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CHUGAI PHARMACEUTICAL CO., LTD.

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CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2024.12 Q3 Financial Results

October 25, 2024

Event Summary

[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.
[Company ID]	4519-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	Conference on FY2024.12 Q3 Financial Results
[Fiscal Period]	FY2024 Q3
[Date]	October 25, 2024
[Number of Pages]	33
[Time]	18:00 – 19:18 (Total: 78 minutes, Presentation: 38 minutes, Q&A: 40 minutes)
[Venue]	Webcast
[Venue Size]	
[Participants]	

[Number of Speakers]	5	
	Osamu Okuda	President & CEO
	Iwaaki Taniguchi	Director, Executive Vice President & CFO
	Tsukasa Kusano	Senior Vice President, Head of Project and Lifecycle Management Unit
	Junichi Takano	Head of Marketing and Sales Div.
	Kae Miyata	Head of Corporate Communications Dept.
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	Hidemaru Yamaguchi	Citigroup Global Markets
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*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

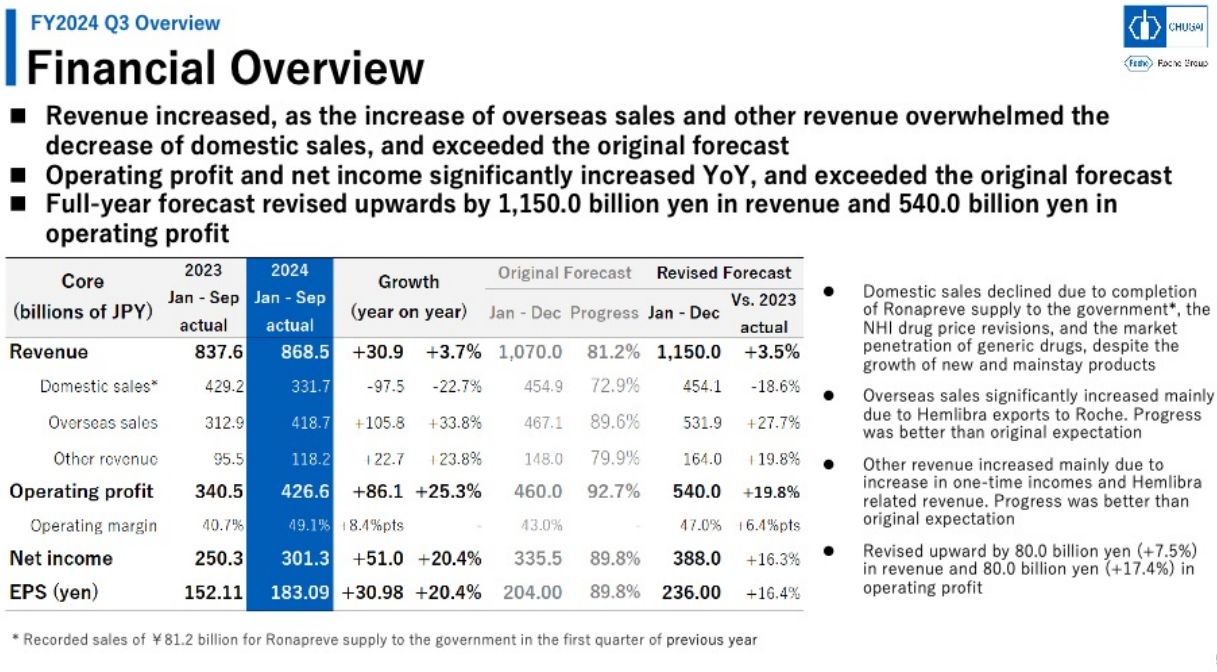
Presentation

Miyata: Thank you for joining Chugai Pharmaceuticals earnings call on the financial results for FY2024 Q3. I am Miyata from Corporate Communications Department. I would like to serve as your moderator today.

Today, we have a Zoom webinar and today's agenda is in the document distributed. Today's call is going to be held in Japanese, but through the Zoom webinar, you will be able to listen to the simultaneous interpretation in English.

We will take questions after the presentation. We plan to have 30 minutes for the question and answer session following the presentation. During the presentation, please allow us to mute your microphones. We thank you for your cooperation.

Now, Dr. Osamu Okuda is going to present FY2024 Q3 overview.



FY2024 Q3 Overview

Financial Overview

- **Revenue increased, as the increase of overseas sales and other revenue overwhelmed the decrease of domestic sales, and exceeded the original forecast**
- **Operating profit and net income significantly increased YoY, and exceeded the original forecast**
- **Full-year forecast revised upwards by 1,150.0 billion yen in revenue and 540.0 billion yen in operating profit**

Core (billions of JPY)	2023 Jan - Sep actual	2024 Jan - Sep actual	Growth (year on year)		Original Forecast Jan - Dec	Original Forecast Progress	Revised Forecast Jan - Dec	Revised Forecast Vs. 2023 actual
Revenue	**837.6**	**868.5**	**+30.9**	**+3.7%**	1,070.0	81.2%	**1,150.0**	**+3.5%**
Domestic sales*	429.2	331.7	-97.5	-22.7%	454.9	72.9%	454.1	-18.6%
Overseas sales	312.9	418.7	+105.8	+33.8%	467.1	89.6%	531.9	+27.7%
Other revenue	95.5	118.2	+22.7	+23.8%	148.0	79.9%	164.0	+19.8%
Operating profit	**340.5**	**426.6**	**+86.1**	**+25.3%**	460.0	92.7%	**540.0**	**+19.8%**
Operating margin	40.7%	49.1%	+8.4%pts	-	43.0%	-	47.0%	+6.4%pts
Net income	**250.3**	**301.3**	**+51.0**	**+20.4%**	335.5	89.8%	**388.0**	+16.3%
EPS (yen)	**152.11**	**183.09**	**+30.98**	**+20.4%**	204.00	89.8%	**236.00**	+16.4%

- Domestic sales declined due to completion of Ronapreve supply to the government*, the NHI drug price revisions, and the market penetration of generic drugs, despite the growth of new and mainstay products
- Overseas sales significantly increased mainly due to Hemlibra exports to Roche. Progress was better than original expectation
- Other revenue increased mainly due to increase in one-time incomes and Hemlibra related revenue. Progress was better than original expectation
- Revised upward by 80.0 billion yen (+7.5%) in revenue and 80.0 billion yen (+17.4%) in operating profit

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

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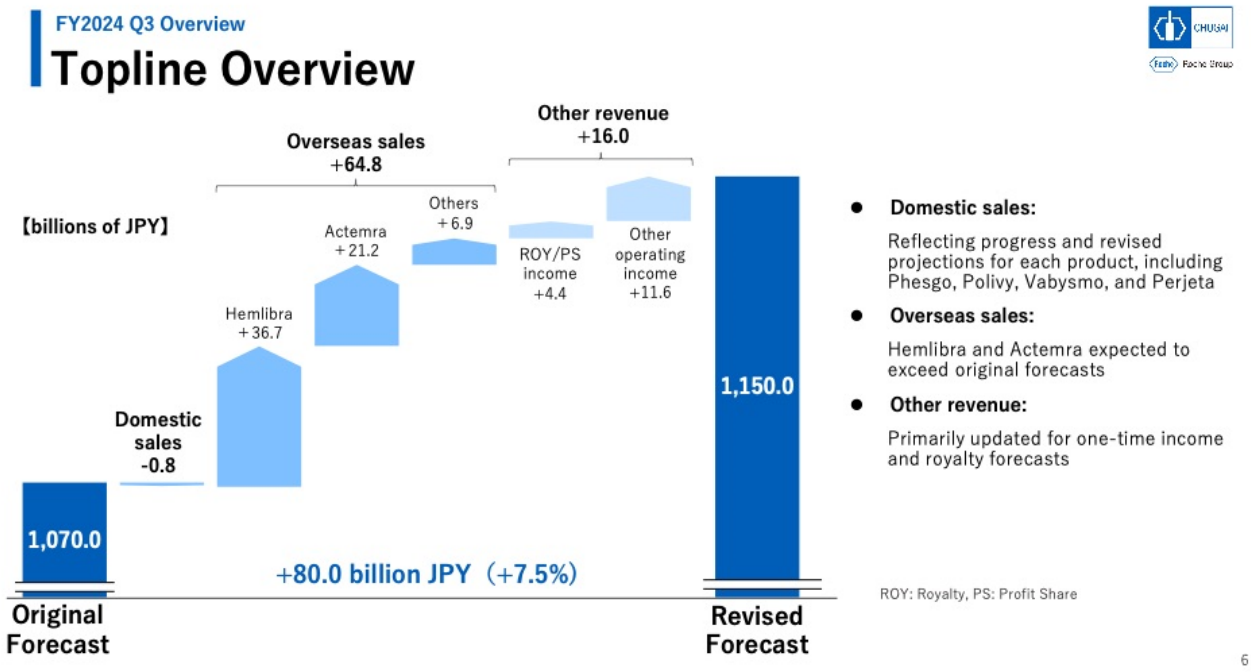
Okuda: I'm Okuda, the President. I'd like to give you Q3 of FY2024. Please take a look at page five. Up to Q3, we have achieved increased revenue and profit. Revenue increased by 3.7% YoY. This is a turnaround from the slight decrease in the revenue in Q2. Operating profit increased by 25.3% YoY so it has continued to increase YoY, and both are higher than our original forecast. Domestic sales decreased significantly due to the completion of the government supply of Ronapreve, which was recorded last year, and NHI drug price revisions as well as the impact of generics.

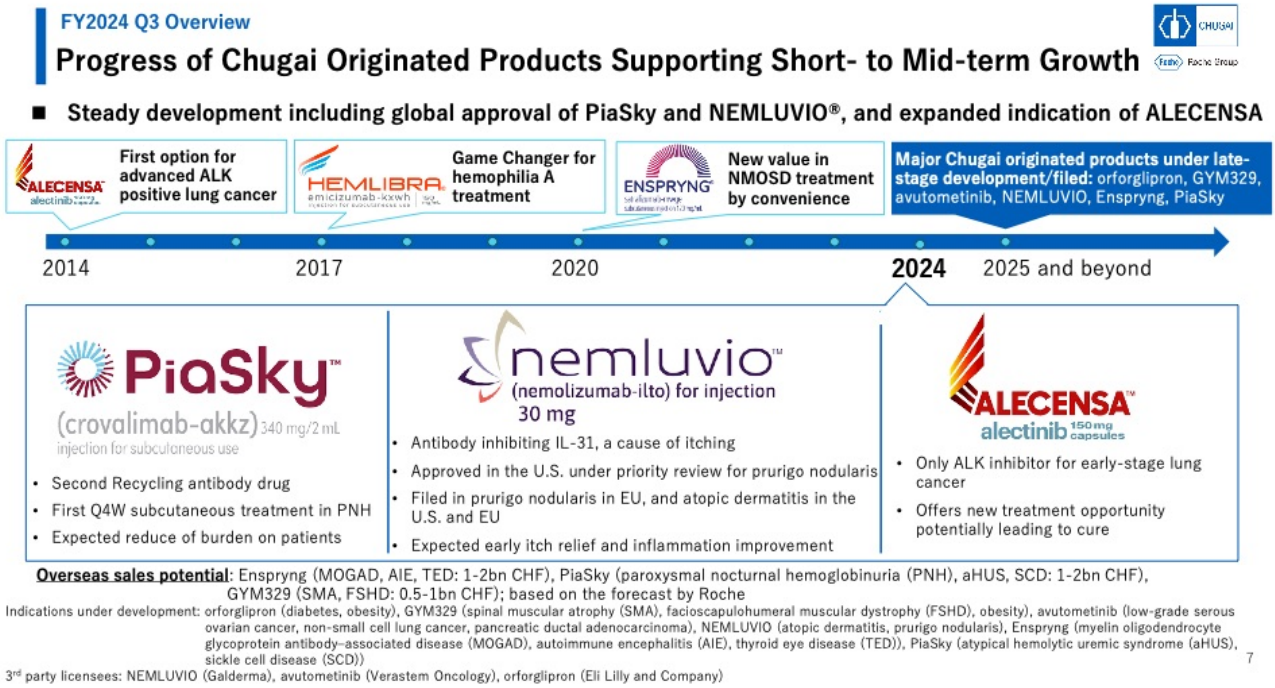
Overseas sales and other revenue increased significantly, particularly due to exports of Hemlibra, the in-house product, to Roche, and royalty income. Based on the strong performance, which exceeded the original expectations, the initial forecast has been revised upwards to a revenue of JPY1,150 billion and an operating profit of JPY540 billion. Compared to the original forecast, revenue, and operating profit have been revised upwards by JPY80 billion each.

