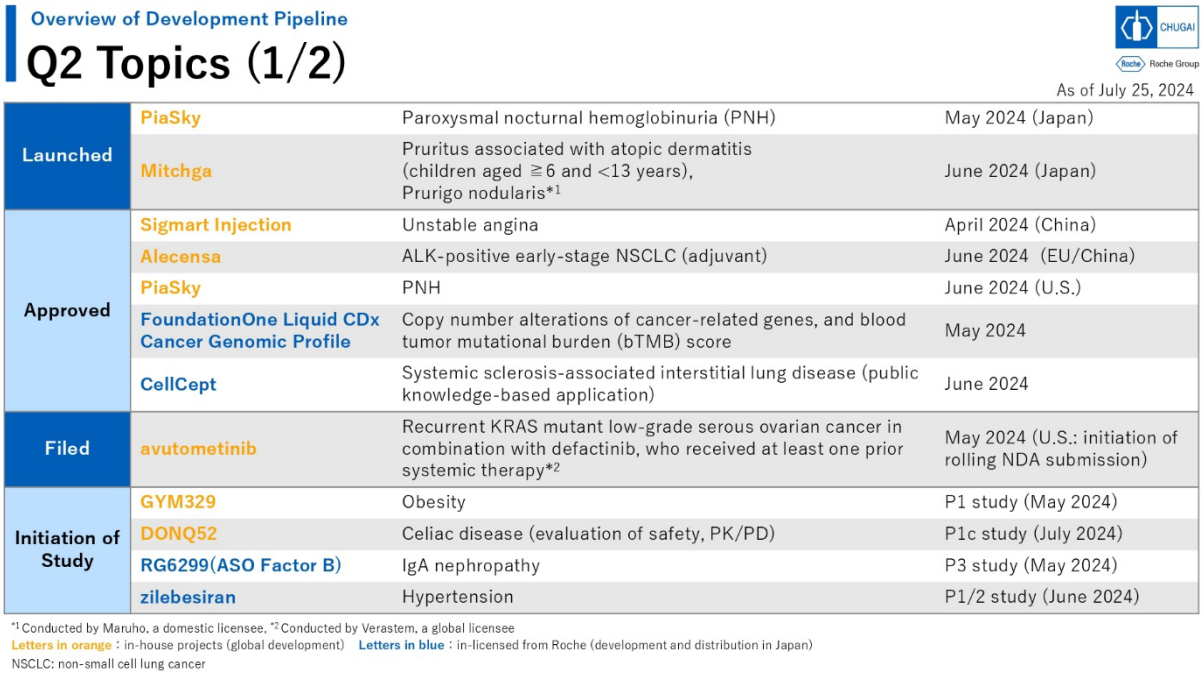
We will not compromise, never compromise the high degree of completeness. Utilizing our science and technological capabilities, we would like to keep producing innovations to address the challenges and unmet medical needs.

And TOP I includes the I. I stands for innovator and I. And that means that each one of us will own the reform challenges. Each and every employee will transform themselves in order to do what they are supposed to do and what they are trying to do. That will create autonomy and that, ultimately, will become a chain to create the strength and synergy of the organization. After achieving the reforms, we believe that the achievement of our ultimate goals will become visible. We'd like to start anew to become the true innovators of the world and do our best towards that end.

That concludes my speech.

Miyata: Now I'd like to ask Kusano-san to give his presentation on the pipeline.

Kusano: I am Tsukasa Kusano from the Project Lifecycle Management Unit. I'd like to give you an update on the development pipeline.



Overview of Development Pipeline

Q2 Topics (1/2)

As of July 25, 2024

Launched	PiaSky	Paroxysmal nocturnal hemoglobinuria (PNH)	May 2024 (Japan)
	Mitchga	Pruritus associated with atopic dermatitis (children aged ≧6 and <13 years), Prurigo nodularis*1	June 2024 (Japan)
Approved	Sigmart Injection	Unstable angina	April 2024 (China)
	Alecensa	ALK-positive early-stage NSCLC (adjuvant)	June 2024 (EU/China)
	PiaSky	PNH	June 2024 (U.S.)
	FoundationOne Liquid CDx Cancer Genomic Profile	Copy number alterations of cancer-related genes, and blood tumor mutational burden (bTMB) score	May 2024
	CellCept	Systemic sclerosis-associated interstitial lung disease (public knowledge-based application)	June 2024
Filed	avutometinib	Recurrent KRAS mutant low-grade serous ovarian cancer in combination with defactinib, who received at least one prior systemic therapy*2	May 2024 (U.S.: initiation of rolling NDA submission)
Initiation of Study	GYM329	Obesity	P1 study (May 2024)
	DONQ52	Celiac disease (evaluation of safety, PK/PD)	P1c study (July 2024)
	RG6299(ASO Factor B)	IgA nephropathy	P3 study (May 2024)
	zilebesiran	Hypertension	P1/2 study (June 2024)

*1 Conducted by Maruho, a domestic licensee, *2 Conducted by Verastem, a global licensee
Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)
NSCLC: non-small cell lung cancer

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Please turn to slide page 24. This shows the Q2 topics. Regarding launch, approval, and filing, apart from Alecensa approval in China and Sigmart, CellCept approval, other topics have already been announced.

PiaSky is the fifth antibody drug developed in-house by Chugai. It was launched in Japan ahead of the rest of the world for the treatment of PNH, and it has been approved in the US, and it has received a recommendation for approval in Europe.

Mitchga has been launched in Japan for the treatment of atopic dermatitis in children and prurigo nodularis.

Alecensa has been approved in Europe and China as an adjuvant treatment for ALK-positive early-stage non-small cell lung cancer following the US. As the first ALK inhibitor for this indication, it has begun contributing to the treatment of patients around the world.

Avutometinib, in combination with defactinib, has begun rolling submissions in the US for the treatment of KRAS-mutated recurrent low-grade serous ovarian cancer.

As for initiation of study, two of them are Chugai in-house projects and two others are in-licensed from Roche.

GYM329, the Phase I clinical trial has been started by Roche for obesity.

DONQ52, the clinical trial to evaluate the pharmacological effects of wheat intake in patients with celiac disease have started. I would like to turn to this later on.

ASO Factor B, global Phase III trial for IgA nephropathy has started.

Zilebesiran has begun a Phase I/II clinical trial in Japan for the treatment of hypertension.

Overview of Development Pipeline

Q2 Topics (2/2)

As of July 25, 2024

Removed from Pipeline	PiaSky	Lupus nephritis: development discontinued	
	tiragolumab+Tecentriq +chemotherapy	Non-squamous NSCLC (1st Line, SKYSCRAPER-06 study): development discontinued	
	Tecentriq + Avastin	Hepatocellular carcinoma (adjuvant, IMbrave050 study): development discontinued	
	migoprotafib (SHP2 inhibitor)	Solid tumors: development discontinued	
	pralsetinib	NSCLC, solid tumors: development discontinued	
Medical Conference	Evrysdi	FIREFISH study (five-year data for Type I SMA): Cure SMA Research & Clinical Care Meeting	June 2024
	Vabysmo	RHONE-X extension study (four-year data for diabetic macular edema): American Society of Retina Specialists Annual Meeting	July 2024
China Breakthrough Therapy Designation	AP306 (EOS789)	Hyperphosphatemia in patients with chronic kidney disease*	June 2024
Business Transfer	Monilac Syrup	Transfer of the business in Japan: Maruishi Pharmaceutical Co., Ltd.	July 2024

*Conducted by Alebund, a global licensee

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)

NSCLC: non-small cell lung cancer, SMA: spinal muscular atrophy

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Next slide. There are five items removed from the pipeline. Tiragolumab and Tecentriq in combination with chemotherapy, which has already been announced. And including this, there are five items.

PiaSky, an in-house project., For lupus nephritis, the study development was discontinued for this indication as a part of the ongoing portfolio revolution by Roche. Therefore, this is now removed from the pipeline.

And the development of Tecentriq plus Avastin was discontinued following results from the IMbrave050 trial evaluating the adjuvant treatment of hepatocellular carcinoma.

Development of migoprotofib, an in-licensed product from Roche, has been discontinued due to the termination of the Collaboration and License Agreement between Roche and Relay Therapeutics.

Development of pralsetinib, also in-licensed from Roche, was discontinued due to the termination of the Global Collaboration Agreement between Roche and Blueprint Medicines.

Two items for medical conferences have already been announced.

AP306, an oral phosphate transporter inhibitor, already out-licensed to Alebund, has received Breakthrough Therapy Designation in China for the treatment of hyperphosphatemia in patients with chronic kidney disease.

Overview of Development Pipeline

2024: Key R&D Milestones

Underlined and bolded are new progress since April 24, 2024

	Product	Indication/Study name	Progress
Projects to be Approved	PiaSky	Paroxysmal nocturnal hemoglobinuria (Japan/EU/U.S.)	Approved (Japan/**U.S.**)
	Alecensa	Non-small cell lung cancer (NSCLC) (adjuvant) (U.S./EU/Japan)	Approved (U.S./**EU**)
	Vabysmo	Retinal vein occlusion	Approved
P3/Pivotal Readouts	Enspryng	Luminesce study: generalized myasthenia gravis	Achieved PE (the results did not reach our expectations on the degree of clinical benefit) /Development discontinued
	Tecentriq＋tiragolumab	SKYSCRAPER-01 study: NSCLC (1st Line)	
	mosunetuzumab	Domestic P1 (Expansion cohort): Follicular lymphoma (3rd Line)	Achieved PE
	mosunetuzumab＋Polivy	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	
	Vabysmo	NIHONBASHI study: Angioid streaks	Achieved PE
P2 Readouts	GYM329＋Evrysdi	MANATEE study: Spinal muscular atrophy (SMA)	

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan)
PE: primary endpoint, r/r: relapsed or refractory

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Page 26. The key R&D events for 2024 were shown in the previous earnings call and the progress since then is shown in bold and underlined.

