

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2025.12 Q3 Financial Results

October 24, 2025

Event Summary

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[Participants]

[Number of Speakers] 5

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Email Support

Presentation

Miyata: Thank you very much for attending the conference on financial results for Q3 for the year ending December 2025. My name is Miyata. I am in charge of today's facilitation. I am from the Corporate Communications department.

Agenda



01	FY2025 Q3 Overview	President & CEO Dr. Osamu Okuda
02	Overview of Development Pipeline	Executive Vice President, Head of Project & Lifecycle Management Unit Tsukasa Kusano
03	FY2025 Q3 Consolidated Financial Overview(Core)	Director, Executive Vice President & CFO Iwaaki Taniguchi

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Today, we are using the Zoom webinar system. The agenda is shown on the presentation slide, page three. The presentation will be conducted in Japanese. However, we do have a simultaneous interpretation service available for English speakers. Please make sure you click on the language of your preference. You can choose either Japanese or English.

We are going to receive questions at the end of the presentation. We have 30 minutes for Q&A. During the presentation, all of your voices and audio are muted.

Now, I would like to ask Dr. Osamu Okuda to give us the FY2025 Q3 overview.



Financial Overview

- Both domestic and overseas product sales have been performing steadily, resulting in increased revenue and profit
- Expecting to achieve the full year forecast, based on the steady progress

Covo	2024	2025	Sep Growth (vear-on-year)		202	5	
Core (billions of JPY)	Jan - Sep actual	Jan - Sep actual			Jan - Dec forecast	Progress	
Revenue	868.5	911.6	+43.1	+5.0%	1,190.0	76.6%	
Domestic sales	331.7	343.7	+12.0	+3.6%	462.5	74.3%	
Overseas sales	418.7	450.9	+32.2	+7.7%	555.5	81.2%	
Other revenue	118.2	117.1	-1.1	-0.9%	172.0	68.1%	
Operating profit	426.6	450.5	+23.9	+5.6%	570.0	79.0%	
Operating margin	49.1%	49.4%	+0.3%pts	-	47.9%	-	
Net income	301.3	320.0	+18.7	+6.2%	410.0	78.0%	
EPS (yen)	183.09	194.44	+11.35	+6.2%	250.00	77.8%	

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Okuda: I'm Okuda. Thank you. I will be talking about the 2025 Q3 performance. Please turn to page five.

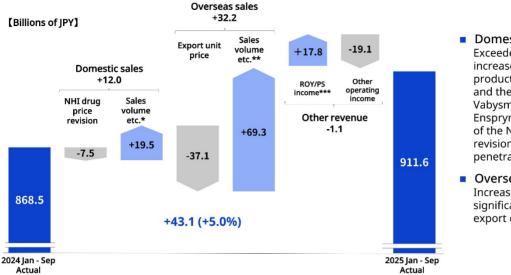
For the 2025 Q3 performance, both domestic and overseas product sales were very strong. Sales and profit were both very good. YoY, revenue was plus 5%. Operating profit, plus 5.6%. Net income for the quarter is 6.2%. Based on the Q3 results and the steady progress, we believe that we will be able to meet the target for the full year.

In terms of the revenue details, I will be presenting them in the next slide.

FY2025 Q3 Overview

Topline Overview





- Domestic sales Exceeded YoY due to the increase in the sales of new products Phesgo and PiaSky, and the mainstay products Vabysmo, Hemlibra and Enspryng, despite the effects of the NHI drug price revisions and the market penetration of generic drugs.
- Overseas sales
 Increased YoY due to the significant increase in the export of Actemra to Roche.

Compared to last year, the revenue increased by JPY43.1 billion, a plus 5% growth. Starting from the left-hand side.

Domestically, with the NHI price revision and the generic drug, that was negative, but we have new products Phesgo and PiaSky and the mainstay products Vabysmo, Hemlibra, and Enspryng, which were very good, JPY12 billion increase in revenue. Overseas, the export unit price did drop. However, the volume and foreign exchange impact were large, which increased dramatically, a JPY32.2 billion increase.

^{*}Including negative impact from generic penetration **Including negative impact from generic penetration and positive impact from foreign exchange (25.9 billion yen)
*** ROY/PS income: Royalty income and profit-sharing income

FY2025 Q3 Overview





- Hemlibra continues to grow, while Actemra sales decline due to biosimilar penetration
- Strong progress of out-licensed products with high sales potential is expected to drive growth in the short to medium term

Hemlibra

- Approved in more than 120 countries, used by over 30,000 people
- International markets are driving growth. Japan, the U.S. and Europe are still in a growth phase
- Autoinjector under development to improve convenience

Actemra

 Global (including Japan):
 While the penetration speed of biosimilars remains unclear, sales are expected to decrease

NEMLUVIO*

- Better-than-expected strong initial performance of overseas local sales
- Paid NBRx weekly market share trend (new patient starts) in the U.S. [PN: ~37%, AD: ~7.3%] **
- Scheduled to start clinical trials for systemic sclerosis and chronic pruritus of unknown origin

orforglipron***

- Potentially large obesity population reach
- The first oral GLP-1 receptor agonist that can be taken without restrictions on food and water intake
- Achieved primary endpoints in all announced P3 clinical trials
- Projected Global regulatory submission plan: obesity in 2025, T2D in 2026

*Licensed out to Galderma ** Source: Galderma's Q3 financial announcement *** Licensed out to Eli Lilly and Company NBRs: New-to-brand prescriptions; rolling 6 week average as of the week ending October 10, 2025 PN: Prurigo nodularis AD: Atopic dermatitis

Next, I would like to explain the short to medium-term outlook for major Chugai-originated projects. Our growth driver, Hemlibra, continues to be led by growth in international regions, while also remaining in a growth phase in Japan, the U. S., and Europe.

On the other hand, regarding Actemra, although the future penetration speed of biosimilars in Japan, the U.S., and Europe remains unclear, we anticipate a decline in sales.

For NEMLUVIO, the product licensed to Galderma showed a better-than-expected market launch.

Also, for the product licensed out to Eli Lilly, orforglipron, all completed readouts for the Phase III studies have met their primary endpoints. Eli Lilly has announced plans to begin global submissions for obesity in 2025 and for type 2 diabetes in 2026.

Therefore, third-party licensed products with great sales potential are performing very well, and these will drive our future growth.



FY2025 Q3 Overview

Strategic Investment Acceleration



- Acquired sparsentan, an IgA nephropathy treatment approved in the U.S. and EU, through acquisition of Renalys Pharma, Inc.
- Aiming for domestic filing for approval in 2026 as a first-in-class therapeutic, strengthening our nephrology pipeline, and contributing to sustainable domestic sales growth



Next, I would like to introduce our acquisition of a new IgA nephropathy treatment, sparsentan, through the purchase of Renalys Pharma Inc., which we announced today.

We have established a capital allocation policy to provide truly valuable solutions for our patients so that we can give a stable return to our shareholders.

As a strategic investment aimed at delivering innovative medicines, we have acquired this product from a third party outside of Roche.

In the U. S., and Europe, it has already been approved and launched. As Renalys Pharma has already released its press release, in the domestic Phase III clinical trial, we have completed the collection of primary endpoint data for all evaluable subjects.

At this moment, the earliest 2026 approval submission is planned to contribute to sustainable growth domestically. As a first-in-class treatment, we would like to deliver it to our patients as soon as possible, even one day earlier. That's all I have for you tonight. Thank you very much.



Overview of Development Pipeline

Q3 Topics (1/3)



As of October 24, 2025

			AS 01 October 24, 2023
Launched	PiaSky	Paroxysmal nocturnal hemoglobinuria (PNH)	October 2025 (Taiwan)
Ammunuad	Tecentriq	Relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type	September 2025 (Japan)
Approved	CellCept	Refractory nephrotic syndrome (public knowledge-based application)	September 2025 (Japan)
Filed	Avastin	Neurofibromatosis type 2 (NF2)	August 2025 (Japan)
Initiation of	glofitamab	Relapsed or refractory diffuse large B-cell lymphoma (domestic P2)	August 2025
	gioritamab	Relapsed or refractory mantle cell lymphoma (domestic P2)	August 2025
Study	afimkibart	Crohn's Disease (P3)	September 2025
	divarasib	Non-small cell lung cancer (NSCLC) [1st line] (P1b/2)	October 2025
Removed	PiaSky	Sickle cell disease: Discontinuation of development	
from Pipeline		NSCLC (SKYSCRAPER-03 study): Discontinuation of development	
	tiragolumab	Hepatocellular carcinoma (HCC) (SKYSCRAPER-14 study): Discontinuation of development	

Kusano: Yes, I am from the project & lifecycle management Unit. I am Kusano. Please take a look at page 10 of the slide. These are the Q3 topics. I will explain them in detail from the top.