As for revenue and operating profit for the next fiscal year, at this moment, we're assuming that they will be at about the same level as the upwardly revised forecast for this fiscal year. The original announcement is scheduled for the end of January next year, and there are some uncertain factors, but we will provide this information as a yardstick based on our current assumption.



Please take a look at page six. We'll show a breakdown of the difference between the original forecast of JPY1,070 billion and the revised forecast of JPY1,150 billion for revenue. Domestic sales are JPY0.8 billion lower than the original forecast, reflecting progress with each product and revision to our assumptions.

For overseas sales, we expect Hemlibra and Actemra to exceed our original forecast. Hemlibra exports have been revised upwards by JPY36.7 billion due to growth in overseas local sales and increased demand. Actemra exports have been revised upwards by JPY21.2 billion due to the impact of biosimilars being lower than expected. Overseas sales overall have been revised upwards by JPY64.8 billion. In other revenue, royalties and profit share income represents an increase of JPY4.4 billion due to increased income related to Hemlibra. Other operating income represents an increase of JPY11.6 billion due to milestone payments from out-licensed products. The topline was revised upwards by JPY80 billion or 7.5% compared to the original forecast.



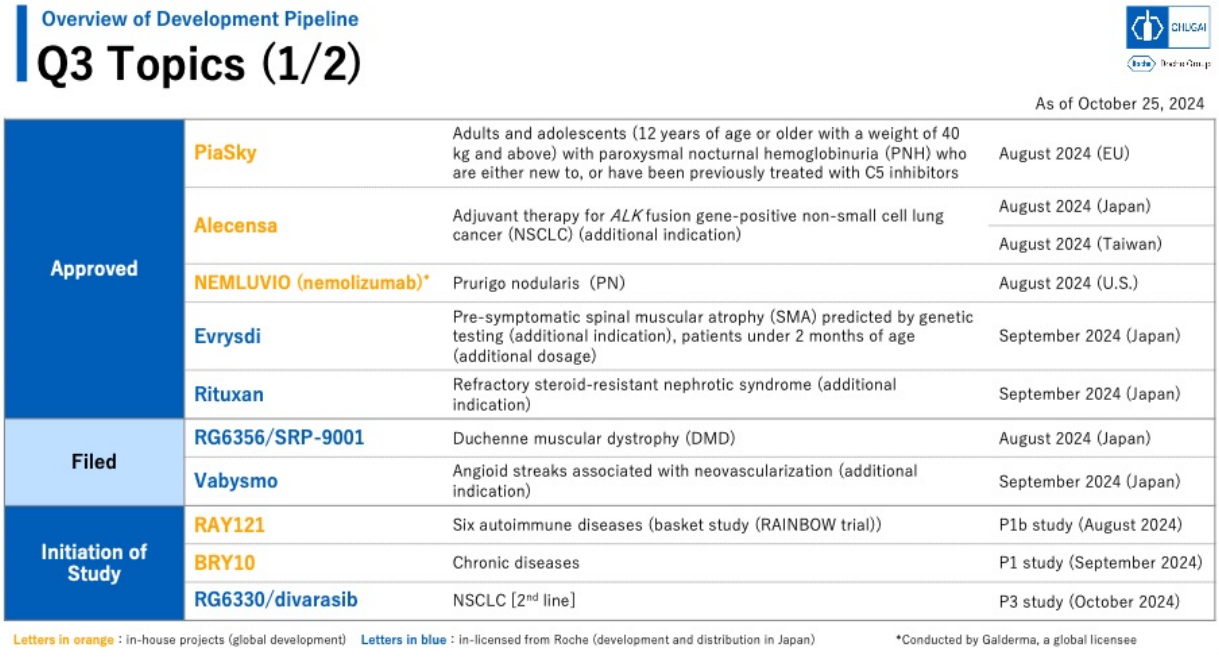
Please turn to the next slide. In 2024, significant progress was made in strengthening the foundation for short to mid-term growth, particularly with three of Chugai-originated products.

PiaSky is our second product using the recycling antibody technology. With the first once every four weeks subcutaneous injections for PNH, we expect to reduce the treatment burden for patients. Next, as you can see at the center, NEMLUVIO, is an antibody drug that inhibits IL-31, which causes itching. Our out-licensed partner, Galderma, has obtained approval under priority review in the United States for prurigo nodularis and filing has been submitted in Europe. The filing was also submitted for the treatment of atopic dermatitis in both the United States and Europe. We expect early itch relief and improvement with inflammation. Later, Kusano will present data on early efficacy and long-term effectiveness recently shared at EADV and others. The third is ALECENSA, approved in Japan, the United States, and Europe as the only ALK inhibitor for early-stage lung cancer treatment. It is expected not only to lower the risk of postoperative recurrence but also to offer new treatment opportunities that may lead to a cure.

We will continue to provide unprecedented new value with Chugai-originated products like orforglipron and GYM329. Aiming for global product launches every year as outlined in TOP I 2030, we will strive to further contribute to global healthcare.

That concludes my explanation. Thank you.

Miyata: Next, I'd like to invite Kusano to talk about the development pipeline.

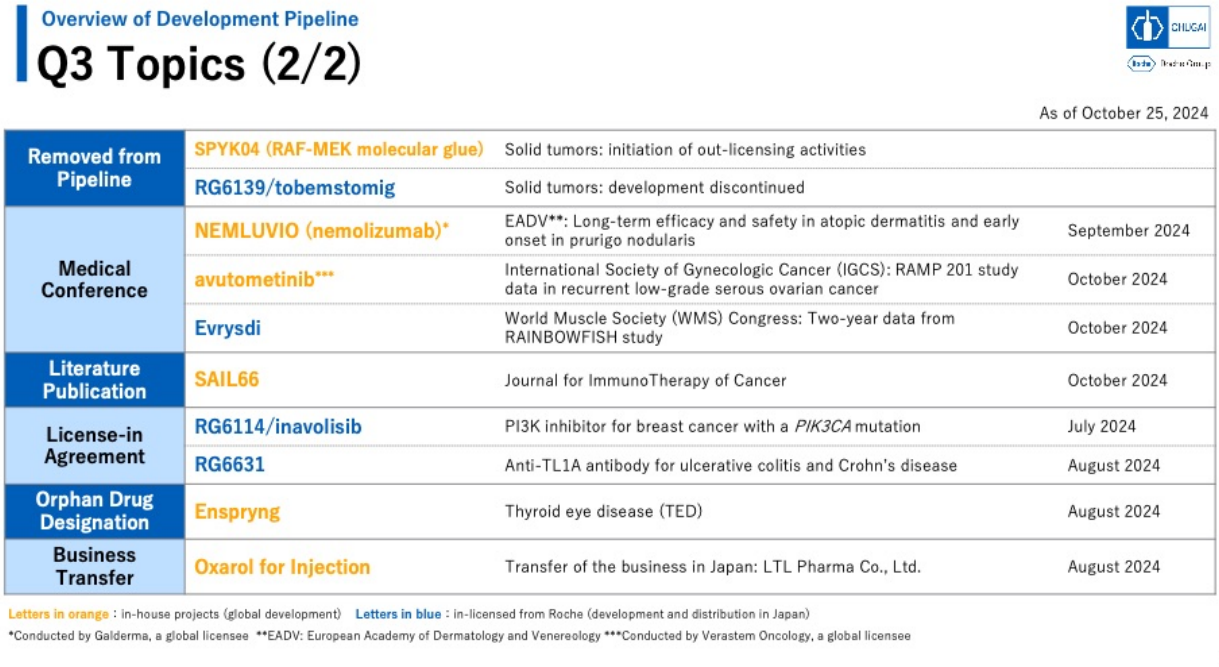


Kusano: I am Kusano, Head of the Project and Lifecycle Management Unit. I'll explain the status of the development pipeline. Please take a look at slide nine. First, I will present the topics for Q3. All of the approvals and applications are already announced.

In terms of approvals, our in-house product PiaSky was approved in Europe in August for PNH. Also for our in-house product, ALECENSA, an expanded indication was obtained in Japan in August for the adjuvant treatment of ALK-positive early-stage non-small cell lung cancer. As a result, PiaSky for PNH, and expanded indication of ALECENSA for the adjuvant treatment of ALK-positive early-stage non-small cell lung cancer were approved in Japan, US, and Europe as initially planned. Also nemolizumab, which was out-licensed to Galderma, was approved in the US in August for prurigo nodularis under the brand name of NEMLUVIO.

For the Roche products, we received approval for Evrysdi and Rituxan. In addition, we submitted applications for approval in August for SRP-9001, a gene therapy product for Duchenne muscular dystrophy and in September for Vabysmo for angioid streaks which can cause visual impairment. Both products have been designated as orphan regenerative medicine products and orphan drugs, respectively and are eligible for priority review.

There are three trials that got started. As for RAY121, the in-house project for anticomplement C1s recycling antibody that we explained in the previous earnings briefing, we started a global Phase Ib basket trial in August. This is for six autoimmune diseases, and we are steadily making progress with the simultaneous development of multiple diseases. BRY10 is also an in-house project. Unfortunately, we're unable to disclose the specific target diseases or mode of action at this time, but we have started Phase I trials for chronic diseases. BRY10 is a clinical antibody designed by MALEXA and is the first project to advance to Phase I trial. MALEXA is Chugai's proprietary AI-based antibody drug discovery support technology. For Roche products, a Phase III trial of the KRAS-G12C inhibitor divarasib, for the second-line treatment of non-small cell lung cancer, was started.



Next slide, please. Now we will discuss the removal of projects from the pipeline. Regarding SPYK04, an in-house project, we have decided to discontinue development in-house and begin our out-licensing activities. Although we have not disclosed the mode of action (MoA) until now, the MoA of SPYK04 is an RAF-MEK molecular glue. Molecular glue is a term for a small molecule compound that acts like glue to bind two or more proteins together. In addition, we have decided to discontinue the development of tobemstomig, a bispecific antibody that targets PD-1 and LAG-3 in light of the results of clinical trials conducted overseas by Roche.

Next, the results of the study of nemolizumab, which was presented at the European Academy of Dermatology and Venereology (EADV) Congress in September will be explained in more detail on the following slides. In Q3, we concluded licensing agreements with Roche for two projects. These two projects are the PI3K inhibitor, inavolisib, and an anti-TL1A antibody which I will also explain later.

In summary, research and development activities are progressing in a variety of ways to continuously create innovative new drugs, including early drug discovery research, late-stage development, including regulatory submissions, and drug discovery using AI.

Overview of Development Pipeline

2024: Key R&D Milestones

Underlined and bolded are new progress since July 25, 2024

	Product	Indication/Study name	Progress
Projects to be Approved	PiaSky	Paroxysmal nocturnal hemoglobinuria (Japan/EU/U.S.)	Approved (Japan/U.S./**EU**)
	Alecensa	Non-small cell lung cancer (NSCLC) (adjuvant) (U.S./EU/Japan)	Approved (U.S./EU/**Japan**)
	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	**Expected in 2025**
	Vabysmo	NIHONBASHI study: Angioid streaks	Achieved PE
P2 Readouts	GYM329＋Evrysdi	MANATEE study: Spinal muscular atrophy (SMA)	**Expected in 2025**

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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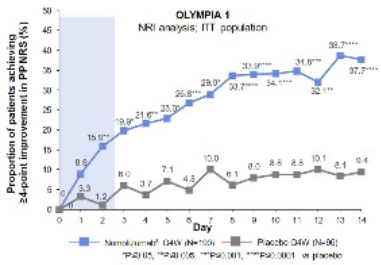
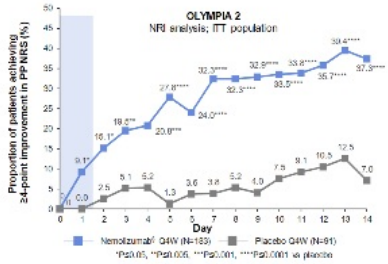
Next slide, please. Next, I'll talk about the progress of major R&D events in 2024. Changes from the previous time are underlined and in bold letters. As I mentioned, we were able to obtain all of the approvals we had planned for this year for PiaSky and ALECENSA. The readout timing of the SUNMO study conducted using mosunetuzumab and Polivy and MANATEE study conducted using combination of GYM329 and Evrysdi has been changed to 2025 as announced by Roche already.

