


Innovation all for the patients



**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group

## **CHUGAI PHARMACEUTICAL CO., LTD.**

Conference on FY2024.12 Financial Results

January 30, 2025

## Event Summary

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[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.	
[Company ID]	4519-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Conference on FY2024.12 Financial Results	
[Fiscal Period]	FY2024 Q4	
[Date]	January 30, 2025	
[Number of Pages]	44	
[Time]	17:30 – 19:07 (Total: 97 minutes, Presentation: 52 minutes, Q&A: 45 minutes)	
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	6	
	Osamu Okuda	Representative Director, President, and CEO
	Iwaaki Taniguchi	Director, Executive Vice President, and CFO
	Michiaki Tanaka	Head of R&D Portfolio Management Department, Project and Lifecycle Management Unit
	Kae Miyata	Head of Corporate Communications Department
	Shinji Hidaka	Vice President, Head of Marketing and Sales
	Takao Suzuki	Associate Vice President, Head of the Digital Transformation Unit
[Analyst Names]*	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities
	Seiji Wakao	JPMorgan Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities

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Stephen Barker  
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Hidemaru Yamaguchi

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Macquarie Capital Securities  
Citigroup Global Markets

\*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.

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# Presentation

**Miyata:** Ladies and gentlemen, thank you for attending the conference on FY2024 December financial results for Chugai Pharmaceutical. I am master of ceremony for today. My name is Miyata from the IR Department.

We are holding this session in a hybrid manner. The agenda for today's presentation is shown on the presentation material page three as well as the screen in the venue. [TD] However, for those who are participating through Zoom webinar, you will be able to listen to the simultaneous translation [TD]. Please [inaudible] the language of your choice by clicking the button at the bottom of your screen. For those who wish to listen to Japanese, please select Japanese. For those who wish to listen to English, please select English. After selecting your preferred language, please click on mute original audio.

At the beginning of each session, we are going to pause for a while for those [TD] to take a photo of the screen. We are going to take questions at the end of the presentation. We allocate about 30 minutes for the Q&A session. Audio is muted during the presentation session.

Now, Okuda will take you through a summary of FY2024 and the outlook into 2025. We are going to pause for a while before the presentation of Okuda. So for those who wish to take a screen capture, please do so.

**Okuda:** I'd like to start the presentation. I am Okuda, the President. I'll explain the summary of 2024 and the forecast for 2025.

FY2024 Overview and FY2025 Forecast



## 2024 Financial Performance

- Achieved record-high revenue, operating profit and net income, exceeding the revised forecast
- Revenue exceeded 1 trillion JPY for the third consecutive fiscal year, and operating profit surpassed 500 billion JPY for the first time. Operating margin of 47.5% demonstrated high profitability

Core (billions of JPY)	2023 Jan - Dec actual	2024 Jan - Dec actual	Growth (year on year)		Revised Forecast Jan - Dec Progress	
<b>Revenue</b>	<b>1111.4</b>	<b>1170.6</b>	<b>+59.2</b>	<b>+5.3%</b>	<b>1,150.0</b>	<b>+1.8%</b>
Domestic sales*	558.0	461.1	-96.9	-17.4%	454.1	+1.5%
Overseas sales	416.5	536.8	+120.3	+28.9%	531.9	+0.9%
Other revenue	136.9	172.7	+35.8	+26.2%	164.0	+5.3%
<b>Operating profit</b>	<b>450.7</b>	<b>556.1</b>	<b>+105.4</b>	<b>+23.4%</b>	<b>540.0</b>	<b>+3.0%</b>
Operating margin	40.6%	47.5%	+6.9%pts	-	47.0%	-
<b>Net income</b>	<b>333.6</b>	<b>397.1</b>	<b>+63.5</b>	<b>+19.0%</b>	<b>388.0</b>	<b>+2.3%</b>
<b>EPS (yen)</b>	<b>202.71</b>	<b>241.31</b>	<b>+38.60</b>	<b>+19.0%</b>	<b>236.00</b>	<b>+2.3%</b>

\* Recorded sales of ¥81.2 billion for government supply in the first quarter of FY2023

- Domestic sales declined YoY due to completion of Ronapreve supply to the government\*, the NHI drug price revisions, and the market penetration of generic drugs, despite growth in new products Phesgo and Vabysmo and strong growth of mainstay products such as Hemlibra and Actemra.
- Overseas sales increased YoY mainly due to the significant increase in the exports of Hemlibra to Roche.
- Other revenue increased YoY mainly due to increase in income related to Hemlibra and one-time income.
- Compared to the revised forecast, both domestic and overseas sales, as well as income related to Hemlibra, performed well. 4

Please take a look at page four of the slides.

The full-year results of 2024 exceeded the revised forecast for revenue, operating profit, and net income, with all figures reaching record highs. Revenue exceeded JPY1 trillion for the third consecutive year, and operating profit exceeded JPY500 billion for the first time. The operating margin also reached a record high of 47.5%.

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Regarding domestic sales, the completion of the JPY81.2 billion government supply of Ronapreve in 2023 had a significant impact. While overseas, exports of Hemlibra to Roche were particularly strong. In addition, other revenue increased mainly due to income related to Hemlibra and one-time income. Overseas and other revenue exceeded the decrease in domestic sales, and overall, the revenue increased.

Compared to the revised forecast announced on October 25, domestic and overseas sales and revenue or income related to Hemlibra was strong. As a result, the full-year results for 2024 exceeded the upward revised forecast, thus achieving increased revenue and profit.

FY2024 Overview and FY2025 Forecast



## 2025 Forecast

- Revenue and operating profit are expected to increase to 1,190.0 billion JPY (+1.7%, YoY) and 570.0 billion JPY (+2.5%, YoY), respectively
- Revenue and profits are expected to reach a record high mainly due to growth in overseas sales. Operating margin is expected to remain at high level of 47.9%

Core (billions of JPY)	2024 Jan - Dec actual	2025 Jan - Dec forecast	Growth (year on year)	
<b>Revenue</b>	<b>1,170.6</b>	<b>1,190.0</b>	<b>+19.4</b>	<b>+1.7%</b>
Domestic sales	461.1	462.5	+1.4	+0.3%
Overseas sales	536.8	555.5	+18.7	+3.5%
Other revenue	172.7	172.0	-0.7	-0.4%
<b>Operating profit</b>	<b>556.1</b>	<b>570.0</b>	<b>+13.9</b>	<b>+2.5%</b>
Operating margin	47.5%	47.9%	+0.4%pts	-
<b>Net income</b>	<b>397.1</b>	<b>410.0</b>	<b>+12.9</b>	<b>+3.2%</b>
<b>EPS (yen)</b>	<b>241.31</b>	<b>250.00</b>	<b>+8.69</b>	<b>+3.6%</b>

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Next, I will explain the forecast for 2025. We expect to achieve record high revenue and profit, mainly due to growth in overseas sales, with revenue of JPY1.190 trillion or plus-1.7% and core operating profit of JPY570 billion or plus-2.5%. At the same time, we expect to maintain a very high operating margin.

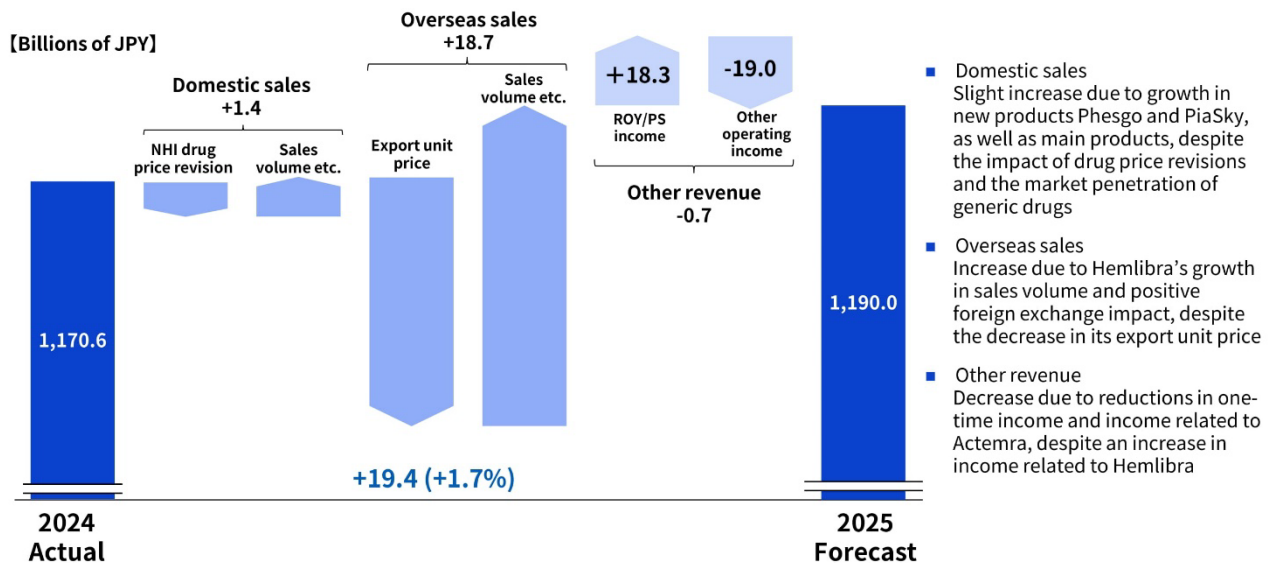
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# Topline Analysis of 2025 Forecast



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On the next slide, I'll show you the trend in sales or revenue. Revenue is expected to increase by JPY19.4 billion or 1.7% in 2025 compared to 2024. Sales are expected to increase both in Japan and overseas. In Japan, the impact of NHI drug price revisions and the penetration of generics will be more than offset our growth in new products and main products, resulting in a slight increase of JPY1.4 billion.

Overseas, the impact of the lower export unit price of Hemlibra will be more than offset by revenue growth due to its volume growth and foreign exchange effects, resulting in an increase of JPY18.7 billion.

On the other hand, other revenue is expected to decrease by JPY700 million due to a decrease in one-time income and Actemra-related income, despite an increase in income related to Hemlibra.

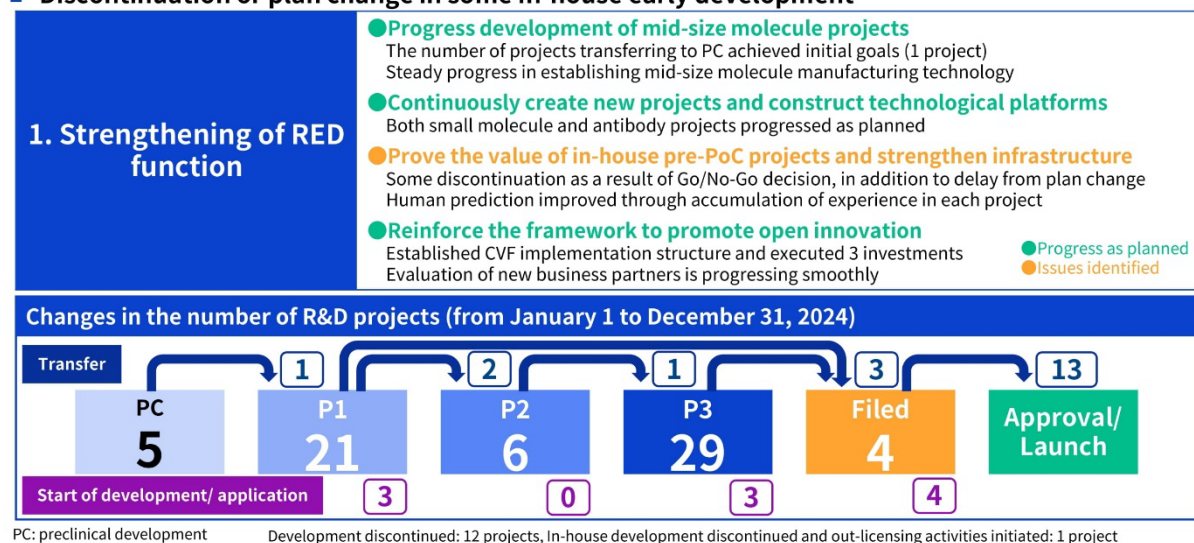
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## Review of Strategic Policies for 2024 (1/2)

- Steady progress in drug discovery and open innovation
- Discontinuation or plan change in some In-house early development



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Next, I will report on the review and results of our key policies for 2024.

First, I'll talk about the RED function for drug discovery and early development. In drug discovery, one project for mid-size molecules, which we are hoping will become our third pillar, has advanced to the preclinical development stage, and we have steadily established manufacturing technology for mid-size molecules. Antibody and small molecule projects have also progressed largely as planned.

Next, early-stage development. We accumulated experience from our own pre-POC projects, and as our ability to predict human responses improved, we started advancing in phases and developing multiple projects.

On the other hand, as a result of the Go/No-Go decision, we decided to discontinue the development of ERY974. The development of SPYK04 in-house was discontinued, and there were delays in some projects due to changes in the plan.

In open innovation, we fully launched the Chugai Venture Fund and it made three investments.

Regarding R&D projects, at the bottom of the slide, early-stage development of in-house products, NXT007, AMY109, advanced to Phase II last year. BRY10 began Phase I clinical trials, while GYM329 began Phase I trials for obesity and RAY121 began a basket trial for six autoimmune diseases.

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## Review of Strategic Policies for 2024 (2/2)

- Progressing smoothly including global approvals for in-house products and growth of key drivers
- Strengthen business foundation progressing well, despite challenges in talent acquisition

● Progress as planned ● Issues identified

<b>2. Maximize the value of growth drivers</b>	<ul style="list-style-type: none"> <li>● <b>Enhance value of post-PoC projects</b> Obtained approval for in-house products (Alecensa, PiaSky, NEMLUVIO)</li> <li>● <b>Maximize value of new products and growth drivers</b> PiaSky and Phesgo are progressing smoothly and exceeded expectations, while some products behind target due to competitor impact</li> <li>● <b>Evolve operating models to build an advanced business model</b> Decide Introduction of disease area-based branches to strengthen and unify the head office functions with the regional management offices functions</li> </ul>
<b>3. Strengthen business foundation</b>	<ul style="list-style-type: none"> <li>● <b>Strengthen HR strategies and business foundations to enable continuous innovation</b> Issues in acquiring and developing highly specialized human resources remain</li> <li>● <b>Further promote sustainability</b> Review the Material Issues based on external requests and the external environment</li> <li>● <b>Organize related systems and reform business processes in preparation for introducing ASPIRE</b> The ASPIRE project moved as planned Including the effects of inflation, the overall budget is expected to exceed the initial plan</li> <li>● <b>Establish new policy for insight business</b> Implementation structure for the continuous creation of PHC solutions established</li> </ul>

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In addition, in the late-stage development, as you can see in the next slide, three of our in-house products, Alecensa, PiaSky, and NEMLUVIO, have achieved approvals, and including all these, 13 approvals and launches were made including global approvals.