The in-house product, PiaSky, has been launched in Taiwan for PNH.

Two Roche products have been approved. Tecentriq is approved in Japan for the treatment of relapsed or refractory extranodal NK/T-cell lymphoma, nasal type, which is a rare disease. It is the first immune checkpoint inhibitor approved in Japan. CellCept submitted a filing based on public knowledge for the treatment of refractory nephrotic syndrome and received approval in September.

One application was submitted for Roche's Avastin for neurofibromatosis type 2 in August this year.

Four Roche products have begun trials. Glofitamab has initiated a domestic Phase II trial for relapsed or refractory diffuse large B-cell lymphoma and relapsed or refractory mantle cell lymphoma. Afimkibart has entered a Phase III trial for Crohn's disease. Additionally, divarasib has entered a Phase Ib trial for the first-line treatment of NSCLC, or non-small cell lung cancer.

Regarding pipeline exclusions, following the results of clinical trials conducted overseas, Roche discontinued the development of PiaSky for sickle cell disease, and it was therefore removed from the pipeline.

For Tiragolumab, development for NSCLC and hepatocellular carcinoma has been discontinued following the results of the SKYSCRAPER-03 and SKYSCRAPER-14 trials, respectively.

Q3 Topics (2/3)



As of October 24, 2025

		P3 ATTAIN-1 study (obesity) : PE was met	August 2025
		P3 ATTAIN-2 study (obesity with type 2 diabetes (T2D)): PE was met	August 2025
Readout		P3 ACHIEVE-J study (T2D): Indicated the potential for safe administration	September 2025
	orforglipron*	P3 ACHIEVE-2 study (T2D, compared to dapagliflozin, SGLT-2 inhibitor): PE was met	October 2025
		P3 ACHIEVE-3 study (T2D, compared to oral semaglutide) : PE was met	September 2025
		P3 ACHIEVE-5 study (T2D with inadequate glycemic control with titrated insulin glargine): PE was met	October 2025
	Enspryng	P3 SatraGO-1 study (thyroid eye disease (TED)): PE was not met P3 SatraGO-2 study (TED): PE was met -In both studies <u>Enspryng</u> showed clinically meaningful improvements across key efficacy endpoints, including proptosis, diplopia, and clinical activity score (CAS) in inactive/active TED	Q3 2025
	PiaSky	P2a CROSSWALK-c study: Sickle cell disease (SCD): PE was not met	Q3 2025
	vamikibart	P3 SANDCAT study: Uveitic macular edema (UME) PE was not met** P3 MEERKAT study (UME): PE was met -In both studies numerically higher proportion of patients treated with <u>vamikibart</u> gained vision	Q3 2025
	Tecentriq	P3 IMvigor011study (Muscle-invasive bladder cancer (adjuvant)): PE was met	August 2025
	giredestrant	P3 evERA study (HR positive breast cancer (1st line to 3rd line)): PE was met	September 2025

In Q3, we had many readouts for our in-house developed products. Orforglipron, which we licensed out to Eli Lilly, is being evaluated for the treatment of obesity in the ATTAIN-1 and ATTAIN-2 trials, both of which achieved their primary endpoints.

In addition, the ACHIEVE-2, ACHIEVE-3, and ACHIEVE-5 studies for type 2 diabetes achieved their primary endpoints, respectively. Furthermore, in the ACHIEVE-J trial conducted in Japan to evaluate safety, it was indicated that orforglipron can be dosed safely in patients with type 2 diabetes.

The results from two global Phase III studies for Enspryng in thyroid eye disease have been obtained. I will explain this in more detail.

Regarding PiaSky for sickle cell disease, we previously announced that it was removed from the pipeline, and the primary endpoint was not met in the Phase II CROSSWALK-c study conducted overseas. Please wait for future conference presentations for detailed data.

Next, we have the readout from Roche.

For vamikibart, we have results from two global Phase III trials targeting uveitic macular edema (UME).

The SANDCAT trial, in which Japan participated, did not meet its primary endpoint, while the MEERKAT trial, in which Japan did not participate, achieved its primary endpoint. In both trials, the proportion of patients whose vision improved after treatment with vamikibart was numerically higher. Based on these results, we plan to hold consultations with regulatory authorities regarding the application for approval.

Tecentriq and giredestrant Phase III trials each met their primary endpoints in the indicated studies.

Q3 Topics (3/3)



As of October 24, 2025

	orforglipron*	European Association for the Study of Diabetes (EASD): P3 ATTAIN-1 study (obesity)	September 2025
	Enspryng	American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS): P3 SatraGO-1, SatraGO-2 studies (TED)	October 2025
	Alecensa	European Society for Medical Oncology (ESMO): P3 ALEX study (NSCLC, OS final data), P3 ALINA study (NSCLC (adjuvant), DFS three-year data)	October 2025
Medical	trontinemab	Alzheimer's Association International Conference (AAIC): P1b/2a <u>Brainshuttle</u> AD study for Alzheimer's disease (AD)	July 2025
Conference	Vabysmo	European Society of Retina Specialists (EURETINA): P3 AVONELLE-X study (4-year data in neovascular or wet age-related macular degeneration (nAMD)), P3b/4 SALWEEN study (one-year data in Asian patients with polypoidal choroidal vasculopathy (PCV) among nAMD)	September 2025
	vamikibart	American Academy of Ophthalmology (AAO): P3 SANDCAT (UME)	October 2025
	Tecentriq	ESMO: P3 IMvigor011 study (Muscle-invasive bladder cancer (adjuvant))	October 2025
	giredestrant	ESMO: P3 evERA study: HR positive breast cancer (1st line to 3rd line)	October 2025
	Roche	In-licensed: CT-388, a long-acting GLP-1/GIP receptor agonist	-
In-licensing of Products/	Rani Therapeutics	License agreement for the development and commercialization of an oral formulation leveraging <u>RaniPill</u> technology	October 2025
Technologies	Renalys Pharma	M&A: obtaining the exclusive development and commercialization rights for sparsentan, a ETAR/AT1R dual Antagonist, in Japan, South Korea and Taiwan	October 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan)
*Conducted by Eli Lilly and Company, a global licensee OS: Overall survival, DFS: Disease free survival, UME: <u>uveitic</u> macular edema

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We presented three of our in-house products and five Roche products at medical conferences.

In addition to the trial results presented so far, the final OS data for the ALEX trial of Alecensa in NSCLC was also released. The Company also announced a positive result in the ALINA trial for adjuvant therapy.

All Roche products have already been announced in press releases.

Regarding product and technology in-licensing, we have signed an agreement with Roche to in-license CT-388, a long-acting GLP-1/GIP receptor agonist. Additionally, as announced in the news release, we have entered into a license agreement with Rani Therapeutics for the development and commercialization of an oral formulation using the RaniPill technology.

Furthermore, as explained by Dr. Okuda earlier, with the acquisition of Renalys, we will acquire the development and sales rights for sparsentan, an IgA nephropathy project. I will provide more details on the scientific aspects of sparsentan, including its MOA.