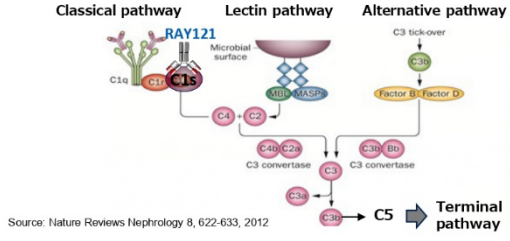
Overview of Development Pipeline

RAY121: Anti-Complement C1s Recycling Antibody

Maximize value through simultaneous development for multiple indications

RAY121

- **Selectively bind to complement C1s and suppress classical complement pathway (CP)**
- **Expected superior efficacy and safety to C3/C5 inhibitors in diseases which CP mainly contributes**
- **Provide convenience (i.e. lower dosing volume and frequency) by recycling antibody technology**
- **Sustained CP suppression and favorable safety profile demonstrated in Ph1a healthy volunteer study**



Source: Nature Reviews Nephrology 8, 622-633, 2012

Project Concept

Deliver the best medical solution (superior efficacy, safety and convenience) to every patient with CP dependent disorders where UMN remains, as early as possible by front-loaded development for multiple indications

[Global Ph1b basket study (RAINBOW trial)]

- **A flagship study in six autoimmune diseases**
- **Evaluate safety & efficacy of RAY121**
- **Preparing for initiation in JP/EU/US**

A RAY121 CLINICAL TRIAL

RAINBOW "Basket" Trial (NCT06371417)

- Anti-phospholipid syndrome
- Bullous pemphigoid
- Behcet's syndrome
- Dermatomyositis
- Immune-mediated necrotizing myopathy
- Immune thrombocytopenia

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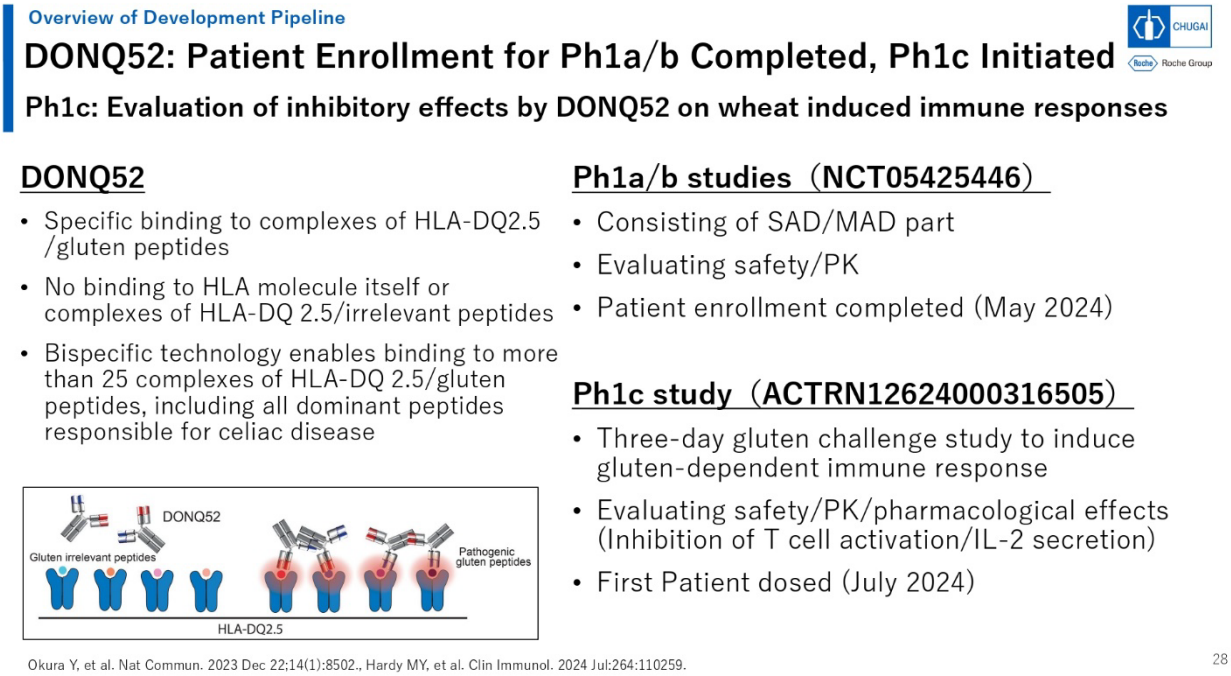
Page 27. Next, I will explain RAY121, which is being developed for the treatment of autoimmune diseases.

This is the first time I am explaining this project, including its mechanism of action. RAY121 is a recycling antibody that selectively binds to complement C1s to suppress classical complement pathway.

It is expected to be more effective and safer than other downstream pathway inhibitors including C3 and C5 in diseases, in which the classical pathway is the predominant contributor of the multiple complement pathways. RAY121 offers convenience by reducing dosage and frequency of administration through our proprietary recycling antibody technology.

In the P1a study conducted to date in healthy adults, we have confirmed sustained suppression of the classical complement pathway and a favorable safety profile. The newly planned global Phase 1b basket study, which is about to start for six autoimmune diseases, is positioned as a flagship study in RAY121.

This is almost unprecedented in the world that such a broad range of diseases have been studied in a single protocol outside of the oncology field. We will pursue the maximization of product values from an early stage through the simultaneous development for multiple disease indications.

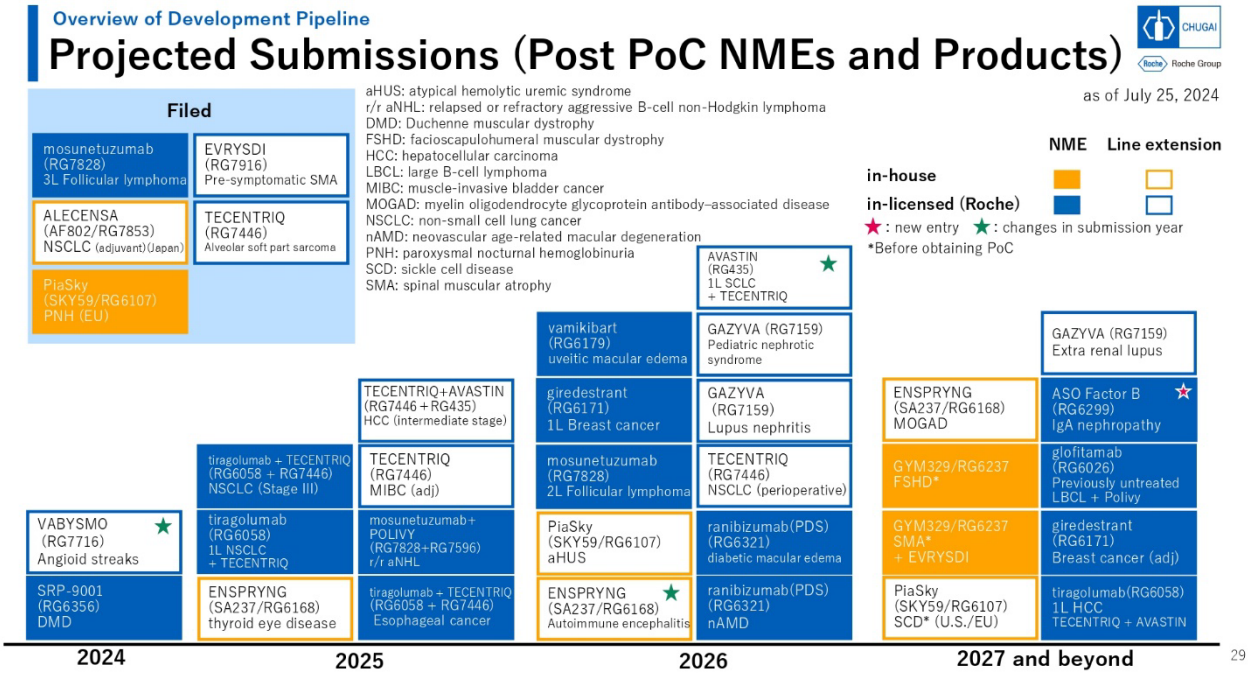


Next, page 28, I would like to explain about our newly initiated study for DONQ52.

DONQ52 is a multi-specific antibody that binds to more than 25 different gluten peptide complexes, which are the main causative agents of celiac disease. Patient enrollment was completed in May of this year for the P1a/b study to evaluate safety and PK in patients with celiac disease.

The newly initiated P1c study is a three-day wheat challenge study for patients with celiac disease. It will evaluate pharmacological effects in addition to safety and pharmacokinetics.

We will evaluate the inhibitory effects of DONQ52 on the immune response induced by wheat ingestion and confirm the usefulness of DONQ52 in celiac disease.