Overview of Development Pipeline

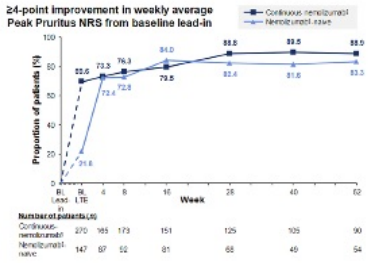
NEMLUVIO: Prurigo Nodularis Early Onset and Long-term Efficacy

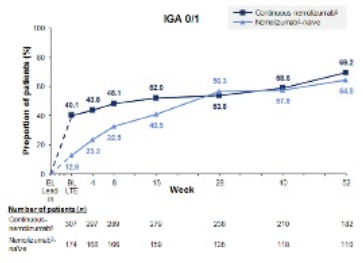
- Nemolizumab exhibited significant pruritus improvement as early as day 2 or 1 in OLYMPIA programs (top) and continuous improvement in pruritus and IGA0/1 up to 52 weeks in OLYMPIA LTE study (bottom)





Source: Ständer S et al. European Academy of Dermatology and Venereology Annual Meeting 2024





Source: Kwatra S et al. American Academy of Dermatology Annual Meeting 2024

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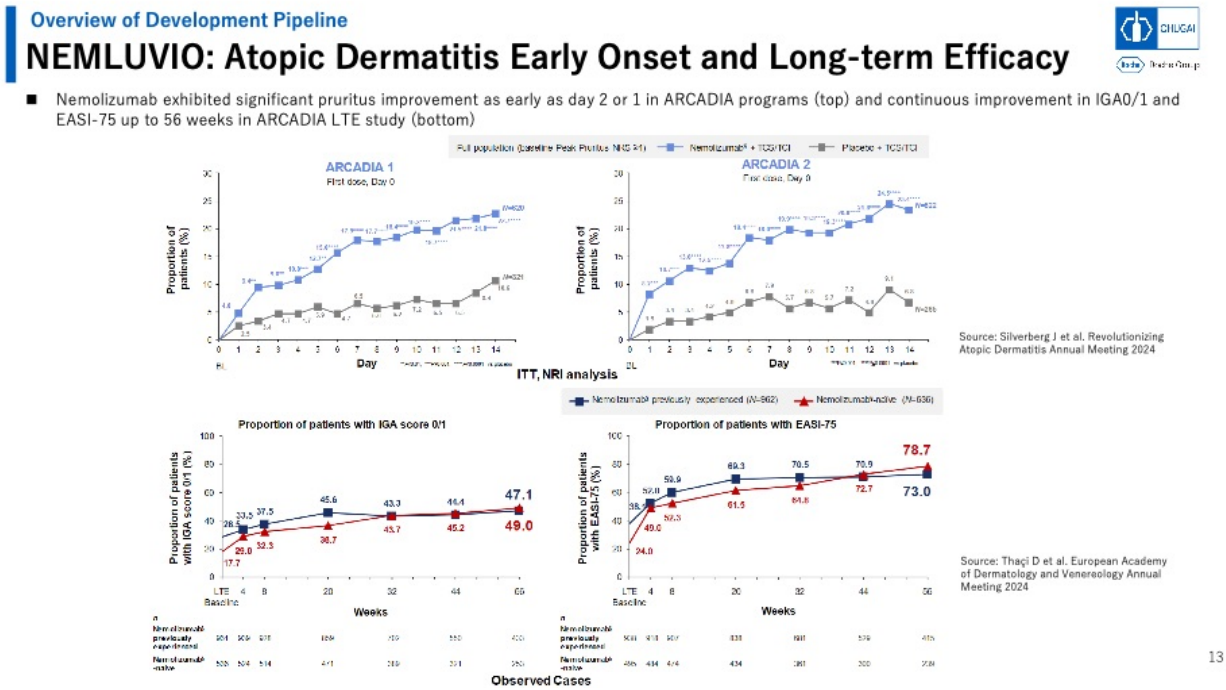
In the next two slides, I would like to show you the characteristics of nemolizumab, also known as NEMLUVIO overseas, including its early onset of action and long-term efficacy.

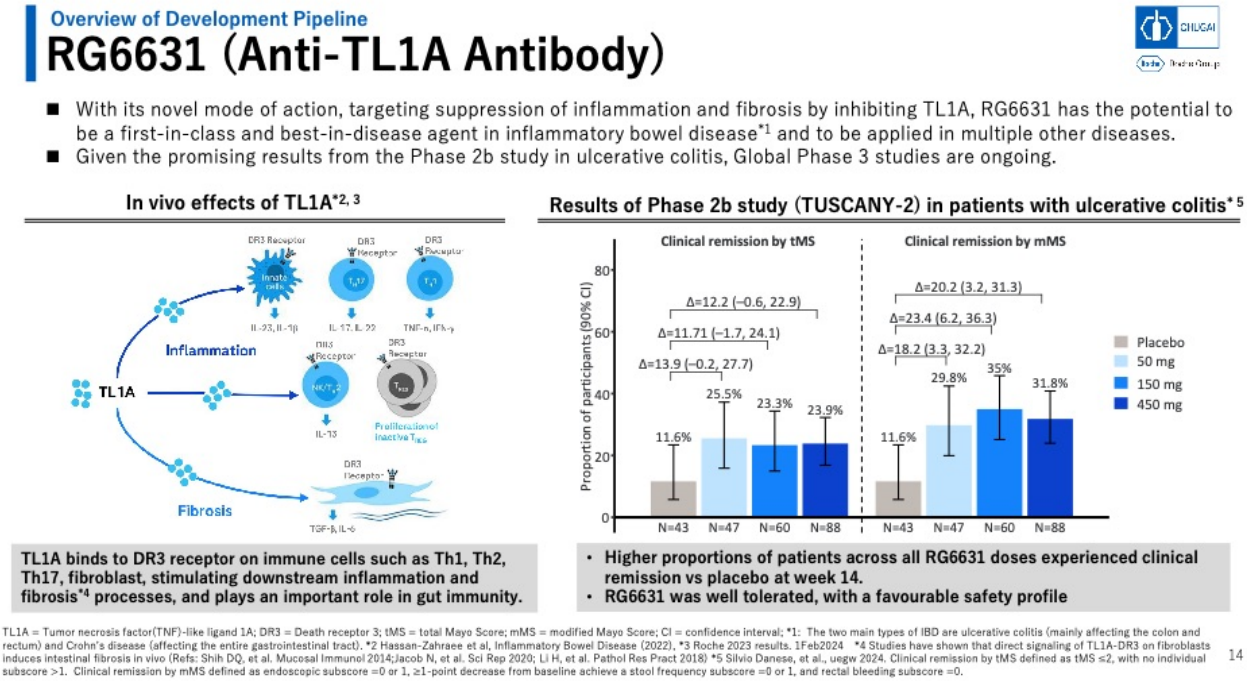
First, let's take a look at prurigo nodularis. The top part shows the results of post-hoc analysis of two Phase III studies presented at EADV up to 14 days from the start of the treatment. After treatment was started, there was an early onset of efficacy with statistically significant and clinically meaningful improvements in pruritus observed as early as the second day or even the first day.

The lower graph shows the long-term data from the Phase III study for prurigo nodularis that was presented at the AAD, American Academy of Dermatology, in March. On the left, the percentage of patients whose pruritus improved over 52 weeks increased with the administration of nemolizumab, and nearly 90% of patients experienced complete or almost complete disappearance of pruritus. On the right, the overall evaluation of skin lesions (IGA0/1) also showed continuous improvement over 52 weeks. From this result, it was shown that nemolizumab can be expected to further improve symptoms with long-term administration. In addition, although not shown here, similar results were obtained in improving sleep disorders, and it was confirmed that safety was the same as before.



Next, atopic dermatitis. The top part row shows the results of post-hoc analysis of the two Phase III trials presented at RAD, Revolutionizing Atopic Dermatitis, in June up to 14 days after the start of treatment. As with prurigo nodularis, statistically significant and clinically meaningful improvements in pruritus were seen as early as second day or even first day. The lower part shows the long-term data from the Phase III study for atopic dermatitis that was presented at EADV recently. Over 56 weeks, the overall evaluation of skin lesions (IGA0/1) on the left side and the severity of the extent of skin lesions (EASI-75) on the right side showed continuous improvement. In addition, although not shown here, similar results were obtained in terms of improvements in sleep disorders, and we have confirmed that the safety profile is the same as before.

What is common to patients with atopic dermatitis and prurigo nodularis is poor sleep and reduced QOL caused by pruritus. We expect the nemolizumab, which targets IL-31 significantly involved in pruritus and inflammation, will be an effective and convenient treatment for patients with these diseases around the world.



Next, I would like to explain about RG6631, an anti-TL1A antibody in-licensed from Roche.

As shown on the left side of the slide, TL1A is known to bind to target molecules on various immune cells, stimulating not only inflammation but also fibrosis, and plays an important role in gut immunity.

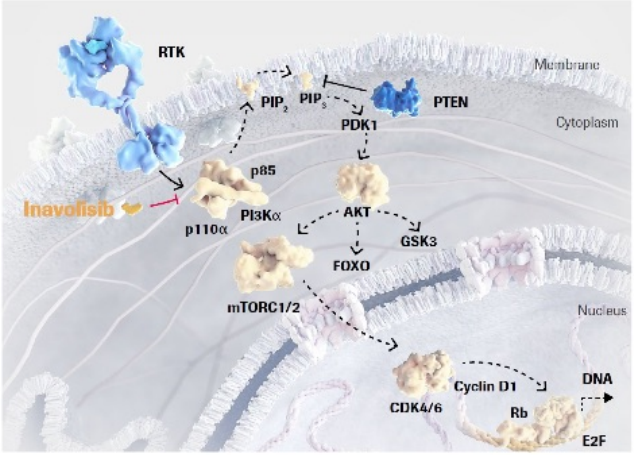
RG6631 is expected to become a first-in-class and best treatment option for inflammatory bowel disease by inhibiting both inflammation and fibrosis through the novel mechanism of action of TL1A inhibition.

On the right side of the slide, we show the results of a Phase IIb trial in ulcerative colitis. High clinical remission rates were observed across a wide range of doses compared to placebo administration. We plan to promptly initiate a global Phase III trial going forward.

Overview of Development Pipeline

Inavolisib (PI3K Inhibitor): Mode of Action

- Inavolisib is a highly potent, selective inhibitor of p110α, the catalytic subunit of PI3Kα. In addition, inavolisib promotes the degradation of mutated p110α (mutant degrader)



- Inavolisib is a new targeted molecular agent that specifically inhibits PI3Kα [1], a key molecule involved in oncogenesis and tumor progression.
- PI3Kα is composed of 2 subunits, p110α and p85, and p110α, called the catalytic subunit, is responsible for the main function of PI3Kα. On the other hand, p85 is called a regulatory subunit and plays a role in controlling the activity of p110α.
- A key feature of inavolisib is that it acts on both of these two subunits, thereby dual inhibiting PI3Kα function. The effect on p110α inhibits PI3Kα and promotes the degradation of mutated p110α (mutant degrader). These effects result in potent and sustained blockade of the PI3Kα pathway.
- In addition, inavolisib selectively inhibits PI3Kα, resulting in less impact on other PI3K molecules and a reduced risk of side effects.

1) Multiple PI3K isoforms (α, β, γ, δ) exist, with the PI3Kα isoform playing a pivotal role in cellular proliferation and survival, exerting its oncogenic effects from the earliest stages of tumorigenesis. In contrast, the other PI3K isoforms are implicated in distinct physiological processes such as immune function and metabolic regulation, distinct from their roles in oncogenesis. Consequently, it is hypothesized that selective inhibition of the PI3Kα isoform could suppress tumor cell proliferation while minimizing disruption of normal physiological functions mediated by the other PI3K isoforms.