2025: Key R&D Milestones



Underlined and bolded: Changes since July 24, 2025 As of October 24, 2025

	Product	Indication / Study name	Progress
Projects to be	Elevydis	Duchenne muscular dystrophy (ambulatory)	Approved
Approved	Vabysmo	Angioid streaks	Approved
	PiaSky	COMMUTE-a study*: atypical hemolytic uremic syndrome (aHUS)	
	Engange	P3 SatraGO-1 study (TED)	Not met PE**
	Enspryng	P3 SatraGO-2 study (TED)	Met PE**
	Lunsumio + Polivy	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	Met PE
P3/Pivotal	Lunsumio	CELESTIMO study: follicular lymphoma (2nd line)	Planned in 2026
Readouts		persevERA study: HR positive breast cancer (1st line)	Planned in 2026
	giredestrant	evERA study: HR positive breast cancer (1st line to 3rd line)	Met PE
	vamikibart	SANDCAT study: noninfectious uveitic macular edema (UME)	Not met PE**
	Vamikibart	MEERKAT study: UME	Met PE**
	GAZYVA	INShore study: pediatric nephrotic syndrome	
	GYM329 + Evrysdi	MANATEE study: spinal muscular atrophy (SMA)	Planned in 2026
	GYM329	MANOEUVRE study: facioscapulohumeral muscular dystrophy (FSHD)	Planned in 2026
P2 Readouts	NXT007	Hemophilia A	PoC confirmed / Decision to proceed to Phase 3****
	<u>PiaSky</u>	CROSSWALK-c study: Sickle cell disease (SCD)	Not met PE
P1/2 Readout	trontinemab	Brainshuttle AD study: Alzheimer's disease	Decision to proceed to Phase 3
Initiation of study	GYM329	Obesity (P2 study)	Study initiated

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan), r/r: relapsed or refractory, PE: primary endpoint, HR: hormone receptor,
PoC: Proof of Concept, *Adult/Adolescent patients, **To be discussed with global health authorities, ***Three phase 3 studies scheduled to initiate in 2026 (vs. FVIII products, vs. Hemlibra, and pediatric patients)

Major R&D events in 2025 are shown here. The bold and underlined parts indicate changes from the previous financial statement.

As I mentioned earlier, Enspryng, giredestrant, vamikibart, and PiaSky study results are now available.

Lunsumio, the CELESTIMO study, and giredestrant, the persevERA study, have had their readout timing changed to 2026.

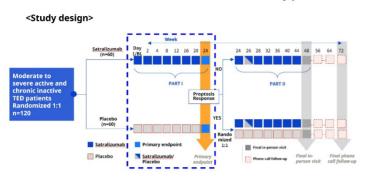
In addition, data for GYM329 for SMA and FSHD are to be presented in H1 next year, primarily for competitive reasons.

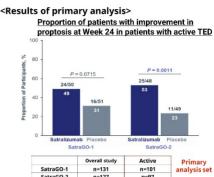


CHUGAI

ENSPRYNG: Phase III Study in Moderate-to-Severe Thyroid Eye Disease

- Continue to analyze the study results, and plan to discuss with regulatory authorities toward filing
- Expected to contribute to the treatment of thyroid eye disease (TED) with convenient once-every-4-week subcutaneous administration and favorable safety profile





- In SatraGO-1/GO-2 studies, satralizumab (Product name: Enspryng) was compared to placebo in patients with moderate-to-severe
 thyroid eye disease (TED). The studies aimed to confirm the utility of IL-6 inhibition based on existing nonclinical and clinical data.
- For the primary endpoint, proportion of active TED patients with proptosis improvement at Week 24, SatraGO-1 did not achieve statistical significance, while SatraGO-2 did. Satralizumab demonstrated consistent efficacy trends across both studies.
- The safety data of satralizumab in TED was consistent with established data in NMOSD, with no new safety concerns and good tolerability.

Next, this slide shows the results of the Phase III studies of Enspryng in thyroid eye disease. These results were recently presented at the American Society of Ophthalmic Plastic and Reconstructive Surgery, ASOPRS Annual Meeting.

First, the study design, the SatraGO-1 and SatraGO-2 studies compared Enspryng with placebo in patients with moderate to severe thyroid eye disease, verifying the usefulness of IL-6 inhibition based on existing non-clinical and clinical data.

Patients with active and inactive thyroid eye disease were enrolled in the studies and were randomized to either the Enspryng arm or the placebo arm in a one-to-one ratio.

The results obtained this time were as follows. At week 24, as indicated in orange, we evaluated the proportion of patients with active thyroid disease who showed a proptosis improvement. Results from the SatraGO-1 trial showed improvement ratio of 49% in the Enspryng arm and 31% in the placebo arm. No statistical difference was obtained. In contrast, SatraGO-2 trial, it was 53% in the Enspryng group and 23% in the placebo group. A statistical difference was proven.

Additionally, although it is not shown in the slide, both studies demonstrated clinically meaningful improvement with Enspryng in key efficacy endpoints, including proptosis, double vision, and clinical activity score in active and inactive thyroid eye disease.

Safety data for Enspryng in thyroid eye disease was consistent with established data for the marketed NMOSD treatment. No new safety concerns were identified, and treatment was well tolerated.

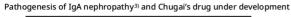
We will continue to analyze the results of this study and plan to hold consultations with the authorities regarding future submissions.

Enspryng offers convenience subcutaneous administration once every four weeks and a favorable safety profile, and we expect it to contribute to the treatment of thyroid eye disease.

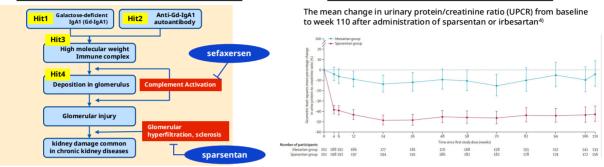


sparsentan (Dual Endothelin/Angiotensin Receptor Antagonist)

- Sparsentan was approved in U.S./EU based on a global Phase 3 study for IgA nephropathy¹⁾. In Japan, small
 Phase 3 study is currently being conducted, and sparsentan has potential to become a first-in-class drug.
- In addition to the RA system²⁾, this drug simultaneously inhibits the endothelin pathway. While being used once daily like conventional RA system inhibitors, this drug is expected to show significant urinary protein reduction.







- Sparsentan is expected to be effective against kidney damage common in chronic kidney diseases.
- Sparsentan and sefaxersen, suppresses inflammation by complement activation, will become new treatment options for IgA nephropathy patients at various disease stages.
- Primary endpoint: At week 36, the sparsentan-treated group showed a significant reduction in UPCR compared to the irbesartan-treated group, with -49.8% change in UPCR from baseline⁵).
- Drug-related adverse events were comparable between two groups.

Rovin *et al.* Lancet. (2023, 2) Renin-angiotensin system, 3) Adapted from Suzuki et al. Journal of the Japanese Society of Nephrology (2015), 4) An angiotensin II receptor blocker, one of the RAS inhibitors. 5)Heerspink et al. Lancet. (2023)

Next is about sparsentan, which will be acquired through the acquisition of Renalys Pharma, which was announced today.

Sparsentan is a drug whose efficacy in treating IgA nephropathy has been evaluated in overseas Phase III trial and is approved in the United States and Europe. Small-scale Phase III clinical trial is currently underway in Japan, and the drug is expected to become a first-in-class treatment.

This drug inhibits the renin-angiotensin system and endothelin pathway simultaneously, providing dual inhibitor effects in a single drug. Therefore, it has been shown to have a strong urinary protein reduction effect as a single drug without the need for combined use with the renin-angiotensin system inhibitor.

Using the diagram on the left, I'll explain the mechanism of IgA nephropathy.

First, due to a combination of genetic and environmental factors, IgA1 with abnormal glycosylation is produced. The human immune system recognizes this abnormal IgA1 as a foreign substance and produces anti-IgA1 IgG antibodies. These form immune complexes, which then deposit in the glomeruli and cause glomerular damage through the complement activity. In damaged glomeruli, the burden on the glomerulus increases, and sclerosis progresses.

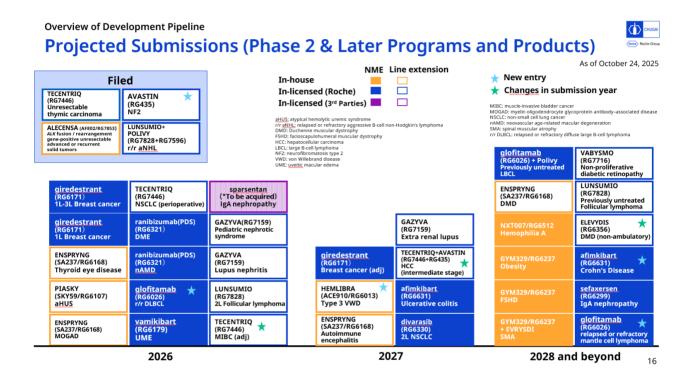
Sparsentan suppresses blood pressure increases and vascular constriction through its dual antagonistic action, thereby suppressing nephritis, reducing the burden on the kidneys, and protecting the nephrotic function.

Sefaxersen, which is also being developed for IgA nephropathy, inhibits complement, and it has different MOA. Through development of these two drugs, sparsentan and sefaxersen, we aim to improve the complex pathology of IgA nephropathy and improve the condition of wide range outpatients.

Next, I will explain the result of a Phase III trial conducted overseas using the graph on the right.