Page 29. Projected submissions are planned. The red star indicate new entry and green stars indicate changes in submission year. The year of submission for some studies has been changed based on the progress of the studies. Several reference materials are attached below, which we hope you will refer to as appropriate.

That concludes my presentation.

Miyata: Thank you very much. Next is from Taniguchi-san, talking about FY2024, Q2 interim consolidated financial overview.

Taniguchi: I am Iwaaki Taniguchi. I am the CFO of the Company. Very nice to meet you. I would like to give you a presentation for the performance of Q2 on the core basis.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

P/L Jan – Jun (Year on Year)

(Billions of JPY)	2023	2024	Growth	
Revenue	**579.7**	**552.9**	**- 26.8**	**- 4.6%**
Sales	523.0	485.5	- 37.5	- 7.2%
Domestic	313.6	217.2	- 96.4	- 30.7%
Overseas	209.4	268.4	+ 59.0	+ 28.2%
Other revenue	56.6	67.3	+ 10.7	+ 18.9%
Cost of sales	-242.3	-160.2	+ 82.1	- 33.9%
(cost to sales ratio)	46.3%	33.0%	-13.3%p	-
Research and development	-76.5	-84.0	- 7.5	+ 9.8%
Selling, general and administration	-45.0	-46.6	- 1.6	+ 3.6%
Other operating income (expense)	16.2	0.8	- 15.4	- 95.1%
Operating profit	**232.0**	**262.8**	**+ 30.8**	**+ 13.3%**
(operating margin)	40.0%	47.5%	+7.5%p	-
Financial account balance	2.7	0.5	- 2.2	- 81.5%
Income taxes	-63.3	-73.8	- 10.5	+ 16.6%
Net income	**171.4**	**189.5**	**+ 18.1**	**+ 10.6%**
EPS (JPY)	**104.19**	**115.15**	**+10.96**	**+ 10.5%**

Domestic sales
Decrease due to the absence of supply of Ronapreve (81.2 billion JPY) to the government recorded in the same period of the previous year, the NHI drug price revisions and the market penetration of generic drugs

Overseas sales
Significant increase in sales of Hemlibra to Roche

Other revenue
Increase in income of Hemlibra and in one-time income

Cost of sales
Cost to sales ratio improved due to a change in product mix, etc.

Research and development expenses
Increase due to investments in research and early development, and progress of development projects

Selling, general and administration expenses
Increase due to impact from foreign exchange and increase in enterprise tax, etc.

Other operating income (expense)
Absence of income from disposal of product rights and gain on sales of property, plant and equipment, etc. recorded in the same period of the previous year

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First, revenue. It declined by 4.6%, or JPY26.8 billion, to JPY552.9 billion. Operating profit increased by 13.3% or JPY30.8 billion to JPY262.8 billion. The big factor for revenue decline was because of the absence of supply of Ronapreve for COVID-19 that was booked in Q1 of last year. Excluding the Ronapreve factor, the revenue actually grew.

Next, let's take a look at the breakdown of the revenue.

First, sales. It was JPY485.5 billion. This was a decline of JPY37.5 billion or 7.2%. Looking at different segments or regions, domestic sales, as I said, because of the Ronapreve impact, it was negative JPY96.4 billion. Excluding Ronapreve, it was only a decline of JPY15.2 billion, and this decline was due to the NHI drug price revisions and the market penetration of generic drugs.

Overseas, Hemlibra exports were very good and compared to the last year, there was an increase of JPY59 billion or 28.2%.

And in other revenue, Hemlibra royalty income increased and also lump sum income increased. Due to that, other revenue was JPY67.3 billion. This was an increase of JPY10.7 billion or 18.9%.

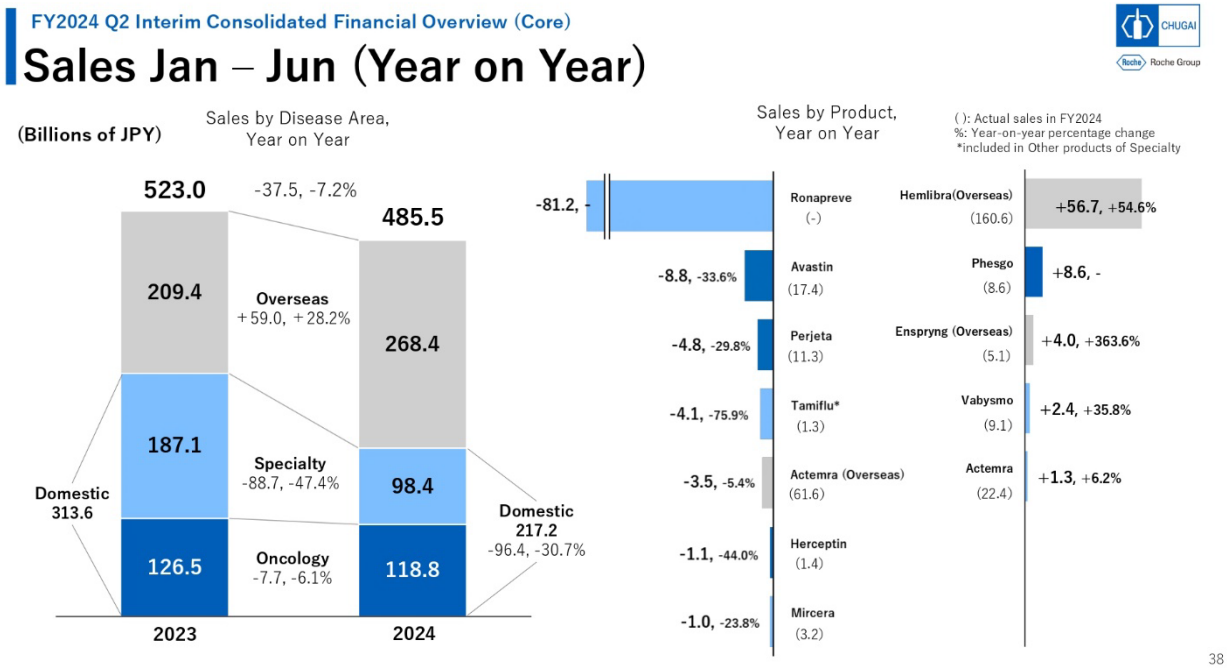
Next are expenses. Cost of sales was JPY160.2 billion, and this is a decline of 33.9% or JPY82.1 billion, because of the elimination of Ronapreve with the high cost of sales. Relatively speaking, in-house products with low cost of sales are increasing. Due to that, the cost of sales ratio improved by 13.3 percentage points to 33%.

As for research and development, because of the research projects and early-stage development projects moving on nicely, it increased by JPY7.5 billion.

In selling, general, and administration, we pursue efficiency improvement, and we were able to suppress the increase only by JPY1.6 billion against the backdrop of inflation and labor cost increase.

And other operating income, there was Bonviva transfer revenue last year. Because of that factor, it decreased by JPY15.4 billion and operating profit increased by JPY30.8 billion to JPY262.8 billion, and operating margin improved by 7.5 percentage points to 47.5%.

Net income increased by 10.6% or JPY18.1 billion to JPY189.5 billion.



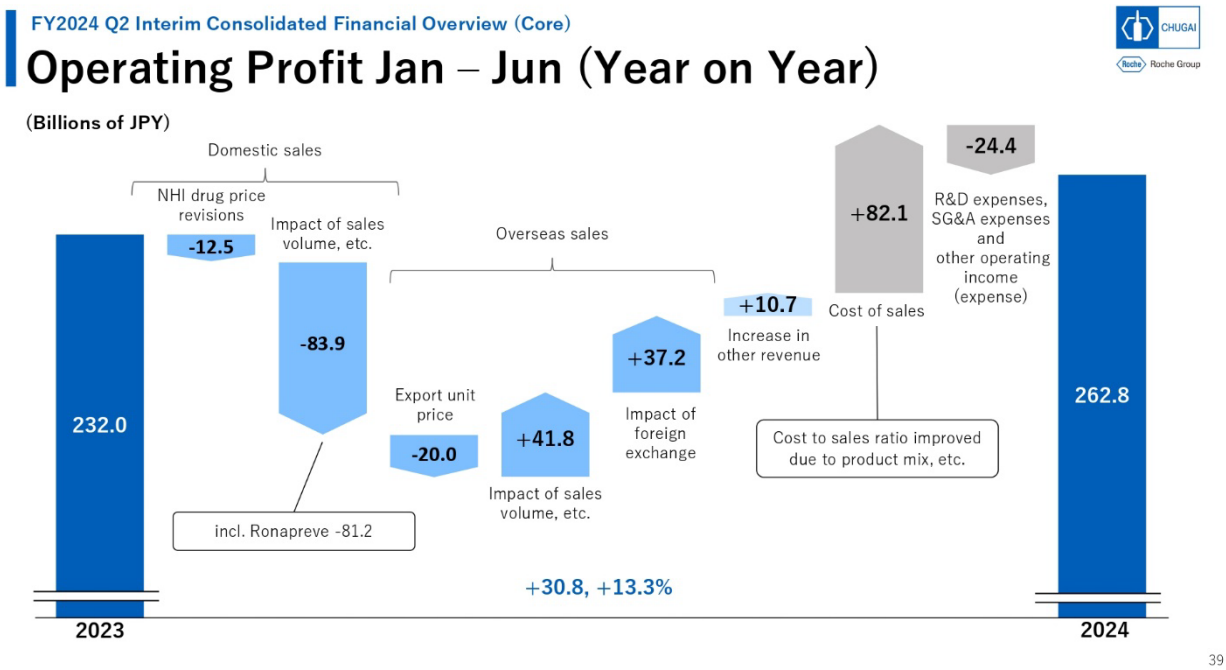
Next is the breakdown of sales increase or decrease.