We are expanding our contribution to further treatment of patients. The number of projects in the pipeline, including Roche-licensed products is 21 in Phase I, six in Phase II, and 29 in Phase III; we continue to have abundant pipeline.

In addition, there are four projects currently under regulatory review, and approvals are expected this year.

Next, growth drivers. In Japan, although some products did not reach their targets due to the impact of competing products, PiaSky and Phesgo grew steadily and more than expected, and exports of Hemlibra overseas also grew significantly.

Finally, as for the business foundation, we have reviewed materiality in light of changes in the external environment, and we have been working to establish PHC solutions implementation system. Although there are issues with the development and acquisition of highly specialized human resources, the strengthening of our business foundation is progressing smoothly overall. The introduction of ASPIRE is an important company-wide project, and as a result of our policy of making sufficient investments to ensure that there are no delays or problems, progress is on schedule, although the budget has been exceeded.

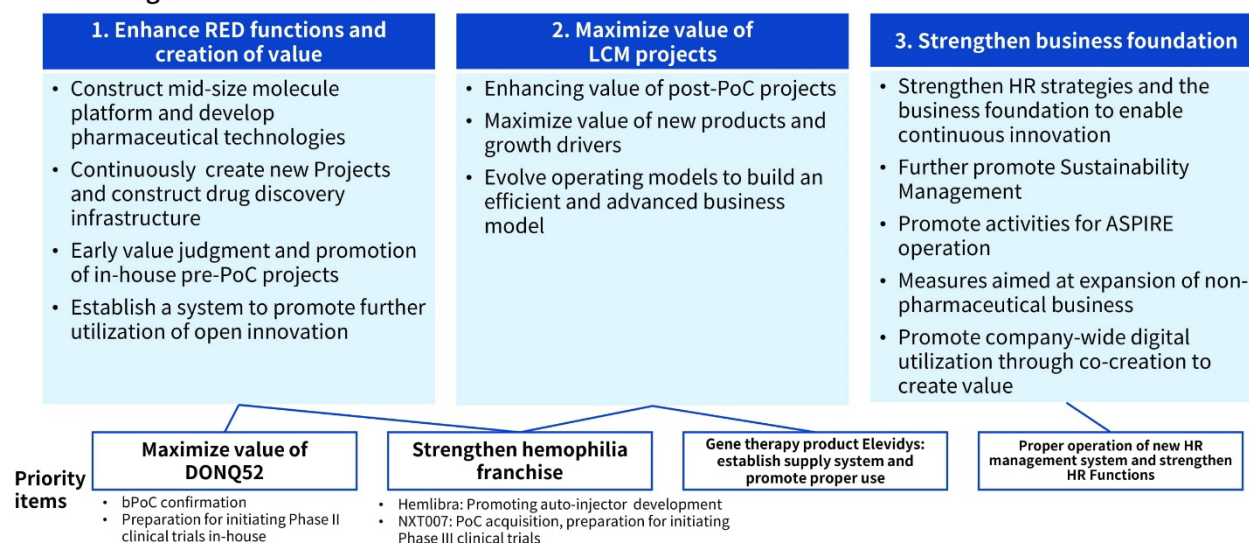
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## Management Policies for 2025

- Addressing 'Enhance RED functions and creation of value', 'Maximize value of LCM projects', and 'Strengthen business foundation'



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Now, I will explain our management policy for 2025, which consists of three policies.

First, with regard to RED capabilities enhancement and value creation, we will focus on building the technology platform and project creation in addition to executing early judgments for the value of our own pre-POC projects based on the Go/No-Go criteria and accelerating the development of valuable projects.

Next, maximizing the value of life cycle management projects. In addition to promoting the development of late-stage development projects and maximizing the value of new products and growth driver products, we will evolve our operating model toward an efficient and advanced business model.

Finally, strengthening of the foundation. Under the new personnel HR system launched in January this year, we will strengthen our foundation through various measures, including our HR strategy, to achieve continuous innovation.

Of these three major policies, we have identified four priority items that we will place emphasis on this year. The four are accelerating the maximization of DONQ52 value, strengthening of the hemophilia franchise, preparing for the launch and the proper use of Elevidys, and the proper operation of the new HR system.

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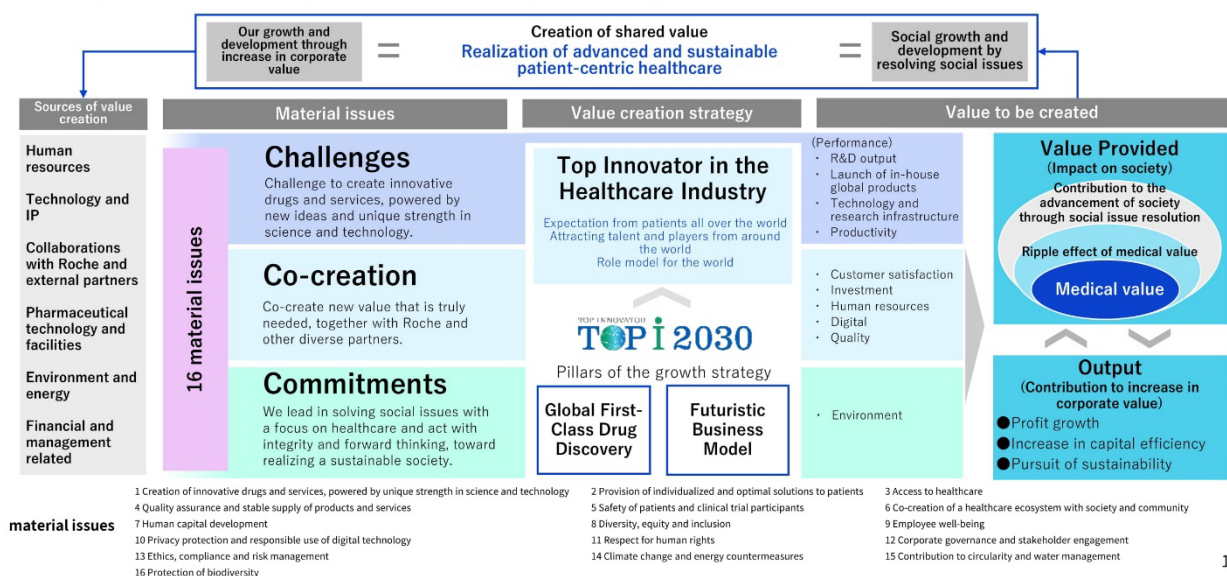
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# New Value Creation Model

- A process for creating shared value using materiality as an axes



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With regard to materiality, five years have passed since the initial establishment of the materiality, and in response to various changes in the environment, we have reviewed materiality last year.

First, we organized and summarized materiality into 16 items, which are summarized under the three axis of challenges, co-creation, and commitments. In this new value creation model, we clarified that materiality is the starting point and that we will link it to specific outputs and the values provided through our business activities. Through this value creation model, Chugai Pharmaceutical aims to realize advanced, sustainable, patient-centric healthcare that is a shared value between the Company and the society.

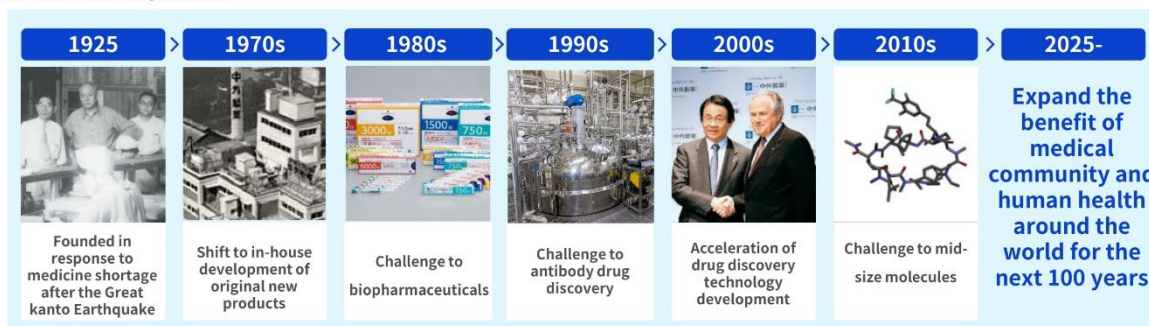
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## For the Sake of Patients - Innovations for the Next 100 Years -

- Since our founding, we have consistently carried on the spirit of "Creating drugs that benefit the world"
- Through **bold challenges**, we have relentlessly pursued **drug discovery unique to us**, for the benefit of medical community and human health around the world
  - Constantly challenged to develop new drug discovery technologies, from small molecules to biologics, antibodies, and now mid-size molecules
  - Established technology-driven drug discovery that is unique to Chugai
  - Contributed to unmet medical needs for various diseases through innovative new drugs
- For the next 100 years, we will continue to expand **the benefit of medical community and human health around the world for the sake of patients**



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This year marks the 100th anniversary of Chugai's founding. Since its foundation, Chugai has carried on the spirit of creating drugs that benefit the world. By continuously taking on the challenges of new drug discovery technologies from small and mid-size molecules, biologics, and antibodies and by establishing Chugai's unique technology-driven drug discovery approach, we've created innovative new drugs and contributed to solving unmet medical needs in a wide range of diseases. For the next 100 years to come, we will continue to expand the benefit of medical community and human health around the world for the sake of the patients.

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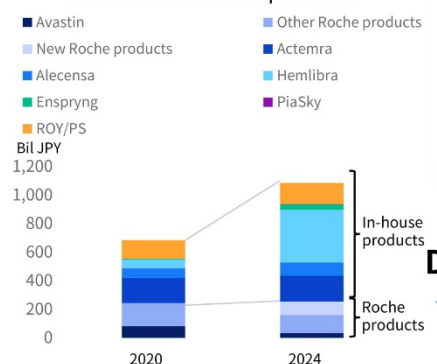
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## Outlook of Mid- to Long-term Growth

- Roche products will continue to be a stable revenue base. Aim for growth through contribution to people worldwide with in-house products.

Revenue contribution from key In-house and Roche products



ROY/PS : royalty and profit-sharing income, New Roche products: New products launched after 2020 (Polivy, Evrysdi, Vabysmo and Phesgo), Other Roche products: Domestic sales excluding other products



NEMLUVIO	US approval in 2024 (AD, PN), filing in EU and several countries	2bn+ USD
Alecensa	Expanded indication in 2024 (ALK+ NSCLCadj), P3 (ALK+ NSCLC Stage III)	-
PiaSky	Global approval in 2024 (PNH), P3 (aHUS: 2026), P2 (SCD: 2027 and beyond)	1-2bn CHF
Enspryng	P3 (TED, AIE: 2026, MOGAD: 2027 and beyond)	1-2bn CHF
avutometinib	Filing accepted in 2024 in US (recurrent KRAS+ LGSOC * <b>possibility of approval in 2025</b> )	-
orforglipron	P3 (obesity, type 2 diabetes)	-
NXT007	P1/2 (hemophilia A: 2027 and beyond) *Planned <b>P2 readout in 2025</b>	>3bn CHF
GYM329	P2/3 (SMA: 2027 and beyond) *planned <b>P2 readout in 2025</b> P2 (FSHD) *planned <b>readout in 2025</b> P2 (obesity) *planned <b>study initiation in 2025</b>	0.5-1bn CHF excl. obesity
Roche Products	Lunsumio, Elevidys, giredestrant, vamikibart, divarasib, glofitamab etc.	-

A total of 25 products under development other in-house and Roche products

**NHI drug price revision (Japan)**  
**Drug price reduction (global)**  
**BS entry (Actemra global sales in 2024: 2,397mCHF)**  
**JPY appreciation**

Listed in order of development stage  
Diseases in parentheses indicate the indications under development.  
Numbers represent the year of submission or planned submission year  
Rightmost column: Sales potential

ALK+NSCLC : ALK positive non-small cell lung cancer, adj: adjuvant therapy, PNH: paroxysmal nocturnal hemoglobinuria, aHUS: atypical hemolytic uremic syndrome, SCD: sickle cell disease, TED: thyroid eye disease, AIE: autoimmune encephalitis, MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease, LGSOG : low-grade serous ovarian cancer, SMA: spinal muscular atrophy, FSHD: facioscapulohumeral muscular dystrophy  
Sales potential (NEMLUVIO: based on the forecast by Galderma (Source: [galderma.com](https://www.galderma.com)), PiaSky/Enspryng/NXT007/GYM329: 12 based on the forecast by Roche)

In explaining our medium- and long-term growth prospects, based on changes from before the start of TOP I 2030 to present, I would like to make some comments.

Four years have passed since 2020, and the revenue structure has evolved dramatically. Please take a look at the graph to your left bottom. With regard to Roche products, biosimilar has penetrated, and we have seen decline in Avastin and mature products.

New products launched after 2021, such as Polivy, Evrysdi, Vabysmo, and Phesgo, however, have offset such decline, and we continue to provide a stable revenue base. While our own products, mainly Hemlibra, have grown notably on a global basis.

Looking ahead into the future from short- to medium-term perspective, growth is expected to be driven by the three products that received global approval last year. In addition to, this year will mark an important milestone for NXT007 and GYM329 as well as for out-licensed products such as orforglipron. These will be our growth drivers in the medium and long term.

For Roche products, a number of products are in late-stage development, including Lunsumio and Elevidys, which will be approved and launched this year.

On the other hand, there are factors contributing to lower sales. For example, drug price reduction in Japan and overseas, the impact of biosimilar on Actemra, and appreciation of the yen.

Despite these factors, we will accelerate sustainable growth over the medium to long term through the growth of our own products and continuous launches.

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## Capital Allocation Policy

Chugai is committed to appropriately allocating capital to provide solutions that create value for patients and deliver stable returns to shareholders. This commitment aligns with its mission: “Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world.”



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Next, I would like to explain our basic policy on capital allocation. In our mission to contribute to the global healthcare through innovative medicines and services, we place highest priority on providing value to patients.

At the same time, we consider stable shareholders' return to be also important.

To achieve these goals, we carefully consider the balance between investment in growth to create shareholder value, including the creation and provision of innovative drugs and expansion of our value creation engine, our drug discovery platform, and shareholder returns such as dividends to ensure optimal capital allocation.

We are convinced that this policy will lead to our sustainable growth and enhance our corporate value, and we'll continue to strive for a balance between providing value to patients and returns to shareholders.

