

Innovation all for the patients



**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group

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

Conference on FY2023. 12 Financial Results

February 1, 2024

## 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 FY2023. 12 Financial Results	
[Fiscal Period]	FY2023 Annual	
[Date]	February 1, 2024	
[Number of Pages]	51	
[Time]	17:45 – 19:22 (Total: 97 minutes, Presentation: 55 minutes, Q&A: 42 minutes)	
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	5	
	Dr. Osamu Okuda	President & CEO
	Toshiaki Itagaki	Director, Executive Vice President & CFO
	Tetsuya Yamaguchi	Executive Vice President
	Shinji Hidaka	Executive Vice President, Supervisory Responsibility for Marketing & Sales
	Kae Miyata	Head of Corporate Communications Department
[Analyst Names]*		
	Kazuaki Hashiguchi	Daiwa Securities
	Seiji Wakao	JPMorgan Securities
	Hidemaru Yamaguchi	Citigroup Global Markets
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Miki Sogi	AllianceBernstein

\*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:** Thank you very much for attending today's CHUGAI PHARMACEUTICAL CO., LTD.'s financial results briefing for the fiscal year ended December 31, 2023.

I am Miyata of Corporate Communications, and I will be facilitating today's session. Thank you.

Today's event will be a combined on-site session and Zoom webinar. The agenda for today's meeting can be found on the audience screen, on the web screen, and on page three of the presentation materials. Our presentation will follow this agenda. Please note that there will be time for screen capture on each section.

Questions will be taken in batches after all presentations have been completed. The Q&A session is expected to last 30 minutes, so we hope you will be proactive and ask questions. Please note that your audio will be muted during the presentation.

Now, Dr. Okuda will give FY2023 overview and FY2024 forecast.

**Okuda:** My name is Okuda, Company President and CEO. I will provide FY2023 overview and FY2024 forecast.

## FY2023 Overview and FY2024 Forecast



# 2023 Financial Performance

- Revenue exceeded 1 trillion JPY for two consecutive fiscal years, and Core operating profit was comparable YoY. The company achieved YoY increases in revenue and profits, excluding the impact of decrease in sales of the COVID-19-related drug
- Core net income increased for seven consecutive fiscal years

Core (billions of JPY)	2022 Jan - Dec actual*	2023 Jan - Dec actual	Growth		2023 Jan - Dec forecast	Progress (%)
Revenue	1167.8	1111.4	-56.4	-4.8%	1,070.0	103.9%
Domestic sales	654.7	558.0	-96.7	-14.8%	541.7	103.0%
Overseas sales	384.6	416.5	+31.9	+8.3%	378.3	110.1%
Other revenue	128.6	136.9	+8.3	+6.5%	150.0	91.3%
Operating profit	451.7	450.7	-1.0	-0.2%	415.0	108.6%
Operating margin	38.7%	40.6%	+1.9%pts	-	38.8%	-
Net income	317.7	333.6	+15.9	+5.0%	306.0	109.0%
EPS (yen)	193.11	202.71	+9.60	+5.0%	186.00	109.0%

\* Starting from FY2023, Chugai has excluded income from disposal of product rights from revenue. In conjunction with this change, the results for FY2022 have been restated accordingly.

- Domestic sales declined YoY due to the major decrease in sales for the supply of Ronapreve to the government, as well as the effects of the NHI drug price revisions and the market penetration of generic drugs, despite the favorable sales of the mainstay products including Enspryng, Hemlibra, and Tecentriq, in addition to the strong growth of new products such as Polivy and Vabysmo
- Overseas sales increased YoY due to the major increase in the exports of Hemlibra and Alecensa to Roche
- Other revenue increased YoY primarily due to the increase in income related to Hemlibra
- As a result, Core operating profit was comparable YoY to be 450.7 billion JPY, and Core net income increased for seven consecutive fiscal years to 333.6 billion JPY due to a decrease in corporate income tax etc.

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Please see page five. For the full year of 2023, revenue exceeded JPY1 trillion for two consecutive years, reaching JPY1.1114 trillion. Operating profit was JPY450.7 billion, comparable YOY. Overall, the financial results showed a decrease in both sales and profit. However, excluding the impact of the decrease in sales related to COVID-19 therapeutic drugs, both sales and profit increased.

Core net income reached JPY333.6 billion, the seven consecutive years of increase.

Domestic sales were down 14.8%. While sales of new products and mainstay products were strong, sales declined YoY due to the impact of the drug price revision and the penetration of generics. Another factor was a decrease in sales of the government delivery of Ronapreve.

Overseas sales increased by 8.3%. Hemlibra and Alecensa exports to Roche increased significantly.

Other revenue increased 6.5%, mainly due to an increase in revenue related to Hemlibra.

In total, domestic sales declined significantly, resulting in lower sales and profits YoY. However, the results exceeded the full-year forecast.

#### FY2023 Overview and FY2024 Forecast



## 2024 Forecast

- Revenue is expected to exceed 1 trillion JPY for three consecutive fiscal years, driven by increase in overseas sales of mainstay products and royalties, despite the decrease in domestic sales due to the decrease in sales of Ronapreve and the impacts of NHI drug price revisions etc.
- Core operating profit and Core net income are expected to reach a record high

Core (billions of JPY)	2023 Jan - Dec actual	2024 Jan - Dec forecast	Growth (year on year)	
<b>Revenue</b>	<b>1,111.4</b>	<b>1,070.0</b>	<b>-41.4</b>	<b>-3.7%</b>
Domestic sales	558.0	454.9	-103.1	-18.5%
Overseas sales	416.5	467.1	+50.6	+12.1%
Other revenue	136.9	148.0	+11.1	+8.1%
<b>Operating profit</b>	<b>450.7</b>	<b>460.0</b>	<b>+9.3</b>	<b>+2.1%</b>
Operating margin	40.6%	43.0%	+2.4%pts	-
<b>Net income</b>	<b>333.6</b>	<b>335.5</b>	<b>+1.9</b>	<b>+0.6%</b>
<b>EPS (yen)</b>	<b>202.71</b>	<b>204.00</b>	<b>+1.29</b>	<b>+0.6%</b>

- Domestic sales are expected to decrease 18.5% due to the decrease in the supply of Ronapreve to the government and the impacts of NHI drug price revisions and the penetration of generics. Domestic sales excluding Ronapreve are expected to decrease by 4.6%
- Overseas sales are expected to increase significantly due to the major increase in export of Hemlibra, despite the decrease in export of Actemra due to the impact of the biosimilars etc.
- Other revenue is expected to increase due to the increase of Hemlibra-related income and one-time income

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Here is our forecast for 2024.