First, the oncology domestic market. Compared to the last year, YoY, it was a decline of JPY7.7 billion or 6.1%. And it's due to the penetration of generics. Avastin sales declined, but on the other hand, Phesgo, which is a new product, increased, outweighing the declines in the sales of Perjeta and Herceptin.

Specialty declined by JPY88.7 billion or 47.4%, but Ronapreve, which I discussed already, was one of the factors, and Tamiflu also declined. Due to these two products, it was negatively affected. If you exclude these two factors, specialty product sales were more or less at the same level compared to the last year.

There was an impact from the NHI price revision, but new products such as Vabysmo grew quite nicely.

Overseas, at the top in gray, sales increased due to Hemlibra as well as Enspryng. As a result of that, there was an increase of JPY59 billion or 28.2%.



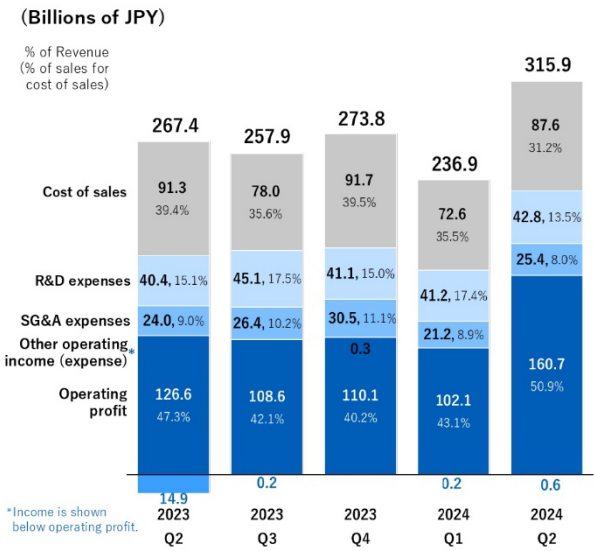
Next, operating profit decrease or increase factors. Compared to previously, we are giving you more information. Starting from the left, look at domestic sales. As you can see, NHI drug price revisions were there, and the Ronapreve impact was quite huge in terms of the negative impact.

Overseas, export unit price declined, but actually, sales volume increased, and ForEx exchange positive impact compensated for the export unit price decline, leading to higher operating profit.

And then other revenue increase was by JPY10.7 billion. Royalty income of Hemlibra and other lump-sum incomes of milestone income, etc., are included. Cost of sales ratio improved due to product mix, and this was a very big positive push factor of operating profit.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Structure of Costs and Profit by Quarter



Year on Year (vs. 2023 Q2)

Cost of sales ratio: improve due to a change in product mix, etc.

R&D: increase due to investments in research and early development, and progress of development projects

SG&A: increase in various expenses

Other operating income (expense): absence of income from disposal of product rights recorded in the same period of the previous year

Operating profit: +34.1 billion JPY, +26.9%

Quarter on Quarter (vs. 2024 Q1)

Cost of sales ratio: improve due to a change in product mix, etc.

R&D: increase due to progress of development projects

SG&A: increase due to various sales activities and in various expenses

Other operating income (expense): same level as the previous quarter

Operating profit: +58.6 billion JPY, +57.4%

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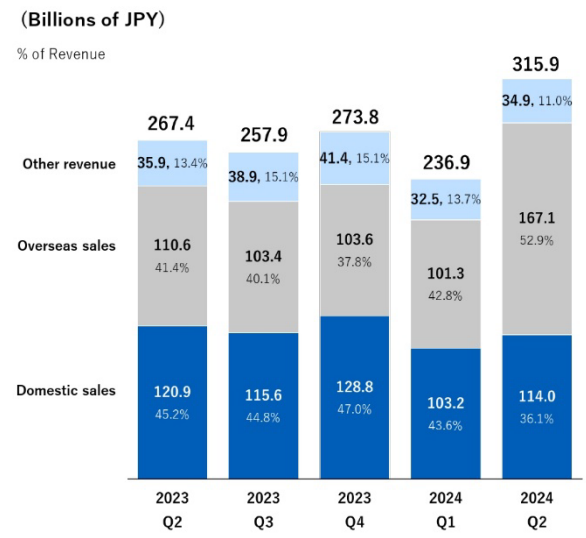
Let's take a look at the costs and profit by quarter. This is a breakdown and development over time. Given the timing shift of export timing, QoQ, there may be some fluctuations. But if you look at only the comparison of Q2 this year and Q2 last year, as you can see, operating profit increased by JPY34.1 billion.

As I said already, there are certain positive factors. Export is one such positive factor.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Structure of Revenue by Quarter



Year on Year (vs. 2023 Q2)

Domestic sales: decrease due to market penetration of generic drugs and impact of disposal of product rights, etc.

Overseas sales: significant increase in sales of Hemlibra

Other revenue: decrease in milestone income, despite increase in royalty income of Hemlibra

Quarter on Quarter (vs. 2024 Q1)

Domestic sales: increase due to growth of mainstay and new products

Overseas sales: significant increase in sales of Hemlibra and Actemra

Other revenue: increase in royalty income of Hemlibra, despite decrease in milestone income

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If you look at the sales structure of revenue by quarter, as you can see, if you compare only Q2 YoY, because of the export sales increase, as you can see, revenue has increased.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

P/L Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual 2024 Jan - Jun	Forecast 2024 Jan - Dec	Progress	2023 Progress*
Revenue	**552.9**	**1,070.0**	**51.7%**	**52.2%**
Sales	485.5	922.0	52.7%	53.7%
Domestic	217.2	454.9	47.7%	56.2%
Overseas	268.4	467.1	57.5%	50.3%
Other revenue	67.3	148.0	45.5%	41.3%
Cost of sales	- 160.2	- 337.5	47.5%	58.8%
(cost to sales ratio)	33.0%	36.6%	-	-
Research and development	- 84.0	- 171.0	49.1%	47.0%
Selling, general and administration	- 46.6	- 102.0	45.7%	44.1%
Other operating income (expense)	0.8	0.5	160.0%	100.6%
Operating profit	**262.8**	**460.0**	**57.1%**	**51.5%**
(operating margin)	47.5%	43.0%	-	-
Net Income	**189.5**	**335.5**	**56.5%**	**51.4%**
EPS (JPY)	**115.15**	**204.00**	**56.4%**	**51.4%**

Domestic sales
Progress in line with forecast of domestic sales (2023 progress excluding Ronapreve: 50.5%)

Overseas sales
Sales of Actemra and Hemlibra to Roche exceeding forecast

Other revenue
Progress nearly in line with forecast

Cost of sales
Cost to sales ratio nearly in line with Jan-Jun forecast

Research and development expenses
Progress nearly in line with forecast

Selling, general and administration expenses
Progress nearly in line with forecast

Other operating income (expense)
Progress nearly in line with forecast

* Jan – Jun 2023 progress versus Jan – Dec 2023 actual

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This looks at the progress against the forecast announced at the beginning of this year.

First, domestic sales. As you can see, the progress to the far right of the last year is described. Because of Ronapreve, 56.2% was the progress last year, which was quite high. This year, at this point in time, it's 47.7%, which is below 50%. But sales activities are going to be higher towards the end of the year, so this is within our expectation.

On the other hand, overseas sales, Actemra and Hemlibra exports are progressing very well. Therefore, we are at the progress ratio of 57.5%.

And other revenue, at this point in time, it's 45.5%. Relatively speaking, it may look a little slower, but the Hemlibra royalty rate is going to go up depending on the cumulative sales of the year, which is a tiered structure. Therefore, towards the end of the year, the sales or royalty income of Hemlibra is going to go up. We are more or less on track for expenses as well.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Sales Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual 2024 Jan - Jun	Forecast 2024 Jan - Dec	Forecast Progress	2023 Progress *
Sales	**485.5**	**922.0**	**52.7%**	**53.7%**
Domestic	**217.2**	**454.9**	**47.7%**	**56.2%**
Oncology	**118.8**	**246.5**	**48.2%**	**48.6%**
Tecentriq	31.1	66.2	47.0%	48.2%
Polivy	15.7	37.3	42.1%	44.8%
Avastin	17.4	33.9	51.3%	52.6%
Alecensa	14.9	31.3	47.6%	47.9%
Perjeta	11.3	22.0	51.4%	47.9%
Kadcyla	7.9	16.2	48.8%	48.1%
Phesgo	8.6	15.5	55.5%	0.0%
Herceptin	1.4	2.2	63.6%	52.1%
Foundation Medicine	3.6	7.1	50.7%	50.0%
Other	7.0	14.8	47.3%	49.4%

(Billions of JPY)	Actual 2024 Jan - Jun	Forecast 2024 Jan - Dec	Forecast Progress	2023 Progress *
Specialty	**98.4**	**208.4**	**47.2%**	**62.8%**
Hemlibra	27.4	56.5	48.5%	48.7%
Actemra	22.4	45.9	48.8%	47.6%
Vabysmo	9.1	22.8	39.9%	43.8%
Enspryng	11.6	22.4	51.8%	45.6%
Evrysdi	7.5	16.5	45.5%	45.5%
Mircera	3.2	6.8	47.1%	50.0%
CellCept	3.1	6.3	49.2%	50.0%
Edirol	2.9	5.6	51.8%	50.7%
PiaSky	0.4	1.8	22.2%	-
Ronapreve	-	-	-	100.0%
Other	10.7	23.9	44.8%	54.8%
Overseas	**268.4**	**467.1**	**57.5%**	**50.3%**
Hemlibra	160.6	267.3	60.1%	48.9%
Actemra	61.6	109.8	56.1%	51.1%
Alecensa	30.5	58.9	51.8%	56.4%
Enspryng	5.1	6.4	79.7%	26.2%
Neutrogin	4.6	6.8	67.6%	48.1%
Edirol	0.2	1.8	11.1%	0.0%
Other	5.7	16.1	35.4%	45.9%

* Jan – Jun 2023 progress versus Jan – Dec 2023 actual

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Now, let's take a look at the progress against the forecast for each product. And of course, there are ups and downs and variations for different products, but overall, across the segment, we are on track in terms of the progress status for the domestic sales.