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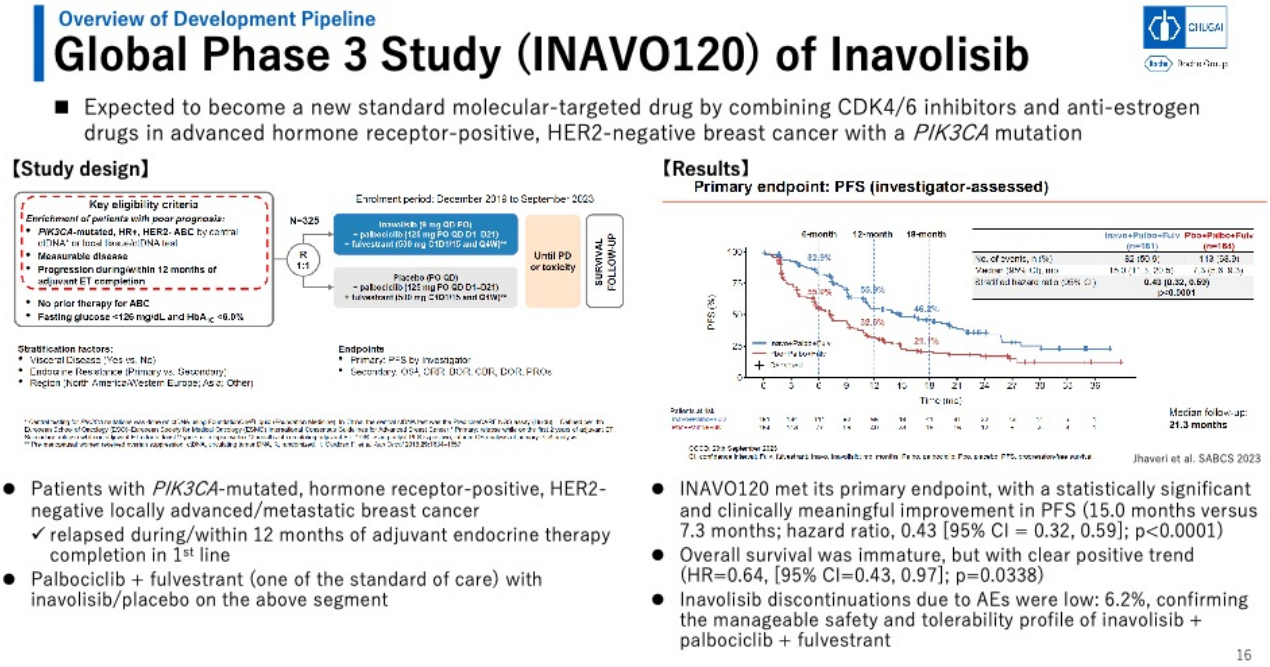
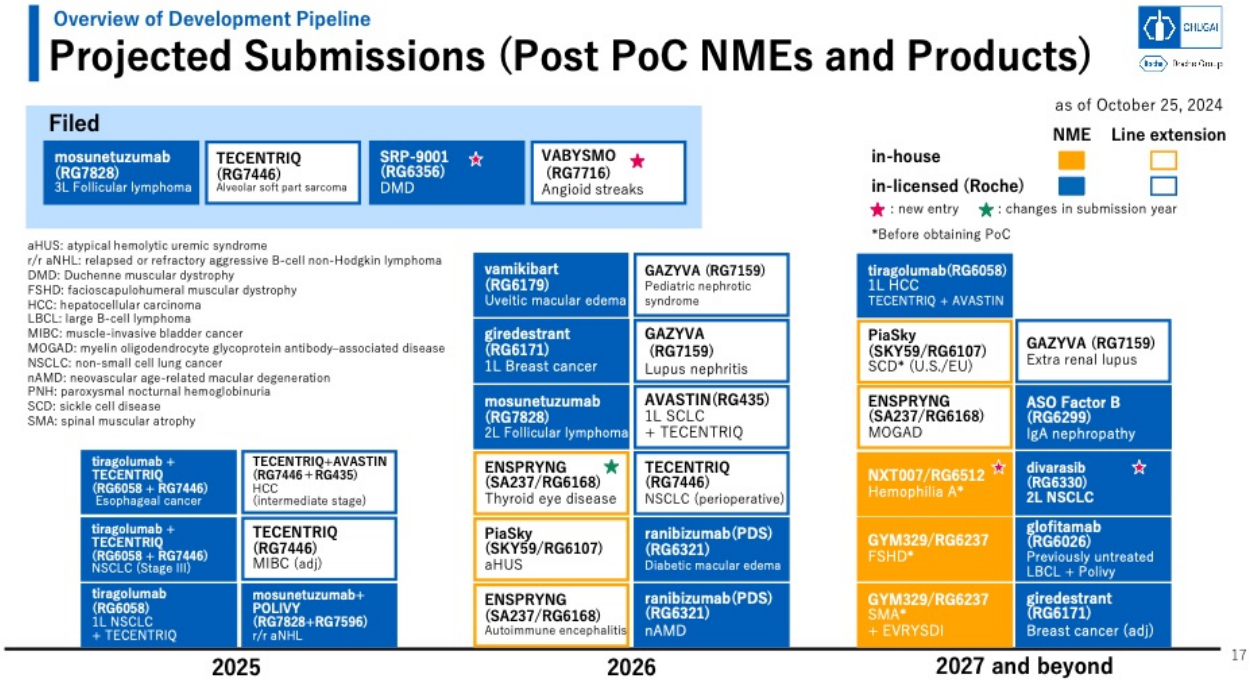
Next, I will explain about inavolisib, a PI3K inhibitor also in-licensed from Roche. This slide shows the mechanism of action of inavolisib. PI3K has multiple isoforms of proteins with partially different structures. Among them, PI3K alpha, in particular, is deeply involved in oncogenesis and tumor progression. Inavolisib is expected to exert a powerful and sustained effect by selectively inhibiting the p110α kinase activity, which is the catalytic subunit of PI3Kα and responsible for the core function of PI3Kα, as well as promoting the degradation of the p110α mutant protein. By specifically inhibiting PI3K alpha, it is expected to have less impact on other PI3K isoforms involved in physiological functions unrelated to cancer, reducing the risk of side effects.



These are the results of the global Phase III trial of inavolisib. The global Phase III trial was conducted for recurrent breast cancer that is *PIK3CA* mutated positive, hormone receptor-positive, and HER2-negative. *PIK3CA* mutation-positive breast cancer is a type of cancer where mutations in the *PIK3CA* genes leading to constant activation of the PI3K/AKT/mTOR or PAM pathway promoting cancer cell proliferation and survival. In the global P3 trial, inavolisib was added to palbociclib and fulvestrant, which are standard treatments for the hormone receptor-positive, and HER2-negative recurrent breast cancer with a *PIK3CA* mutation. A statistically significant and clinically meaningful improvement was observed in progression-free survival, which was included in the primary endpoints. Specifically, the combination of inavolisib, palbociclib, and fulvestrant reduced the risk of disease progression or mortality risk by 57% compared to the palbociclib and fulvestrant.

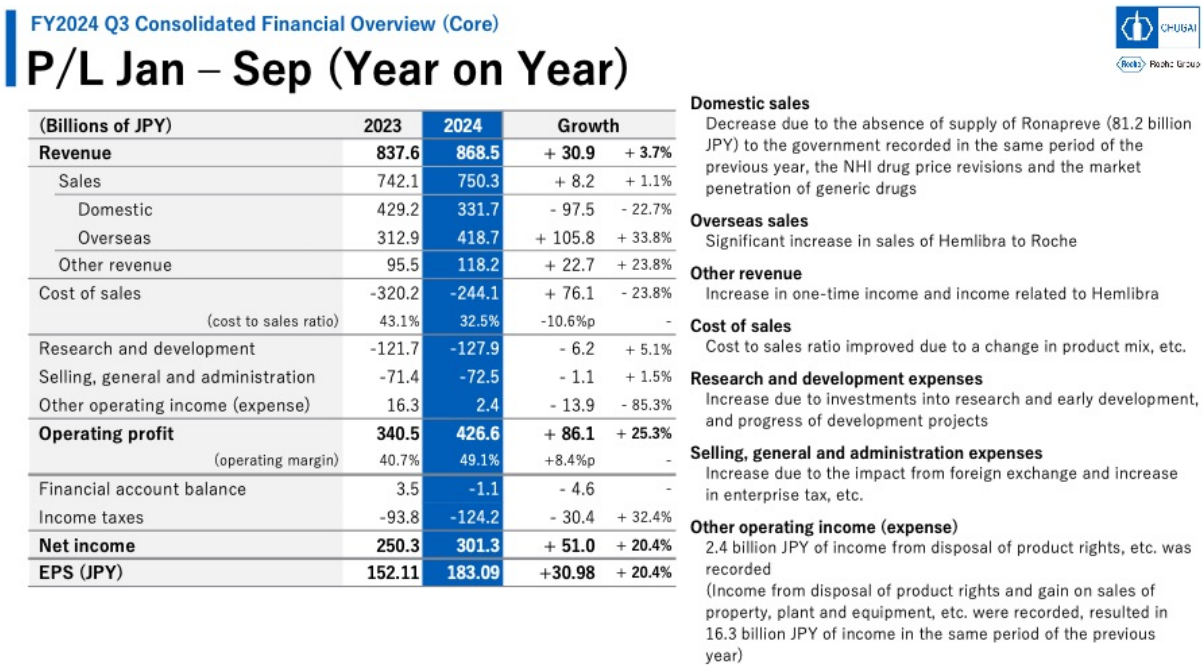
Evaluation of the overall survival was immature at this point but showed a positive trend and follow-up will continue until the next analysis. *PIK3CA* mutation-positive breast cancer has a poor prognosis and high unmet needs. Development of inavolisib is progressing ahead in Europe and in the United States. In the United States, inavolisib has been designated a breakthrough therapy by the FDA and approved on October 10 of this year for *PIK3CA* mutated-positive, hormone receptor-positive, and HER2-negative locally advanced or metastatic breast cancer with a priority review designation. It is also under review for approval in Europe. In Japan, we will swiftly advance development to deliver this innovative drug to patients.



Here are the future submission plans. Red stars indicate new additions and green stars indicate changes in submission timing. I would like to add one note. Regarding NXT007 currently in Phase I/II trials, it was previously listed in the Phase I category in the development pipeline slide but has now been updated to Phase II with the submission planned for 2027 and beyond. This aligns with the transition to the patient part to obtain efficacy, safety, and dosage setting data and Roche's update to Phase II adding it to the submission plan table.

The readout of the ongoing Phase I/II trial is planned for the next year 2025, which will be the basis of our decision as to whether to proceed to Phase III. The following few reference materials are attached for your reference as needed. This concludes my presentation.

Miyata: Last but not least, I'd like to invite Taniguchi to talk about FY2024 Q3 consolidated financial overview on a core basis.

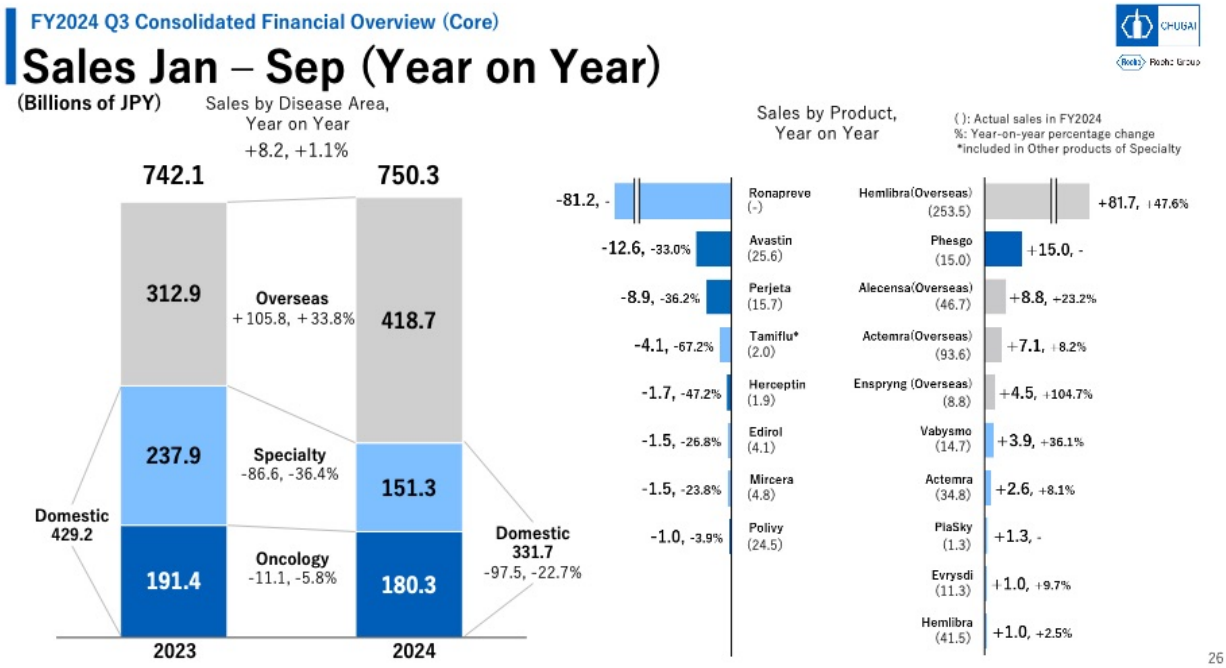


Taniguchi: I'm Taniguchi, CFO. I'd like to explain about the results of Q3 based on the core basis. First of all, revenue was JPY868.5 billion, YoY increase of JPY30.9 billion or 3.7%. Operating profit was JPY426.6 billion or rather a YoY increase of 25.3% or JPY86.1 billion. The main factor behind the increase in sales was a significant increase in export sales of products such as Hemlibra and Actemra. This growth in sales completely absorbed the impact of the loss of sales of JPY81.2 billion from Ronapreve and even exceeded it.