In this trial, sparsentan was compared to the renin-angiotensin system inhibitor, irbesartan. Both drugs were administered orally once daily for 110 weeks. Primary endpoint was the mean change from baseline in urinary protein to creatinine ratio at week 36.

The mean change was 15.1% in the irbesartan and 49.8% in the sparsentan arm, demonstrating a significant reduction with sparsentan compared to the irbesartan group. Additionally, AE were comparable between the two arms.



Finally, these are the projected submissions.

Projects marked with a light blue star are newly added projects.

We have added a new category of in-licensed third-party projects, which are shown in purple. We expect to submit an application for sparsentan next year in 2026.

The following slides are attached as reference material.

That's all for my presentation.

Miyata: Lastly, Mr. Taniguchi will talk about the Q3 consolidated core outline. Mr. Taniguchi.

P/L Jan - Sep (Year on Year)

(Billions of JPY)	2024	2025	Growth		
Revenue	868.5	911.6	+ 43.1	+ 5.0%	
Sales	750.3	794.6	+ 44.3	+ 5.9%	
Domestic	331.7	343.7	+ 12.0	+ 3.6%	
Overseas	418.7	450.9	+ 32.2	+ 7.7%	
Other revenue	118.2	117.1	- 1.1	- 0.9%	
Cost of sales	-244.1	-263.3	- 19.2	+ 7.9%	
(cost to sales ratio)	32.5%	33.1%	+0.6%p	-	
Research and development	-127.9	-128.8	- 0.9	+ 0.7%	
Selling, general and administration	-72.5	-69.4	+ 3.1	- 4.3%	
Other operating income (expense)	2.4	0.4	- 2.0	- 83.3%	
Operating profit	426.6	450.5	+ 23.9	+ 5.6%	
(operating margin)	49.1%	49.4%	+0.3%p	-	
Financial account balance	-1.1	-1.9	- 0.8	+ 72.7%	
Income taxes	-124.2	-128.6	- 4.4	+ 3.5%	
Net income	301.3	320.0	+ 18.7	+ 6.2%	
EPS (JPY)	183.09	194.44	+11.35	+ 6.2%	



Domestic sales

Increase due to growth of new products and mainstay products, despite decrease due to the NHI drug price revisions and the market penetration of generic drugs

Overseas sales

Increase due to growth of mainstay products exported to Roche

Other revenue

Decrease in the one-time income, despite increase in the income related to Hemlibra

Cost of sales

Rise in cost to sales ratio 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, etc.

Selling, general and administration expenses

Decrease in various expenses, etc.

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Taniguchi: First, I would like to report that for the third quarter, revenue was 911.6 billion yen, an increase of 43.1 billion yen, or 5.0%, year-on-year. Core operating profit also reached 450.5 billion yen, an increase of 23.9 billion yen, or 5.6%.

Next, I would like to go over our revenue performance. Sales amounted to 794.6 billion yen, an increase of 44.3 billion yen, or 5.9%, year-on-year.

Breaking down the sales by region, Japan recorded 343.7 billion yen, an increase of 12.0 billion yen, or 3.6%, year-on-year. This was driven by the strong performance of our new and mainstay products, which more than offset the negative impacts from the NHI price revisions and the penetration of generic drugs.

Overseas sales were 450.9 billion yen, an increase of 32.2 billion yen, or 7.7%, year-on-year. This was driven by continued strong exports of our core products to Roche.

Next, let's look at other revenue, which includes royalties. This category amounted to 117.1 billion yen, nearly flat year-on-year with a slight decrease of 1.1 billion yen.

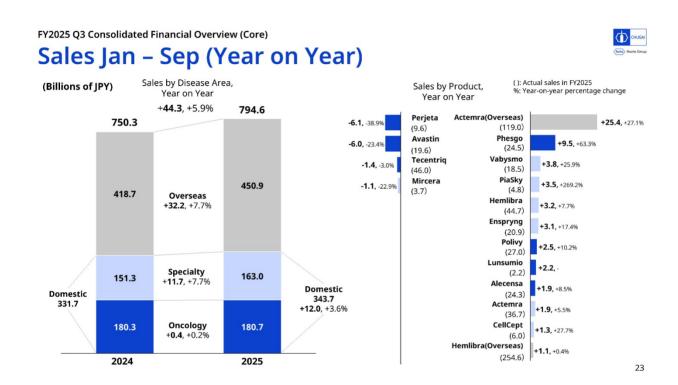
Although royalty income from Roche for Hemlibra continued to increase, this was offset by a decrease in one-time payments from third parties compared to the same period last year.

Cost of sales amounted to 263.3 billion yen, an increase of 19.2 billion yen, or 7.9%, year-on-year. This increase in absolute terms was in line with the growth in product sales. However, the cost to sales ratio rose by 0.6 percentage points year-on-year to 33.1%. This was mainly due to a slight increase in the proportion of Actemra, a product with a relatively high cost, in our overall product mix.

Moving on to SG&A expenses, despite facing inflationary pressures and rising personnel costs, we continued our efforts to improve efficiency, which led to a year-on-year decrease of 3.1 billion yen. R&D expenses increased by 0.9 billion yen year-on-year, reflecting the steady progress of our drug discovery research and

early-stage development projects. As for other operating income, it decreased by 2.0 billion yen year-on-year, primarily due to a slight decline in gains from product transfers and other related items.

Taking these factors into account, our operating profit, as mentioned earlier, increased by 23.9 billion yen year-on-year to 450.5 billion yen. Our operating profit margin also rose by 0.3 percentage points year-on-year to 49.4%. Net profit after tax was 320.0 billion yen, an increase of 18.7 billion yen, or 6.2%.



Next, I will explain the breakdown of changes in product sales.

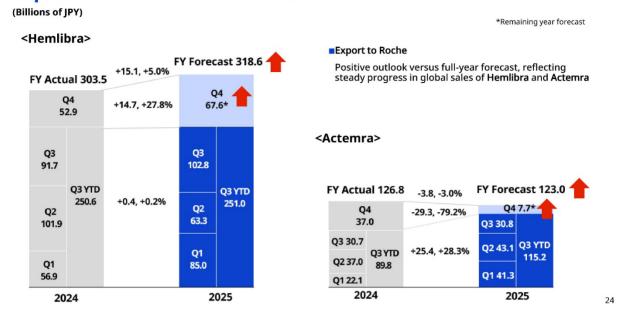
First, looking at the domestic oncology area, represented by the dark blue section at the bottom, sales amounted to 180.7 billion yen, an increase of 0.4 billion yen, or 0.2%, year-on-year. Specifically, while Avastin continued to decline due to the penetration of generics, sales of our new product, Phesgo, showed extremely robust growth, significantly exceeding the decline in Perjeta, which it is replacing. Additionally, our new product, Lunsumio, has also shown a strong launch.

The specialty area recorded 163.0 billion yen, an increase of 11.7 billion yen, or 7.7%, year-on-year. Despite being generally affected by drug price revisions, our key products — Hemlibra, Actemra, Enspryng, and Vabysmo — all performed well, resulting in solid positive growth. Furthermore, our new product, Piasky, continued its momentum from last year and steadily grew sales this fiscal year as well.

Overseas, as we have explained before, especially Actemra, in particular, contributed 32.2 billion yen, marking a 7.7% year-on-year increase in sales. Hemlibra also saw a positive contribution of 1.1 billion yen.



Export of Hemlibra and Actemra to Roche



Now, I'd like to discuss the status of Hemlibra and Actemra exports to Roche, which we also touched upon in the second quarter.

Regarding Hemlibra, as we previously mentioned, approximately 38.0 billion yen in shipments that were originally scheduled for revenue recognition in late June were delayed to July due to procedural delays in delivery. These sales have now been properly recognized. For the cumulative third quarter, Hemlibra sales show a positive increase of 0.4 billion yen year-on-year. Assuming the current shipment schedule and planned shipments towards the end of the year, we anticipate full-year cumulative sales to exceed our full-year forecast of 318.6 billion yen. As I mentioned previously, we expect sales to exceed the forecast by more than 10.0 billion yen, a similar amount to what we stated last time.