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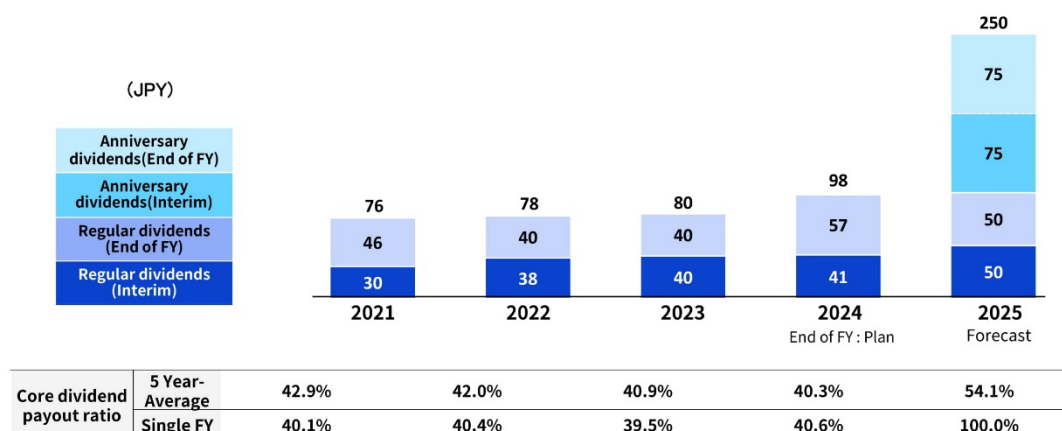
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## Contribution to Shareholders

- An annual dividends of 98 yen per share (57 yen at year-end) is planned for 2024
- In 2025, an annual dividends of 250 yen per share is expected, which includes a regular dividends of 100 yen per share and 100th anniversary dividends of 150 yen per share



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Next, I would like to explain about the dividend. Reflecting the good performance in 2024, we plan to pay a year-end dividend of JPY57 per share, JPY16 higher than the forecast at the beginning of the fiscal year. As a result, together with the interim dividend of JPY41 per share, the annual dividend will be JPY98 per share.

For 2025, we forecast an annual dividend of JPY250 per share, consisting of an regular dividend of JPY100 per share and a anniversary dividend of JPY150 per share to celebrate our 100th anniversary to express our gratitude to our shareholders for their past support and understanding.

We'll continue to strive to deliver innovation to patients around the world. We look forward to your continued support.

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## Summary

- In 2024, revenue, operating profit, and net income exceeded revised forecasts, all reaching record highs. Revenue surpassed 1 trillion yen for the third consecutive year, and operating profit exceeded 500 billion yen for the first time.
- In 2025, we expect both sales and profits to reach new record highs, primarily due to growth in overseas sales.
- Strategic policies for 2024 have been progressed smoothly, producing outcomes. In 2025, we will conduct 'Enhance RED functions and creation of value', 'Maximize value of LCM projects', and 'Strengthen business foundation' including Accelerating value maximization of DONQ52, Strengthening the hemophilia franchise, Establishment of a gene therapy product Elevidys supply system and promotion of proper use, and Promoting proper implementation of new HR management system and strengthening HR functions.
- This year marks our 100th anniversary. For the next 100 years, we will continue to expand the benefit of medical community and human health around the world through our innovations, for the sake of patients.

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This is the summary. That's all from myself.

**Miyata:** Next, I would like to invite Mr. Tanaka to talk about the development pipeline. At the outset, there will be a moment where you can take advantage of your screen capture. Thank you. Over to you.

**Tanaka:** I would like to talk about the status of the development pipeline. I am Tanaka, Head of the R&D Portfolio Management Department.

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## Q4 Topics (1/2)



As of January 30, 2025

Approved	<b>NEMLUVIO® (nemolizumab)*</b>	Moderate-to-severe atopic dermatitis (additional indication)	December 2024 (U.S.)
		Moderate-to-severe atopic dermatitis and prurigo nodularis (CHMP positive opinion)	December 2024 (EU)
	<b>Rituxan</b>	Chronic idiopathic thrombocytopenic purpura in children	November 2024 (Japan)
	<b>Lunsumio</b>	r/r follicular lymphoma after receiving two or more prior standard therapies	December 2024 (Japan)
Filed	<b>avutometinib**</b>	Under review for accelerated approval for recurrent KRAS mutant low-grade serous ovarian cancer (combination with defactinib)	December 2024 (U.S.)
	<b>Tecentriq</b>	r/r extranodal natural killer/T-cell lymphoma, nasal type	October 2024 (Japan)
Initiation of Study	<b>Lunsumio</b>	Previously untreated follicular lymphoma (domestic P3)	November 2024 (Japan)
Readout	<b>tiragolumab</b>	SKYSCRAPER-01 (NSCLC 1st line): Primary endpoint was not achieved	November 2024
	<b>delandistrogene moxeparvovec</b>	EMBARK study (Duchenne muscular dystrophy): two-year data	January 2025
Removed from Pipeline	<b>ERY974</b>	Solid tumors: development discontinued	
	<b>tiragolumab</b>	NSCLC (1st line, SKYSCRAPER-01 study): development discontinued	
	<b>Tecentriq</b>	Breast cancer (perioperative): development discontinued	
	<b>Tecentriq</b>	Prostate cancer (2nd line, CONTACT-02 study): development discontinued	
	<b>RG6194/runimotamab</b>	Solid tumors: development discontinued	

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan)

r/r: relapsed or refractory

\*Conducted by Galderma, a global licensee \*\*Conducted by Verastem Oncology, a global licensee

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Please take a look at page 17. This is a summary of the topics for Q4. All approvals and applications have been already announced.

First, we have NEMLUVIO, which was out-licensed to Galderma. In the US, it received approval for additional indication for atopic dermatitis. In Europe, EMEA's CHMP issued a positive opinion for approval for atopic dermatitis and prurigo nodularis. Lunsumio received approval for the third-line treatment of follicular lymphoma.

Next, we have the applications. We have avutometinib, which we licensed out to Verastem Oncology. The application for accelerated approval in the US for patients with recurrent low-grade serous ovarian cancer with KRAS mutations was accepted in December 2024. The target date for completion of the review is June 30, 2025.

As for the start of the trials, we began a domestic Phase III study of Lunsumio for treatment of naive follicular lymphoma.

As for the readout, the SKYSCRAPER-01 study of tiragolumab for first-line treatment of non-small cell lung cancer was discontinued. In addition to failure to meet primary endpoints of PFS, OS had not been met either.

Next, I'll present the two-year data from the EMBARK study of delandistrogene moxeparvovec, the gene therapy for Duchenne muscular dystrophy. The study showed statistically significant and clinically meaningful results in the North Star Ambulatory Assessment, time to rise and 10-meter walk and run compared to the pre-specified external control group. In addition, no new safety signals were observed, and it consistently demonstrated benefit.

Other items removed from the pipeline are shown here. ERY974 had been undergoing Phase I trial for solid tumors and hepatocellular carcinoma, but we have decided to discontinue the trials based on comprehensive evaluation of efficacy and safety to date.

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As of January 30, 2025

Medical Conference	Lunsumio	Four-year data from P2 (G029781) study in r/r follicular lymphoma	December 2024
	Polivy	Five-year data from POLARIX study (P3) in previously untreated diffuse large B-cell lymphoma (DLBCL)	December 2024
Orphan Drug Designation	Enspryng	Autoimmune encephalitis (AIE), myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)	November 2024
	ASO Factor B (RG6299)	IgA nephropathy	December 2024
Business Transfer	Tarceva	Business transfer in Japan: CHEPLAPHARM K.K.	January 2025
Open Innovation	Chugai Venture Fund, LLC	Investments implemented (3 items*): Leal Therapeutics, HYKU Biosciences, and one company	

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) Black: Other

\*Leal Therapeutics: <https://lealtx.com/>  
 HYKU Biosciences: <https://www.hykubiosciences.com/>  
 Another company is not publicly disclosed

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At medical conferences, we presented positive four-year data from the Phase II clinical trial of Lunsumio in patients with relapsed or refractory follicular lymphoma. Approximately 60% of patients who achieved a complete response were alive and in sustained remission at month 45.

In addition, we announced five-year data from the Phase III POLARIX study of Polivy in previously untreated diffuse large B-cell lymphoma. The data showed a favorable trend in OS in the ITT population, reinforcing the new standard treatment position.

Enspryng received orphan drug designation for AIE and MOGAD. The review period is expected to be shortened.

In the area of open innovation, we have made three investments through the Chugai Venture Fund, which began full-scale operation in Boston last year, and steady progress is being made.

As announced in the press release today, and what is not shown here in the slide, AID351, GSK Global Health, the global health unit of GlaxoSmithKline in UK, we had concluded a collaboration agreement with them to advance development of AID351. I'll explain the details later.

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## 2024: Key R&D Milestones

Underlined and bolded are new progress since October 25, 2024

	Product	Indication / Study name	Progress
Projects to be Approved	<b>PiaSky</b>	Paroxysmal nocturnal hemoglobinuria (PNH) (Japan/EU/U.S.)	Approved (Japan/U.S./EU)
	<b>Alecensa</b>	Non-small cell lung cancer (NSCLC) (adjuvant) (U.S./ EU/Japan)	Approved (U.S./EU/Japan)
	<b>Vabysmo</b>	Retinal vein occlusion	Approved
P3/Pivotal Readouts	<b>Enspryng</b>	Luminesce study: generalized myasthenia gravis	Achieved PE (the results did not reach our expectations on the degree of clinical benefit) /development discontinued
	<b>Tecentriq + tiragolumab</b>	SKYSCRAPER-01 study: NSCLC (1st Line)	<b><u>NOT achieved PE /development discontinued</u></b>
	<b>Lunsumio</b>	Domestic P1 (Expansion cohort): follicular lymphoma (3rd Line)	Achieved PE
	<b>Lunsumio + Polivy</b>	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	Expected in 2025
	<b>Vabysmo</b>	NIHONBASHI study: angiod streaks	Achieved PE
P2 Readouts	<b>GYM329 + Evrysdi</b>	MANATEE study: spinal muscular atrophy (SMA)	Expected in 2025

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

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This is a summary of the major R&D events for 2024. Changes from the last time are underlined and in bold. Despite some setbacks, such as delays in trials and development discontinuations, we believe that the results were generally satisfactory. We're able to achieve important milestones with our in-house developed products such as Alecensa, which is one of our current growth drivers, and PiaSky, which we expect to be a future growth driver. We have made steady progress toward a future leap forward.

## 2025: Key R&D Milestones

As of January 30, 2025

	Product	Indication / Study name	Progress
Projects to be Approved	<b>delandistrogene moxeparvovec</b>	Duchenne muscular dystrophy	
	<b>Vabysmo</b>	Angiod streaks	
P3/Pivotal Readouts	<b>PiaSky</b>	COMMUTE-a study*: atypical hemolytic uremic syndrome (aHUS)	
	<b>Lunsumio + Polivy</b>	SUNMO study: r/r aggressive B-cell non-Hodgkin lymphoma	
	<b>Lunsumio</b>	CELESTIMO study: follicular lymphoma (2nd line)	
	<b>giredestrant</b>	persevERA study: HR positive breast cancer (1st line)	
	<b>vamikibart</b>	MEERKAT/SANDCAT study: noninfectious uveitic macular edema (UME)	
P2 Readouts	<b>GYM329 + Evrysdi</b>	MANATEE study: spinal muscular atrophy (SMA)	
	<b>GYM329</b>	MANOEUVRE study: facioscapulohumeral muscular dystrophy (FSHD)	
	<b>NXT007</b>	Hemophilia A	
Initiation of study	<b>GYM329</b>	Obesity (P2 study)	

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) \*Adult/Adolescent patients

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Next, I will explain the major events for 2025. For in-house products, we are expecting a readout for the Phase III trial of PiaSky for aHUS. In addition, readouts for the Phase II trials of GYM329 for SMA and FSHD, and NXT007 for hemophilia A are also planned.

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All of these are important milestones for determining whether to move on to Phase III trials or not. In addition, we plan to start a Phase II study of GYM329 for obesity by the end of this year.

## Overview of Development Pipeline

# AID351: Dengue fever



- In January 2025, Chugai and GSK entered into a collaboration agreement to develop AID351 for the treatment of dengue fever, a neglected tropical disease<sup>†</sup>. Both companies will work together to explore opportunities in global health R&D.
- Antibody drug utilizing Chugai's proprietary technologies that can avoid antibody-dependent enhancement (ADE)<sup>‡</sup> of infection, and retain virus removal activity

## Dengue: Mosquito-borne Fever

- It affects ~400 million people<sup>§</sup> a year globally. When the disease becomes severe, it progresses to DHF (Dengue Hemorrhagic Fever) or DSS (Dengue Shock Syndrome). The standard of care is to treat with antipyretic analgesics and fluid infusion. There is no specific treatment currently.

## AID351: Antibody drug which binds to all 4 types of dengue virus (DENV1-4)

- With the support of the GHIT Fund, antibody identification, antibody optimization, and preclinical development have been completed in collaboration with A\*STAR SigN, NUS, CPR, and Chugai.



GHIT Fund: Global Health Innovative Technology Fund | A\*STAR: Agency for Science, Technology and Research | SigN: Singapore Immunology Network | NUS: National University of Singapore | CPR: Chugai Pharmabody Research | GSK is a pharmaceutical company in the UK, highly regarded for its contribution to global health, such as improving access to medicines and vaccines in low income countries | † Neglected tropical diseases (NTDs) are a diverse group of conditions that are mainly prevalent in tropical areas, where they thrive among people living in impoverished communities. | ‡ ADE: Antibody dependent enhancement (A phenomenon that the antibodies acquired by vaccines or previous infections cause severe disease in the case of infection with similar viruses.) | § WHO Dengue Information Page |

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Next, I'll explain AID351, which was created at Chugai Pharmabody Research, CPR, our research subsidiary in Singapore. AID351 is an antibody drug for dengue fever, which is one of the neglected tropical diseases. As previously said, we have concluded a collaboration agreement with GSK Global Health to advance the development of this product.

Dengue fever is a mosquito-borne fever that affects 400 million people approximately worldwide each year. When it becomes serious, it could be fatal and progress to dengue hemorrhagic fever or dengue shock syndrome, but there is still no established treatment for dengue fever. Every year, 500,000 patients worldwide become seriously ill and require hospitalization and treatment, and there is a high level of unmet medical needs.

AID351 is an antibody that can bind to all four different types of dengue viruses (DENV1-4) that cause dengue fever. With support from Global Health Innovative Technology Fund, or GHIT Fund, the antibody was identified and optimized through collaboration between industry, government and academia in Singapore, including CPR, and is currently in the preclinical stage or it's completed with the preclinical stage.

The unique aspect of AID351 is that it is an antibody with both safety and efficacy as it avoids the phenomenon known as antibody-dependent enhancement of infection, which is one of the causes of severe dengue fever, by applying Chugai's proprietary antibody technology while also retaining its ability to eliminate the virus. It is expected to be developed as a treatment for early relief of symptoms of dengue fever and as a prophylactic for medical professionals and others who are at the risk of contracting secondary infections during outbreaks or severe cases of the disease.

Neglected tropical diseases have threatened the health and livelihoods of many people. But to date, no effective treatments have been established. In order to fulfill our social responsibility in global health, we will work with GSK Global Health to develop innovative drugs to address this unmet medical needs.