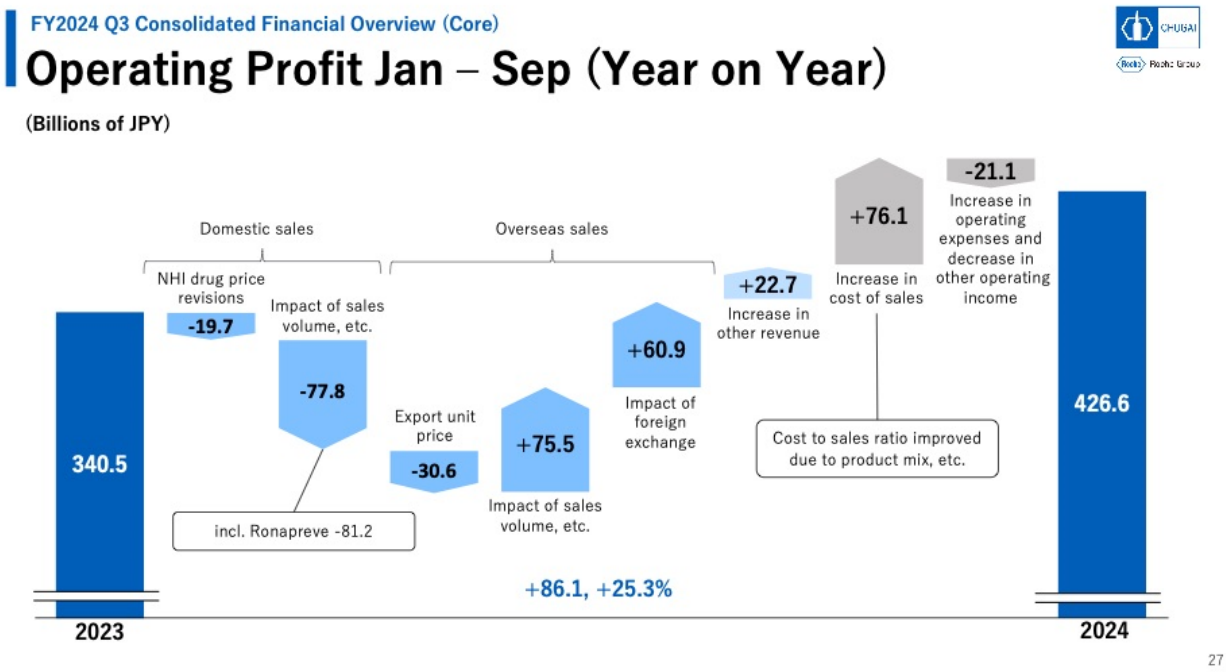
Let's take a look at the breakdown. Sales were JPY750.3 billion, an increase of JPY8.2 billion or 1.1%. Looking at the sales by region, domestic sales, and overseas sales, but as for domestic sales, they were down JPY97.5 billion YoY. But excluding Ronapreve, the decrease was JPY16.3 billion. The main factors were the impact of NHI drug price revisions and penetration of generic drugs. Overseas, exports of products such as Hemlibra were extremely strong and sales grew by JPY105.8 billion or 33.8% YoY. Other revenue increased by JPY22.7 billion or 23.8% YoY to JPY118.2 billion due to factors such as an increase in royalty income from Hemlibra and one-time income.

Now the cost items. The cost of sales was JPY244.1 billion, a decrease of JPY76.1 billion or 23.8% YoY. The reason for this is that the cost of sales of Ronapreve, which had a high cost-of-sales ratio had disappeared and the relatively low cost-of-sales ratio of our in-house products has increased. As a result, cost of sales ratio has improved by 10.6 points to 32.5%. R&D expenses increased by JPY6.2 billion YoY as the projects in drug discovery research and early development progressed smoothly.

As for SG&A expenses, they only increased expenses by JPY1.1 billion YoY. Despite the impact of rising prices and higher personnel costs, we made efforts to improve efficiency. Other operating income decreased by JPY13.9 billion due to a significant decrease in gains on sales of products transferred this year. As a result, operating profit increased by JPY86.1 billion YoY to JPY426.6 billion. The operating margin increased by 8.4 percentage points to 49.1%. Net income was JPY301.3 billion, an increase of JPY51 billion or 20.4%.



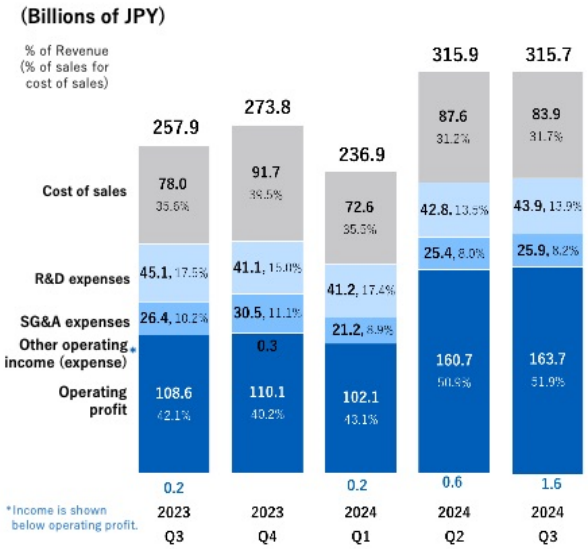
The next page shows the breakdown of changes in sales. First, in the domestic oncology field, the sales decreased by JPY11.1 billion or 5.8% YoY. As for the breakdown, sales of Avastin decreased due to the impact of the penetration of generic products, but sales of the new product Phesgo increased to a greater extent than the decrease in sales of Perjeta and Herceptin. In the specialty area in the domestic market, the decrease in sales was JPY86.6 billion or 36.4%, but this was due to the decrease in sales of previously mentioned Ronapreve and Tamiflu, which is a large seasonal fluctuation trend. Excluding the decrease in sales of those two, sales were generally at the same level as the previous year. While overall sales were affected by the NHI drug price revision, sales of new products such as Vabysmo and PiaSky grew steadily. Overseas sales of products in gray at the top increased by JPY105.8 billion or 33.8%, mainly due to growth in sales of all four core products including Hemlibra.



The next page shows the breakdown of the increase in operating profit. The content of the slide has been enhanced since the previous quarter with a more detailed disclosure of information such as domestic and overseas breakdown and the impact of foreign exchange rates. As for the domestic ones at left, the impact of NHI drug price revisions and the impact of Ronapreve were the factors that led to the decline in operating profit. As for overseas sales, the increase in sales volume and the positive impact of foreign exchange rates greatly exceeded the decrease in export unit prices driven by increase of developing countries in the sales market, and this was a factor in the increase in operating profit. Other revenue increased by JPY22.7 billion and the increase in royalties compared to the last year for Hemlibra and one-time income such as milestone payments contributed to an increase in operating profit. In addition, the significant decrease in the cost of sales due to changes in the product mix was a major factor in boosting operating profit. There are some cost items increased, but a JPY86.1 billion increase was achieved.

FY2024 Q3 Consolidated Financial Overview (Core)

Structure of Costs and Profit by Quarter



Year on Year (vs. 2023 Q3)

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

R&D: same level as the same period of the previous year

SG&A: same level as the same period of the previous year

Other operating income (expense): increase in income from disposal of product rights, etc.

Operating profit: +55.1 billion JPY, +50.7%

Quarter on Quarter (vs. 2024 Q2)

Cost of sales ratio: same level as the previous quarter

R&D: same level as the previous quarter

SG&A: same level as the previous quarter

Other operating income (expense): increase due to income from disposal of product rights, etc.

Operating profit: +3.0 billion JPY, +1.9%

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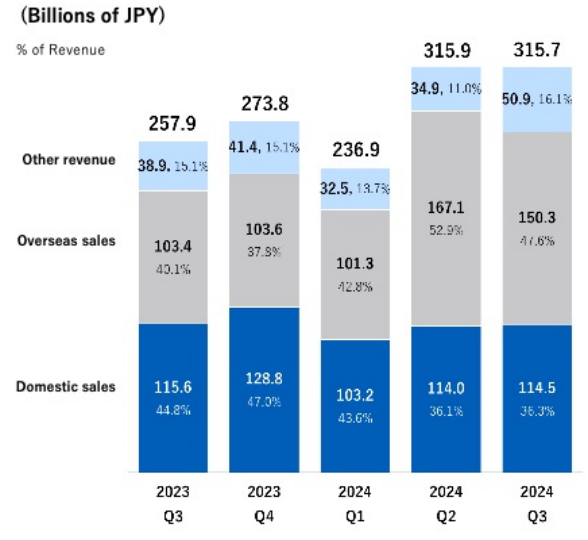
The next page is the trend of profit and loss items by quarter by every three months. This has been shown since a year before and there are some ups and downs and the timing delay in exports. But as you can see, in Q2 and Q3, operating profit grew significantly because of export growth.

FY2024 Q3 Consolidated Financial Overview (Core)

Structure of Revenue by Quarter



Year on Year (vs. 2023 Q3)

Domestic sales: decrease due to the market penetration of generic drugs and the NHI drug price revisions, etc.

Overseas sales: significant increase in sales of Hemlibra and Actemra

Other revenue: increase mainly due to an increase in milestone income

Quarter on Quarter (vs. 2024 Q2)

Domestic sales: same level as the previous quarter

Overseas sales: decrease in sales of Hemlibra and Actemra

Other revenue: increase in royalty income of Hemlibra in addition to the increase mainly due to an increase in milestone income

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Next page, likewise, every three months from Q3 last year, you see the sales composition. I'm not going to go into details, but the overseas sales of products have made significant progress since Q2 of this year.

FY2024 Q3 Consolidated Financial Overview (Core)

P/L Jan – Dec (Revision of Forecast)

(Billions of JPY)	Original Forecast 2024 Jan - Dec	Revised Forecast 2024 Jan - Dec	Revision		Year-on-Year	
Revenue	**1,070.0**	**1,150.0**	**+80.0**	**+7.5%**	**+38.6**	**+3.5%**
Sales	922.0	986.0	+64.0	+6.9%	+11.5	+1.2%
Domestic	454.9	454.1	- 0.8	-0.2%	- 103.9	-18.6%
Overseas	467.1	531.9	+64.8	+13.9%	+115.4	+27.7%
Other revenue	148.0	164.0	+16.0	+10.8%	+27.1	+19.8%
Cost of sales	- 337.5	- 335.0	+2.5	-0.7%	+77.0	-18.7%
(cost to sales ratio)	36.6%	34.0%	-2.6%p	-	-8.3%p	-
Research and development	- 171.0	- 175.0	- 4.0	+2.3%	- 12.2	+7.5%
Selling, general and administration	- 102.0	- 103.0	- 1.0	+1.0%	- 1.0	+1.0%
Other operating income (expense)	0.5	3.0	2.5	+500.0%	- 13.1	-81.4%
Operating profit	**460.0**	**540.0**	**+80.0**	**+17.4%**	**+89.3**	**+19.8%**
(operating margin)	43.0%	47.0%	+4.0%p	-	+6.4%p	-
Net income	**335.5**	**388.0**	**+52.5**	**+15.6%**	**+54.4**	**+16.3%**
EPS (JPY)	**204.00**	**236.00**	**+32.00**	**+15.7%**	**+33.29**	**+16.4%**
Annual Dividend (JPY)	**82.00**	**Undecided**	-	-	-	-

Main reasons for revision:

Domestic sales
Reflects the progress and revised assumptions for each product

Overseas sales
Mainly exports of Hemlibra and Actemra to Roche will exceed the original forecast

Other revenue
One-time income and royalty income, etc. will exceed the original forecast

Cost of sales
Reflects the improvement in cost to sales ratio due to the change in product mix from the original forecast and to other factors

vs. Year on Year:
Expects increases in revenues and profits by revenues+3.5%, operating profit+19.8%

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As I have explained, our performance this time has been extremely solid. Considering the current situation, we have decided to revise our earnings forecast at this time. Details are stated in this slide. Sales is revised upward by JPY80 billion to JPY1.15 trillion compared to the initial forecast. We've also revised operating profit upward by JPY80 billion to JPY540 billion and net profit by JPY52.5 billion to JPY388 billion, all upward revisions.