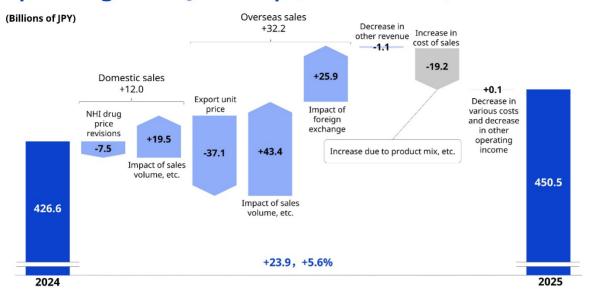
As for Actemra, as a result of continued slower-than-expected biosimilar penetration, sales reached 115.2 billion yen by the third quarter, already quite close to our full-year forecast of 123.0 billion yen. Based on the current shipment plans and schedule, we currently anticipate full-year cumulative sales to exceed our full-year forecast of 123.0 billion yen by more than 20.0 billion yen.

FY2025 Q3 Consolidated Financial Overview (Core)

Operating Profit Jan – Sep (Year on Year)



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Now, let's look at the breakdown of changes in operating profit up to September.

Starting from the left, first, regarding domestic factors, domestic sales increased by 12.0 billion yen. Although there was a 7.5 billion yen negative impact from drug price revisions, this was more than offset by a significant increase in volume. The volume effect contributed 19.0 billion yen, effectively offsetting the 7.5 billion yen drug price impact.

Overseas sales increased by a total of 32.2 billion yen. This was driven by expanded sales in emerging markets and a significant increase in volume, despite a continued decline in export unit prices. Furthermore, a foreign exchange impact of 25.9 billion yen was added, resulting in an overall sales increase of 32.2 billion yen.

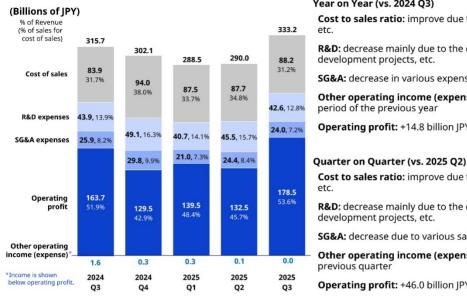
Moving on, cost of sales increased by 19.2 billion yen, in proportion to the rise in product sales.

These are the main components contributing to the 23.9 billion yen increase in operating profit.

FY2025 Q3 Consolidated Financial Overview (Core)



Structure of Costs and Profit by Quarter



Year on Year (vs. 2024 Q3)

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

R&D: decrease mainly due to the collective discontinuation of

SG&A: decrease in various expenses, etc.

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

Operating profit: +14.8 billion JPY, +9.0%

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

R&D: decrease mainly due to the collective discontinuation of

SG&A: decrease due to various sales activities, etc.

Other operating income (expense): same level as the

Operating profit: +46.0 billion JPY, +34.7%

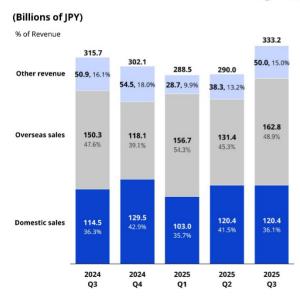
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Next, I will discuss the trends in sales, profits, and various expense items on a quarterly basis.

It is important to note that when viewed quarter-by-quarter, these figures inevitably show some fluctuations. We believe these are largely attributable to factors such as relatively higher sales in the fourth quarter in the domestic market, and export timings overseas that are not always regular and can be sporadic.

FY2025 O3 Consolidated Financial Overview (Core)

Structure of Revenue by Quarter



Year on Year (vs. 2024 O3)

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

Overseas sales: increase due to the timing of shipment of

Other revenue: decrease in the one-time income, despite increase mainly in the royalty income of Hemlibra

Quarter on Quarter (vs. 2025 Q2)

Domestic sales: same level as the previous quarter

Overseas sales: increase due to the timing of shipment of

Other revenue: increase mainly in the royalty income of Hemlibra

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Next, I will present the quarterly breakdown of sales. Here again, you will likely observe some fluctuations, which reflect seasonal and other factors.





P/L Jan - Sep (vs. Forecast)

	Actual	l Forecast		2024	Domestic sales
(Billions of JPY)	2025 2025 Progress		Progress*	Steady progress in mainstay products and new products	
	Jan - Sep	Jan - Dec	•		
Revenue	911.6	1,190.0	76.6%	74.2%	Overseas sales
Sales	794.6	1,018.0	78.1%	75.2%	Steady progress in Hemlibra and Actemra
Domestic	343.7	462.5	74.3%	71.9%	exported to Roche, exceeding the forecast
Overseas	450.9	555.5	81.2%	78.0%	
Other revenue	117.1	172.0	68.1%	68.4%	Other revenue Mostly in line with the forecast
Cost of sales	- 263.3	- 341.0	77.2%	72.2%	Mostly III line with the forecast
(cost to sales ratio)	33.1%	33.5%	-	-	Cost of sales
Research and development	- 128.8	- 178.0	72.4%	72.3%	Cost to sales ratio from January to September was
Selling, general and administration	- 69.4	- 101.0	68.7%	70.9%	mostly in line with the forecast
Other operating income (expense)	0.4	-	-	88.9%	
Operating profit	450.5	570.0	79.0%	76.7%	
(operating margin)	49.4%	47.9%	-		Mostly in line with the forecast
Net Income	320.0	410.0	78.0%	75.9%	Selling, general and administration expenses
EPS (JPY)	194.44	250.00	77.8%	75.9%	Mostly in line with the forecast

^{*} Jan - Sep 2024 progress versus Jan – Dec 2024 actual

2

Here, we present the progress of our financial results against our initial full-year forecast as of the end of September.

Typically, a 75% progress rate is considered average for the third quarter. Against this benchmark, you can see that both sales and profits are progressing quite favorably.

Furthermore, compared to the progress rate as of the end of September last year, sales are up by 2.4% and operating profit is up by 2.3%. This clearly demonstrates that we are progressing even more favorably than last year.



Sales Jan - Sep (vs. Forecast)

	Actual	Original	Forecast	2024		Actual	Original	Forecast	2024
(Billions of JPY)	2025	2025	Progress	Progress *	(Billions of JPY)	2025	2025	Progress	Progress *
	Jan - Sep	Jan - Dec					Jan - Dec		
Sales	794.6	1,018.0	78.1%	75.2%	Specialty	163.0	223.3	73.0%	70.9%
Domestic	343.7	462.5	74.3%	71.9%	★ Hemlibra	44.7	59.4	75.3%	70.3%
Oncology	180.7	239.2	75.5%	72.8%	Actemra	36.7	50.0	73.4%	72.5%
Tecentriq	46.0	62.0	74.2%	72.5%	★ Enspryng	20.9	26.0	80.4%	72.1%
◆ Polivy	27.0	35.8	75.4%	71.8%	◆ Vabysmo	18.5	23.5	78.7%	68.4%
Alecensa	24.3	34.0	71.5%	72.3%	Evrysdi	12.0	15.9	75.5%	71.1%
◆ Phesgo	24.5	31.6	77.5%	63.8%	◆ CellCept	6.0	5.8	103.4%	69.1%
Avastin	19.6	25.5	76.9%	75.7%	Mircera	3.7	5.0	74.0%	73.8%
Kadcyla	11.9	16.6	71.7%	72.6%	♠ PiaSky	4.8	4.4	109.1%	50.0%
◆ Perjeta	9.6	11.9		78.5%	Other	15.6	33.2	47.0%	71.2%
Lunsumio	2.2	3.7		-	Overseas	450.9	555.5	81.2%	78.0%
■ Herceptin	1.0	1.4		79.2%	★ Hemlibra	254.6	324.2	78.5%	82.4%
◆ Foundation Medicine	6.0	7.1	84.5%	76.3%	★ Actemra	119.0	127.6	93.3%	71.0%
Other	8.5			75.6%	Alecensa	46.0	67.0	68.7%	74.4%
2333333333	0.5	5.0		73.070	Enspryng	8.6	12.6	68.3%	63.8%
exceed forecast below forecast					◆ Sigmart	6.7	7.8	85.9%	76.3%
- pelow lorergst					◆ Neutrogin	6.7	6.5	103.1%	77.9%
* Jan - Sep 2024 progress versus Jan -	Dec 2024 actua	il			Other	9.2	9.8	93.9%	82.1%

Here, we present a more detailed breakdown of the progress rate for each individual product.

Using 75% as a benchmark, products that are significantly exceeding our expectations are indicated by an upward blue arrow, while those slightly below expectations are shown with a downward gray arrow. We hope this information will be helpful for your reference.