We expect a decrease in revenue and an increase in profit, with revenue of JPY1.0700 trillion and core operating profit of JPY460 billion.

In Japan, sales are expected to decline significantly due to the impact of the NHI drug price revision and the penetration of generics, in addition to the decline in sales of Ronapreve.

Overseas, while Actemra exports are expected to decline due to the impact of biosimilars, we anticipate a significant increase in Hemlibra exports.

For other revenue, in addition to revenue related to Hemlibra, we expect an increase in one-time income.

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We expect revenue to exceed JPY1 trillion for the three consecutive fiscal years, as the substantial decline in domestic sales and the impact of Actemra biosimilars overseas will be offset by increases in sales of mainstay overseas products and royalty income.

We also forecast record high core operating profit and core net income.

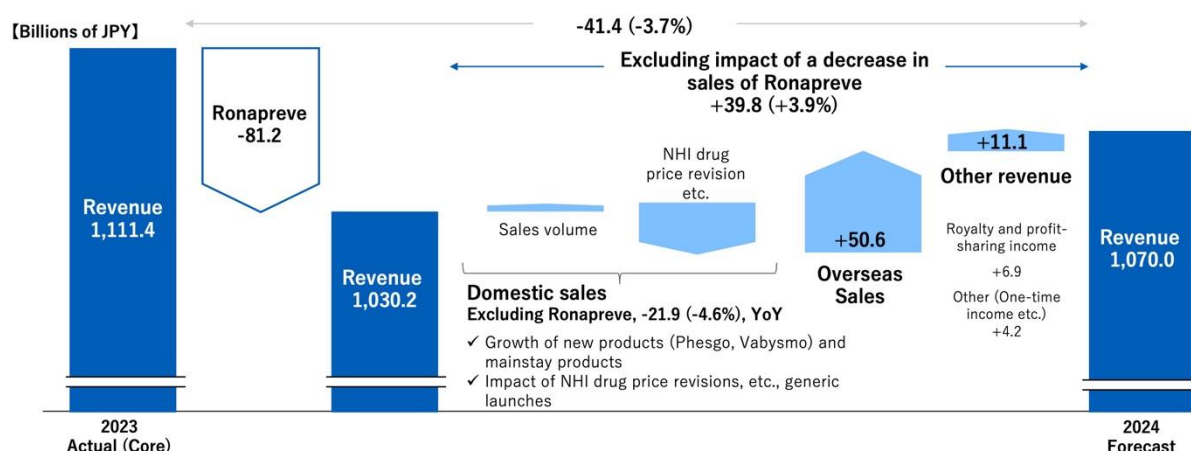
On the next slide, we will look at the change in revenue excluding the impact of the decrease in Ronapreve sales.

FY2023 Overview and FY2024 Forecast



## Topline Analysis of 2024 Forecast

- Overseas sales and other revenue increased while domestic sales decreased mainly due to the impact of decrease in Ronapreve, the NHI drug price revisions and the market penetration of generics
- Increased revenues (+39.8 billion JPY, +3.9%, YoY) excluding the impact of a decrease in sales of Ronapreve (-81.2 billion JPY, YoY)



First, on the left side, subtracting Ronapreve's sales loss of JPY81.2 billion from the FY2023 revenue, we arrive at JPY1.0302 trillion. Comparing this figure to the revenue forecast for FY2024, we see a revenue increase of JPY39.8 billion, or 3.9%. Therefore, excluding the one-time impact of the decrease in Ronapreve revenue, our core business is expected to grow.

The breakdown of the increase in revenue is shown in this waterfall chart.

Domestic sales are expected to be minus JPY21.9 billion YoY, as the impact of drug price revisions and generics could not be fully absorbed by the growth of new and mainstay products.

On the other hand, sales of overseas products and other revenue are expected to grow significantly, increasing by JPY50.6 billion and plus JPY11.1 billion, respectively.

The impact of the decrease in Ronapreve revenue on operating profit will be explained in detail in Mr. Itagaki's financial presentation.

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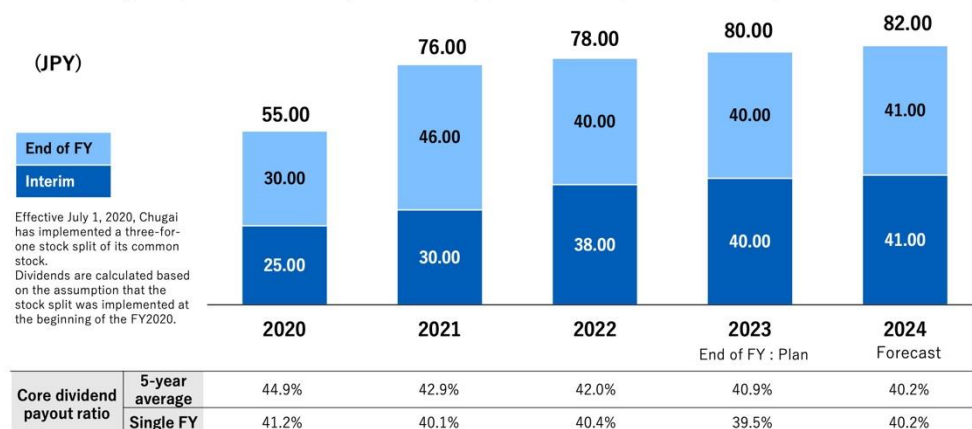


## Contribution to Shareholders

- Focusing on the continuous provision of stable dividends, we expect annual dividends of 82 JPY for FY2024

- Basic profit distribution principles

- ✓ Taking into account strategic funding needs and earnings prospects, Chugai sets a target for a consolidated dividend payout ratio of 45% on average compared with Core EPS, to continuously provide a stable profit allocation of profit to all shareholders.