But on the other hand, overseas, actually, it's 57.5%, as I mentioned already. On the bottom right, overseas sales are doing very well. And of course, there are still some uncertainties remaining. There is a possibility that these numbers exceed our forecast.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Impact from Foreign Exchange Jan – Jun

(Billions of JPY)	vs.2023 Actual rate 【C】vs.【A】	vs.2024 Forecast rate 【C】vs.【B】
Revenue	**+45.3**	**+4.0**
Sales	+37.2	+3.4
Other revenue	+8.1	-0.6
Cost of sales	**-3.0**	**-0.1**
Other than above*1	**-2.6**	**-0.8**
Operating profit	**+39.7**	**+3.1**

Exchange Rate (JPY)	2023 Actual rate*2 Jan - Jun 【A】	2024 Forecast rate Jan - Jun 【B】	2024 Actual rate*2 Jan -Jun 【C】	2024 Forecast rate Jan - Dec
1CHF	138.30	158.77	160.90	159.00
1EUR	141.96	157.00	164.63	157.00
1USD	133.45	137.58	135.45	136.00

*1 Total of R&D, SG&A and other operating income (expense)
*2 Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

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Next is the ForEx impact.

Since the last time, we have renewed the slide contents, and we're showing the quarterly assumed rate and actual rate on the righthand side.

We have conducted a more detailed analysis and the results are here that regarding foreign currency-denominated exportation and importation and royalty, 80% of that is hedged through the forward FX contracts in the previous year. But due to the adoption of hedge accounting, 20% of the remaining portion is in open position.

This is the portion that is exposed to the ForEx fluctuation, and it's the variance from the assumption at the beginning of the year.

As for the assumed rate for the Q2, we have seen JPY3.1 billion positive impact on the operating profit. And as for the revenue side, where the forward FX contract is not done, the actual rate was more favorable than the assumed rate.

And as for the forward FX, contracts are allocated to the revenues and costs and the allocated rate changes from month to month. For the assumed rate for the quarter and for the full year, there is a slight variance.

And the lefthand side, the comparison against the actual rate, this is the ForEx impact.

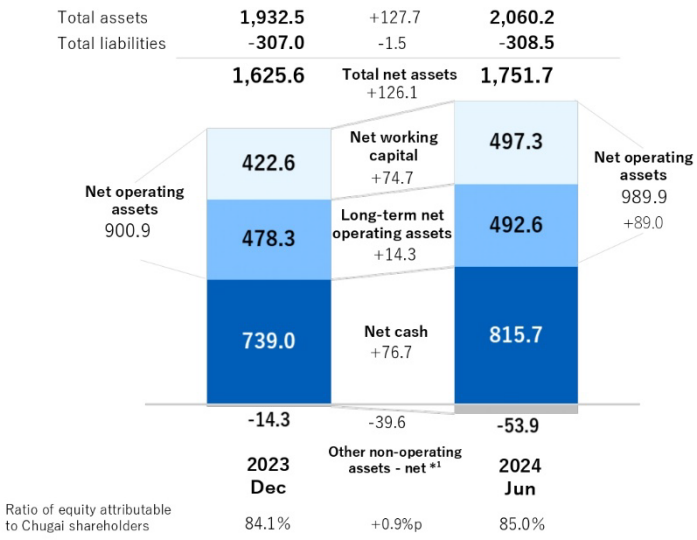
Based on our business structure, the yen depreciation will produce a positive impact in revenues, and that will cause a negative impact on the expenses. But in the net position, we are seeing a significant positive impact.

On the operating profit basis, compared to last year, we have the positive impact of JPY39.7 billion on the cumulative basis or the end of Q2.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Financial Position (vs. 2023 Year End)

(Billions of JPY)



Increase in net working capital

Increase mainly due to an increase in accounts receivable

Increase in long-term net operating assets

Increase in property, plant and equipment mainly due to the investment in

- the manufacturing building for active pharmaceutical ingredients (FJ3) at Fujieda Plant
- the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant

Increase in net cash

(See next page)

Decrease in other non-operating assets – net

Increase in current income tax liabilities and other items

* 1 E.g., deferred income tax assets, accrued corporate tax, etc.

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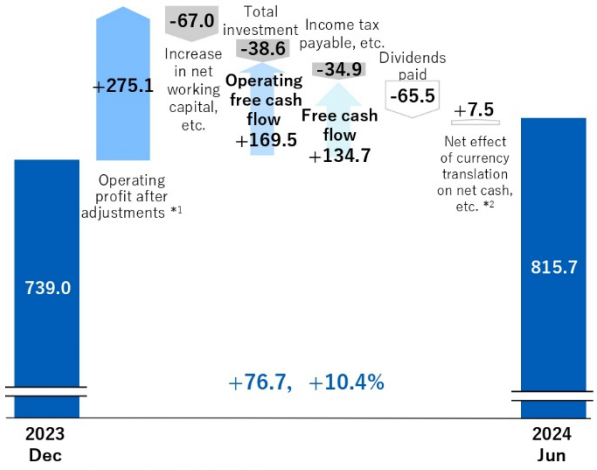
As for the Balance Sheet, the total assets stood at JPY2,060.2 billion. There was an increase in cash and cash equivalents, and there is an increase in the account receivables, so it was an increase by JPY127.7 billion from the end of last year.

As for the net asset as well, due to the net owned capital accumulation due to profit, it stood at JPY1,751.7 billion. As a result, the shareholders' equity ratio remained at the very high level of 85%, and the net cash increased by JPY76.7 billion from the end of last year and stood at JPY815.7 billion as of the end of June.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Net Cash (vs. 2023 Year End)

(Billions of JPY)



Operating profit after adjustment *1	**+275.1**
Operating profit *1	+258.2
Depreciation, amortization and impairment *1	+15.7
Increase in net working capital, etc.	**-67.0**
Total investment	**-38.6**
Property, plant and equipment	-32.9
Payment for lease liabilities	-4.0
Intangible assets	-1.7
Operating free cash flows	**+169.5**
Income tax payable, etc.	**-34.9**
Income tax payable	-40.0
Free cash flows	**+134.7**
Dividends paid	**-65.5**
Net effect of currency transaction on net cash, etc. *2	**+7.5**

*1 Including Non-Core (IFRS results)
*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash(*3)
*3 Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

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These slides show the factors that contributed to the results.

The cash in from the operating profit and from here, we deducted the net working capital increase and the decline due to investment. The operating free cash flow stood at JPY169.5 billion. And from here, we deducted corporate tax and dividend, etc., the cash increased by JPY76.7 billion. It has been added to last year's 739.0 billion yen, totaling 815.7 billion yen.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

P/L Jan – Jun (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenue	**552.9**			**552.9**
Sales	485.5			485.5
Other revenue	67.3			67.3
Cost of sales	-160.9	+0.7		-160.2
Research and development	-84.3	+0.2	+0.1	-84.0
Selling, general and administration	-49.9		+3.3	-46.6
Other operating income (expense)	0.4		+0.4	0.8
Operating profit	**258.2**	**+0.9**	**+3.8**	**262.8**
Financial account balance	0.5			0.5
Income taxes	-72.4	-0.3	-1.1	-73.8
Net income	**186.3**	**+0.6**	**+2.6**	**189.5**
EPS (JPY)	**113.19**			**115.15**

Non-core items (Billions of JPY)

Factors affected operating profit

Intangible assets

Amortization	+0.8
Impairment	+0.1

Others

Business rebuilding expenses	+3.3
Restructuring expenses	+0.5

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It shows the IFRS-based actual and core actuals. These are the adjustments made.

Business rebuilding expenses are starting this year. Well, right now, we are working to renew the operation and business core systems company-wide. We recorded JPY3.3 billion as business rebuilding expenses.