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## Early Development Strategy to Evaluate Drug Potential in the Shortest Time (1/2)

- From preclinical stage, determine optimal development route, precise Go/No-Go criteria, and effective development plans
- Steadily progress towards the realization of TOP I 2030 by making swift Go/No-Go decisions and accelerating overall early development

### Up to now (2015\*-)

**Go/No-Go decisions based on science**

- Design clinical development for a wide range of populations, and thoroughly evaluate the drug potential in every project
- Formulate ePOC as Go/No-Go decision point and development plans in early development
- Make decisions based on clinical trial data and science, prioritizing the acquisition of necessary data for decision-making, even if it takes time

### 【Outcomes】

- Achievement of a high commercialization rate after Phase 3 transition
- Realization of continuous pharmaceutical development



1. With the improvement in drug discovery capabilities, the number of in-house projects advancing to clinical stage has increased.
2. Based on the knowledge accumulated over 10 years, there is an improved understanding of the indicators that should be evaluated earlier and the types of data needed to determine a drug potential.
3. Human predictability has enhanced through human organoids and Modeling and Simulation.

### 【Expected outcomes】

- In addition to acceleration of each project, strategic resource allocation will also accelerate overall early-stage development
- Early Go/No-Go decision criteria contribute to improving the probability of success in subsequent stages
- Maintaining high commercialization rates after Phase 3 transition
- ↓
- Acceleration of the product launch cycle

### From now on (2024\*\*-)

**“Swift” Go/No-Go decisions based on Science**

- Assess the drug potential in the shortest time possible by determining the optimal development route, more precise Go/No-Go decision criteria and development plans in each project from preclinical stage. In addition to ePoC, set earlier Go/No-Go criteria.
- Decisions based on clinical trial data and science will continue to be emphasized. Data acquisition will be focused on critical data directly linked to decision-making.

\*After establishment of TR division, \*\*Refinement of Five Reforms on TOP I 2030

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Regarding the five reforms of the TOP I 2030 growth strategy, I would like to explain about how to strengthen the Go/No-Go decision process because this has been a frequently asked question.

Chugai has been promoting science-based Go/No-Go decisions. As a result, many of the projects have processed to the Phase III and been brought to the market.

In the future, we will achieve both science and speed. We'll continue to find the optimal development pathway for each project even in the non-clinical stage and evaluate the drug's potential in the shortest possible time. In addition to an increase in the number of projects due to improved drug discovery capabilities, we are now able to see the potential of a drug earlier and more quickly, and we have improved human predictabilities, including a prediction of effective dose and safety profile.

These efforts will enable us to maintain our high success rate of the Phase III, accelerate each project, and strategically allocate resources to ensure that we can accelerate the development as a whole in the early stage.

As a result, we'll be able to accelerate the launch cycle and make progress toward achieving TOP I 2030.

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**Acceleration strategy for high-potential projects**

- Projects with high-potential expected from the preclinical stage
- Pursue development through optimal routes towards ePoC

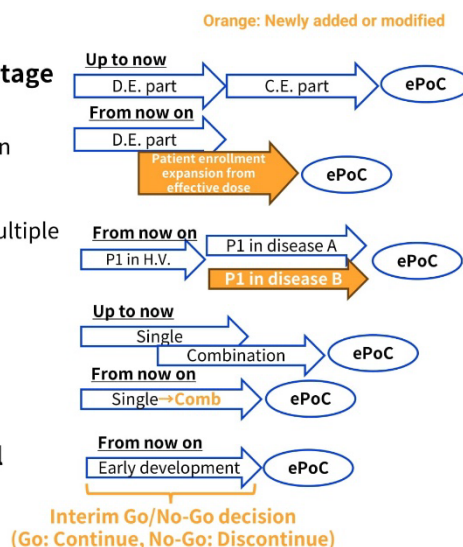
ex) Efficient Phase I trial design through precise effective dose prediction

ex) Early value maximization through simultaneous development for multiple diseases in early development

ex) Acceleration of combination therapy evaluation

**Early evaluation strategy for minimizing development risk**

- Projects requiring rapid potential assessment at the clinical stage
- Set earlier Go/No-Go criteria in addition to ePoC criteria to determine drug potential in the shortest time possible



D.E.: dose escalation, C.E.: cohort expansion, H.V.: health volunteers

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More specifically, we'll accelerate the high potential projects and conduct early assessment to minimize development risk. For example, we'll promote efficient Phase I study design based on precise effective dosage prediction, simultaneous development for early-stage development, and accelerated evaluation of combination therapy.

Six months have passed since the revision of the TOP I strategy, and we will apply this strategy to new projects to promote speed. We have also applied this strategy to projects that have already started development.

As explained in the review of the strategic policies, development of ERY974 was discontinued based on the clinical trial results, and we have stopped the in-house development of SPYK04 due to the results of the clinical trial.

In 2025, we plan to make Go/No-Go decisions for more projects. We'll accelerate early development by making Go/No-Go decisions that combine science and speed and identify potential of drugs in the shortest possible time.

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# Potential Market Sales of Main Projects

## Domestic Sales

In-house products	Indications	Domestic Sales <sup>*1</sup>	Peak Sales Year	Changes from Previous Disclosure
Hemlibra	Hemophilia A, Acquired Hemophilia A	50 bn+ JPY	-2030	—
Alecensa	NSCLC, ALCL	30 bn+ JPY	-2030	—
Enspryng	NMOSD, MOGAD, AIE, TED	30 bn+ JPY	-2030	Changes in market landscape
PiaSky	PNH, aHUS	10 bn+ JPY	2031 and beyond	—
GYM329	SMA	< 10 bn JPY	2031 and beyond	—

Roche products	Indications	Domestic Sales <sup>*1</sup>	Peak Sales Year	Changes from Previous Disclosure
Tecentriq	LC, BC, HCC, Urological cancer, and others	100 bn+ JPY	-2030	—
Polivy	DLBCL, aNHL	30 bn+ JPY	2031 and beyond	Changes in market landscape
Vabysmo	nAMD, DME, RVO, AS	30 bn+ JPY	2031 and beyond	—
Phesgo	BC, Colorectal cancer	30 bn+ JPY	-2030	Changes in market landscape
Evrysdi	SMA	15 bn+ JPY	-2030	—
giredestrant	BC	10 bn+ JPY	2031 and beyond	—
divarasib	NSCLC	10 bn+ JPY	2031 and beyond	new
tiragolumab	HCC, NSCLC, Esophageal cancer	< 10 bn JPY	-2030	Development discontinued in multiple indications
ranibizumab (PDS)	nAMD, DME	< 10 bn JPY	2031 and beyond	—
ASO Factor B	IgA nephropathy	< 10 bn JPY	2031 and beyond	new
vamikibart	UME	< 10 bn JPY	2031 and beyond	new

As of January 30, 2025

## Overseas Sales

### <Projects licensed out to Roche>

- Enspryng (MOGAD, AIE, TED): 1-2bn CHF
- PiaSky (PNH, aHUS, SCD): 1-2bn CHF
- GYM329 (SMA, FSHD): 0.5-1bn CHF
- NXT007 (Hemophilia A): >3bn CHF

Roche's forecasted peak sales

### <Out-licensed product to 3<sup>rd</sup> party>

- NEMLUVIO (AD, PN):

forecasted peak sales 2bn+ USD

(Source: [Galderma.com](https://www.galderma.com))

\*1 without considering success rate

ALCL: anaplastic large cell lymphoma, NMOSD: neuromyelitis optica spectrum disorders, AIE: autoimmune-mediated encephalitis, MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease, TED: thyroid eye disease, PNH: paroxysmal nocturnal hemoglobinuria, aHUS: atypical hemolytic uremic syndrome, DLBCL: diffuse large B-cell lymphoma, aNHL: aggressive B-cell non-Hodgkin lymphoma, nAMD: neovascular age-related macular degeneration, DME: diabetic macular edema, RVO: retinal vein occlusion, AS: angioid streaks, UME: uveitic macular edema, SCD: sickle cell disease, FSHD: facioscapulohumeral muscular dystrophy, AD: atopic dermatitis, PN: prurigo nodularis

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This chart shows the market sales of major projects. Of the domestic sales, the orange in the upper row shows the sales of in-house products and the blue in the lower row shows the sales of Roche products. You see the overseas sales of the in-house products at right side.

For domestic sales, the reasons for any changes from the previous disclosure are given in the right-hand column of the table. Of the overseas sales, Galderma expects NEMLUVIO to reach USD1 billion per year by the end of 2027, and after that, peak sales are expected to exceed USD2 billion.

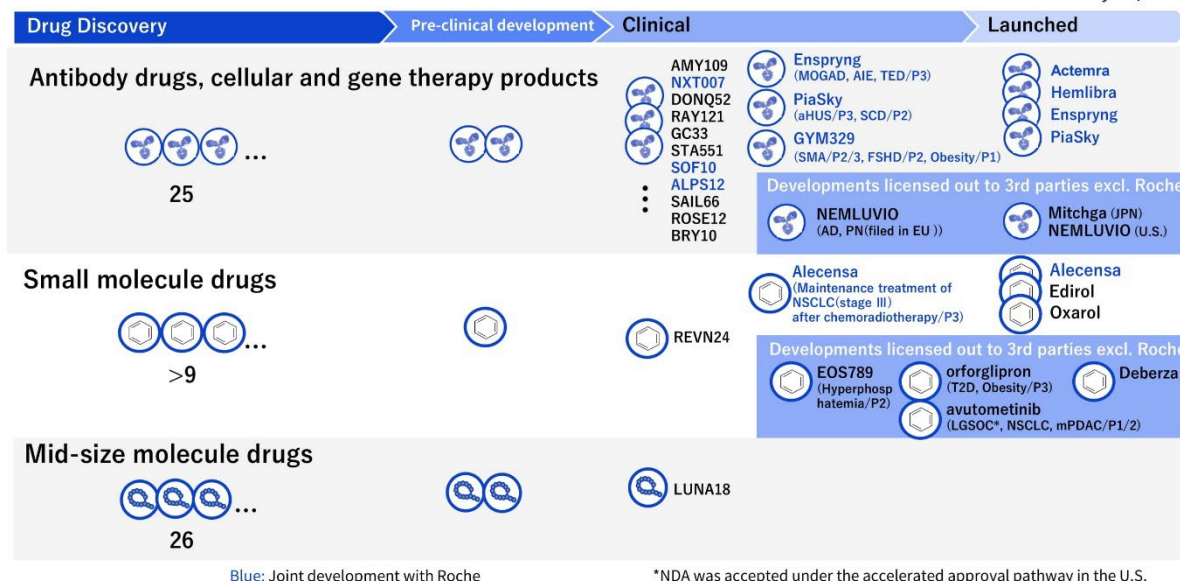
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# Portfolio of Each Modality

As of January 30, 2025



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This slide shows the status of the portfolio for each modality. We continue to have an abundance of in-house projects, all of which are progressing well. In the third pillar of our focus mid-size molecules, two projects are in the preclinical phase and 26 other projects are in the drug discovery phase.

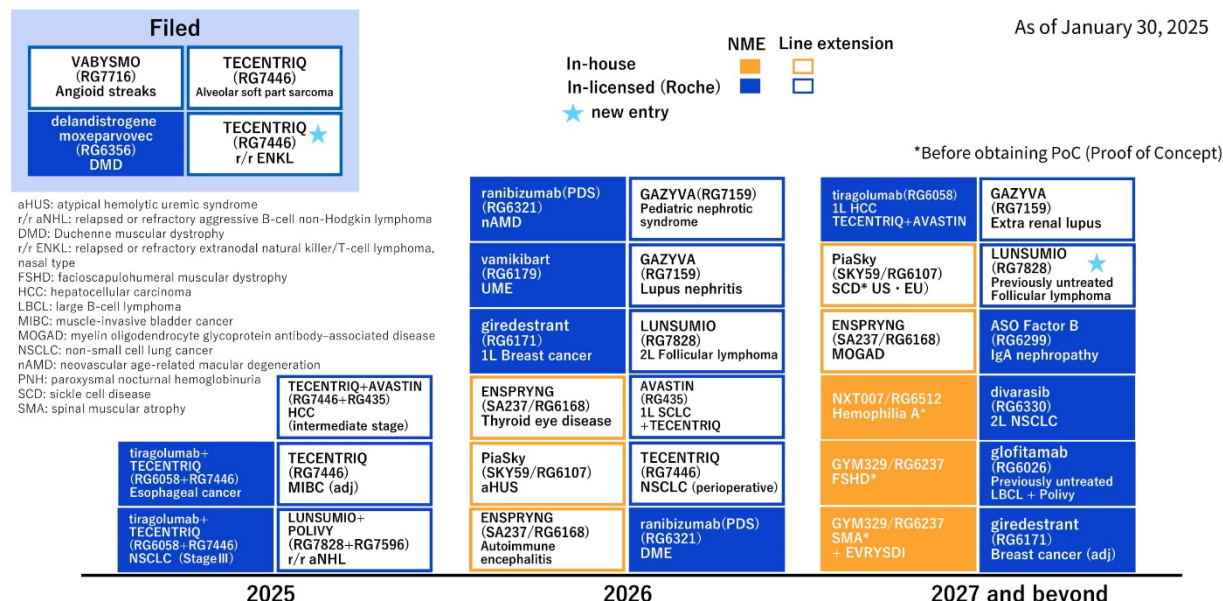
As a reference material, we have included a detailed status of small molecular drugs, mid-size molecule drugs and antibody drugs, and cellular and gene therapy products. Please refer to them as necessary.

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# Projected Submissions (Post PoC NMEs and Products)



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Here is a schedule for future filings. The blue star represents newly added projects.

The slides which follow this page are attached as appendix. This is the end of my presentation.

## FY2024 Consolidated Financial Overview (Core)

## P/L Jan – Dec (Year on Year)

(Billions of JPY)	2023	2024	Growth	
<b>Revenue</b>	<b>1,111.4</b>	<b>1,170.6</b>	<b>+ 59.2</b>	<b>+ 5.3%</b>
Sales	974.5	997.9	+ 23.4	+ 2.4%
Domestic	558.0	461.1	- 96.9	- 17.4%
Overseas	416.5	536.8	+ 120.3	+ 28.9%
Other revenue	136.9	172.7	+ 35.8	+ 26.2%
Cost of sales	-412.0	-338.1	+ 73.9	- 17.9%
(cost to sales ratio)	42.3%	33.9%	-8.4%p	-
Research and development	-162.8	-176.9	- 14.1	+ 8.7%
Selling, general and administration	-102.0	-102.2	- 0.2	+ 0.2%
Other operating income (expense)	16.1	2.7	- 13.4	- 83.2%
<b>Operating profit</b>	<b>450.7</b>	<b>556.1</b>	<b>+ 105.4</b>	<b>+ 23.4%</b>
(operating margin)	40.6%	47.5%	+7.0%p	-
Financial account balance	4.6	1.0	- 3.6	- 78.3%
Income taxes	-121.8	-160.0	- 38.2	+ 31.4%
<b>Net income</b>	<b>333.6</b>	<b>397.1</b>	<b>+ 63.5</b>	<b>+ 19.0%</b>
<b>EPS (JPY)</b>	<b>202.71</b>	<b>241.31</b>	<b>+38.60</b>	<b>+ 19.0%</b>

### Domestic sales

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

### Overseas sales

Significant increase in sales of Hemlibra to Roche

### Other revenue

Increase in income related to Hemlibra and one-time income

### Cost of sales

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

### Research and development expenses

Increase due to investments into research and early development, and progress of development projects

### Selling, general and administration expenses

Same level as the same period of the previous year

### Other operating income (expense)

2.7 billion JPY of income from disposal of product rights, etc. was recorded  
 (Income from disposal of product rights and gain on sales of property, plant and equipment, etc. were recorded, resulted in 16.1 billion JPY of income in the same period of the previous year)

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**Taniguchi:** Taniguchi, CFO. Thank you very much. I will now explain the full-year results for 2024. These will be shown in core basis as compared to the previous year, mainly.