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Next, I will talk about dividends.

The year-end dividend for FY2023 is JPY40 per share, as planned. Together with the interim dividend of JPY40 per share, the annual dividend was JPY80 per share.

In 2024, we forecast an annual dividend of JPY82, an increase of JPY2 from 2023. This is based on our core policy of providing shareholders with stable dividends on an ongoing basis.

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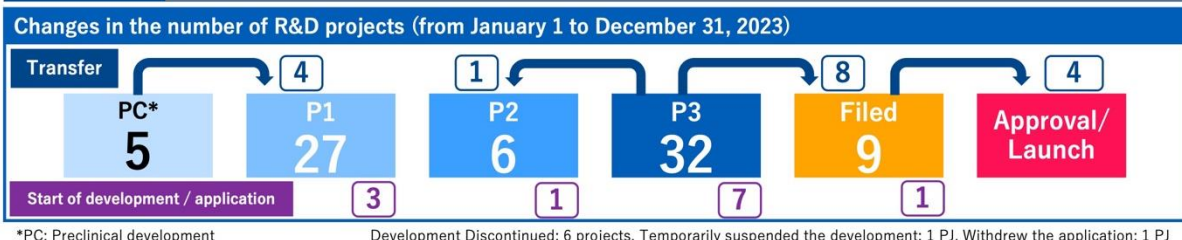
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## Review of Strategic Policies for 2023 (1/2)

### ■ Generally on track in late-stage, early-stage and preclinical-stage development, respectively

<b>Strengthening of RED Function</b>	<b>● Development for mid-size molecule project:</b> Progressed in both quality and quantity despite some delay ✓ Expected delay to obtain ePoC for LUNA18 from 2024 ✓ On the other hand, subsequent mid-size molecule projects have progressed, and 1 project achieved transfer to PC*
	<b>● Continuous creation of new projects and construction of technology infrastructure:</b> Progressed steadily in establishment of technology infrastructure. Open innovation and DX need to be further promoted toward challenging goals
	<b>● Proof of value of in-house pre-PoC projects and strengthening of foundation:</b> Achieved bPoC/ePoC across multiple projects
	<b>● Accelerating open innovation:</b> Established Chugai Venture fund (CVF) and completed its preparation for the full-scale start in 2024



Next, we will review the strategic policies for FY2023.

First of all, in terms of R&D, we are making good progress in late-stage development, early-stage development, and preclinical projects.

The mid-size molecule project, which we expect to be the third pillar of our business, is progressing well in most areas, although the timing of the ePoC acquisition for LUNA18 will be delayed.

With respect to the acceleration of open innovation, we established the Chugai Venture Fund last year and completed its preparations. Starting this year, we will be investing in startup companies to accelerate innovation.

As for early-stage in-house discovery projects, four projects ALPS12, SAIL66, ROSE12, and REVN24 started Phase I trials last year. The pipeline, including Roche in-licensed products, remains extensive, with 27 in Phase I, 6 in Phase II, and 32 in Phase III. We also have nine projects pending and expected to be approved this year.

The FY2023 projects going in and out are summarized in the picture at the bottom of this slide.

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## Review of Strategic Policies for 2023 (2/2)

### ■ Although some gaps remain, we are generally on track

Maximize the value of growth drivers	<ul style="list-style-type: none"> <li>● <b>Enhance value of post-PoC projects:</b> In-house products successfully achieved to file the regulatory applications as planned</li> <li>● <b>Maximizing value of new products and growth drivers:</b> Although Vabysmo did not achieve the challenging plan, Polivy and Enspryng are steadily growing more than expected</li> <li>● <b>Operation model evolution for futuristic business model:</b> Stable operation of SPIRITS, the digital foundation for production functions</li> </ul>
Strengthen business foundation	<ul style="list-style-type: none"> <li>● <b>Foster an organizational culture that continues to produce innovation:</b> Implementation of Early retirement incentive program and promotion of career recruitment/dialogue between supervisors and subordinates, expansion of digital human resource development contents, implementation of measures to improve company-wide digital literacy</li> <li>● <b>Resource creation by business process reform:</b> While ASPIRE* progressed, we are midway through resolving the lack of resources raised as an issue in the employee awareness survey</li> <li>● <b>Sophistication of risk management functions:</b> Progress in building a system to establish a company-wide third-party risk management</li> <li>● <b>Promotion of autonomous management of affiliated companies:</b> Changes to the decision-making process</li> <li>● <b>Measures to address mid-term environmental goals:</b> Decided to implement the measures for Halogenated Hydrocarbon-Free in UK3</li> </ul>

\*ASPIRE: The name of a business and digital transformation program that will deliver cutting edge global standard processes and the next-generation ERP platforms across Chugai Group

#### Hemlibra: Trends of domestic hemophilia A patient share

Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023
29.2%	30.0%	30.8%	31.7%	32.5%

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Next, we discuss growth drivers. For in-house products, applications were filed as planned. In terms of new products, Vabysmo showed a high growth rate of 139%, although it did not achieve its ambitious sales target. Polivy saw growth of 129%. Enspryng, our mainstay product, significantly exceeded the sales target.