FY2025 Q3 Consolidated Financial Overview (Core)



Impact from Foreign Exchange Jan – Sep

(Billions of JPY)	vs.2024 Actual rate	vs.2025 Forecast rate	
	[C] vs. [A]	[C] vs. [B]	
Revenue	+34.7	+0.2	
Sales	+25.9	+0.2	
Other revenue	+8.8	-0.1	
Cost of sales	-2.7	+0.0	
Other than above ^{*1}	-1.6	-1.3	
Operating profit	+30.5	-1.1	

Exchange Rate (JPY)	2024 Actual rate* ² Jan - Sep 【A】	2025 Forecast rate Jan - Sep 【B】	2025 Actual rate ^{*2} Jan -Sep 【C】	2025 Market average rate* ³ Jan – Sep	2025 Forecast rate Jan – Dec
1CHF	160.43	171.36	171.62	175.95	171.00
1EUR	163.89	160.00	165.47	165.29	160.00
1USD	136.39	146.30	146.36	148.19	148.00

^{*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
*3 Market average rates in during the fiscal period

Next, let's look at the impact of foreign exchange.

Compared to last year, the yen has depreciated by approximately 11 yen against the Swiss Franc. The leftmost figures, based on actual exchange rates, indicate that the weaker yen compared to last year's rates resulted in a positive impact of 34.7 billion yen on sales and 30.5 billion yen on profit.

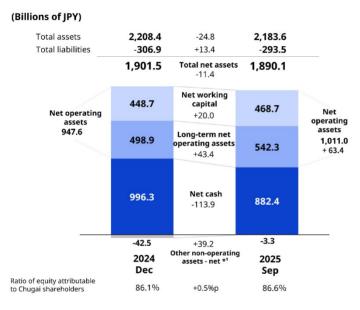
Additionally, we had already completed about 80% of our foreign exchange forward contracts last year for this fiscal year, so we had budgeted based on certain assumed exchange rates. However, there have been some deviations in the unhedged portion. As a result of this difference from our assumed rates in that portion, as shown here, sales saw a positive impact of 0.2 billion yen, but profit experienced a negative impact of 1.1 billion yen.

FY2025 Q3 Consolidated Financial Overview (Core)

Financial Position (vs. 2024 Year End)



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Increase in net working capital

Increase in accounts receivable and decrease in accounts payable for property, plant and equipment, etc.

Increase in long-term net operating assets

Increase due to investments in the following facilities and increase in intangible assets, etc.

- the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant
- the manufacturing building for injectables (UTA) at Utsunomiya Plant

Decrease in net cash

(See next slide)

Increase in other non-operating assets – net

Increase mainly due to a decrease in accrued corporate tax

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

This slide shows our Balance Sheet.

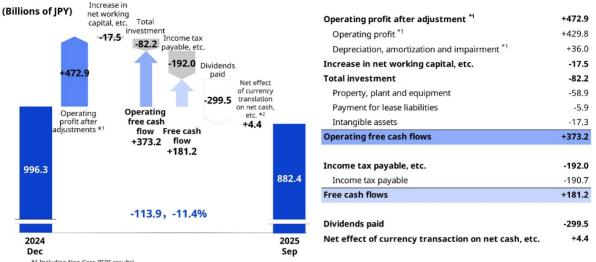
Net cash decreased by 113.9 billion yen this time. This was primarily due to tax payments made in August, as well as dividend payments, including a special dividend, which were also made in August. These factors led to a reduction in our cash and cash equivalents.

Total assets also consequently decreased by approximately 24.8 billion yen. In contrast to this, our net assets currently stand at 1,890.1 billion yen, and our shareholders' equity ratio actually increased by approximately 0.5 percentage points compared to the end of December.

FY2025 Q3 Consolidated Financial Overview (Core)

Net Cash (vs. 2024 Year End)





As I mentioned earlier, our cash position decreased by 113.9 billion yen. While we generated 373.2 billion yen in operating free cash flow, this amount was utilized for corporate income tax payments and dividend payments, ultimately leading to the 113.9 billion yen reduction in cash.

FY2025 Q3 Consolidated Financial Overview (Core)

P/L Jan - Sep (Non-core adjustment)



	IFRS	Non-core	eitems	Core
(Billions of JPY)	results	Intangible assets	Others	results
Revenue	911.6			911.6
Sales	794.6			794.6
Other revenue	117.1			117.1
Cost of sales	-276.1	+0.9	+11.9	-263.3
Research and development	-135.2	+0.3	+6.1	-128.8
Selling, general and administration	-79.5		+10.2	-69.4
Other operating income (expense)	9.0		-8.6	0.4
Operating profit	429.8	+1.2	+19.5	450.5
Financial account balance	-1.9			-1.9
Income taxes	-122.3	-0.4	-6.0	-128.6
Net income	305.6	+0.8	+13.6	320.0
EPS (JPY)	185.70			194.44

Non-core items	
Factors affected operating profit	
Intangible assets	
Amortization	+1.1
Impairment	+0.1
Others	
Business rebuilding expenses	+10.2
Expenses due to the collective discontinuation of development projects, etc.	+17.8
Restructuring expenses, etc. including gain on disposal of assets	-8.4

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This table shows the reconciliation for Non-Core items.

As we present each quarter, this table reconciles the difference between our IFRS results and the Core results that I have been discussing so far.

^{*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)

The adjustments include, as usual, the amortization and impairment of in-licensed intangible assets, as well as restructuring expenses, such as those related to the ongoing replacement of our ERP system.

In addition, following the discontinuation of certain development projects announced in the second quarter, we have incurred asset impairments and other charges. These include the impairment of assets like inventories of investigational drugs, and termination costs paid to external CROs associated with the discontinuations.

Conversely, there is a gain on the sale of assets of 8.4 billion yen, which relates to the sale of our land in Kamakura in January of this year.

FY2025 Q3 Consolidated Financial Overview (Core)



Summary of Chugai Originated Global Products

					(Billions of JPY)
Product (Billions of JPY)	FY2025 Q3	Results	Y on Y	FY2025 Forecast	Comments
Hemlibra	Domestic:	44.7	+7.7%	59.4	 Japan: Sales increased year on year as domestic market share steadily increased. Overseas: Sales increased in all regions. Expect to exceed export forecast for the full year.
	Export:	254.6	+0.4%	324.2	 We provide value to patients worldwide through its convenience and accumulated clinical
	Overseas local:	3,251mCHF	13%	-	evidence.
	Domestic:	36.7	+5.5%	50.0	 Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated.
Actemra	Export:	119.0	+27.1%	127.6	Overseas: Sales increased in the U.S. and International, while decreasing in EU. Expect to exceed
	Overseas local:	1,662mCHF	+1%	-	 export forecast for the full year. We provide value to patients through the established evidence as an originator of IL-6 inhibitor.
	Domestic:	24.3	+8.5%	34.0	 Japan: Maintains its high share in the first-line therapy despite competitors' entry since 2021. Overseas: Sales increased especially in the U.S. and International. No change in export forecast
Alecensa	Export:	46.0	-1.5%	67.0	for the full year
	Overseas local:	1,038mCHF	+8%	-	 We provide value to patients for early-stage NSCLC as the first ALK inhibitor, in addition to advanced NSCLC.
	Domestic:	20.9	+17.4%	26.0	Japan: Sales increased solidly year on year as the switching from other drugs progressed
Enspryng	Export:	8.6	-2.3%	12.6	steadily, despite the significant drug price revision implemented in 2024*1. Overseas: Sales increased in all regions. Exports also performed mostly as expected.
	Overseas local:	149mCHF	+33%	-	We provide a convenient treatment option for patients who wish to avoid steroids.
	Domestic:	4.8	+269.2%	4.4	Japan: The product successfully penetrates the market, gaining favorable evaluation in medical facilities due to the convenience of subcutaneous administration and reduced hospital time.
PiaSky	Export:	-	-%	-	 Overseas: Market introduction is progressing in EU. We aim to penetrate markets in various
гіазку	Overseas local:	5mCHF	-%	-	 countries worldwide. We provide an improved convenience and a broad range of treatment opportunities for patients including C5 gene polymorphisms.

'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. Yon Y: year on year, NSCLC: non-small cell lung cancer

*1 Market expansion re-pricing in April 2024 (-25.0%)

ieiiiibi aj b	omestic Hem	opinna A rati	ent Juai e me	ilus
Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025
34.9%	35.3%	36.2%	37.0%	37.7%

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The following pages provide our regular update on the status of our global products.

For each product, we show the performance as of the third quarter for domestic sales, exports, and local sales by Roche. We have also included our qualitative comments.