FY2024 Q2 Interim Consolidated Financial Overview (Core)

Summary of Chugai Originated Global Products

Product (Billions of JPY)	FY2024 Q2 Results		Year on Year	Full Year Forecast	Comments
Hemlibra®	Domestic:	27.4	+2.6%	56.5	・Japan: Sales slightly increased YoY despite last year's drug price revision *1. Domestic market share steadily increased
	Export:	160.6	+54.6%	267.3	・Overseas: Sales increased especially in International and EU. Exports are progressing better than expectations
	Overseas local:	1,972mCHF	+8%	-	・We provide value to patients worldwide through convenience and accumulated clinical evidence
Actemra®	Domestic:	22.4	+6.2%	45.9	・Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated
	Export:	61.6	-5.4%	109.8	・Overseas: Impact of BS is minimal, with slight increase in local sales. Exports are progressing better than expectations
	Overseas local:	1,130mCHF	+3%	-	・We provide value to patients through the established evidence as an orginator of IL-6 inhibitors
Alecensa®	Domestic:	14.9	+2.8%	31.3	・Japan: Competitors entered first-line therapy since 2021, but maintained a high market share
	Export:	30.5	-2.9%	58.9	・Overseas: Continued market penetration in all regions. Exports are generally in line with expectations
	Overseas local:	670mCHF	+8%	-	・We anticipate that the expanded indication for NSCLC adj. will further contribute to the treatment of patients
Enspryng®	Domestic:	11.6	+6.4%	22.4	・Japan: Sales increased YonY despite this year's April drug price revision *2
	Export:	5.1	+363.6%	6.4	・Overseas: Sales increased in international and the US. Exports are progressing better than expectations
	Overseas local:	74mCHF	+67%	-	・We provide a convenient treatment option for patients who wish to avoid steroids

* "Export" in the table includes Taiwan local sales in the Chugai territory. 'Overseas local' refers to overseas local sales by Roche, and Year on Year (%) is on a constant exchange rate basis.
BS: biosimilar, NSCLC: non-small cell lung cancer

*1 Market expansion re-pricing in November 2023 (-9.4%)
*2 Market expansion re-pricing in April 2024 (-25.0%)

[Hemlibra] Domestic Hemophilia A Patient Share Trends

Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024
30.8%	31.7%	32.5%	33.2%	33.8%

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Next is the qualitative and quantitative information for the Chugai-originated global products, and the current situations and full-year guidance and qualitative comments are provided just for your reference.

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Outline of Arrangements for Sales, Royalties, and Expenses of Five Products Out-licensed to Roche

P/L account of Chugai	Details of transactions	Actemra	Alecensa	Hemlibra	Enspryng	PiaSky
Sales (Export to Roche)	Export to Roche at the agreed supply price*1	✓	✓	✓	✓	
Royalty and profit-sharing income	Royalty income	✓	✓	✓	✓	✓
	Profit Sharing income in co-promotion counties *2			✓		
M&D expenses	Cost sharing in co-promotion countries *2			✓		
	Receive promotion service fee from Roche (reimbursement of expenses) *3		✓			

*1 PiaSky is manufactured by Roche
*2 Trading schemes of Actemra was changed from co-promotion to royalty in 2023, co-promotion countries of Hemlibra are UK, Germany, France and China
*3 Chugai provides promotion services in UK and Germany

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It shows the major five Chugai-originated products and out-licensing scheme to Roche, whether or not there is a royalty or the burden of selling and general expenses. I believe that the same information was shown two to three years ago.

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Current Status / Plan for Major Investments

		~2023	2024	2025	2026	2027	2028	2029~	Planned investment: Total amount	Planned investment: Investment to-date	Planned investment: Unit	Start of investment	Planned completion
Manufacturing	Fujieda plant	FJ3: Manufacture APIs of small and mid-size molecule drugs for late-stage clinical development and early commercial use							55.5	53.0	billion JPY	2021	2024
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later- stage clinical development and early commercial use							37.4	10.4	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use							19.0	5.9	billion JPY	2023	2025
	Ukima plant		UK3(modification): Manufacture bio drug substance						20.3	0.1	billion JPY	2024	2027
Research and development	CPR		Move and renovate facilities to enhance research functions						60	0	million SGD	2024	2026
	IFReC	Funding to IFReC per comprehensive collaboration agreement							10.0	7.3	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030							109.5 estimated total amount	3.1	billion JPY	2022	2033

* incl. part of investments described in the schedule above

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The last slide is the CapEx. No major change has been observed from Q1 this year. And the UK3 project for manufacturing bio-drug substances in Ukima, as well as the relocation of facilities to enhance research functions in Singapore, these kinds of investments will start from this year.

As for the environmental investments, to achieve the 2030 Mid-Term Environmental Targets, there will be investments exceeding JPY100.0 billion for facility renewals and upgrades in the coming years.

That concludes my explanation. Thank you.

Question & Answer

Miyata [M]: We will move on to the Q&A, question-and-answer session. We are joined by Shinji Hidaka, who is the Executive Vice President, Supervisory responsibility for Marketing & Sales.

Muraoka [Q]: Thank you. I am Shinichiro Muraoka from Morgan Stanley. My first question is about the Company performance. It was a stellar Q2. And one big factor is export of Hemlibra and Actemra. And Q3 and beyond, is there going to be any repercussion? Looking at the sales figures of Roche, Actemra may go further up. But Hemlibra, probably not. This quarter looked a little bit weaker for Hemlibra as well. That's my own impression. For Hemlibra and Actemra exports, Q3 and beyond, what are your thoughts?

Okuda [A]: Hemlibra sales Q1 this year, in the United States, was a negative growth because of the purchasing pattern on the part of the pharmacies. And if you look at the Q2, in the United States, it was a growth of 3%, so it's quite a steady growth. January to June, there was a growth of plus 1%. And Europe and internationally, excluding Japan and US, the growth of the international and EU market is quite significant, driving the overall growth of Hemlibra. And overall, the growth rate is 7%. In terms of the local sales, Hemlibra is growing.

And Actemra, local sales compared to the same period as last year, it's a plus 3% growth rate. Europe biosimilars have been launched. And in the United States, biosimilars have been launched too. How they are going to penetrate the market, it's difficult to read, but they are quite weak. Towards the latter half of the year, what would be the biosimilar penetration? This is something that we need to monitor and watch out for. These are the local sales.

Taniguchi [A]: First, about Hemlibra, Q3 and beyond, we do not expect any worsening of the situation. In international sales, inventories need to be stocked. Because of the long supply chain and because of government tendering, there are certain fluctuations. Therefore, in terms of the exports from our company, we do believe that international sales are going to be quite solid going forward.

And as for Actemra, there is a delay of biosimilar penetration. I think this delay in biosimilar penetration is more than we expected, and our exports are growing accordingly more than we expected. Compared to the forecast, we do not believe we have any concerns to achieve the forecast.

Muraoka [Q]: So regarding Hemlibra exports, Taniguchi-san, what you said is we do not have to be concerned about the export of Hemlibra or expect an upward trend. And for Actemra also, looking at the sales of Hemlibra in the US, there may be repercussions going forward, but we don't have to be worried about that.

Taniguchi [A]: Yes, for exports, we don't have to be worried about both Hemlibra and Actemra.

Muraoka [Q]: And it will be a discussion for more than six months down the line, is there going to be any repercussion in 2025 or beyond? Is there such a risk?

Taniguchi [A]: Well, as for the plan for the next year, we have to work on the plan for the next year from now on. As for Actemra, of course, the penetration of biosimilars is going to be progressing, which has to be incorporated. But Hemlibra international sales are still expanding. Therefore, I do believe this momentum is going to continue. That's our expectation.

Muraoka [Q]: No risk of reduced inventory due to Mim8?

Taniguchi [A]: Well, this is really beyond our time frame, so we can't really say anything about that, but there is still a trend of volume increase.

Muraoka [Q]: Thank you. The second question is about R&D or in-licensing, planning for in-licensing of Carmot GLP-1 products from Roche. Two of them, injectable as well as oral, had good results just the other day. What are your plans for opting in those products to the Japanese market? This is an often-asked question by overseas investors. How are you going to incorporate these products, Roche GLP-1 products, into your strategy in Japan?

Kusano [A]: Roche acquired this subcutaneous once-weekly administration, GLP-1 and GIP agonist CT-388, and once daily oral GLP-1 agonist, CT-996. The Phase I top-line data was announced by Roche. For both studies, this is just initial data, but they look very good, that is, the data is attractive. But having said that, these are the results of Phase I trials and only the top-line results are being announced as of now. I would really like to refrain from making any evaluation of the potential of these products going forward. We would have to monitor the follow-up data going forward.

In terms of licensing in, we can't really give you any details just yet. But generally speaking, we have the development marketing first refusal rights in Japanese market for Roche products. And therefore, we have to consider what is the domestic market for these products and evaluate the products accordingly. Not just for these products, but for all of the products, we can't really give you any answer in terms of the probability of licensing in of those products from Roche.

Muraoka [Q]: What about compared to orforglipron? In terms of GYM329 maximization, how should we understand these Roche products?

Kusano [A]: Chugai in-house products, , GYM329 has been licensed out to Roche. We have licensed out orforglipron to Eli Lilly. These present new treatment options to patients. And these products may create a big value going forward. We have high expectations for that. And currently, there are a lot of products including incretin under development for obesity by each company.

And GYM329, first, as has been explained already, Roche has started development and we would like to really watch the Phase I data for GYM329. We would like to tap into the characteristics of GYM329, an anti-latent myostatin sweeping antibody. Muscle mass or muscle strengths can be improved quite dramatically by that. And subcutaneous injection every once in four weeks presents a lot of convenience. There is a lot of potential in combination with other treatment including incretin or synergistic efficacy and so on. There are many different potentials existing for GYM329.