With respect to the business foundation, we saw positive results in several initiatives, including the implementation of early retirement incentive program and the promotion of career recruitment. For initiatives where issues remain, we will accelerate our response by clarifying the gaps with our goals.

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## Strategic Policies for 2024

- Continue to focus on strengthening of RED functions, maximizing the value of growth drivers, and strengthening business foundation
- In regard to strengthening business foundation, the strategic policy items were reviewed based on changes in the environment inside and outside the company

1) Strengthening of RED Function	2) Maximize the value of growth drivers	3) Strengthen business foundation
<ul style="list-style-type: none"> <li>➢ Promotion and expansion of development of mid-size molecule projects</li> <li>➢ Continuous creation of new projects and construction of technology infrastructure</li> <li>➢ Proof of value of in-house pre-PoC projects and strengthening of Foundation</li> <li>➢ Accelerating promotion system of Open Innovation</li> </ul>	<ul style="list-style-type: none"> <li>➢ Enhance value of post-PoC projects</li> <li>➢ Maximizing value of new products and growth drivers</li> <li>➢ Operation Model Evolution for futuristic business model</li> </ul>	<ul style="list-style-type: none"> <li>➢ Strengthen HR strategy and business foundation that continues to produce innovation</li> <li>➢ Further promotion of sustainability</li> <li>➢ Organize related systems and reform business processes to introduce ASPIRE</li> <li>➢ New insight business promotion policy</li> </ul>

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In FY2024, as in FY2022 and beyond, we have established three strategic policies. As in the previous year, we will continue to focus on three key areas: strengthening RED function, maximizing the value of growth drivers, and strengthening business foundation.

For strengthening RED function, we will focus on building technical infrastructure, creating and promoting projects, and proving value, with specific goals.

Regarding value maximization of growth drivers, we will promote late-stage development products, work to maximize the value of new and core products and evolve to a more efficient and productive operating model.

In parallel, we will ensure that the foundations described here are strengthened in each value chain.

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## Outlook of Mid- to Long-term Growth to Achieve TOP I 2030

- In the mid term, overcome the impact of overseas Actemra BS and domestic BS/NHI drug price revisions by expanding the indications of in-house products and launching new products, and view sustainable growth
- In the long term, continuous development success of in-house projects will drive further growth

[Hemlibra] Further continuous growth						
[Alecensa] Expected to obtain additional indication for postoperative adjuvant therapy for NSCLC within 2024						
[Enspryng] Following NMOSD, expected to file and obtain approvals for 4 other additional indications sequentially in 2024 and beyond						
[crovalimab] PNH: Expected to be approved and launch in Japan/U.S./EU/China in 2024. In 2025 and beyond, expected to file and obtain approvals for 3 other indications sequentially						
[Projects out-licensed to 3rd parties] Expected to contribute to revenue through filing, approval, and launch of multiple projects sequentially						
[In-house projects] Expected revenue contribution from global launch						
[In-licensed from Roche] Stable contribution to revenue from exclusive marketing of Roche products in Japan						
[Domestic: Impacts of BS/NHI drug price revisions] [Overseas: Impact of Actemra BS]						
2024	2025	2026	2027	2028	2029	2030 and beyond

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Next, I will explain our medium- to long-term growth prospects.

In the medium term, the impact of Actemra biosimilars overseas, the impact of biosimilars in Japan, and NHI drug price revisions in Japan are expected to continue. We anticipate sustainable growth by overcoming these challenges through growth of in-house products, expansion of indications, and the launch of new products.

Although it is difficult to foresee the impact of Actemra biosimilars overseas, we believe that the timing of the launch and the speed of penetration in the U.S., where the market is large, will be key.

In the long term, further growth will be driven by the success of the continuous development of Chugai originated products.

We will continue to strengthen our RED function with the goal of doubling our R&D output and launching in-house global products every year.

Despite uncertainties in the external environment and the success or failure of developed products, we expect the domestic and overseas core business to continue to progress steadily in the future.

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## Expand Research Function in Chugai Pharmabody Research

- Expanding the mid-size molecule drug discovery function of CPR, and repositioning it as a permanent overseas drug discovery research function
- Aim to further promote the provision of innovative new drugs to patients through continuous creation of projects, including joint research with research institutions in Singapore

### Chugai LSP Yokohama:

Creation of development candidate compounds  
Mid-size molecule technology development



Technology Transfer



### CPR :

Primary screening  
Hit generation



Technology transfer for screening of mid-size molecule drug discovery to CPR  
Chugai LSP Yokohama focuses on mid-size molecule drug discovery technology development



Provision of primary lead molecules for antibodies and mid-size molecules

CPR original research

+

External joint research:

- Provision of tools necessary for deep cultivation of disease biology
- New drug discovery targets



Continuous drug discovery  
Project creation

Evaluation of novel drug discovery targets

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We have made the decision to expand our mid-size molecule drug discovery capabilities at Chugai Pharmabody Research (CPR) in Singapore.

Specifically, Chugai Life Science Park (LSP) Yokohama will transfer its screening technology for mid-size molecule drug discovery to CPR, and Chugai LSP Yokohama will focus more on technology development for mid-size molecule drug discovery.

In addition, CPR has operated as a time-limited organization that makes renewal decisions every five years. This time, it will be eliminated and repositioned as a permanent overseas drug discovery research function. In expanding functions, we will relocate to suitable facilities and renovate them, and make the associated ongoing investments.

Chugai provides innovative drug and solutions to patients with its unique science and technology capabilities. Through continuous project creation, including collaborations with research institutions in Singapore, we will aim to promote the provision of further innovative new drugs to patients.