As for sales, the main factor for this revision is the significant increase in overseas exports to Hemlibra and Actemra by JPY64.8 billion from initial forecast, and other one-time income, there was an upside as well and increased by JPY16.0 billion. Those are the main factors for an increase of JPY80.0 billion.

As I mentioned before, the sales cost because of the sales mix, the low-cost products increased in the overall composition, and the less Forex impact as expected. With the sales increase, the sales-cost ratio remained the same, so that's why we revised upward by JPY80 billion for both sales and profit. For the dividends, we will reconsider based on the revision and based on the progress towards the year-end forecast, but it remains Undecided at this time.

FY2024 Q3 Consolidated Financial Overview (Core)

Sales Jan – Dec (Revision of Forecast)

(Billions of JPY)	Original Forecast 2024 Jan - Dec	Revised Forecast 2024 Jan - Dec	Revision		Year-on-Year	
Sales	**922.0**	**986.0**	**+64.0**	**+6.9%**	**+11.5**	**+1.2%**
Domestic	**454.9**	**454.1**	**- 0.8**	**-0.2%**	**- 103.9**	**-18.6%**
Oncology	**246.5**	**246.0**	**- 0.5**	**-0.2%**	**- 14.2**	**-5.5%**
Specialty	**208.4**	**208.1**	**- 0.3**	**-0.1%**	**- 89.7**	**-30.1%**
Overseas	**467.1**	**531.9**	**+64.8**	**+13.9%**	**+115.4**	**+27.7%**
Hemlibra	267.3	304.0	+36.7	+13.7%	+91.7	+43.2%
Actemra	109.8	131.0	+21.2	+19.3%	+3.5	+2.7%
Alecensa	58.9	63.3	+4.4	+7.5%	+7.6	+13.6%
Enspryng	6.4	13.8	+7.4	+115.6%	+9.6	+228.6%
Neutrogin	6.8	8.2	+1.4	+20.6%	+0.1	+1.2%
Edirol	1.8	0.4	- 1.4	-77.8%	+0.3	+300.0%
Other	16.1	11.1	- 5.0	-31.1%	+2.6	+30.6%

Main reasons for revision: (Billions of JPY)	
Oncology	**-0.5**
Polivy	-3.4
Perjeta	-2.1
Tecentriq	-1.3
Phesgo	+7.0
Specialty	**-0.3**
Vabysmo	-2.2
Evrysdi	-0.8
Actemra	+1.9
Enspryng	+1.9
Overseas	**+64.8**
Hemlibra	+36.7
Actemra	+21.2
Enspryng	+7.4

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The next page shows the difference between the initial forecast and the revised forecast for sales by segment and major products for each major category. As you can see, the product sales, JPY64.8 billion is the increased portion and the right-hand side shows the main reasons for revisions by product. Hemlibra is generating an upside compared to the initial forecast, as you can see.

FY2024 Q3 Consolidated Financial Overview (Core)

Impact from Foreign Exchange Jan – Sep

(Billions of JPY)	vs.2023 Actual rate 【C】vs.【A】	vs.2024 Original Forecast rate 【C】vs.【B】
Revenue	**+74.0**	**+14.7**
Sales	+60.9	+8.2
Other revenue	+13.1	+6.5
Cost of sales	**-6.3**	**-0.7**
Other than above*1	**-3.8**	**-1.3**
Operating profit	**+64.0**	**+13.4**

Exchange Rate (JPY)	2023 Actual rate*2 Jan - Sep 【A】	2024 Original Forecast rate Jan - Sep 【B】	2024 Actual rate*2 Jan -Sep 【C】	2024 Original Forecast rate Jan – Dec	2024 Revised Forecast rate Jan-Dec
1CHF	138.62	157.62	160.43	159.00	161.00
1EUR	149.03	157.00	163.89	157.00	163.00
1USD	133.42	137.41	136.39	136.00	138.00

*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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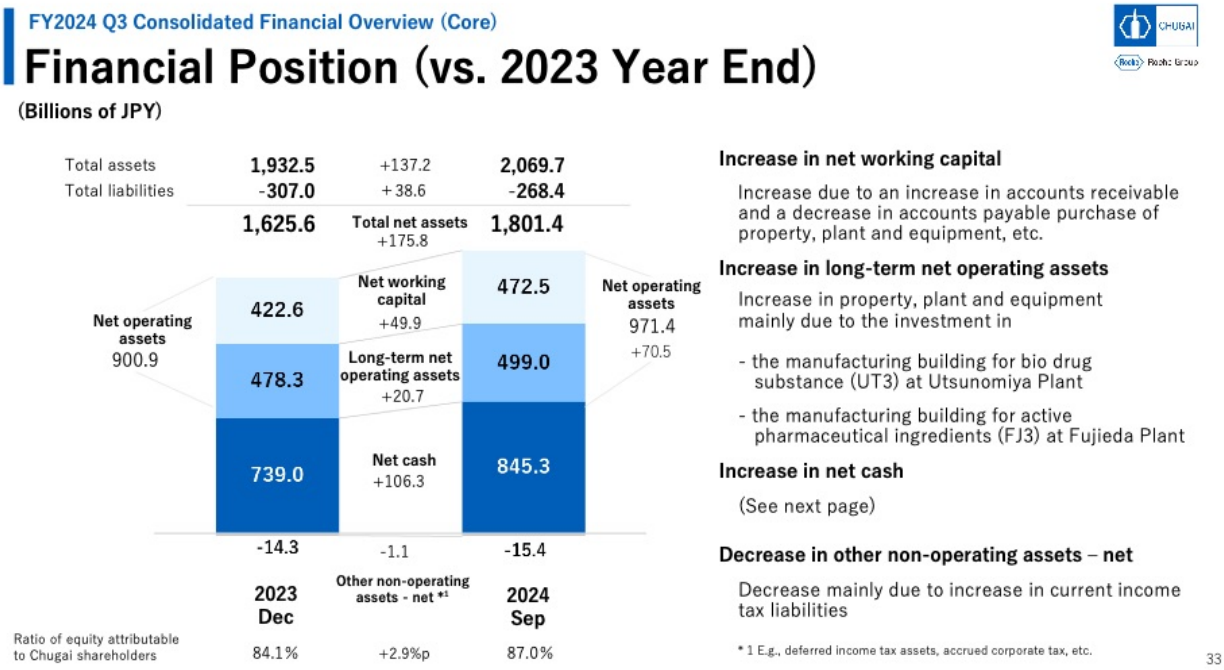
These are the impact of ForEx. This is the updated slide from last time. The left-hand side, C versus A shows the actual rate comparison between last year and this year and its impact on sales and profit. C versus B in the middle, compared to the initial ForEx assumption, the actual ForEx is compared here. Those portions that

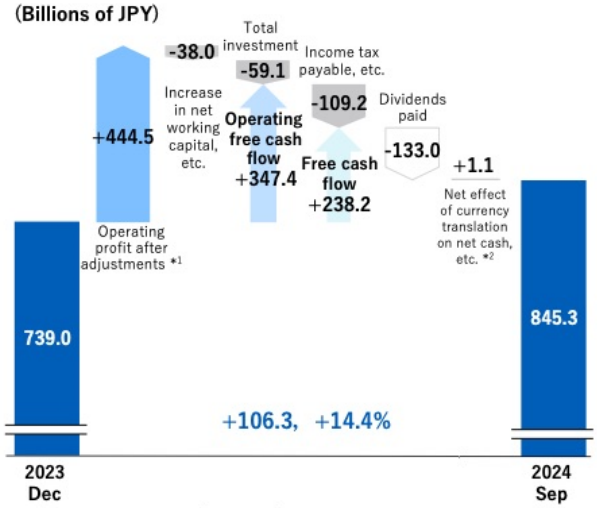
do not have the forward ForEx contracts, there has been some positive impact from that open position. These are the effects.



Next page. These are balance sheets. On the top side, the cash and equivalent have been accumulated and accounts receivable has accumulated. Thanks to increased long-term investment, the fixed asset has increased, the total assets have increased to JPY2 trillion and JPY69.7 billion compared to December, an increase of JPY137.2 billion. The liability, there was a minus of JPY38.6 billion. The total net assets have increased by JPY175.8 billion, to JPY1trillion and JPY801.4 billion compared to December. The equity ratio is now standing at 87%.

FY2024 Q3 Consolidated Financial Overview (Core)

Net Cash (vs. 2023 Year End)



Operating profit after adjustment *1	**+444.5**
Operating profit *1	+418.6
Depreciation, amortization and impairment *1	+24.7
Increase in net working capital, etc.	**-38.0**
Total investment	**-59.1**
Property, plant and equipment	-50.2
Payment for lease liabilities	-6.1
Intangible assets	-2.9
Operating free cash flows	**+347.4**
Income tax payable, etc.	**-109.2**
Income tax payable	-100.4
Free cash flows	**+238.2**
Dividends paid	**-133.0**
Net effect of currency transaction on net cash, etc. *2	**+1.1**

*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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Net cash, there is an increase of JPY106.3 billion. There was an increase of JPY 347.4 billion in operating free cash flows derived from the operating profit. After deducting the tax payments and dividend payments, the increase amounted to JPY106.3 billion. As a result, the cash at the end of the period was 845.3 billion yen, showing an increase over the 9-month period from last year's 739.0 billion yen.

FY2024 Q3 Consolidated Financial Overview (Core)

P/L Jan – Sep (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items: Intangible assets	Non-core items: Others	Core results
Revenue	**868.5**			**868.5**
Sales	750.3			750.3
Other revenue	118.2			118.2
Cost of sales	-245.1	+1.0		-244.1
Research and development	-129.2	+1.3	+0.1	-127.9
Selling, general and administration	-77.7		+5.2	-72.5
Other operating income (expense)	2.1		+0.4	2.4
Operating profit	**418.6**	**+2.3**	**+5.7**	**426.6**
Financial account balance	-1.1			-1.1
Income taxes	-121.8	-0.7	-1.7	-124.2
Net income	**295.8**	**+1.6**	**+4.0**	**301.3**
EPS (JPY)	**179.72**			**183.09**

Non-core items (Billions of JPY)

Factors affected operating profit

Intangible assets
- Amortization +1.2
- Impairment +1.0

Others
- Business rebuilding expenses +5.2
- Restructuring expenses +0.5

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Next page, please. We have been discussing the core base performance. This slide covers the non-core adjustments such as amortization and impairment of intangible assets and other items. There is JPY5.2 billion recorded for business rebuilding and ERP. These are reflected in these numbers here.

FY2024 Q3 Consolidated Financial Overview (Core)

P/L Jan – Sep (vs. Forecast)

(Billions of JPY)	Actual 2024 Jan -	Original Forecast 2024 Jan - Dec	Reivised Forecast 2024 Jan - Dec	Progress	2023 Progress*
Revenue	**868.5**	**1,070.0**	**1,150.0**	**75.5%**	**75.4%**
Sales	750.3	922.0	986.0	76.1%	76.2%
Domestic	331.7	454.9	454.1	73.0%	76.9%
Overseas	418.7	467.1	531.9	78.7%	75.1%
Other revenue	118.2	148.0	164.0	72.1%	69.8%
Cost of sales	- 244.1	- 337.5	- 335.0	72.9%	77.7%
(cost to sales ratio)	32.5%	36.6%	34.0%	-	-
Research and development	- 127.9	- 171.0	- 175.0	73.1%	74.8%
Selling, general and administration	- 72.5	- 102.0	- 103.0	70.4%	70.0%
Other operating income (expense)	2.4	0.5	3.0	80.0%	101.2%
Operating profit	**426.6**	**460.0**	**540.0**	**79.0%**	**75.5%**
(operating margin)	49.1%	43.0%	47.0%	-	-
Net Income	**301.3**	**335.5**	**388.0**	**77.7%**	**75.0%**
EPS (JPY)	**183.09**	**204.00**	**236.00**	**77.6%**	**75.0%**

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

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Next page, please. This slide shows the progress for the sales, profits, and costs compared to the revised forecast. As you can see, mid 70% to high 70%, this is for the remaining three months, so these are the levels that we are looking at. We are comparing this against the progress rate we saw in the same period of last year.