First of all, 2024 revenue. Revenue increased by JPY59.2 billion or 5.3% YoY to JPY1,170.6 billion. Operating profit increased by 23.4% to JPY556.1 billion. That is the first message that I'd like to convey.

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Let me go into the details of revenue. The main reason for this increase in revenue was a significant increase in export sales of products such as Hemlibra overseas. The sales growth completely absorbed the impact of the loss of sales of Ronapreve, a COVID-19 drug to the Japanese government, was JPY81.2 billion and actually exceeded it.

Looking at the breakdown of revenue, first of all, the sales were JPY997.9 billion, an increase of JPY23.4 billion or 2.4%. If you look at the sales by domestic sales and overseas sales, domestic sales decreased by JPY96.9 billion YoY or 17.4% to JPY461.1 billion. As I said, for Ronapreve, the JPY81.2 billion that was posted in 2023 is now gone, but decrease would be JPY15.7 billion, excluding Ronapreve. The main factors were the impact of NHI drug price revisions and penetration of generic products.

For overseas, export products such as Hemlibra were strong and sales grew by JPY120.3 billion or 28.9% to JPY536.8 billion. Other revenue, including royalty income and one-time income, actually increased mainly because of Hemlibra income. It was JPY172.7 billion or an increase of JPY35.8 billion or 26.2%.

Next, I'd like to move to the cost items. Cost of sales decreased by JPY73.9 billion or 17.9% YoY to JPY338.1 billion. Sales increased, but the cost of sales decreased. Why? The reason is that cost of Ronapreve, which had a high cost of sales ratio, has disappeared, and relatively low cost of sales ratio of in-house products has increased in the sales mix. Relative increase and changes in the product mix actually reduced the cost of sales. The cost of sales ratio has improved by 8.4 points to 33.9%.

Regarding R&D expenses, due to the steady progress of projects in the drug discovery research and early-stage development, it increased by JPY14.1 billion YoY. And SG&A expenses, despite the impact of rising prices and personnel costs, we made efforts to improve efficiency, and the increase was limited to just JPY200 million YoY. Now, other revenue decreased by JPY13.4 billion YoY to JPY2.7 billion due to the significant decrease in gains on sales of products transferred in 2024 because that was posted in large amounts in 2023.

As a result of these factors, operating profit increased to JPY556.1 billion or an increase of JPY105.4 billion or 23.4%, and operating margin increased to 47.5% or a 7-point increase. The net income was JPY397.1 billion, increase of JPY63.5 billion or 19.0% YoY. EPS was JPY241, a JPY38.6 increase YoY.

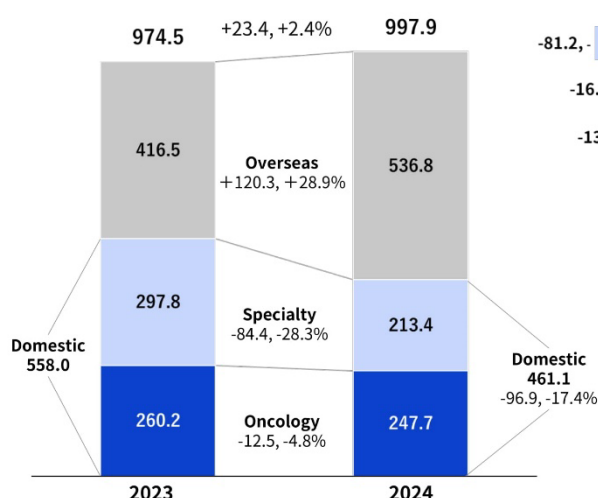
#### FY2024 Consolidated Financial Overview (Core)

### Sales Jan – Dec (Year on Year)



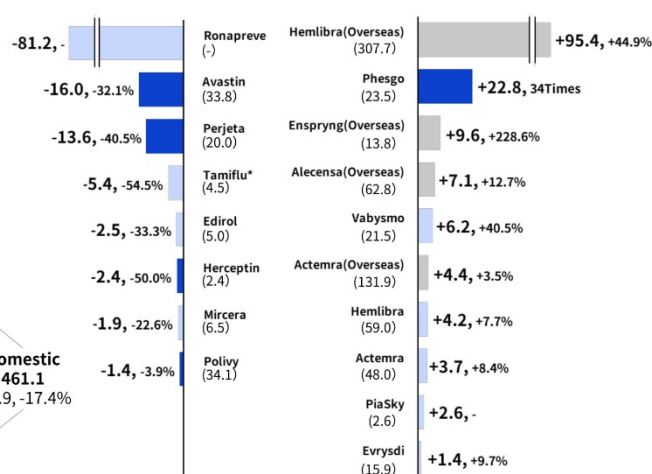
(Billions of JPY)

Sales by Disease Area,  
Year on Year



Sales by Product,  
Year on Year

( ): Actual sales in FY2024  
%: Year-on-year percentage change  
\*included in Other products of Specialty



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Let me go into the breakdown of changes in sale products. First of all, this is the YoY comparison. There are oncology and specialty business units in Japan. As for oncology, the sales decreased by 4.8% or JPY12.5 billion. Sales of Avastin decreased by JPY16.0 billion due to the impact of penetration of generic products.

The sales of new product Phesgo increased by JPY22.8 billion. Phesgo is a combination drug of Perjeta and Herceptin, and its sales figures have exceeded the amount of decrease in Perjeta and Herceptin sales.

Specialty sales decreased by JPY84.4 billion. Ronapreve, JPY82.1 billion. For Tamiflu, from around December last year, influenza had an outbreak, but in 2023, the previous year, there was much more outbreak. Because of that impact of Ronapreve and Tamiflu, it declined, but without that, a JPY2.2 billion increase would have been achieved.

There was a revision of NHI drug price, but Vabysmo and PiaSky are steadily increasing as the new products.

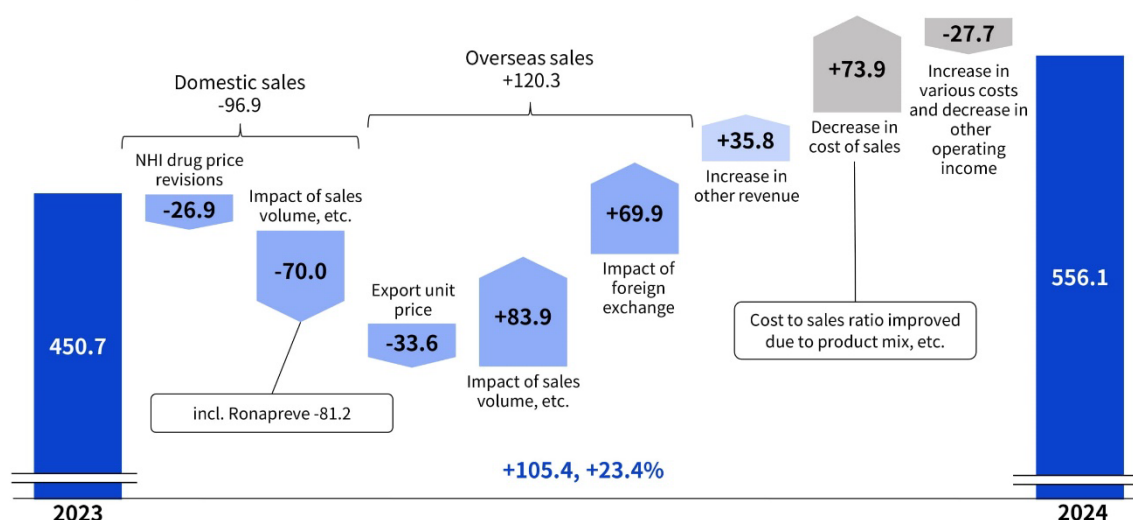
Overseas sales, JPY120.3 billion increase. It was because four main products including Hemlibra increased. It's clear that Hemlibra has shown overwhelming growth. In addition, Enspryng and Alecensa have also grown. Even Actemra, which has reached its Loss of Exclusivity (LOE), has continued to grow, partly due to the delayed entry of biosimilars into the market.

FY2024 Consolidated Financial Overview (Core)



## Operating Profit Jan – Dec (Year on Year)

(Billions of JPY)



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The next page shows the breakdown of increase in operating profit, JPY450.7 billion to JPY556.1 billion. There's a change. There was an impact of NHI drug price revisions, but Ronapreve were the main factors.

But on the other hand, there was an increase of JPY120.3 billion in overseas sales. Hemlibra, the more sales in emerging countries, the price would be lower. There is also positive impact of increase in volume. The positive impact of foreign exchange rate from 2023 to 2024, a JPY69.9 billion impact, was seen.

Other revenue, the royalty income increased and Hemlibra is the main one, but there are others. Roche local sales increased, and that has increased the royalty income. In expenses, JPY73.9 billion in cost of sales declined, but there were R&D expenses increased slightly. Overall, a JPY105.4 billion increase was achieved.

The following page shows the trend in profit and loss items every three months from Q4 2023.

### Support

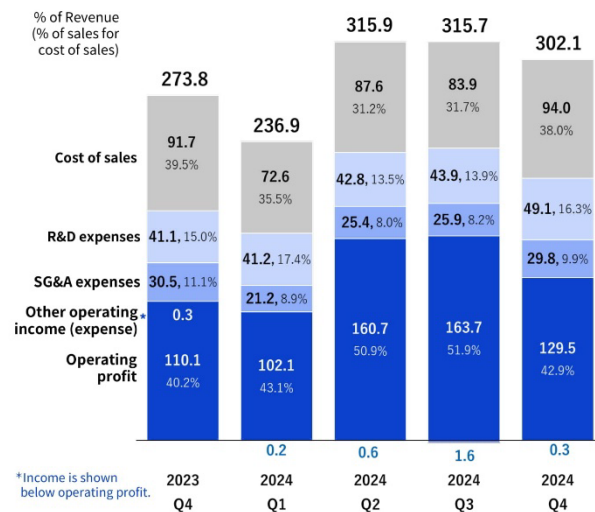
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## Structure of Costs and Profit by Quarter

(Billions of JPY)



### Year on Year (vs. 2023 Q4)

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

**R&D:** increase due to progress of development projects

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

**Other operating income (expense):** same level as the same period of the previous year

**Operating profit:** +19.4 billion JPY, +17.6%

### Quarter on Quarter (vs. 2024 Q3)

**Cost of sales ratio:** cost to sales ratio increased due to a change in product mix, etc.

**R&D:** increase due to progress of development projects

**SG&A:** increase in line with the trend of previous years

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

**Operating profit:** -34.2 billion JPY, -20.9%

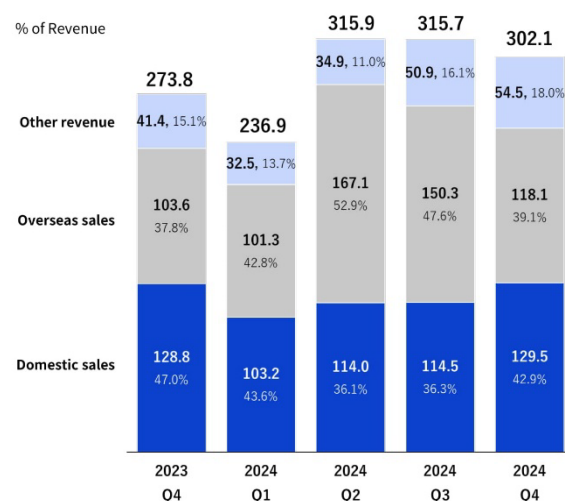
41

By quarter, there are timing changes in export shipment. In Q2 and Q3, operating profit was quite high, as you can see. Compared to a comparison of Q4 in 2024 and 2023, JPY19.4 billion increase was achieved in operating profit.

I will explain in more detail on the next page.

## Structure of Revenue by Quarter

(Billions of JPY)



### Year on Year (vs. 2023 Q4)

**Domestic sales:** same level as the previous year due to growth of mainstay products, despite the NHI drug price revisions and market penetration of generic drugs

**Overseas sales:** significant increase in sales of Hemlibra

**Other revenue:** increase in royalty income of Hemlibra

### Quarter on Quarter (vs. 2024 Q3)

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

**Overseas sales:** significant decrease in sales of Hemlibra due to the timing of shipment

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

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In terms of Q4 to Q4, in other revenue, between 2023 and 2024, JPY13.0 billion increase was achieved. But this is a revenue mix. As you can see, Q2 and Q3 have seen relatively larger sales as compared to the other quarters.