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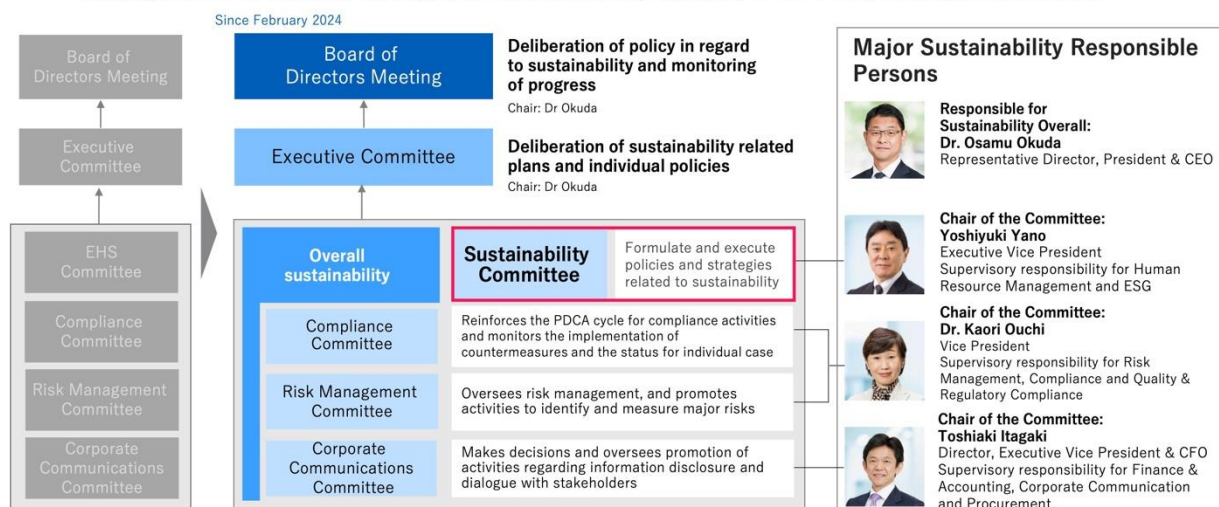
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# Sustainability Promotion System - Review of Management Advisory Committees -

- Established a new management committee to consolidate functions and enable cross-organizational management to further strengthen sustainability initiatives as a key management issue



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With regard to sustainability, we have strengthened our expertise by consolidating functions such as compliance and risk in recent years. On the other hand, with the accelerating changes and sophistication of social demands, including information disclosure, we have determined that we need a scheme to discuss sustainability as a whole in a more specialized and holistic manner. The Sustainability Committee was established on February 1, 2024, to replace the EHS Committee, which was a management advisory committee specializing in environmental, safety, and health issues.

Compliance, risk, and external communications will continue to be discussed and promoted by the existing management advisory committee.

There is no change in the promotion of sustainability and the role of the Board of Directors and the Executive Committee. I chair the Board of Directors and the Executive Committee. I will continue to be responsible for sustainability overall. Executive responsibility is assumed by all members of the Management Committee.

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## New Management Structure

Underline: new position/role  
Excluding removal effective on April 1, 2024

Name	Rank	Supervisory responsibility
Dr. Osamu Okuda	Representative Director, President CEO	Chair of the Board of Directors Chair of the Executive Committee External Affairs and Audit
Iwaaki Taniguchi	<u>Director</u> , Executive Vice President <u>CFO</u>	<u>Finance &amp; Accounting, Corporate</u> <u>Communication and Procurement</u>
Dr. Hitoshi Iikura	<u>Director</u> , <u>Executive Vice President</u> Head of Translational Research Div.	<u>Research, Translational Research, Clinical</u> <u>Development</u>

- Iwaaki Taniguchi and Dr. Hitoshi Iikura are scheduled to be appointed as directors upon approval at the 113th Annual General Meeting of Shareholders to be held on March 28, 2024
- Dr. Hisafumi Yamada, Director, Executive Vice President, and Toshiaki Itagaki, Director, Executive Vice President & CFO, will retire on March 28, 2024

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Finally, I would like to explain our new management structure. At a meeting of the Board of Directors held today, the Company informally decided on the changes to the Board of Directors as indicated here.

Hisafumi Yamada, Director and Executive Vice President, and Toshiaki Itagaki, Director, Executive Vice President and CFO, will retire as of March 28, 2024, and Iwaaki Taniguchi and Hitoshi Iikura will be newly appointed as Directors. The appointment of the new directors will be officially decided at the annual general meeting of shareholders scheduled to be held on March 28.

## Summary

- In 2023, revenue exceeded 1 trillion JPY for two consecutive fiscal years, and Core operating profit was comparable YoY. The company achieved YoY increase in revenue and profits, excluding the impact of decrease in sales of the COVID-19-related drug. Core net income increased for seven consecutive fiscal years
- In 2024, we continue to promote RED SHIFT under the three frameworks of Strengthening of RED function, Maximize the value of growth drivers, and Strengthen business foundation. Chugai aims to promote further provision of innovative new drugs to patients through expansion of CPR functions, etc.
- Revenue for 2024 is expected to exceed 1 trillion JPY for three consecutive fiscal years, driven by increase in overseas sales of mainstay products and royalties, despite the decrease in domestic sales due to the decrease in sales of Ronapreve and the impacts of NHI drug price revisions etc. Core operating profit and Core net income are expected to reach a record high
- In the mid term, we will overcome the impact of overseas Actemra BS and domestic BS/NHI drug price revisions by expanding the indications of in-house products and launching new products, and view sustainable growth. In the long term, we aim for further growth through continuous development success of in-house projects

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That has been my summary. Thank you.

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**Miyata:** Thank you very much. Mr. Yamaguchi will now explain the status of the development pipeline.