FY2025 Q3 Consolidated Financial Overview (Core)



Current Status / Plan for Major Investments

		~2024		Planned investment									
			2025	2026 2	2027	2027 2028	2029 203	2030~	Total amount	Investment to-date	Unit	Period*	od*
	Utsunomiya plant			ig substance f arly commerci		later- stage o	clinical		37.4	32.6	billion JPY	2023	2026
Manufacturing	Utsunomiya plant	ant UTA: Manufacture sterile injectables for early commercial use					19.0	16.1	billion JPY	2023	2025		
Ukima pla	Ukima plant	UK3(modifie	ation): Manu	ıfacture bio dı	rug substanc	e			20.3	5.8	billion JPY	2024	2027
	CPR	Move and re	enovate facil	ities to enhan	ce research f	unctions			60	17	million SGD	2024	2026
and development	IFReC	Funding to I	FReC per cor	mprehensive o	ollaboration	agreement			10.0	8.5	billion JPY	2017	2027
	Ukima Site	-	thening the	process devel	opment func	tion of small-	and-mid-siz	ze molecule	80.0	0.8	billion JPY	2026	2028
Environment	Environmental investment**	Equipment (ipgrade to ac	hieve Mid-Tei	m Environm	ental Goals 2	030		135.9 estimated tot	6.5 al amount	billion JPY	2022	2032

^{*}For capital investments, the period indicates the years from project start to planned completion
** incl. part of investments described in the schedule above

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These are already approved CAPEX items. No major change from the last presentation. That's all from myself. Thank you.

Question & Answer

Wakao [M]: Wakao from JPMorgan. Thank you. Two questions. One is about FILSPARI. Why did you decide to buy FILSPARI, the project of the IgA nephropathy (IgAN) area? Can you give me more details about the background again? I would like to understand the rationale behind the decision to in-license the drug for IgAN. Was it because the IgAN market is considered attractive, or was the product's profile itself particularly reasonable and favorable? Or is this part of a strategy to strengthen your renal franchise? Additionally, should we anticipate the possibility of in-licensing products from companies other than Roche in the future? If so, I would also like to understand why you have begun to consider non-Roche products and the reasons behind this strategic shift.

Okuda [A]: Thank you for the question, Wakao-san. If I may answer that for you. In general, I would like to talk about the sparsentan acquisition.

We have decided, as the slide shows you, our capital allocation policy for creating shared value is based on three pillars. The first is the creation and delivery of innovative medicines, which is a core strength of Chugai. The second involves expansion of our value creation engine, which specifically means strengthening our R&D capabilities. And the third is other investment opportunities. On top of that, shareholder returns remain a fundamental principle for us.

Within these framework, we believe we must also allocate capital to the delivery of our innovative medicines. As you know, Chugai has become very strong in development, marketing, and sales in Japan. In fact, if you

look at us in terms of our commercial organization, we have grown to become the number one company in Japan. It was to leverage this strength that we proceeded with the acquisition of Renalys, which in other words, led to our securing of sparsentan.

The renal field has been one of our areas of strength for some time. As shown on this slide, we have several products in development—Gazyva and Piasky—as well as a candidate called sefaxersen for IgA nephropathy. Part of our goal here is to expand our pipeline in the renal field. Therefore, our acquisition of sparsentan represents an effective use of our capital allocation.

In response to your second question on whether we might see more of this in the future: Absolutely. We are open to pursuing similar opportunities when they present themselves. Our strategy is to leverage our core strengths—our R&D capabilities and our expertise in domestic development, sales, and marketing—to bring innovative pharmaceuticals to the market.

Wakao [Q]: If this matches your area, are you going to aggressively do more of these same products? Am I correct?

Okuda [A]: We are constantly exploring for such opportunities. In this case, we found a highly attractive asset in development that aligns with our strategy, which led to the acquisition of Renalys and its asset, sparsentan.

Wakao [Q]: Understood. On a related note, in the IgA nephropathy space, anti-APRIL antibodies seem to be a very hot topic right now. Have you considered in-licensing such an asset?

Kusano [A]: Thank you, Wakao-san. You are correct that anti-APRIL antibodies are indeed a very hot area in IgA nephropathy. However, we believe that sparsentan, which we have just in-licensed, is also a highly compelling asset. Specifically, it has a dual-antagonist mechanism of action, inhibiting the endothelin pathway in addition to the renin-angiotensin system. This gives it the potential to be used as a first-line treatment. Furthermore, as you know, we already have sefaxersen in our pipeline for IgA nephropathy. Therefore, we see a strong potential for synergy between these two assets. We are always willing to evaluate various options, including groundbreaking anti-APRIL antibodies if they become available. In this context, sparsentan was simply the perfect strategic fit for us at this time.

Wakao [Q]: Number two question, orforglipron, Eli Lilly. What kind of communication do you have with Eli Lilly? In 2026, for obesity, we expect to have approval and launch. Regarding timing of the approval and the sales number for next year, are you getting numbers from Eli Lilly? From next fiscal year, it's probably going to hit your numbers, so I want to know what kind of communications you have with Eli Lilly, that would be my interest.

Okuda [A]: Thank you very much for the question. Regarding orforglipron, as has been publicly announced, Lilly plans to submit it for regulatory approval for obesity within 2025, and for diabetes in the following year, 2026.

Typically, the process from there involves a regulatory review, followed by approval, and then the commercial launch. Therefore, we are also expecting an approval and launch to happen at some point next year.

Wakao [Q]: Is there a high probability that orforglipron will be included in your initial forecast for the fiscal year? Or do you only factor it in after it has been approved?

Okuda [A]: Mr. Taniguchi can probably talk about that.

Taniguchi [A]: Thank you for your question. We are still carefully reviewing the situation for next year's budget, which is a topic we will discuss during our earnings announcement in January. However, you can understand that if there is a high probability of approval, it is possible that we will incorporate the figures into our forecast.

Wakao [Q]: Regarding the timing of approvals and submissions, could we think that Eli Lilly is always keeping you up to date?

Taniguchi [A]: We certainly maintain channels of communication with Lilly. However, we are not at liberty to disclose the specifics of what we discuss.

Wakao [M]: Thank you very much.

Muraoka [Q]: I am Muraoka from Morgan Stanley. I'd like to follow up on Wakao-san's question regarding next year. It has become something of a custom for your company to discuss the next year's outlook around the third quarter, so I'd like to ask you to share your thinking for the upcoming year. Taniguchi-san mentioned that orforglipron will be included in next year's guidance if its likelihood is high. NEMLUVIO is also performing well, and the only major negative factor I see is Actemra. Given this, I think it's natural to assume you will see profit growth next year compared to this year. Could you share your outlook for next year, to the extent that you are able?

Okuda [A]: Mr. Muraoka, thank you for your question. I would like to respond. It is difficult to forecast next year with precision at this stage. Of course, there is orforglipron, which was just mentioned. Then there is the erosion from Actemra biosimilars, which has begun, but it is difficult to predict the speed of this erosion.

On the other hand, as you pointed out, NEMLUVIO is showing strong post-launch sales, primarily in the U.S., which are exceeding our expectations. So, putting it all together—and I must reiterate that this is our current projection—we are currently assuming that revenues will be slightly higher than this fiscal year.

Muraoka [Q]: Thank you. What about the core OP? Is there anything that you can comment?

Okuda [A]: At this point of time, nothing I can comment. Please wait until next year's earnings presentation.

Muraoka [Q]: Okay. With regard to next year's dividend, am I correct to understand that dividend will come back to like a normal range of 45%?

Okuda [M]: Taniguchi will respond to your question.

Taniguchi [A]: This year's special dividend was specifically for our 100th anniversary. Fundamentally, the expected scenario is that we will make dividend payments in accordance with our standard dividend policy going forward.

Muraoka [Q]: Allow me to ask my second question. It's about GYM. Please correct me if I misheard Roche's conference call yesterday, but I believe they said they would be presenting various data at next year's ADA. It sounded to me like this would include data for GYM in obesity, with a focus on GLP-1s.

However, I was under the impression that the Phase II combination trial data for GYM in obesity would surely not be ready in time for ADA, and would more likely be presented around EASD. Could you clarify how we should think about this and provide your perspective on the timeline?

Kusano [A]: Yes. Mr. Muraoka, thank you for your question. Regarding the Phase II trial for GYM, it is a trial targeting obesity. Roche has completed patient enrollment. They have announced that the readout will be in 2026. As for the specific conference, nothing has been publicly disclosed at this point.