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## P/L Jan – Dec (vs. Revised Forecast)

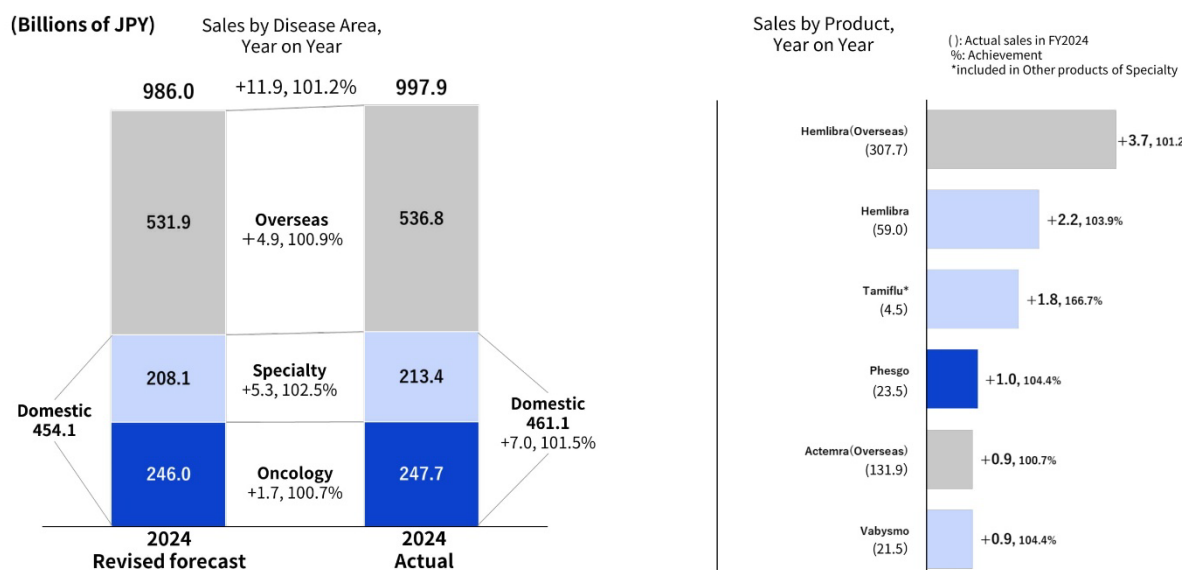
(Billions of JPY)	2024		+/-	Achiev.	
	Revised Forecast	Actual			
<b>Revenue</b>	<b>1,150.0</b>	<b>1,170.6</b>	<b>+ 20.6</b>	<b>101.8%</b>	<b>Domestic sales</b> Outperformed the forecast due to favorable progress of mainstay products
Sales	986.0	997.9	+ 11.9	101.2%	<b>Overseas sales</b> Sales of Hemlibra exceeded the forecast
Domestic	454.1	461.1	+ 7.0	101.5%	<b>Other revenue</b> Income related to Hemlibra exceeded the forecast
Overseas	531.9	536.8	+ 4.9	100.9%	
Other revenue	164.0	172.7	+ 8.7	105.3%	
Cost of sales	- 335.0	- 338.1	- 3.1	100.9%	<b>Cost of sales</b> Mostly in line with the forecast
(cost to sales ratio)	34.0%	33.9%	-0.1%p	-	
Research and development	- 175.0	- 176.9	- 1.9	101.1%	<b>Research and development</b> Mostly in line with the forecast
Selling, general and administration	- 103.0	- 102.2	+ 0.8	99.2%	
Other operating income (expense)	3.0	2.7	- 0.3	90.0%	
<b>Operating profit</b>	<b>540.0</b>	<b>556.1</b>	<b>+ 16.1</b>	<b>103.0%</b>	<b>Selling, general and administration expenses</b> Mostly in line with the forecast
(operating margin)	47.0%	47.5%	+0.5%p	-	
<b>Net income</b>	<b>388.0</b>	<b>397.1</b>	<b>+ 9.1</b>	<b>102.3%</b>	<b>Other operating income (expense)</b> Mostly in line with the forecast
<b>EPS (JPY)</b>	<b>236.00</b>	<b>241.31</b>	<b>+ 5.31</b>	<b>102.3%</b>	

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Next, 2024 actual results. As I explained, the revised forecast at the time of earnings results for Q3, JPY80.0 billion was the upward revision for both revenue and profit, JPY20.6 billion in sales, and JPY16.1 billion profit ahead of those revised forecast. JPY7.0 billion in sales in the domestic market, that was achieved because of the strong sales after Q3. So JPY7.0 billion in domestic sales and JPY4.9 billion in overseas.

As for royalty income, due to Roche's Q4 overseas sales exceeding expectations, there was an increase in income and royalty income related to Hemlibra. However, cost of sales and expenses were mostly as expected. Operating profit increased by JPY16.1 billion.

## Sales Jan – Dec (vs. Revised Forecast)



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In Q3, the guidance was changed. Compared to that, what was the actual results, a JPY7.0 billion increase in domestic sales; specialty, JPY5.3 billion. This includes Hemlibra, Tamiflu, and Vabysmo. In oncology, Phesgo also grew. Hemlibra overseas grew JPY3.7 billion.

#### FY2024 Consolidated Financial Overview (Core)



## Impact from Foreign Exchange Jan – Dec

(Billions of JPY)	vs.2023 Actual rate [C] vs. [A]	vs.2024 Revised Forecast rate [C] vs. [B]
<b>Revenue</b>	<b>+91.0</b>	<b>+1.0</b>
Sales	+69.9	+0.2
Other revenue	+21.1	+0.7
<b>Cost of sales</b>	<b>-10.1</b>	<b>-0.3</b>
<b>Other than above<sup>*1</sup></b>	<b>-4.5</b>	<b>-0.2</b>
<b>Operating profit</b>	<b>+76.4</b>	<b>+0.5</b>

Exchange Rate (JPY)	2023 Actual rate <sup>*2</sup> Jan - Dec [A]	2024 Revised Forecast rate Jan - Dec [B]	2024 Actual rate <sup>*2</sup> Jan - Dec [C]
<b>1CHF</b>	140.31	161.00	161.02
<b>1EUR</b>	151.38	163.00	163.30
<b>1USD</b>	134.21	138.00	139.11

<sup>\*1</sup> Total of R&D, SG&A and other operating income (expense)

<sup>\*2</sup> Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

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This shows the FX impact. Compared to the actual rate in 2023, in terms of revenue, JPY91.0 billion positive. A negative impact of JPY 10.1 billion in cost of sales, and JPY 4.5 billion in others including SG&A and R&D. OP-based, we've had a positive impact due to FX rate of JPY76.4 billion. The exchange rate, in particular, Swiss Franc, we have seen approximately JPY20 depreciation of yen, from JPY 140 to JPY161.

#### FY2024 Consolidated Financial Overview (Core)



## Financial Position (vs. 2023 Year End)

(Billions of JPY)

Total assets	1,932.5	+ 275.9	2,208.4
Total liabilities	-307.0	+0.1	-306.9
	<b>1,625.6</b>	<b>Total net assets +275.9</b>	<b>1,901.5</b>
Net operating assets 900.9	422.6	Net working capital +26.1	448.7
	478.3	Long-term net operating assets +20.6	498.9
	739.0	Net cash +257.3	996.3
	-14.3	-28.2	-42.5
2023 Dec		Other non-operating assets - net <sup>*1</sup>	2024 Dec
Ratio of equity attributable to Chugai shareholders	84.1%	+2.0%p	86.1%

### Increase in net working capital

Increase mainly due to a decrease in account payable

### Increase in long-term net operating assets

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

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

- the manufacturing building for active pharmaceutical ingredients (FJ3) at Fujieda Plant

### Increase in net cash

(See next page)

### Decrease in other non-operating assets - net

Decrease mainly due to increase in accrued corporate tax

<sup>\*1</sup> E.g., deferred income tax assets, accrued corporate tax, etc.

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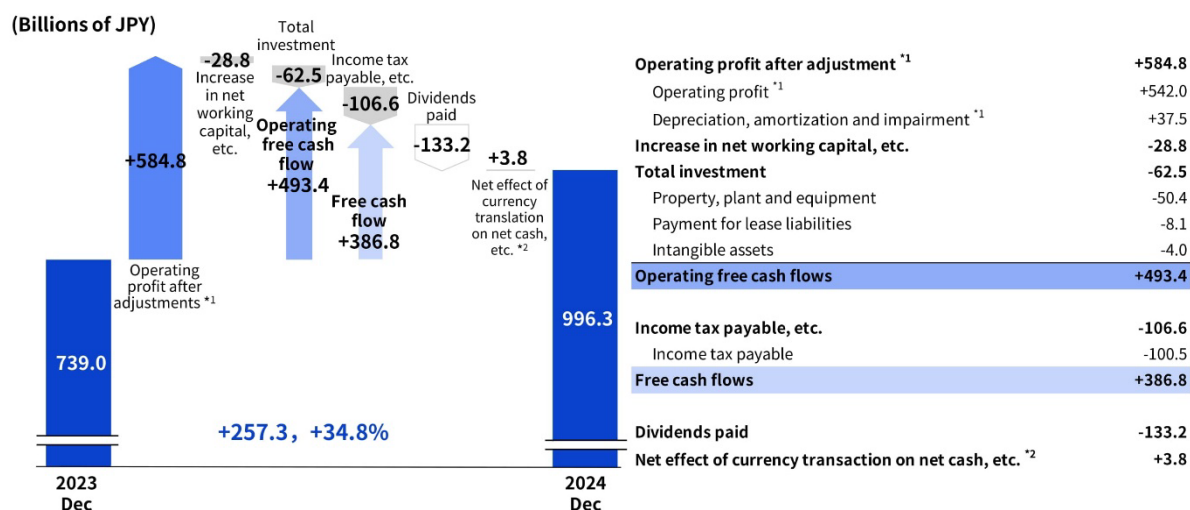


Next is the balance sheet, as of the end of December, 2024. Due to the increase of sales, our working capital increased. We made capital investments, and our operating assets grew. The most significant change was the accumulation of net cash, which increased by JPY257.3 billion, due to profit retention. Total assets was JPY2,208.4 billion, an increase of JPY275.9 billion from the same period last year. Liability remains almost the same, at JPY306.9 billion. Total net assets has grown up to JPY1,901.5 billion, with the shareholders' equity ratio increasing to 86.1%.

#### FY2024 Consolidated Financial Overview (Core)



## Net Cash (vs. 2023 Year End)



<sup>\*1</sup> Including Non-Core (IFRS results)

<sup>\*2</sup> Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash (<sup>\*3</sup>)

<sup>\*3</sup> 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 increased from JPY739.0 billion at the end of December 2023 up to JPY996.3 billion, an increase of JPY257.3 billion. Operating free cash flow was plus JPY493.4 billion, reflecting our performance. Deducting the corporate tax and dividend payment and so on from this amount, we have seen an increase in cash. Acquisition of tangible fixed asset of JPY50.4 billion was recognized.

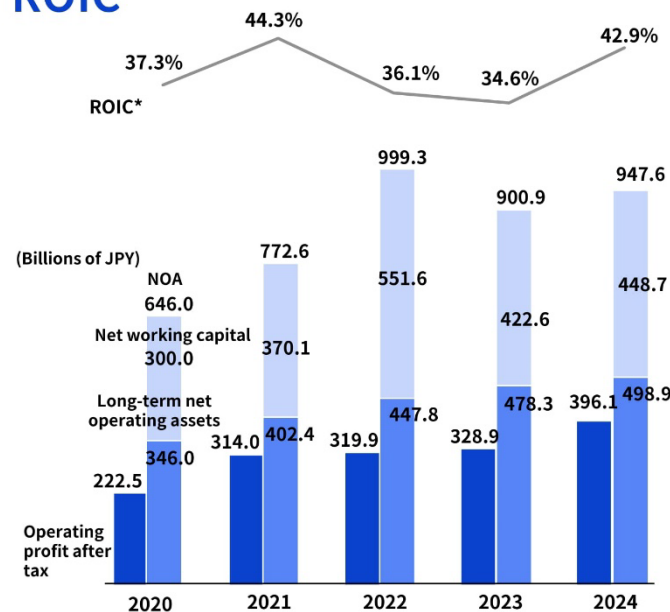
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## ROIC



### ● Core operating profit after tax [A]

Steady increase due to export and royalty income for Hemlibra

### ● NOA [B]

Increase mainly in long-term net operating assets due to aggressive capital investments, such as the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant and for active pharmaceutical ingredients (FJ3) at Fujieda Plant, etc.

Significant movement in net working capital in 2022 and 2023 due to supply of Ronapreve to the government



### ● ROIC [= A/the average of opening and ending of B]

In 2024, fluctuations of net working capital due to supply of Ronapreve to the government converged. ROIC significantly increased to 42.9% compared to the previous year due to the increase in operating profit after tax

\*ROIC = operating profit after tax / the average of opening and ending NOA balances

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Capital efficiency is quite important. In FY 2024, our ROIC was 42.9%. From 2023, ROIC increased by 8.3 percentage points. As we have disclosed, our cost of capital is around 7%, so we believe our ROIC is sufficiently exceeding this threshold.

## P/L 2025 Forecast

(Billions of JPY)	2024 Actual	2025 Forecast	Growth	
<b>Revenues</b>	<b>1,170.6</b>	<b>1,190.0</b>	<b>+ 19.4</b>	<b>+ 1.7%</b>
Sales	997.9	1,018.0	+ 20.1	+ 2.0%
Domestic	461.1	462.5	+ 1.4	+ 0.3%
Overseas	536.8	555.5	+ 18.7	+ 3.5%
Other revenue	172.7	172.0	- 0.7	- 0.4%
Cost of sales	- 338.1	- 341.0	- 2.9	+ 0.9%
(cost to sales ratio)	33.9%	33.5%	- 0.4%p	-
Research and development	- 176.9	- 178.0	- 1.1	+ 0.6%
Selling, general and administration	- 102.2	- 101.0	1.2	- 1.2%
Other operating income (expense)	2.7	-	- 2.7	- 100.0%
<b>Operating profit</b>	<b>556.1</b>	<b>570.0</b>	<b>+ 13.9</b>	<b>+ 2.5%</b>
(operating margin)	47.5%	47.9%	+ 0.4%p	-
<b>Net income</b>	<b>397.1</b>	<b>410.0</b>	<b>+ 12.9</b>	<b>+ 3.2%</b>
<b>EPS (JPY)</b>	<b>241.31</b>	<b>250.00</b>	<b>+ 8.69</b>	<b>+ 3.6%</b>

### Domestic sales

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

### Overseas sales

Increase in sales of Hemlibra, Alecensa and NEMLUVIO, despite decrease in sales of Actemra

### Other revenue

Mostly the same level as the previous year

### Cost of sales

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

### Research and development

Mostly the same level as the previous year

### Selling, general and administration expenses

Mostly the same level as the previous year

### Other operating income (expense)

Income from disposal of product rights was recorded in previous year

Exchange Rate (JPY)	2024 Actual	End of December 2024	2025 Assumption
1CHF	161.02	173.50	171.00
1EUR	163.30	163.08	160.00
1USD	139.11	156.83	148.00

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This is the forecast for this fiscal year, which was already explained by Okuda, so I would like to skip the details. But the revenue is expected to be JPY1,190 billion, growing by 1.7%, which is JPY19.4 billion. Both domestic and overseas sales are forecasted to grow. For domestic sales, despite the impact of NHI price revisions and market penetration of generic drugs, we expect a JPY1.4 billion increase due to growth of new and mainstay products. Overseas, Hemlibra and Alecensa are expected to grow and NEMLUVIO, which we export to

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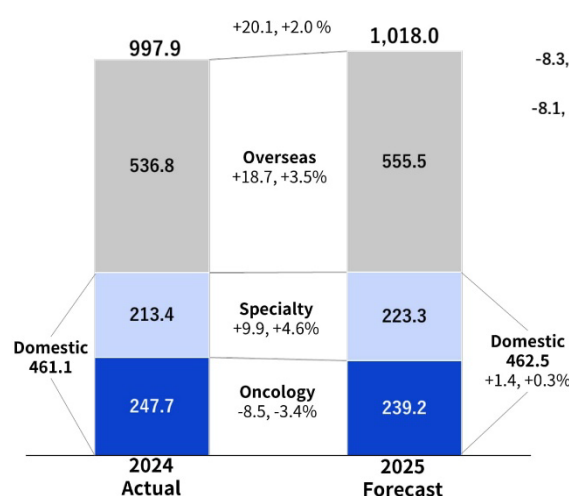
Galderma, is also expected to increase. Actemra is impacted by the biosimilar entry so we expect some drop. SG&A and R&D costs mostly are expected to stay flat. OP is expected to be JPY570.0 billion, growing by 2.5%, which is JPY13.9 billion, exceeding the revenue growth rate. Net income is expected to be JPY410.0 billion, an increase of JPY12.9 billion.