Overview of Development Pipeline			
Q4 Topics (1/2)			
As of February 1, 2024			
Launched	<b>Phesgo</b>	"HER2+ BC" and "advanced or recurrent HER2+ CC that has progressed following cancer chemotherapy and is not amenable to curative resection"	November 2023
Approved	<b>Rituxan</b>	Suppression and treatment of antibody-mediated rejection in organ transplantation	December 2023
Filed	<b>Alecensa</b>	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	November 2023 (US/EU/China) December 2023 (Japan)
Initiation of study	<b>avutometinib/VS-6766</b> <b>REVN24</b>	Recurrent LGSOC (combination with defactinib) * Acute diseases	P3 study (December 2023) P1 study (October 2023)
Phase Transition	<b>AMY109</b>	Endometriosis	P1 study→P2 study (January 2024)
Readout	<b>RG6356/SRP-9001</b> <b>Tecentriq</b>	EMBARC study (DMD) did not meet its primary endpoint (favorable secondary endpoints) IMvoke010 study (head and neck carcinoma) did not meet its primary endpoint	October 2023 2023 Q4
Removed from pipeline	<b>Tecentriq</b> <b>semorinemab</b>	IMvoke010 study (head and neck carcinoma): development discontinued Domestic P1 (Alzheimer's disease): development discontinued	

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan) \*Conducted by Verastem Oncology, a global licensee

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**Tetsuya Yamaguchi:** Okay, I will now present the status of the development pipeline.

I will focus on Q4 in this presentation.

We have already announced launches and application filings. Of these, applications have been filed for Alecensa in Japan, the US, Europe, and China as an adjuvant therapy for non-small cell lung cancer. The ALINA trial, for which data were submitted, showed a 76% reduction in the risk of recurrence or death.

In terms of trial initiation, our licensee Verastem Oncology has initiated a Phase III trial of avutometinib in patients with recurrent low-grade serous ovarian cancer.

In addition, REVN24, a small molecule developed in-house, has started Phase I trial. This project is intended for acute illnesses for which there is no curative medication.

Next, items in Phase transition. A Phase II study of AMY109 for endometriosis was initiated in Europe. In Phase I, which was completed, good tolerability and hemodynamics were confirmed in healthy adults and patients with endometriosis.

I will go to the readout and mention SRP-9001 in more detail later.

The head and neck carcinoma IMvoke010 study for Tecentriq was discontinued after the primary endpoint was not met.

Based on the results of the Phase II study conducted by Roche, the development of semorinemab was discontinued and the license will be returned.

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## Q4 Topics (2/2)



As of February 1, 2024

Medical conference	Hemlibra	HAVEN 7 study (babies with severe hemophilia A): American Society of Hematology (ASH)	December 2023
	Kadcyla	KATHERINE study (HER2+ early-stage breast cancer): San Antonio Breast Cancer Symposium (SABCS)	December 2023
Literature publication	nemolizumab	OLYMPIA 2 study* (prurigo nodularis): New England Journal of Medicine (NEJM)	October 2023
	NXT007	Non-clinical research results: Journal of Thrombosis and Haemostasis	November 2023
	DONQ52	Non-clinical research results: Nature Communications	December 2023
Orphan drug designation	Alecensa	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	December 2023 (Japan)
Priority review designation	Alecensa	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	January 2024 (US)
Exercise of option rights by out-licensing partners	EOS789	Worldwide exclusive license to develop, manufacture, and commercialize: Alebund Pharmaceuticals Ltd.	October 2023
Business Transfer	Xeloda	Transfer of the business in Japan: CHEPLAPHARM K.K.	November 2023

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan) \*Conducted by Galderma, an overseas licensee

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Regarding medical conference presentations, we presented the results of HAVEN 7 study in infants up to 12 months with Hemlibra. There was no spontaneous bleeding requiring treatment at the 2-year follow-up and the treatment was well tolerated. The results further strengthen Hemlibra's position as a standard of care.

We are presenting follow-up data from KATHERINE, a Phase III trial for early-stage breast cancer, in Kadcyla. At seven years, a statistically significant survival benefit was observed, indicating the potential contribution of Kadcyla postoperative adjuvant as a standard of care.

In a literature publication, the results of the prurigo nodularis Phase III study of nemolizumab, OLYMPIA 2, have been published in the New England Journal of Medicine.

NXT007 will be explained later.

The binding mechanism of DONQ52 to more than 25 gluten peptides that cause celiac disease was published in Nature Communications.

As an individual case below, the postoperative adjuvant use of Alecensa has received Orphan Designation in Japan and Priority Review designation in the United States. The review period is expected to be shortened.

EOS789 is a drug candidate for the treatment of hyperphosphatemia, which inhibits multiple phosphate transporters. This was discovered by our company. It has been out-licensed to Alebund, which has confirmed in a Phase II trial that it is more effective than phosphorus adsorbent sevelamer. The Company has exercised its option rights and has been granted worldwide development, manufacturing, and marketing rights.

The Japan business for Xeloda has been transferred to CHEPLAPHARM.

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## 2023: Key R&D Milestones

Underlined and bolded are new progress since October 24, 2023

	Product	Indication/Study name	Progress
Projects to be approved	<b>Actemra</b>	Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)	<b>withdrawal</b>
	<b>Hemlibra</b>	Moderate hemophilia A (EU)	<b>approved</b>
	<b>crovalimab</b>	PNH (China)	<b>2024</b>
	<b>Phesgo</b>	<b><u>HER2+ breast cancer/colorectal cancer</u></b>	<b><u>Approved/launched</u></b>
P3/Pivotal readouts	<b>Alecensa</b>	<b><u>ALINA study: NSCLC [adjuvant]</u></b>	<b><u>met PE/filed</u></b>
	<b>crovalimab</b>	COMMODORE 1/2 study: PNH	<b><u>met PE/filed</u></b>
	<b>nemolizumab</b>	ARCADIA 1/2 study <sup>1</sup> : Atopic dermatitis	<b><u>met PE</u></b>
	<b>Tecentriq + Avastin</b>	IMbrave050 study: Hepatocellular carcinoma [adjuvant]	<b><u>met PE</u></b>
	<b>Tecentriq</b>	IMpassion030: early breast cancer [adjuvant]	<b>Development discontinued</b>
	<b>Tecentriq</b>	<b><u>IMvoke010 study: Head and neck carcinoma [adjuvant]</u></b>	<b><u>did not meet PE /development discontinued</u></b>
	<b>Tecentriq+ tiragolumab</b>	SKYSCRAPER-01 study: NSCLC [1st line]	<b>H2 2024<sup>2</sup></b>
	<b>mosunetuzumab+Polivy</b>	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	<b>2024</b>
	<b>delandistrogene</b>	<b><u>EMBARK study: Duchenne muscular dystrophy (DMD)</u></b>	<b><u>did not meet PE (favorable secondary endpoints)</u></b>
	<b>moxeparvovec</b>		