FY2024 Q3 Consolidated Financial Overview (Core)

Sales Jan – Dec (Revision of Forecast)

(Billions of JPY)	Actual 2024 Jan - Sep	Original Forecast 2024 Jan - Dec	Reivised Forecast 2024 Jan - Dec	Progress	2023 Progress *
Sales	**750.3**	**922.0**	**986.0**	**76.1%**	**76.2%**
Domestic	**331.7**	**454.9**	**454.1**	**73.0%**	**76.9%**
Oncology	**180.3**	**246.5**	**246.0**	**73.3%**	**73.6%**
Tecentriq	47.4	66.2	64.9	73.0%	73.1%
Avastin	25.6	33.9	33.9	75.5%	76.7%
Polivy	24.5	37.3	33.9	72.3%	71.8%
Alecensa	22.4	31.3	31.3	71.6%	72.6%
Phesgo	15.0	15.5	22.5	66.7%	0.0%
Perjeta	15.7	22.0	19.9	78.9%	73.2%
Kadcyla	12.2	16.2	16.6	73.5%	73.1%
Herceptin	1.9	2.2	2.2	86.4%	75.0%
Foundation Medicine	5.8	7.1	7.7	75.3%	75.7%
Other	9.9	14.8	13.1	75.6%	72.9%

(Billions of JPY)	Actual 2024 Jan - Sep	Original Forecast 2024 Jan - Dec	Reivised Forecast 2024 Jan - Dec	Progress	2023 Progress *
Specialty	**151.3**	**208.4**	**208.1**	**72.7%**	**79.9%**
Hemlibra	41.5	56.5	56.8	73.1%	73.9%
Actemra	34.8	45.9	47.8	72.8%	72.7%
Enspryng	17.8	22.4	24.3	73.3%	70.7%
Vabysmo	14.7	22.8	20.6	71.4%	70.6%
Evrysdi	11.3	16.5	15.7	72.0%	71.0%
Mircera	4.8	6.8	6.8	70.6%	75.0%
CellCept	4.7	6.3	6.3	74.6%	74.3%
Edirol	4.1	5.6	5.2	78.8%	74.7%
PiaSky	1.3	1.8	2.3	56.5%	-
Ronapreve	-	-	-	-	100.0%
Other	16.2	23.9	22.4	72.3%	70.9%
Overseas	**418.7**	**467.1**	**531.9**	**78.7%**	**75.1%**
Hemlibra	253.5	267.3	304.0	83.4%	80.9%
Actemra	93.6	109.8	131.0	71.5%	67.8%
Alecensa	46.7	58.9	63.3	73.8%	68.0%
Enspryng	8.8	6.4	13.8	63.8%	102.4%
Neutrogin	6.7	6.8	8.2	81.7%	74.1%
Edirol	0.3	1.8	0.4	75.0%	100.0%
Other	9.0	16.1	11.1	81.1%	72.9%

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

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The next page shows the numbers based on the revised forecast, and the progress rate that we are observing right now. There are some variances among products, but the remainder is just three months. The progress rate is somewhat lower for some of the categories, but we are confident that we'll be able to achieve the forecast.

FY2024 Q3 Consolidated Financial Overview (Core)

Summary of Chugai Originated Global Products

Product (Billions of JPY)	FY2024 Q3 Results		Year on Year	Revised Forecast	Comments
Hemlibra®	Domestic:	41.5	−2.5%	56.8	• Japan: Sales slightly increased YoY despite last year's drug price revision*1. Domestic market share steadily increased
	Export:	253.5	+47.6%	304.0	• Oversees: Sales increased especially in International and EU. Exports are progressing better than the initial expectation
	Overseas local:	3,021mCHF	+10%	-	• We provide value to patients worldwide through convenience and accumulated clinical evidence
Actemra®	Domestic:	34.8	−8.1%	47.8	• Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated
	Export:	93.6	+8.2%	131.0	• Oversees: Impact of BS below the initial expectation, with steady progress in local sales. Exports are progressing well
	Overseas local:	1,723mCHF	+4%	-	• We provide value to patients through the established evidence as an originator of IL-6 inhibitors
Alecensa®	Domestic:	22.4	−1.8%	31.3	• Japan: Competitors entered first line therapy since 2021, but maintained a high market share
	Export:	46.7	+23.2%	63.3	• Oversees: Continued market penetration in all regions. Exports are generally in line with the initial expectation
	Overseas local:	1,007mCHF	+8%	-	• Expanded indication for NSCLC adj. will further contribute to the treatment of patients
Enspryng®	Domestic:	17.8	−5.3%	24.3	• Japan: Sales increased YonY despite this year's drug price revision*2 in April
	Export:	8.8	+104.7%	13.8	• Oversees: Sales increased in all regions. Exports are progressing better than the inital expectation
	Overseas local:	117mCHF	+62%	-	• 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

Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024
31.7%	32.5%	33.2%	33.8%	34.9%

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Next page. This was included in the appendix last time. This time, for products other than PiaSky, the actual performance up to Q3 and the growth rate in local sales have been reflected. Hemlibra grew by 10%, Actemra by 4%, Alecensa by 8%, Enspryng 62%, so significant growth has been achieved. This is the overall situation of our business at this point in time.

FY2024 Q3 Consolidated Financial Overview (Core)

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	53.8	billion JPY	2021	2024
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later- stage clinical development and early commercial use							37.4	12.3	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use							19.0	6.2	billion JPY	2023	2025
	Ukima plant			UK3(modification): Manufacture bio drug substance					20.3	0.2	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	7.5	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030							109.5 estimated total amount	3.7	billion JPY	2022	2033

* incl. part of investments described in the schedule above

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The last page, well, this is the same slide we have been showing for a while. These are the CapEx plans. For the time being, at this point in time, these are the CapEx plans that have been authorized internally. That concludes my presentation. Thank you.

Question & Answer

Miyata [M]: Thank you very much for your attention. I would like to move to the question-and-answer session. As for Q&A, we also have Mr. Takano, Head of Marketing and Sales Division, present as well. In order to receive questions from as many people as possible, we will limit the questions to two per person. The sound of the questions will be posted on the website together with the presentation, so I'd like to ask for your kind understanding.

Now, we'd like to start taking questions. From JPMorgan, Mr. Wakao, please go ahead and ask questions.

Wakao [M]: Thank you very much. Wakao from JPMorgan. Can you hear me?

Miyata [M]: Yes.

Wakao [Q]: Thank you. The first question as President Okuda talked about, the forecast for the next fiscal year, the upward revised number for this fiscal year would be the one that you would reach in the next fiscal year. But what will be increased and what will be decreased, especially exports of Hemlibra and exports of Actemra, and the other revenue which is the reason for upward revision this time. What would happen to those items, especially?

Okuda [A]: Wakao-san, thank you very much for your question. The next fiscal year forecast, we are not in a position to give you details. At this moment, what we can see is quite uncertain. As Wakao-san said, Hemlibra, and Actemra, and other revenue forecast, there are a lot of uncertainties involved. Therefore, we cannot give you any details at this moment. At the end of January next year, when we will have an earnings briefing, looking at the situation, we'll come up with more details for next fiscal year's forecast so I'd like to ask for your kind understanding.

Wakao [Q]: Understood. Then one question. The same level as this fiscal year's level for the next fiscal year, so there are a lot of uncertainties, but at least you can reach that level, or flat performance is expected. Is that true?

Okuda [A]: I'm so sorry, but there's a lot of uncertainty. So many different factors could change or be subject to change, so just a yardstick for the moment is given as more or less the same as the forecast for this fiscal year. That's how I put it. Thank you.

Wakao [Q]: Okay. Then another question. As for Actemra, the impact of biosimilar has been less than expected more recently, so how has it been analyzed in the Roche group? Also for the next fiscal year onward, what will be the forecast? Along with that, export sales, how are we supposed to forecast that? Can you elaborate more on that?

Taniguchi [A]: Taniguchi speaking. Thank you for your question. As for Actemra, for this fiscal year, as I said, biosimilar entry has been weaker than expected or delayed. As for the next fiscal year, it's hard to say. But at this moment, if you look at the situation in the US, biosimilar penetration is still weak. But that's as far as I can go today.

Wakao [Q]: Thank you. If that's the case, then in the US, if the situation stays the same, then there is a possibility that export sales won't drop that significantly. Is that correct?

Taniguchi [A]: Yes, I think that might be possible. But for the next fiscal year, of course, we are now sorting out the things so I would like to refrain from commenting.

Wakao [Q]: Well, another question. Why the impact of biosimilars was weaker or milder? The timing of the launch of biosimilar was just as expected. Then why was the impact less? What was the factor?

Taniguchi [A]: Well, it's about other companies, so I shouldn't comment that much. But from our perspective, what we understand is that biosimilar companies are facing quite a bit of hardship, especially when it comes to their supply chain, such as sourcing raw materials. Also, there's a question of whether the pricing is actually attractive for biosimilar companies. Based on these overall factors, I get the impression that they might not be able to invest sufficient resources. But again, this is about other companies, so I can't really say for certain.

Wakao [Q]: "I see. And it's your company's view that this situation is unlikely to change for a while, correct?"

Taniguchi [A]: Well, for the moment, that is true, but I'm not sure about the next fiscal year.

Wakao [M]: Thank you.

Miyata [M]: Next, we will take questions from Yamaguchi-san from Citigroup Securities. Please go ahead with your questions.

Yamaguchi [Q]: Thank you. This is Yamaguchi from Citi. The first question is regarding the revision to the earnings forecast, the policy around that. The actual performance was reflected, and it was a good thing that you made upward revisions. In the past, I believe there were times when you wouldn't adjust the forecast unless sales increased by 10% or profits by 30%. But this time, the variance is not as much as 10% and 30% in sales and profit. Did you change any policies around revision to the earnings forecast?

Taniguchi [A]: Thank you for your question. It is not a policy that we have, but this is regarding the policy about the voluntary disclosure of how we are disclosing. We have a strong desire to meet the expectations of various stakeholders and align with the current state of affairs in the world. It is not related to the change in CFO, but personally, I want to disclose what we can as much as possible. In this case, although sales growth didn't quite reach 10%, it was still a significant 7.5%, which is fairly close. We made the decision to revise our forecast based on our judgment of its importance.

Ultimately, it comes down to our assessment of materiality. The criteria for judging materiality can change depending on the current state of affairs and the overall environment. We intend to make these judgments appropriately as circumstances evolve.

Is that explanation satisfactory?

Yamaguchi [Q]: Yes, thank you. Regarding the changes to the export sales of Hemlibra, the sales at Roche, and the shipment from your side, there is a time lag. In Q2, the export sales was large. In Q3 as well in terms of the sales, it is on par with Q2. If we subtract the results up to Q3 from the full-year forecast, the export value for Q4 ends up being about half of Q3's figure.. So in Q2, the local sales, especially in emerging markets, there is a building up of inventory and you needed to respond to that. This trend has been continuing in Q2 and Q3, and the situation will settle in Q4. Is that right? Please comment on the difference between the local sales as well as the export timing.

Taniguchi [A]: Thank you for asking an important question. As for the export, this is related to Roche's inventory status, but it is also dependent upon the shipment timing. We are not shipping our products evenly every month. In the factory situation and supply chain situations, we are sometimes shipping our products in a large volume, but sometimes do not do that. As you can see, from the financial results of Roche, the international growth rate is very high so this strength and momentum has been evident in Q2 and Q3. We

question whether this trend will all of a sudden change in Q4. So in terms of the situation, the overarching trend will continue for a while. The international growth is expected to continue as far as we can logically estimate.

Yamaguchi [Q]: So for Q4, instead of 50 billion, 80 or 90 billion can be achieved. Is that right?

Taniguchi [A]: Well, it is not true to say that we are shipping our products evenly every month. It depends on the supply chain situation. For the remainder of the two months, we'd like to forecast as much as possible. But towards the end of the year, there will be a holiday season for which the export process would not proceed. But as much as we can anticipate, the assumptions will be reflected in our plans.

Yamaguchi [M]: Thank you.

Miyata [M]: Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [Q]: Thank you. I'd like to ask about the pipeline. First of all, NXT007, as was mentioned earlier and by Roche, you could go to Phase III next year based on the result of Phase II. Just recently, things have seemed to have been accelerated while it had taken so much time up until recently. What was the factor for this accelerated process? Mim8 was something that cautioned you and you were in a rush. That's what I was suspecting, but can you elaborate more on that?

Kusano [A]: Thank you very much, Muraoka-san. Kusano speaking. I'd like to pick that up. Previously, and now we are always trying to go forward with the study as fast as possible. During the COVID-19, the study progressed slowly, but we are trying to maximize the speed, not the Mim8, but we are making steady progress on our own, and Phase I/ II study that is ongoing is expected to have readouts next year.

Muraoka [Q]: The next-generation products, whether they can replace them, that is often talked about in the improved products. PNH, it went well. But as for hemophilia, with the next-generation products, the conventional ones would be completely replaced. Would that be correct? Then the Mim8 could take over the share. That's our concern if that is the case. Can you elaborate on that?