Chugai and Roche are looking at a very wide portfolio of the products, and for those patients who have complications with obesity, we will be able to address a wide variety of patients in that regard. There is such a potential. It's not just about the widening of the access, but type 2 diabetes or myocardial infarction, cardiovascular complications, several vascular complications, all of these complications can be prevented with this kind of a product.

Those who are patients waiting for treatment or who have concerns about the event of complications, we may be able to give a lot of value to these patients. We'd like to explore a variety of potential together with Roche.

Muraoka [Q]: What about the orforglipron, CT-996?

Kusano [A]: As for orforglipron, clinical trials are ongoing right now. And probably next year, the results of the Phase III trials are going to come out. Let's take a look at the results of this data and evaluate the product.

Muraoka [M]: Thank you very much.

Matsubara [Q]: This is Hiroyuki Matsubara from Nomura Securities. Thank you very much for taking my question. First question is with regard to Vabysmo. When you look at the materials from Roche, the US and Europe growth is very strong. But on the other hand, it seems like there is not much growth in Japan compared to the United States and Europe. Regarding those patients that didn't have the efficacy with the existing drugs, well, how are you going to drive the sales in the clinical sense with this product?

Hidaka [A]: Thank you very much for the question. I'd like to explain the Japanese status with regard to Vabysmo. At the end of March, additional indication for RVO was approved. At that time, we saw a significant change in terms of the sales curve. The sales growth itself has been driven—and as was mentioned before, this is for patients for whom the existing drugs didn't have any efficacies. But at this point in time, the evaluation of safety has been confirmed. And for those patients who are using it for the first time, this has been adopted widely.

On the other hand, the long-term safety with Japanese and the efficacy-related data with Japanese have started to be announced at conferences. After two years, the improvement in efficacy in eyesight is expected to be continued. This is what was not existent in the past. I believe that this will contribute to the treatment of RVO continuously in the future. We'd like to promote this with that in mind. Right now, you are seeing more new patients adopting this.

Matsubara [Q]: I understand. Then will new patients continue to increase by degrees?

Hidaka [A]: I'm sure it is.

Matsubara [Q]: Next is with regards to Hemlibra and Pfizer's gene therapy. They're delivering results of the clinical trials. Will they become a threat to the Hemlibra? What's your take on that?

Okuda [A]: The question asked right now is not just about Japan, but this question applies to the globe. As for the point mentioned, in ISTH, the International Conference, the Phase III data was announced, and comparison of the results that come out of different studies is considered as a taboo and this is not appropriate.

But as far as we look at the efficacy data , compared to the efficacy of Hemlibra, this does not seem to be the case. As was explained with regard to Hemlibra, more than 26,000 people have administered the drug and the long-term efficacy and safety-related evidence have been established. For those who are going through the treatment, when they are satisfied with the treatment, there is hesitancy shown by the patients to change the drugs. As for Mim8, we are not expecting that the drug will cause a huge impact on Hemlibra.

As for gene therapy, as far as we know, only a small number of patients have been administering the gene therapy or have been taking the gene therapy. We do not expect that to have a huge impact on our business.

Haruta [Q]: I am Kasumi Haruta from UBS Securities. I'd like to ask you a question about Actemra versus its biosimilars. Biosimilars penetration is a little bit delayed, slower than expected. Do you have any further information about that? What is the reason of the delay? I recognize that IV products are now launched and subcutaneous products are now being approved. Is that correct? And what about Actemra exports? Subcutaneous biosimilars are going to come to the market going forward. Can you give us more details about the Actemra overall situation?

Okuda [A]: Concerning the Actemra biosimilar situation in the market, according to the public information, we are just collecting public information just like you. Fresenius Kabi has developed a biosimilar product, and they have launched Actemra biosimilar for both IV and SC. Back in April of 2024, the product IV was launched in the United States. And as for SC, July 2 was the launch date in the United States. And as for Europe, at the

beginning of November of 2023, both IV and SC were launched. But which countries in Europe have those products been launched? We have not been able to confirm that information.

But looking at the situation of Actemra, the penetration of biosimilars is slower than we expected. Biogen/ Bio-thera, biosimilar was launched in May, 2024 in U.S. Their product is developed in form of IV only. In Europe, the product was approved on June 24. Across Europe, this biosimilar is going to be launched one by one, I think. And Celltrion is also developing the biosimilar product for both IV and SC. They have filed for IV and SC on January 28, 2024, in U.S., and in February 2024 in Europe as well. That's as far as we know. And I think this is only public information.

Taniguchi [A]: As for exports, our budget or expectations, compared to that, we are actually exceeding. And as I gave you an idea of the progress status, our progress is better than our forecast. We may actually overachieve the targets set at the beginning of the year.

The launch of biosimilars, because of our good results, we are assuming that the biosimilar penetration is slower than we expected. But I would like to refrain from making further comments.

Haruta [Q]: Phesgo, the penetration is quite good in Japan as well. In terms of switching, is it moving forward? And globally, switch to Phesgo has been already over 40%. Can we expect the same in Japan as well?

In addition, while there may be some cannibalization between Perjeta and Herceptin versus Phesgo, if Phesgo will continuously penetrate in the market, including in terms of drug pricing, will the HER2 franchise as a whole see a net increase? Is that correct?

Hidaka [A]: Yes. Regarding switching to Phesgo and whether this is going to be positive, there is a case switching from original Herceptin and Perjeta to Phesgo, or , switching from Herceptin biosimilar plus Perjeta to Phesgo, and both can be expected, so this is going to be positive.

And in terms of switching to Phesgo, it's within the line of our expectation or better than our expectation. Where are we going to be landing? Of course, we have to monitor the situation. Whether it's going to be 40% or above, we would like to aim for a little higher than that. And the current situation, depending on hospitals, the situation may be very different.

What is the focus of each hospital? Depending on that, the switching situation may differ from hospital to hospital. Some hospitals may switch all the patients to Phesgo or, depending on patients, especially those patients who have, in combination with chemotherapy, not just Phesgo, but chemotherapy infusion time needs to be considered. Therefore, they would probably like to continue with the conventional infusion.

And then conventional chemotherapy can give outpatient insurance points, but subcutaneous injection cannot give outpatient points. Depending on what's the focus of each hospital, the situation may be different from hospital to hospital. But the convenience is there, and I think more doctors are feeling the convenience of Phesgo, so we'd like to continue to promote this product strongly.

Haruta [M]: Thank you very much.

Wakao [Q]: This is Wakao from JPMorgan. Thank you for taking my questions. Regarding the export revenue of Hemlibra, would you give us more details if there is—well, I understand that there is an upside compared to your plan. And quantitatively, how much upside did you see? If there is an up quarter in H2, the Q2 progress is very good. We are not sure how we can anticipate the full-year revenue. And Q2, the GP margin was very strong. And with regard to this, the export sales of Hemlibra, was that because of this, that your GP margin was strong in Q2?

Taniguchi [A]: As for the full year forecast, it has been disclosed. And we said that there is a high probability that we are exceeding this. But in terms of how much we can expect in Q3 and Q4, we cannot provide you with the details at this point in time. But one thing we can tell you is that we have a strong momentum.

With regard to the cost, Ronapreve no longer coming into our revenue, this has improved the GP margin and Hemlibra grew significantly as well. And with Hemlibra, the cost/ratio improvement was significant. Please let us refrain from giving you the breakdowns. Q3 and Q4 Hemlibra revenue details cannot be provided.

Wakao [Q]: But in Q2, how much upside did you see with the Hemlibra? Can you tell us that?

Taniguchi [A]: As we mentioned before, please refer to the information for progress rates and how much upside we had as of the end of Q2, please utilize this information. The progress compared to the previous quarter—from the previous quarter is equivalent to the upside.

Wakao [Q]: Thank you very much. And as part of the President's explanation, the TOP I revision, as for the mid-size molecule, where did you see the challenges? Can you elaborate on that once again? The timing at which we will be able to see the LUNA18 data will be next year. Is my understanding correct?

Okuda [A]: Thank you, Mr. Wakao, for your question. As for the mid-size molecule, TOP I 2030 has been started and the clinical study of LUNA18 has started. And the Oral absorption in humans have been confirmed. This increased the probability of success with the mid-size molecule.

On the other hand, in 2024, the ePoC achievement was one of the milestones, but we haven't reached that point. Within 2024, it seems like we are not getting the ePoC and it has taken some time, and that was one of the challenges we faced. But for other projects with the mid-size molecule, in the nonclinical side, we have certain progress with some of the projects. Overall, with regards to mid-size molecule, we have had solid progress.

The other is that the pharmaceutical technologies, with regard to the mid-size molecule manufacturing technologies, we have considered significantly, and we have had solid progress with regard to that.

Wakao [Q]: So as for LUNA18, timing of ePoC has delayed from the original plan, but for the technical side of the efforts, there is not much delay. Is that right?

Okuda [A]: Yes. The oral absorption was confirmed. And the concept that we had with the mid-size molecule was now confirmed, and that was a big progress.

Wakao [Q]: The LUNA18 ePoC is expected to be obtained next year. Is that right?

Okuda [A]: Well, when it comes to when we will be able to obtain the ePoC, the information is not disclosed at this point in time. As soon as we are ready, we'd like to share the information. We'd like to say that this is 2025 or onwards.

Wakao [Q]: So when you say—this will be in 2024, with some delay, the early timing in 2025 is when we can expect. That was the early explanation. That according to what I have just heard, it could be possible that this will be realized only in 2026.