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan)  
 1. Conducted by Galderma, an overseas licensee 2. 2024→H2 2024

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Here is a summary of major R&D events in FY2023. In general, we consider the results satisfactory. We have achieved important milestones for our in-house developed products, including Hemlibra and Alecensa, which are current growth drivers, and crovalimab and nemolizumab, which are expected to be future growth drivers. We believe that we have made steady progress toward future growth.

## 2024: Key R&D Milestones

	Product	Indication/Study name	Progress
Projects to be approved	<b>crovalimab</b>	Paroxysmal nocturnal hemoglobinuria (Japan/US/EU)	
	<b>Alecensa</b>	NSCLC (adjuvant) (Japan/US/EU)	
	<b>Vabysmo</b>	Retinal vein occlusion	
P3/Pivotal readouts	<b>Enspryng</b>	Luminesce study: generalized myasthenia gravis	
	<b>Tecentriq + tiragolumab</b>	SKYSCRAPER-01 study: NSCLC(1st Line)	
	<b>mosunetuzumab</b>	Domestic P1 (Expansion cohort): Follicular lymphoma (3rd Line)	
	<b>mosunetuzumab + Polivy</b>	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	
	<b>Vabysmo</b>	NIHONBASHI study: Angioid streaks	
P2 readouts	<b>GYM329 + Evrysdi</b>	MANATEE study: Spinal muscular atrophy (SMA)	

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

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The next slide shows major events for FY2024. As for in-house discovered products, in addition to the initial approval of crovalimab for PNH and the addition of the Alecensa adjuvant indication, we anticipate the Enspryng readout for the treatment of generalized myasthenia gravis.

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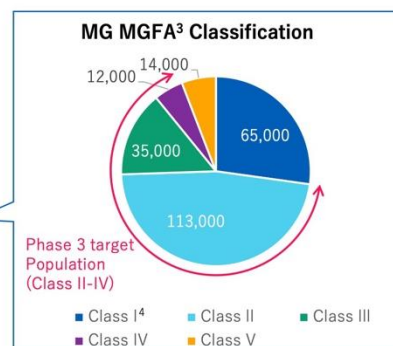
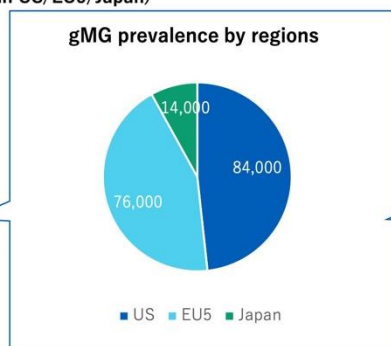
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## Market Opportunity of Enspryng

- Launched in 2020 for the indication of NMOSD. Global sales in 2023 total 256 mCHF
- Readout of Global P3 study for gMG and regulatory filing are expected in 2024. Four indications are simultaneously under development
- First antibody utilizing Chugai's proprietary Recycling Antibody® technology which enables convenient every four-week subcutaneous injection. Confirmed favorable safety profile in the data from clinical studies for NMOSD

Diagnosed prevalence in 2025 (# of patients in US/EU5/Japan)

MOGAD	26,000
TED	69,000 <sup>2</sup>
AIE	3,000-12,000 <sup>1</sup>
gMG	174,000
NMOSD	24,000



1. AIE; Incidence-based with ranges 2. TED: Incidence-based

Source: Citeline data as of Dec. 2023, numbers are rounded

NMOSD: neuromyelitis optica spectrum disorder, gMG: generalized myasthenia gravis, AIE: autoimmune encephalitis, TED: thyroid eye disease, MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease

3. MGFA: Myasthenia Gravis Foundation of America

4. Class I is not included in gMG

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The readout shows the marketability of Enspryng.

Enspryng was launched in 2020 for the indication of NMOSD, with global sales exceeding JPY40 billion last year. We expect further growth with the four indications currently under development.

We believe that the success of the trial for generalized myasthenia gravis, which has a large number of patients in major countries, is particularly significant. Although there are several competing products, we believe that Enspryng's mechanism of action of inhibiting IL-6 signaling, the convenience of four-weekly subcutaneous administration, and its favorable safety profile will be important differentiating factors.

The slide shows the number of patients with generalized myasthenia gravis by major country or MGFA class. The Phase III trial targets Class II to Class IV.

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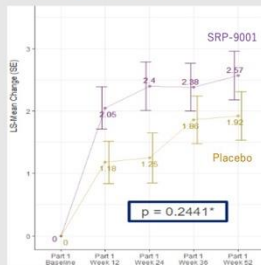
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# delandistrogene moxeparvovec (RG6356/SRP-9001)

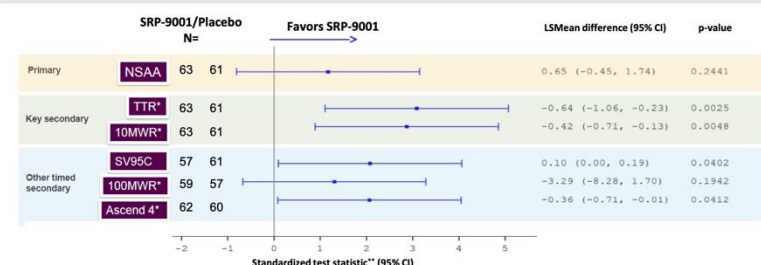
Global Phase 3 EMBARK study did not reach the primary endpoint, but shows positive efficacy outcomes on all timed functional key endpoints.