## FY2024 Consolidated Financial Overview (Core)

# Sales 2025 Forecast

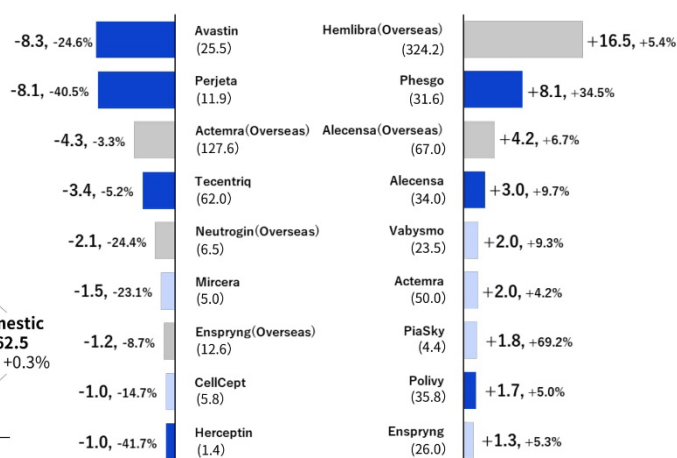


(Billions of JPY) Sales by Disease Area



Sales by Product

( ): Forecast sales in FY2025  
%: Year-on-year percentage change  
Excluding products out-licensed 3rd parties



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This is the comparison against the actual of 2024. Domestic, plus JPY1.4 billion. For oncology, we still see some impact by biosimilars for Avastin, expecting a decrease by JPY 8.3 billion. However, we expect that Phesgo will grow, and Polivy is also expected to grow again this year. Specialty products are expected to grow by JPY 9.9 billion. This is expected to come from Vabysmo, PiaSky, and Enspryng. Overseas sales are expected to grow by JPY 18.7 billion, including growth in Hemlibra, and in Alecensa by JPY 4.2 billion.

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## P/L Jan – Dec (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenue</b>	<b>1,170.6</b>			<b>1,170.6</b>
Sales	997.9			997.9
Other revenue	172.7			172.7
Cost of sales	-339.4	+1.3		-338.1
Research and development	-181.4	+4.4	+0.1	-176.9
Selling, general and administration	-110.1		+7.9	-102.2
Other operating income (expense)	2.3		+0.4	2.7
<b>Operating profit</b>	<b>542.0</b>	<b>+5.7</b>	<b>+8.4</b>	<b>556.1</b>
Financial account balance	1.0			1.0
Income taxes	-155.7	-1.7	-2.6	-160.0
<b>Net income</b>	<b>387.3</b>	<b>+4.0</b>	<b>+5.8</b>	<b>397.1</b>
<b>EPS (JPY)</b>	<b>235.36</b>			<b>241.31</b>

### Non-core items

#### Factors affected operating profit

#### Intangible assets

Amortization	+1.6
Impairment	+4.1

#### Others

Business rebuilding expenses	+7.9
Restructuring expenses	+0.5

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Finally, as additional information, this shows the adjustments between Core-based accounting figures and IFRS-based figures. JPY7.9 billion business restructuring costs are related to the implementation of a new ERP system, specifically a new SAP platform that we are currently building. Regarding intangible assets, we are basically treating the amortization and impairment of in-licensed technologies as Non-Core items.

## Current Status / Plan for Major Investments

			~2023	2024	2025	2026	2027	2028	2029~	Planned investment			Start of investment	Planned completion
										Total amount	Investment to-date	Unit		
Manufacturing	Fujieda plant	FJ3: Manufacture APIs of small and mid-size molecule drugs for late-stage clinical development and early commercial use								55.5	54.7	billion JPY	2021	2024 Completed
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later-stage clinical development and early commercial use								37.4	17.1	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use								19.0	9.3	billion JPY	2023	2025
	Ukima plant	UK3(modification): Manufacture bio drug substance								20.3	0.6	billion JPY	2024	2027
Research and development	CPR	Move and renovate facilities to enhance research functions								60	1	million SGD	2024	2026
	IFReC	Funding to IFReC per comprehensive collaboration agreement								10.0	7.8	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030								109.5 estimated total amount	4.1	billion JPY	2022	2033

\* incl. part of investments described in the schedule above

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Next page shows the current status and near-term plans for major investments. Major capital investments that have been officially approved by the executive committee / the board of directors, are shown here. Environmental investments are also shown here.

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## Summary of Chugai Originated Global Products

- Actemra has obtained regulatory approval in 116 countries and has been delivered to over 690,000 Japanese patients in total after its release in Japan. In 2025, Actemra celebrates its 20th anniversary since launch as the world's first IL-6 inhibitor originated in Japan.

Product (Billions of JPY)	FY2024 Results	Y on Y	FY2025 Forecast	Comments
<b>Hemlibra®</b>	Domestic: 59.0 Export: 307.7 Overseas local: 4,136mCHF	+7.7% +44.9% +13%	59.4 324.2 -	<ul style="list-style-type: none"> <li>Japan: Sales increased year on year despite the drug price revision in 2023*1. Domestic market share steadily increased.</li> <li>Overseas: Sales increased in all regions. Exports also performed favorably.</li> <li>We provide value to patients worldwide through its convenience and accumulated clinical evidence.</li> </ul>
<b>Actemra®</b>	Domestic: 48.0 Export: 131.9 Overseas local: 2,337mCHF	+8.4% +3.5% +4%	50.0 127.6 -	<ul style="list-style-type: none"> <li>Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated.</li> <li>Overseas: Sales increased especially in the U.S. and International. Exports also increased.</li> <li>We provide value to patients through the established evidence as an originator of IL-6 inhibitor.</li> </ul>
<b>Alecensa®</b>	Domestic: 31.0 Export: 62.8 Overseas local: 1,350mCHF	+2.3% +12.7% +8%	34.0 67.0 -	<ul style="list-style-type: none"> <li>Japan: Maintain its high share in the first-line therapy despite competitors' entry since 2021.</li> <li>Overseas: Sales increased especially in the U.S. and International. Exports also performed favorably.</li> <li>Expanded indication for NSCLC adj. will further contribute to the treatment of patients.</li> </ul>
<b>Enspryng®</b>	Domestic: 24.7 Export: 13.8 Overseas local: 165mCHF	+3.3% +228.6% +67%	26.0 12.6 -	<ul style="list-style-type: none"> <li>Japan: Sales increased year on year as the switching from other drugs progressed steadily, despite the significant drug price revision implemented in 2024*2.</li> <li>Overseas: Sales increased in all regions. Exports also performed favorably.</li> <li>We provide a convenient treatment option for patients who wish to avoid steroids</li> </ul>
<b>PiaSky®</b>	Domestic: 2.6 Export: - Overseas local: 1mCHF	- % - % - %	4.4 - -	<ul style="list-style-type: none"> <li>Japan: Launched in May 2024, the product successfully penetrates the market, gaining favorable evaluation in medical facilities due to the convenience of subcutaneous administration and reduced hospital time.</li> <li>Overseas: Market introduction is progressing in the EU. We aim to penetrate markets in various countries worldwide.</li> <li>We provide an improved convenience and a broad range of treatment opportunities for patients with C5 gene polymorphisms.</li> </ul>

\*'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.  
Y on Y: year on year, 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

Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024
32.5%	33.2%	33.8%	34.9%	35.3%

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Lastly, for your reference, we have added PiaSky here. This is the status of our in-house global products. We have provided domestic sales, export sales, and Roche's overseas local sales, along with qualitative comments.

That's all from myself. Thank you very much for listening.

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## Question & Answer

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**Miyata [M]:** Now, I would like to move to question-and-answer session. In Q&A, there will be two more people to answer questions: Hidaka, the Vice President of Supervisory Responsibility for Marketing and Sales, and Digital Transformation Unit Head, Suzuki.

There are three joint releases by three companies, our company, SoftBank, and SoftBank Intuitions, today.

In order to have as many people as possible asking questions, please let us limit the questions to two per person. Also, the presentation as well as the question-and-answer session will be posted on the website of our company on a later date. We'd like to take questions from the people in person in the venue, and then take questions from those who are participating on Zoom webinar.

Now if you have any questions, if you are in the room, please raise your hands. The microphone will be brought to you. Please identify yourself and your affiliation first before asking the questions.

The person in the first row please, the microphone will be brought to you.

**Hashiguchi [Q]:** Hashiguchi from Daiwa Securities. The first question is about the pipeline. This year, the priority items include the preparation of DONQ52 Phase II initiation and NXT007 Phase III initiation. Also, in the presentation, you said that GYM329 Phase II for obesity will be initiated.

For each, to what extent have you seen the decisions made for initiation? The previous phase, which must be the reason for the next phase initiation, has not been disclosed. But as far as you see, to what extent do you have the confidence of being able to initiate actually? Is it also part of your wishful thinking?

Also, compared to the previous year, you said that you are going to accelerate your development. You have not decided yet whether to be able to start the next phase. You may also start preparation for the following phase. Is that what is included for each of those? Can you answer that question?

**Okuda [A]:** Thank you for the questions. DONQ25, NXT007, and GYM329, I think those are the three in-house developed product milestones that are expected. Has it already been fully decided? Or is it just the preparation because of acceleration of development? Well, DONQ52 Phase II initiation, at the moment, we are conducting Phase I study and data is coming out. Based on the data, we would do the interpretation and then move on to Phase II. These are the usual steps. In terms of timing, we can start preparation for Phase II. As we do so, we can expect the Phase I data to come out. As for NXT007, Phase I/II is also being conducted and the result will come out, and we are at the timing of being able to move to the next phase.

The second part of your question, in order to accelerate the speed, you're assuming that the result will be positive. We are starting the preparation, as you have guessed. We're not saying that we know the result, but based on the result that will come out, we will make decisions for the next one.

GYM329, what about Phase II for obesity? Phase I was done in last year. With regard to Phase II, the combination study is going to be started.

**Hashiguchi [Q]:** Thank you. The next question is about the dividend. JPY250 includes JPY150 commemorative dividend for this year. If you can look at the other companies, the commemorative dividend is used for increase in dividend. But usually, the following year, the comparable dividend will be paid even though there is no commemorative dividend so that there will be no decline in the dividend received.

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When you increase the dividend, you say this is under all species of cumulative dividend, but actually, you would increase further in the following year. When you look at the cash flow forecast from your company, the JPY250 dividend per share is really an unusual level of dividend because of this 100th anniversary. Do you think that it's highly probable that you can continue to maintain this level years after that?

**Okuda [A]:** Let me explain. This anniversary dividend, in total, JPY250, but JPY150 out of that is an anniversary dividend. The regular dividend is JPY100. So if you can distinguish that, that will be appreciated. To celebrate the 100th year and thank for the support and cooperation from the shareholders, we are paying JPY150, and then regular dividend will be JPY100. Following our dividend policy, we are going to pay stable dividend, which is about regular dividend.

If there is additional comment from the CFO?

**Taniguchi [A]:** But actually, we're not familiar with the other companies' practices, but we do make distinction between these two. We look at the current financial position. We have made this decision. We're not able to talk about the future. 45% payout ratio for ordinary dividend, but other than that, we're not in a position to comment on any other part.

**Miyata [M]:** Please raise your hand if you have any questions.

**Sakai [Q]:** Hi. I am from UBS Securities, Sakai. You are now trying to accelerate drug development. This has been your challenge in the past one or two decades. When I look at page 23 and when I look at your news release regarding the collaboration with SB Intuitions, I wonder what is the realistic probability of you accelerating the drug development speed? At the same time, I think you are contemplating whether Japanese subjects in Phase I is really necessary. In that case, what will be the expected impact? Is it really viable or not?

Can you please comment on the feasibility of this project or impact of this project? By when are we able to start seeing the tangible result of this project?

**Okuda [M]:** In terms of the acceleration of our development process or enhancement of the Go/No-Go decision, Tanaka will answer that. With regard to the collaboration with SoftBank, I would like to ask Suzuki to respond to your question. And if I have any additional comments, I would like to cut in.

**Tanaka [A]:** Thank you very much for your question. I am Tanaka speaking. The Go/No-Go decision enhancement, how do we apply our strategy to do so? Existing projects and future new projects that are entering in the clinical development phase, for all of those projects, we are going to apply this strategy. Some of the projects, we have already started early assessment of efficacy, and we have already started efforts to simultaneous development for multiple number of diseases.

Science-based project decision, what kind of development pathway is most suitable to what kind of project? It's been 10 years since the establishment of translational research division, so we have accumulated know-how from the past clinical research activities. Based on such, setting up the most optimum timeline for development activities have been now realized. We would like to continue doing so.

**Okuda [A]:** As to your question, what is the timeline in order for us to see the tangible result? As Tanaka mentioned, these criteria has already been applied to the existing projects, and this strategy will also apply to the newly added projects. As we work on a greater number of projects, we should be able to see more tangible results.

To your second question in relation to the collaboration with SoftBank, Suzuki would like to respond.

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**Suzuki [A]:** Thank you for your question. I am from the Digital Transformation Unit. My name is Suzuki. The collaboration with SoftBank and SB Intuitions, with regard to the basic agreement for the partnership with both companies, I would like to make some comments. How can we shorten the development timeline through this collaboration? When I look at the report issued by METI, by utilizing gen AI, we may be able to shorten the timeline by four years in general. This year, we are focusing on the clinical development operations to further optimize. We will start the study and see what the probable impact will be.

**Okuda [A]:** Mr. Sakai, I think you asked one more question, which is regarding the necessity of Japanese subjects to be involved in the Phase I study. As Tanaka explained about the Chugai Pharmaceutical original product, no impact. When it comes to the licensed in-product from Roche, ultimately speaking, we may be able to skip Phase I with the Japanese population but it's project by project, and we need to consult with the authority to see if a Japanese Phase I is really necessary or can be skipped.

**Sakai [Q]:** My next question, I think it goes to Taniguchi-san. In Q4, the royalty and profit sharing number amount increased quite a bit. I'm sure you will say, sorry, we can't comment on that. But indeed, it has gone up. Why? I think it's due to Hemlibra. But in the Roche earnings, they didn't disclose a lot of numbers for Hemlibra, and they may really talk a lot about Hemlibra. I would like to ask Taniguchi-san to explain.

Is there any change in the rate? Or has there been any change in the threshold? The global price should have come down, right? But still, this number is quite big.