Kusano [A]: Thank you very much. As we have been saying from the last time, if you look at the result of Mim8, especially, there is no data that would show that it is superior to Hemlibra so we are able to maintain the patients. Also, they are able to control the disease with Hemlibra so there's no reason to switch over toMim8. But NXT007, of course, it depends on future results, but the objective of NXT007 is to achieve normal level of blood coagulation activity, and expecting hemostatic performance as same as healthy adults. Even the children doing sports can live a normal life. That is the objective. Also in terms of PK, we have seen improved data, so the convenience will also be improved. So Hemlibra and NXT007 could be used by different groups of patients depending on their purpose.

Muraoka [Q]: GYM329 is the next question. As for GYM329, you produce the products and then supply the products to Roche. Is that correct?

Kusano [A]: Yes, you're correct.

Muraoka [Q]: If that is the case, then Roche is getting quite serious about obesity indication. The production capacity, is it enough with UT3 or would you have to consider something even bigger?

Taniguchi [A]: Taniguchi speaking. Thank you very much for your question, Muraoka-san. Well, at this moment, the project has a long way to go. As for the capacity to manufacture investigational drug for the clinical studies,

we are on the conservative side and there shouldn't be much of a problem. But after the launch, we have to predict the order of magnitude from now. But of course, we can use CDMO, not just our own production capacity, so we can depend on various networks.

Muraoka [Q]: Then with regard to R&D aspect of GYM329, success of Scholar Rock SMA the other day had a positive implication for you, and Roche is talking about that. I was wondering why they are talking about that. The data score was 1.8 points out of 66-level rating, 1.8 improvement. But would that be enough? Is your expectation for MANATEE is higher? So are there any metrics that you have about this data?

Kusano [A]: Thank you very much for your question, Muraoka-san. For Scholar Rock Phase III study result for anti-myostatin antibody has achieved the primary endpoint in neuromuscular disease such as SMA for the first time. GYM329 has a similar mode of action, so I think this has been quite positive and the probability of success has been enhanced. As for your question, so this is about the clinical study results of other companies. We're not in a position to comment on whether 1.8, is it really big enough. If you look at the data, the lower dose has more positive results compared to a higher dose. How to interpret this is going to be what we would look at the sub-analysis in the future. In addition, what will be the point in the primary endpoint setting in our study? That is a confidential matter related to development strategy. At this moment, we are not able to disclose that.

Muraoka [Q]: Thank you. Early next year, Phase II results from MANATEE will be out, right?

Kusano [A]: Well, at what point in time next year, we cannot say, but within next year, we'd like to come up with the result.

Miyata [M]: Next, Macquarie Capital, Tony Ren. Please go ahead with your question.

Ren [Q]*: Hi there, this is Tony Ren from Macquarie. First of all, congratulations on a set of very strong data for Q3. This is my first time participating live on your briefing call, so I appreciate the opportunity. A couple of questions from me. The first one is hemophilia, NXT007. I attended the Roche Pharma Day in London and I was very pleasantly surprised when they said they would release the Phase II NXT007 data. Then on Wednesday night, we were even more surprised when they said that they expect the data to be Phase III enabling, which is another positive step forward. That being said, in my estimation, you should be able to run a Phase III program fairly quickly, given historically, you've run these Phase III studies only about six months of dosage, right, dosing the patients for six months. Just curious why do you expect the biologic license application to be in 2027 and possibly later, but not in 2026? It feels a little bit longer than I would have expected.

Kusano [A]: Tony Ren-san, thank you very much for your question. Firstly, Phase I/II study results, in next year, we will be able to disclose the data as we need to determine whether or not to move on to Phase III. At what timing we'll be able to move on to Phase III, of course, we'll be working throughout the clinical study so as to deliver the solution to patients as fast as possible. Whether it's going to take three months or six months, we would like to refrain from disclosing the timing at this point in time.

Ren [Q]*: Okay, understood. A key selling point from Novo Nordisk that may made is their dosing schedule, which appears to be more convenient as well as the subcutaneous auto-injection. Would you be able to comment on the dosage form and the frequency at this point for NXT007?

Kusano [A]: Thank you very much for the question. Phase I study with the healthy adults was conducted and NXT007, the half-life has been extended to 10 weeks, and it has been elongated. Going forward with the further study, we would like to consider the optimal frequency. At this point in time, we cannot comment on that. But based on the study results from Phase I/II in patients, we'd like to consider the optimal dosage frequency going forward. Thank you.

Ren [Q]*: Okay. Great, thank you. My next and the last question is on obesity and GYM329. Typically, we see similar trial designs in the same indication. But in this case, in spinal muscular atrophy, your MANATEE studies and the Scholar Rock SAPPHIRE studies are quite different. Notably, you have decided to combine GYM329 with Evrysdi. Just wanted to see what is the thinking behind that trial design using two agents versus doing a single agent study of GYM329. Roche also commented on Wednesday night that they believe the Scholar Rock and GYM329 are very similar antibodies. So now that you've seen the SAPPHIRE study succeeded, are you planning to design a similar trial, Phase III trial as using the SAPPHIRE design?

Kusano [A]: Thank you for the next question. I will start from the GYM329 and risdiplam combination rationale. As you may know, risdiplam has been already approved, and in terms of the mode of action, this will increase the central nerve function and SMA protein level, and this will be effective for nerves and genes. As for the SMA patients, their muscle has been weakened so with the GYM329, we are targeting to increase the muscle. We believe that the combination therapy has a certain rationale from that perspective. With regard to MANATEE study, those patients who are able to walk and who are not able to walk and for each age group, we are conducting the testing. As for the protocol for Phase III, based on the results of the MANATEE study, we'd like to consider the optimal protocol for Phase III.

Miyata [M]: Thank you very much. Next, SMBC Nikko Securities, Wada-san. Mr. Wada, please.

Wada [M]: Wada from SMBC Nikko Securities. Regarding GYM329 obesity Phase I data, is there any plan to disclose that? The combination study is going to be started in next year, right? So what about that?

Kusano [A]: Mr. Wada, thank you very much for your question. The Phase I study is ongoing. The data is not going to be disclosed. But next year, GYM329 combination study is planned to be started.

Wada [Q]: What is the agent that you're going to combine with the GYM329?

Kusano [A]: We have yet to decide.

Wada [Q]: Thank you. Then the next question, related to avutometinib. SPYK04 is a RAF-MEK molecular glue, and you are going to start the out-licensing activity. What is the difference between this drug and avutometinib? Avutometinib, as a mode of action, RAF-MEK clamp is what you mentioned. But is SPYK04 an evolved version of this mode of action?

Kusano [A]: Thank you for your question. Avutometinib, as for that, it has been out-licensed to Verastem. As for the details of the compound, we cannot answer the question as we already had out-licensed it. But SPYK04 that has been decided to be out-licensed like in avutometinib, RAF-MEK inhibitor. I mentioned a mode of action slightly, but RAF-MEK molecular glue, RAF-MEK binding will be stabilized and form inactivated RAF-MEK complex, and MAPK signal will be strongly inhibited. It is expected that MAPK signal dependent tumor will be attacked. SPYK04 and avutometinib are, in terms of molecules, they are quite similar.

Wada [Q]: I asked this question because in terms of platform, you can create a group of molecular glues. Is there any platform that you have that can be used for something other than RAF-MEK?

Kusano [A]: Thank you for your question. As for the early research direction, I'm so sorry, but we are not in a position to disclose that strategy. I would like to refrain from commenting on that.

Wada [Q]: Understood, thank you.

Miyata [M]: Thank you. Next, Daiwa Securities, Hashiguchi-san.

Hashiguchi [Q]: This is Hashiguchi. Thank you for taking my question. My first question is regarding the dividend forecast, why you changed it to undetermined. As you mentioned, the business environment has been evolving significantly, but what has changed since you disclosed JPY82 forecast earlier? As I heard your presentation, I wasn't sure about that. Will the revision of basic policy for profit distribution be considered in the future? Or the policy remain unchanged, but the earnings forecast and strategic investment needs may change? As for the business performance, the next fiscal year will be on par with this fiscal year. That was what clearly mentioned. The strategic investment needs may increase in the future, at least that's my impression. Could you elaborate further on these points?

Taniguchi [A]: This is Taniguchi. Thank you. As for the upward revision of the business performance, based on this, of course, the net profit in the bottom line and EPS may change. But what's going to happen by the end of the year, we'd like to monitor that, and then we would like to consider dividends. At the time we are disclosing this fiscal year's performance, we'd like to talk about this. Other than that, at this point in time, we cannot make any comments, unfortunately.

Hashiguchi [Q]: Compared to the beginning of the fiscal year, we have now completed Q3, and we believe that the probability of achieving the full-year forecast has increased. But when it comes to dividends, you changed the description to undetermined. How should I understand the discrepancy?

Taniguchi [A]: Well, in the past, when we made the revisions as of the end of Q3, we also changed the dividend forecast to undetermined, and we recognize that other companies are also doing the same thing. Since the full-year net profit is something that is not finalized. Based on the fixed net profit, we'd like to disclose and explain dividends.

Hashiguchi [Q]: Thank you. GYM329 sales potential is the second question I'd like to ask. As for Roche, they have been showing the forecast between USD 0.5 billion to 1 billion at the Pharma Day last month. Up until last year, it was above USD 1 billion so I believe this is effectively a downward revision. How do you understand the revision? And if you have any different views, would you be able to share that?

Okuda [A]: This is Okuda. Thank you for the question. In terms of our understanding, as is shown in my slide, at this point in time, GYM329 Roche's forecast, for SMA and FSHD is between CHF 0.5 billion to CHF 1 billion, and obesity-related sales forecasts are not included in this number. That's something that we wanted to share.

Hashiguchi [Q]: So, the unit is Swiss franc, not US dollars. Compared to one year ago, can you comment on the change from one year ago?

Okuda [A]: As far as I know, the sales forecast explained by Roche is between CHF 0.5 million to CHF 1 million. That's all we have in terms of the information.

Hashiguchi [M]: Thank you.

Miyata [M]: Ms. Haruta from UBS Securities, please.

Haruta [M]: Haruta from UBS Securities. One question. GYM329, obesity study. At the moment, with SMA, patients with small body weights are targeted, but obesity patients, once they use the GYM329, the dose should be increased higher. But with the sweeping antibody, can you suppress the dose to some extent? And if you combine this with GLP-1 drugs in the future, there are demands for elderly people with problems in muscle strength. So are you going to also consider enrolling those types of patients as well?

Kusano [A]: Thank you very much for your question, Ms. Haruta. As you rightly pointed out, Roche is now running the Phase I study. So, healthy overweight people are looked at for PK/PD, tolerability, and safety for

GYM329. Instead of SMA, for obesity patients, what will be the right dosing is now being sought out with this study. That is ongoing.

Haruta [Q]: So, what about the elderly people with less strength in their muscles and with higher demand? How are you looking at targeting those people

Kusano [A]: Well, inclusive of that, the results of Phase I and various data will be taken into account for Phase III.

Haruta [Q]: So, the Phase I obese GYM study, once this is over, then you're going to start a combination study for GYM next year. Is that correct?

Kusano [A]: Well, whether it is going to be sequential or in parallel, we have not disclosed yet. But as for the next study, of course, we have to take a look at the result of Phase I closely to decide. Thank you.

Haruta [Q]: Then to change the gear slightly, DMD gene therapy in Roche earnings in regions other than Europe and US, they are starting up quite well in sales. But what about the demand in Japan? The exon skipping drug is not used by some patients, and that will be the demand coming from. What do you think of that? Could you utilize SMA patients sales network, even though the diseases are different?

Takano [A]: Takano from Marketing and Sales. Thank you for your question. As you said, the new therapy is what we are going to enter. Gene therapy is quite complex, and we need several systems as you may understand. The neuromuscular disease including Evrysdi is something that we're working on and the market launching plan is going to be worked out based on that.

Haruta [Q]: Understood. Basically, exon skipping drugs cannot be used by some patients, and that is going to be the target basically. Is that correct?

Takano [A]: Correct. We are preparing our plans to roll out the product to the market in line with the approved indications.

Haruta [M]: Thank you.

Miyata [M]: Thank you. We are very sorry, but we have come to the end of the allocated time so we'd like to close this Q&A session. Now, we'd like to close the earnings call for Chugai Pharmaceuticals for FY2024 Q3. For those questions we weren't able to answer, please reach out to the Corporate Communications Department with your questions and the contact details have been provided on the last page of the presentation materials. Thank you very much for taking the time out of your busy schedule to attend this earnings call. Thank you.

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