Okuda [A]: Well, we have never articulated the clear timing from Chugai, but when it comes to obtaining the early PoC, this will depend on the progress of the project and the start-up changes day by day. One of the learnings that we had this time is that the best timing of the project is assumed within the team. We have the internal milestone, but there are some unexpected events. Communicating all of these unexpected events to external parties is something that we'd like to refrain from at this point in time.

Wakao [M]: Thank you very much.

Sogi [Q]: This is Miki Sogi speaking. First, this is on the extension of Wakao-san's question. Okuda-san, in your presentation, you spoke about acceleration of the early-stage clinical development, and there are challenges there, and you are going to respond to this problem. What kind of measures are you thinking of in order to respond to this problem of the acceleration of the early-stage development?

Okuda [A]: Regarding TOP I 2030, we started it, and we have obtained major outcomes, which means that from drug discovery to development stage, many of the projects are moved to development stage, eight of them altogether. Many projects on the early-stage development are there. But from your perspective, also I assume that they are not really moving to the next stage as quickly as we would like to see.

For each project, I'm not going to go into the details because of the competition, but we do believe that we need to accelerate each project in the early stage of development.

So what should be done? We have some specific ideas. One is the clinical study design. Go/no-go decision criteria when designing a clinical trial should be set clearer, and then we should conduct clinical trials towards that end. When the results of the clinical trial are out, we do have scientific assessments to judge whether to go ahead or not. If the hypothesis that we assume was not really backed up by the results of the clinical study, then we would have to say no, so we would have to make that judgment appropriately and earlier than before.

By doing that, we have a lot of projects in the early stage of development right now. And for some projects, we can concentrate more of our resources on some projects and accelerate some of those projects even further.

Sogi [Q]: Thank you. May I ask you another question? So as a challenge, what you have defined is that once the data is out, it's too slow for you to make a decision to move on to the next step. Is that one of the reasons why you think you are too slow?

Okuda [A]: Well, yes. Data is obtained in many different forms and go/no-go criteria set at the beginning, that has to be more scientific so that we can make a judgment on go/no-go more clearly.

Sogi [Q]: Understood. Another one is a question about Hemlibra. According to what you said, and looking at the results of Roche, overall sales growth, where I think your export overseas sales actually exceed the actual sales on the ground. And Taniguchi-san already explained to us that the sales volume alone is not the factor. But international sales are growing very strongly. And because of that, the inventory is increasing. That's how I understood the comments given by Taniguchi.

If that is correct—or is my understanding correct to begin with? And if that is the case, over time, international inventory is going to be stabilized, so to speak. Is my understanding correct?

Taniguchi [A]: Well, local sales growth is exceeded by our export sales. Yes. And if that is the case, yes, it's because of the inventory being built. But then there are certain differences across different regions. As for International, our growth is 32%, and unit prices are lower. But volume-wise, I think that is well compensated and export sales are really increasing. And I think that is the background, but I can't really give you any further breakdown.

Sogi [M]: Understood. Thank you.

Hashiguchi [Q]: This is Kazuaki Hashiguchi. Thank you for taking my questions. Open innovations, with regard to this TOP I 2030, this is the first time hearing an explanation about this. Compared to the past, the open innovation, strengthening policy is where I felt a difference from the past years. But after this, I haven't seen

conspicuous progress. It's been just three years. There are not many outcomes that get publicized, and that's not a surprise given the reflection made by Dr. Okuda and the guidelines for the future. He rarely referred to the open innovations. And at this point in time, how do you evaluate the progress to date? And how are you going to take on these initiatives going forward?

The reason why you didn't mention this is because the resources internally have been bolstered. The necessity of open innovation has come down, and that's what I felt it is about. Is my understanding correct?

Okuda [A]: Mr. Hashiguchi, thank you for your question. With regards to open innovation, TOP I 2030, this is one of the three key drivers, and we have focused on this for a while. There are not many deals and projects related to the third pillar of drug discovery for Five Reform that we are able to explain to the external stakeholders. . External technologies will be leveraged at the same time as the internal technologies, and the target molecule technologies and our own technologies will be utilized and to expand the scope of drug discovery, so we'd like to make sure this will generate output.

Well concerning the Chugai Venture Fund, the corporate venture fund was established this year, and it started its operations. Their activities have already started. And because of this, the start-up in US, their information started to come through. We cannot talk about the future, but based on the information we're getting from them, there could be some projects where we can collaborate, and we may be able to consider providing funds. And as that company grows, then that may create opportunities where Chugai will be able to collaborate.

In JPMorgan Health Care Conference, we actually declared that this is something we're starting. But at this point in time, in terms of the flow of the information from them, we are getting a strong stream of information inflow.

Going forward, the open innovation through the collaboration with external stakeholders is something that we are expecting to see in the future out of these initiatives.

Hashiguchi [M]: Thank you very much.

Miyata [M]: Thank you. From Bloomberg, Duan, please.

Duan [Q]: Thank you. I would like to ask you about the Inflation Reduction Act, putting a lot of pressure on drug prices in the United States. What kind of impact are you seeing?

And the presidential election is just around the corner. How is it going to affect your company going forward?

Okuda [A]: Thank you for your question. The first question, I couldn't really hear that. Inflation Reduction Act in the United States, how is it affecting our products in the US? Is that your question, I think? About the IRA, I think 10 or so products have already been designated and more products are to be added this year. But so far, none of our products are being affected because of IRA. But depending on the size of the molecules, 9 or 13 years after those years, price negotiation may start. This is the scheme proposed. Drug discovery and the development strategy of our company may be affected to a certain extent, and that has to be kept in our mind in coming up with our strategy.

In terms of the presidential election, it's quite a murky situation. Biden has stepped down from the race. Harris is probably the candidate. It's very difficult to see what is going to happen. But Republicans or Democrats, either way, in terms of drugs, I don't think any positive wind is growing in that regard.

Duan [Q]: Thank you very much. In terms of development, which may be affected going forward in the US and that has to be kept in mind, in the long run, right, what you are saying is regarding the direction of development, is that going to be affected or are prices?

Okuda [A]: Well, low molecules, with smaller molecular weights, the exclusivity period is only nine years. A price negotiation can take place earlier, much earlier. And this is generally speaking, drug discovery-wise, when we come up with new projects and if it's bigger molecules like antibodies, is that a better approach? Or are we going to go for more low molecules or midsized molecules? If we have options, which one should we go for? I think that is the kind of consideration we need to have.

And IRA, I wonder whether this law or act is going to be kept intact. Of course, we have to take a look at that. Depending on the rule of IRA, should the strategy of drug discovery be altered? Is that a good idea? That is a fundamental question. That's why I said it has to be kept at the back of our mind. There are certain needs on the part of the patients. And if our technology and science can satisfy those needs, we would like to go for it all the time. That's why I said at the back of the mind, it has to be kept. That's all.

Duan [M]: Thank you. Understood.

Wada [M]: This is Hiroshi Wada from SMBC Nikko Securities. Regarding GYM329, the development is underway for the indication of obesity. Bimagrumab is an activin receptor inhibitor which is in Phase II stage, and good results coming out. What is the positioning are you aiming at with GYM329? And right now, in Phase I, what kind of data are you expecting out of the Phase I this point in time?

Kusano [A]: Mr. Wada, thank you for your question. This is Kusano. I will answer your question. Firstly, phase I initiated by Roche, let me briefly explain about this. Roche initiated the study with the healthy and overweight people, and the PK/PD and safety will be evaluated.

As you know, GYM329, in combination with risdiplam, we are progressing the clinical trial, targeting SMA, and this time, we are utilizing healthy, overweight adult people to evaluate the PK/PD and safety. Based on the results of this study, we'd like to determine the endpoints in order for this to move on to Phase II.

With regard to the comparison with other drugs, as I mentioned before, GYM329 is targeting latent myostatin with sweeping antibody. This is administered once every four weeks. And for Activin receptor 2B, there is another antibody for that. But as a result of nonclinical test, GYM329 has been confirmed to have the efficacy in increasing muscle power stronger than that.

Why we are seeing this result is that myostatin has similar proteins and GDF11 is what it is called. The structure is quite similar with this, especially the mature type and active type myostatin. Almost all of them, 90% of the structure is the same. For the mature type and active type myostatin and if the antibody targets that, it also binds to GDF11. The antibody which binds to Activin receptor IIB also neutralizes the mature type and active type of myostatin, so it would neutralize GDF11 as well. Regarding GDF11 neutralization, if there is no problem, then that is okay.

However, when it comes to increase the muscle, the mechanism is quite different, and it will have the negative mechanism in my opinion. GYM329, which inhibits latent myostatin, will not inhibit GDF11. Therefore, we can expect a stronger efficacy by GYM329. That is our hypothesis.

We are going to do further studies to validate the hypothesis based on the results of the clinical trials. That's what we are currently thinking.

Wada [M]: Thank you.

Miyata [M]: Thank you very much. With that, we're now approaching the end of the allocated time, so we'd like to conclude this Q&A session.

With that, we'd like to close the earnings call for Chugai Pharmaceuticals for Q2 of FY2024. For those questions which we weren't able to answer, we'd like to follow up individually. The last page of the presentation document shows the email address and phone numbers for your further questions.

Thank you very much again for participating in this earnings call.

[END]

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