**Taniguchi [A]:** Roche is holding a conference this evening, but January to December numbers are already available. If you look at the delta as of the end of Q3 and Q4, you should be able to analyze for Hemlibra. But Q4 was better than our expectation. Again, I cannot comment on a specific product. But this is Roche external sales basically, which performed strongly. It's not like we have changed the contract. It's a tiered royalty. When the number exceeds a certain threshold, the rate will go up, but I can't comment any further on that. But when the volume grows and even at the same percentage, royalties can grow.

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

**Miyata [M]:** Thank you very much. If you have any questions, please raise your hand, for those of you who are in the room in person. No more questions? Then, let's move to the participants through Zoom webinar.

If you're using PC and tablet PC to participate, please click on the raise-hand function at the bottom of the screen. If your turn [is here], then your name will be called and the secretariat will ask you to unmute yourself. Please identify yourself and your affiliation before asking questions. If you'd like to cancel the question, please push the function of lower hand. If you are participating in a telephone, press # and [nine]. If you wish to cancel the question, also push # and nine.

From JPMorgan, Mr. Wakao, please ask your question.

**Wakao [Q]:** The first question, the changes from Q3 for the forecast for this year, at the time of Q3, there's a forecast, but there have been changes. At the time of Q3, for this year's forecast, JPY540 billion is the previous one. You said that this is going to be flat, but it is announced JPY570 billion for core operating profit guidance. So there is a JPY30 billion increase. I'd like to know about this change from Q3. If you look at the Roche earnings, the export sales of Hemlibra and Actemra seem to reflect strong local sales. Am I right? If that is correct, then the export sales of Hemlibra and Actemra, what sort of level that you're looking at in this year?

**Taniguchi [A]:** Thank you very much. Taniguchi speaking. At the time of Q3, yes, we said JPY540 billion or around that. That's what Okuda said, and we officially announce JPY570 billion. Basically, what is strong is the export sales. It has been stronger than we had expected. Actemra, Hemlibra, starting from Actemra, the entry of biosimilar, how do you look at that? From October last year, in our view, of course, our export and local

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sales from Roche are not exactly consistent, but the inventory is in short supply. Maybe there will be more in export. As for Hemlibra, there is a very strong number, especially international sales. There could be some room for upside.

Does that answer your question?

**Wakao [Q]:** Thank you. As for Hemlibra, a follow-up question. Up to Q3, international was about inventory buildup. That was the reason for the increase in international sales. We had thought that in this year the sales could be flat. That's what the equity market expected, but actually, it is going to increase this year. Is it only for international? Or would it be also seen in the US? I'd like to know by country breakdown.

Also, next year and beyond, given the peak sales that you have shared with us, do you have room for growth for Hemlibra? Can we expect an increase in export sales for Hemlibra as well?

**Taniguchi [A]:** For this year, I can't go into details. There may be some misunderstanding that buildup of inventory behind the international sales is the only reason. Up to Q3, according to the disclosure of Roche, I think, in terms of actual sales, it has been greatly increasing. There is a pure net increase that we can expect. But it doesn't mean that sales outside of international are weaker. Continuously, there will be some growth in the US especially, and that has led our export sales as well. From next year onward, it's too early to tell because we have to look at the competitive environment to make comprehensive decisions. I'd like to refrain from commenting further.

**Wakao [Q]:** Thank you. The second question, there are several Go/No-Go decisions to be made for several items. What would be specifically the ones that you're looking at? In the document, for example, in antibodies, there are several projects. Of those antibodies, those that are in the clinical studies, are they subject to Go/No-Go decision? And LUNA18, what is the status?

DONQ52, from early last year, I think you are engaged in out-licensing activities, but now you're more focused on in-house development. From the out-licensing activities perspective, have you encountered some challenges? With the data that you have, you may not be able to do out-licensing as you had expected, and that's why you are more focused on in-house products. Is that true?

**Okuda [A]:** I'd like to answer the question on DONQ52, and as for which one is subject to Go/No-Go decisions, Tanaka will answer the question.

As for DONQ52, as I explained earlier, Phase I clinical trial is underway. In parallel, out-licensing partners are being looked for, and that has been done since last year. As we look for potential partners, what we've decided is that we, on our own, can conduct a Phase II study to maximize DONQ52 value. By conducting the Phase II trial on our own, we can accumulate our insights and experiences. Those are the two reasons why we have decided to conduct Phase II study on our own.

For the second question, Tanaka will answer which one of those projects will be subject to Go/No-Go decision this year.

**Tanaka [A]:** Tanaka speaking. I was asked to answer this question, but at this moment, we're not in a position to comment on which one will be subject to Go/No-Go decision. As for LUNA18, the combination dose escalation study and the monotherapy study are underway. We are not in a position to talk about any progress or results. I'd like to refrain from answering that.

**Wakao [M]:** In 2025 and beyond, whether you can achieve ePoC or not, I think that was the target, but this is not part of the milestone for this year. I would understand that there is not going to be any changes in particular this year. Is my understanding correct?

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**Tanaka [A]:** At this moment, we would like to refrain from answering that question.

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

**Miyata [M]:** Next question is from Mr. Yamaguchi from Citigroup Securities, please.

**Yamaguchi [Q]:** Thank you. My first question is related to NXT007 Phase II. What is the timing of that top line readout? I think there are some major academic society meetings, such as World Hemophilia or ISTH. I believe that there may be few words to tell at the moment, but I would like to understand when you are planning to present the result of Phase II for NXT007.

**Tanaka [A]:** At this point of time, I cannot comment on the timing of the presentation of Phase II study.

**Yamaguchi [Q]:** But I think you are confident in this profile. This has a potential to do better than Hemlibra as some data shows NXT007 have ability to maintain thrombin activity the same as that of a healthy person, right?

**Tanaka [A]:** As a concept of the drug, there is no change in our aim to achieve a level of coagulation activity that reaches the level of healthy individuals or non-hemophiliacs.

**Okuda [A]:** In the Phase I study, we were able to confirm long half-life, which is 10 weeks.

**Yamaguchi [Q]:** My second question is related to the Go/No-Go decision, which has been the focus of today's session. For mid-size molecule, it seems like it's taking longer than expected. Not just LUNA18, but should we expect some impact as a result of Go/No-Go decision on mid-size molecule?

**Tanaka [A]:** Thank you for your question. Tanaka would like to respond. Whether we apply a Go/No-Go decision on mid-size molecule or not, basically, for any project, we are going to apply this Go/No-Go decision approach.

**Yamaguchi [Q]:** Then mid-size molecules are also included and you should be able to accelerate the speed of the development for mid-size molecule.

**Tanaka [A]:** Yes. Enhancement of the speed is the goal of science-based Go/No-Go decision.

**Taniguchi [A]:** This is Taniguchi speaking. For NXT007, I think you kind of asked for the peak sales of NXT007. If you look at page 12, it says over CHF3 billion. That's the category we are referring to.

**Yamaguchi [Q]:** Is this over CHF3 billion?

**Taniguchi [A]:** Yes.

**Yamaguchi [M]:** Thank you. That's all from me.

**Miyata [M]:** Next, Jefferies Securities, Barker-san, please.

**Barker [Q]:** Hi. Stephen Barker. For the forecast for this year, revenue and profit forecast, NEMLUVIO export and royalty income, how much have you incorporated in this year's forecast?

**Taniguchi [A]:** Taniguchi speaking. Thank you for the question. As for NEMLUVIO, it has not reached the threshold yet so it is a part of the "Other products" in overseas sales in the disclosure. If you look at the Supplementary Materials, there are items like others. But how much of that is NEMLUVIO is not disclosed.

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The breakdown information is not subject to disclosure. But the sales in others from this year to next year, there will be more than doubling of increase. A majority of that is from NEMLUVIO.

**Barker [Q]:** Thank you. Then, other revenue and royalty income, Hemlibra was the main reason, as you said. But for this year, export to Hemlibra, if you look at the value, there is not much increase in royalty income.

**Taniguchi [A]:** The Other revenue of JPY172.7 billion is last year. Not much change, but actually, mix has changed. I can't disclose that, but there are products that are slowing down. But there's also one-time income that is included. So there's some increase and decrease. We cannot talk about which product is growing and which product is slowing down.

**Barker [Q]:** The overseas sales of Enspryng are expected to decrease this fiscal year. What is the reason for this?

**Taniguchi [A] :** In terms of Enspryng, the sales scale is smaller compared to Hemlibra and Actemra, much smaller. The timing of shipment and export is not happening like every month or every two months, not regularly. Because of the timing of shipment and exports, there were some changes and fluctuations in numbers in the past, but this is also what is happening in this year.

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

**Miyata [M]:** Thank you very much. Next is from Macquarie Capital, Tony Ren, please.

**Ren [Q]\*:** Hello. Just a couple from me. You guys alluded to that, in 2025, in terms of exports of Hemlibra to Roche, there will be a unit price reduction. I just want to get some understanding of the magnitude of the unit price reduction here. If I look at slide 53, you can see that there is a column called YoY. Hemlibra export appears to be growing at 44.9%. But if you look at the revenue forecast of JPY324.2 billion, that's about a 5% increase. So would it be correct to assume that there will be roughly a 39%, 40% average price reduction on Hemlibra sold to Roche? This feels quite large of price reduction. That's my first question.

The second question, you guys alluded to a few times that GYM329, you will start a combination study in obesity. I just want to see if you have any thinking about what the combination partner would be. Would that be one of the incretins GLP-1s from Roche and Carmot Therapeutics? Thank you.

**Taniguchi [A]:** Thank you for your question. Taniguchi will respond to your first question. With regard to Hemlibra, from 2023 to 2024, it has grown by 44.9%, and from 2024 to 2025, we are not expecting that much growth. We are expecting a 5.4% revenue growth from 2024 to 2025. Volume and FX will be affected on top of the unit price. The detailed breakdown is not disclosed. Because the percentage of emerging markets will grow, then the unit price will come down. However, for the emerging market, volume will grow. So plus/minus net-net, for this fiscal year, we are still expecting a positive growth. The magnitude of the decline of unit price, in terms of that, we are not expecting a big decline of unit price.

**Tanaka [A]:** For the GYM329 obesity combination study, what is the combination drug? That's your question. At this point of time, we haven't decided on that, but incretin is one option we are looking into as a combination drug.

**Ren [Q]\*:** Okay. Thank you very much on both. You guys alluded to last time that the biosimilar Actemra had some supply chain issues. Now that the whole GLP-1 supply chain issue, particularly with Eli Lilly's tirzepatide, has been resolved, do you have any update on your biosimilar Actemra competitors? Has their supply chain issue been resolved?

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**Taniguchi [A]:** We cannot make a comment on the situation of the other company. But Actemra biosimilar, on top of the supply chain issue, there are other factors such as the price of biosimilars and other composite factors. Also, in some of the markets, Actemra, which is the branded product, is preferred by rheumatologists. In 2024, the entry of the biosimilar was slower than our expectation. For 2025, what will be the speed of the entry? I cannot make any comment. But if you look at our sales forecast, we are setting up a somewhat conservative forecast for 2025, anticipating some entry of biosimilars in 2025.

**Ren [Q]\*:** Okay, understood. Very good. Thank you.

**Muraoka [Q]:** Thank you. This is Muraoka from Morgan Stanley. I'd like to ask about DONQ52. Just for clarification, you were looking for partners, but in order to increase value, you decided to conduct Phase II on your own. That's how I understood it. Did you show the PoC or Phase Ic results to potential partners and then decided to proceed on your own, either because you couldn't find any partners or because you thought that it would be more interesting to develop it yourself? Could you explain the decision-making process?

**Okuda [A]:** Okuda speaking. Thank you for the question. We're still conducting Phase I. Also, as for those strategic issues, we would like to refrain from commenting at this point.

**Muraoka [Q]:** I understand. In the Roche pipeline, DONQ52 is clearly included. Is it correct to understand that Roche is just showing this as information from its subsidiary?

**Okuda [A]:** Yes, that is correct. There is no fact that we have licensed out DONQ52 to Roche.

**Muraoka [Q]:** Thank you. Second question. Q1 that we are now in, how do you look at that? Q4 that ended, when viewed on a QoQ basis, the numbers dropped because Q3 was relatively good. But January to March, I think there could be some reactionary effect. Also, Q1 last year had a slow start. So, what I wanted to ask is, do you think it's reasonable to expect that you might be able to report a fairly good start for the first quarter three months from now, even though you've started with flat guidance?

**Taniguchi [A]:** Well, it's been only one month so we don't know what is going to happen for the remaining two months. It's very difficult to figure out. In terms of level of probability or confidence, I would like to refrain from commenting on that.

**Muraoka [Q]:** I understand. The way I put the question wasn't clear. Including the remaining two months, is there anything that you can expect, like changes in inventory or some one-time factors, that could be something that we should be mindful of, either positive or negative factors within the information that can be disclosed?

**Taniguchi [A]:** Nothing in particular.

**Muraoka [M]:** Okay. Thank you.

**Miyata [M]:** Thank you. Next, we'll move on to Ms. Sogi from Sanford Bernstein. Please go ahead.

**Sogi [Q]:** I have two questions. First of all, page 6, the changes from this year to next year. Looking at the overseas sales, the impact of export unit price and sales volume seems to be quite different from the balance shown in previous years. The export unit price reduction impact seems to be high.

My first question is, is the impact coming mainly from Hemlibra in terms of export unit price and sales volume?

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With Hemlibra, international market volume seems to be growing, but in terms of the overall sales, majority of sales are coming from the US and Europe. So I would have assumed that the unit price impact would be limited, although there might be some price lowering pressure. I'm surprised to see this price impact.

Within your scheme of defining export unit price, is it possible for the volume impact to be outweighed by the export unit price reduction?

**Taniguchi [A]:** Taniguchi would respond to this question. This is not only driven by Hemlibra. The contribution of Hemlibra is high, but when you look at the international market, Roche itself has Actemra, which is growing. Alecensa is also growing. All of these are contributing. As long as we have international exposure, this unit price will give us some impact.

We have a contract per product, and I cannot comment or disclose the contract for specific products, but it's not like it's internally fixed. It's a contract between two parties. As long as the two parties agree, if necessary, we can make amendments or changes. But for the specifics, I cannot comment.

The size of this arrow doesn't really have big significance. I know some people measure the size of this arrow, but it's not really a meaningful thing to do.

**Sogi [Q]:** Thank you. From 2023 to 2024, compared to the change between those two years, it seems like 2024 to 2025, the size of the change is bigger now.

**Taniguchi [A]:** Yes.

**Sogi [Q]:** Thank you. My second question is about the early development strategy. I understand that your company has a sound strategy, but what kind of KPIs do you follow to see that your strategy is functioning well or not?

**Tanaka [A]:** Regarding the Go/No-Go decision, it's not like we have set forth clear KPIs. We don't have such KPIs. But when Go/No-Go decisions are thoroughly executed, our development cycle should see faster speed. This would result in outcomes such as faster phase transitions or earlier decisions on project discontinuation.

**Sogi [Q]:** In that case, that is your KPI?

**Tanaka [A]:** No, we don't have a specific KPI for that.

**Sogi [M]:** Understood. Thank you.

[END]

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