Muraoka [M]: Understood. Thank you very much. That's all.

Yamaguchi [M]: Hello, this is Yamaguchi from Citi. My question is on reconciling your Hemlibra exports with Roche's end-user sales. Roche's results yesterday showed some volatility between Q2 and Q3, both in the U.S. and internationally. Your own shipments also showed timing differences between Q2 and Q3. You are guiding for a strong Q4, but I'm trying to better understand the lag between Roche's local sales performance and your export patterns. Furthermore, I think Roche guided low-single-digit growth for Hemlibra next year. Should we expect these kinds of timing differences to persist into next year? Sorry to ask again, but could you walk me through your thinking on this?

Taniguchi [A]: Thank you for the question, Taniguchi will address that. As we've stated previously, there is not always a direct parallel between Roche's local sales and our product exports on a quarterly basis.

However, we manage our exports based on order forecasts we receive from Roche. For the near term, the next six months of orders are largely firm commitments. Based on these commitments, we anticipate Q4 will show significant year-over-year upside. For the full year, this gives us confidence that we will surpass our ¥318.6 billion forecast by more than ¥10 billion, which is our current projection.

As for next year, our internal review is still underway. But regarding Roche's guidance of low-single-digit growth you mentioned, we believe that is the right trend. Accordingly, our working assumption is that Hemlibra will also post a slight year-over-year increase.

Yamaguchi [Q]: Thank you. My question on Actemra is similar, but as you mentioned, there will be a ¥20 billion upside for this fiscal year.

Taniguchi [A]: For this fiscal year, the figure is now ¥115.2 billion. This is already very close to the full-year forecast, so when we factor in the confirmed export numbers for Q4, we arrive at that figure—the ¥20 billion upside you mentioned.

As for next year, it will depend on the extent of biosimilar penetration. Realistically, we expect sales to decline from this year's level, but we are still scrutinizing the details. We hope to share more concrete numbers at the earnings announcement in January. Is that clear?

Yamaguchi [Q]: For now, has your general feeling that the impact will be "basically mild" remained unchanged?

Taniguchi [A]: I'm sorry, what do you mean by "basically mild"?

Yamaguchi [Q]: By "mild," I mean that compared to the originally expected decline, the actual drop has been less severe. I'm asking if you see that trend continuing.

Taniguchi [A]: As of today, that may be true for the remainder of this year. However, when it comes to next year, there is a wide range of possibilities. I can't say whether the situation this time next year will be "mild" or "bitter," but that is how we are thinking about it.

Yamaguchi [M]: Thank you very much. That's all. Thank you.

Wada [Q]: I am Wada from SMBC Nikko. I would like to ask about Enspryng for TED (Thyroid Eye Disease). My question is, how do you see its points of differentiation against Tepezza, which is the approved drug? Also, given the trial results were something of a "one win, one loss" situation, could you tell us what you currently view as the most likely scenario for a regulatory filing?

Okuda [A]: Thank you very much, Wada-san. Kusano would like to answer.

Kusano [A]: First, regarding the comparison with Tepezza, we did not directly compare or study it against Tepezza within the same trial, so a precise comparison is not possible. However, looking at our results, Enspryng demonstrated a very favorable safety profile. Adverse events commonly seen with IGF-1R inhibitors—such as hearing loss, hyperglycemia, hair loss, or muscle spasms—were not observed.

On the efficacy side, as you know, we recognize that Tepezza has shown high efficacy in improving proptosis.

On the other hand, regarding the improvement in the Clinical Activity Score (CAS), which is an indicator of disease activity, we believe Enspryng showed efficacy that was largely equivalent to that of IGF-1R inhibitors.

Considering patients who have hearing impairments, diabetes, or inflammatory bowel disease, as well as patients who discontinue treatment due to side effects or who relapse, we believe there is a need for a drug from a different class than IGF-1R inhibitors.

In addition, as mentioned at the beginning, considering that Enspryng is a subcutaneous injection administered once every four weeks, we believe it is highly convenient.

From these perspectives, we plan to carefully analyze the data and consult closely with regulatory authorities going forward.

Wada [Q]: My second question is about the in-licensing of sparsentan. I'd like to ask about the filing schedule. I believe that for your partner, Renalys Pharma, Phase III trials are already complete in South Korea and other parts of Asia. For Japan, you have stated that you will file based on a bridging study. Will you be making a simultaneous submission for all regions, or is the plan to seek approval sequentially, starting with the regions where you can file earliest? What is your approach?

Kusano [A]: Regarding the filing timeline, we are planning to file in Japan next year. For the other countries, we are still in the process of reviewing the details.

Wada [Q]: Okay. Japan Phase III can be conducted in a small number of patients because you're taking a bridging approach?

Kusano [A]: Yes. As has been publicly disclosed, it is a study with approximately 30 patients based on a bridging strategy.

Wada [M]: Thank you, very clear. That's all from me.

Sakai [Q]: Thank you. This is Sakai from UBS. My question is about Rani Therapeutics. Their technology is for oral delivery, which I assume means you are considering the oral delivery of antibodies. At what stage do you plan to integrate this technology into your own drug discovery process?

Looking at the contract details, it seems to involve escalating milestone payments that could become quite large. It appears that if you develop a major new antibody product, you will pay significant royalties. Could you please share your expectations for this deal, including that aspect? That is my first question.

Okuda [A]: Regarding your question about the "level" of integration for the Rani Therapeutics technology, I will give you a general overview.

This technology is a device—a capsule—that enables drugs that are difficult to administer orally, especially antibody drugs, to be absorbed from the gastrointestinal tract. As you know, Chugai has exceptional expertise in antibody engineering technology, and we decided to in-license this technology because we see it as an excellent match.

Under our agreement, Rani's technology has already been demonstrated in clinical trials to successfully deliver a drug into the bloodstream via GI absorption. Therefore, as we develop our own antibodies, we intend to use this technology for diseases where oral administration is particularly desirable.

The total potential value of the deal is very large if all projects are successful, but this is because we have acquired the rights for up to five projects, in addition to the first project. If all of them succeed, the total amount will become quite substantial.

Sakai [Q]: Five projects. The first one, first pipeline, what will be the timeline or the timing?

Okuda [A]: We are not in a position to comment on the timing. We have not disclosed which of our antibodies will utilize this technology or how, so I ask for your understanding.

Sakai [Q]: I see. So something will emerge eventually.

Okuda [A]: That's right. We will make a disclosure once a project officially enters our pipeline. We ask for your patience until then.

Sakai [Q]: Thank you. I have one more question, and I apologize that it is unrelated to the financial results, but I would like to ask about the current status of FoundationOne and the cancer genomics field. Is it fair to say that growth has been sluggish? Is adoption slow because a matching therapy is often not found even after diagnosis? Or is it an issue of cost? I would appreciate it if you could clarify these points.

Okuda [A]: Thank you for the question. In terms of performance, we have recorded sales of 6.0 billion yen through the third quarter of this fiscal year. In addition to FoundationOne CDx, we have launched FoundationOne Liquid, and the demand has been expanding considerably.

Furthermore, the number of institutions that can conduct Expert Panels has recently increased. The implementation of these Expert Panels had been something of a bottleneck, but 38 new facilities were added, bringing the national total to 83 as of October 1st of this year.

Therefore, we now believe we can expect slightly more growth from our cancer genomics offerings, FoundationOne CDx and FoundationOne Liquid CDx, going forward.

Sakai [M]: That's all, thank you.

Mamegano [Q]: This is Mamegano from BofA Securities. Thank you for taking my question.

I would also like to ask about GYM. The data readout for SMA and FSHD is now scheduled for 2026. I believe for SMA, the disclosure was originally planned for last year, which then slipped to this year, and now it has become next year. Could you please provide any comments on this situation?

Kusano [A]: Mamegano-san, thank you for your question on GYM. This is Kusano.

Regarding the previous timeline of a disclosure last year, patient enrollment for the trial was actually significantly delayed. Due to that, we had been publicly stating that we would manage to have a readout sometime this year.

The reason for the latest change, based on discussions with Roche, is that given the large number of competing products for GYM329, and after considering the most appropriate timing and venue—be it a scientific conference or a publication—they have determined that a presentation in the first half of next year would be best. Therefore, we have made this slight adjustment and are now indicating a presentation in the first half of next year.

Mamegano	[M]: Understood.	Thank you

Document Notes

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