## Primary Endpoint (NSAA)



- SRP-9001-treated patients improved 2.6 points on their NSAA total score at 52 weeks compared to 1.9 points in placebo-treated patients (0.65; n=125; p=0.24).
- The NSAA is a 17-item rating scale used to measure functional motor abilities in ambulant children with DMD. It is used to monitor the progression of the disease and treatment effects in clinical studies for DMD.

## Key secondary functional EPs (TTR, 10MWR) with clinically significant treatment benefit



- Both key pre-specified functional secondary endpoints demonstrated robust evidence for a clinically meaningful treatment benefit across age groups in SRP-9001-treated patients (age of 4-7) compared to placebo at 52 weeks.
- TTR (Time To Rise) predicts altered trajectories for the time to loss of ambulation in natural history. At 52w, 3% of SRP-9001-treated patients showed a TTR >5sec compared to 16% in the placebo group (n=124, p=0.0135)<sup>a</sup>.
- Safety: Pattern and severity of AE/SAE were consistent with prior studies, no deaths and no discontinuations occurred.
- Based on the results, Chugai will work together with Sarepta and Roche to consult with regulatory authority in Japan.

NSAA: North Star Ambulatory Assessment; TTR: Time To Rise from floor; 10MWR: 10m walk run test; SV95C: stride velocity 95C measured with ankle pedometer Syde; 100MWR: 100m walk run test; Ascend 4: time to climb 4 stairs  
 \*\*Lines plot standardized t-test statistic (+/- 1.96) after dividing LSM (95%CI) by standard error; t-test statistic signs reversed to align favorable directions among effect endpoints (endpoints with \*)  
 Source: Sarepta Therapeutics Update, 30 Oct 2023 <https://investorrelations.sarepta.com/static-files/4871976b-aebc-4ab1-b598-b9ad13c560b1> (Accessed Jan 2024)

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The next slide shows the results of the Phase III study of SRP-9001 for Duchenne muscular dystrophy.

First, the EMBARK study is for patients between the ages of four and seven years who are ambulatory. Although the primary endpoint of motor function evaluation, NSAA was not met, clinically meaningful results were obtained for important secondary endpoints.

In particular, time to rise, or TTR, is associated with loss of ambulatory function. At 52 weeks, only 3% of patients in the SRP-9001 group had a TTR greater than five seconds, compared to 16% in the placebo group, indicating that SRP-9001 is expected to improve the TTR.

We will work with Sarepta and Roche to file an application in Japan to contribute to the treatment of Duchenne muscular dystrophy, a serious and progressive neuromuscular disease.

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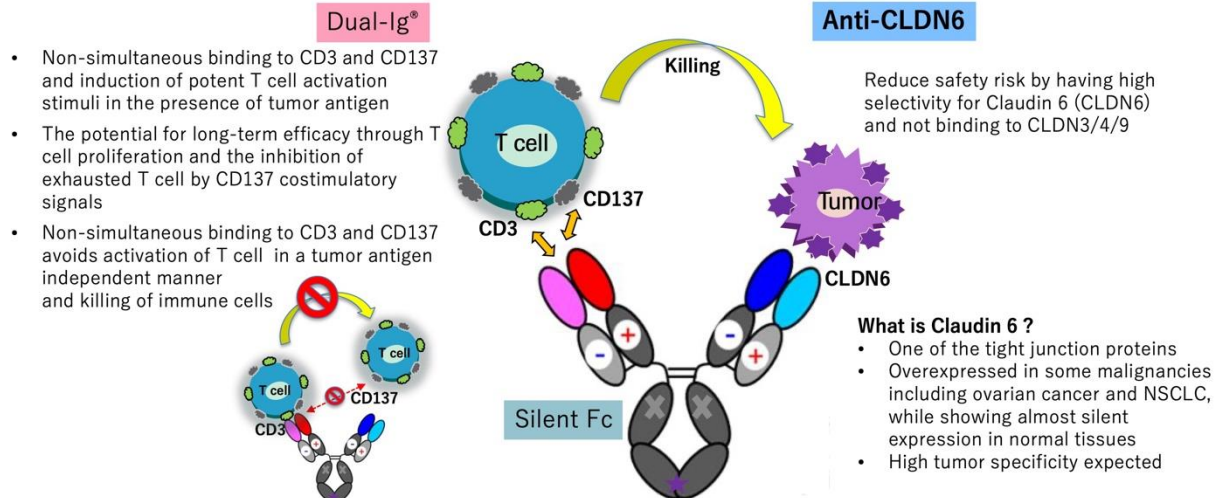


# SAIL66: Anti-CLDN6/CD3/CD137 trispecific (Dual-Ig®)



## Next Generation T-cell Redirecting Antibody Targeting Claudin 6 using our Dual-Ig® Technology

Phase 1 study in patients with CLDN6-positive solid tumors is currently ongoing.



25

In the next slide, we will introduce the mechanism of action of SAIL66, which was discovered in-house and presented at the American Association for Immunology of Cancer in November last year.

SAIL66 is a next-generation T cell redirecting antibody based on our proprietary Dual Ig technology. It targets CLDN6, which is overexpressed in some malignant tumors.

Dual Ig technology allows one arm of the antibody to bind to CD3 and CD137 expressed on T cells, but not simultaneously. This induces CD3 activation and CD137 co-stimulation of T cells in the presence of tumor cells, without inducing T cell-to-cell killing.

SAIL66 is highly selective for CLDN6 and is expected to exert a strong anti-tumor effect through potent and sustained T-cell activation at the site of tumor.

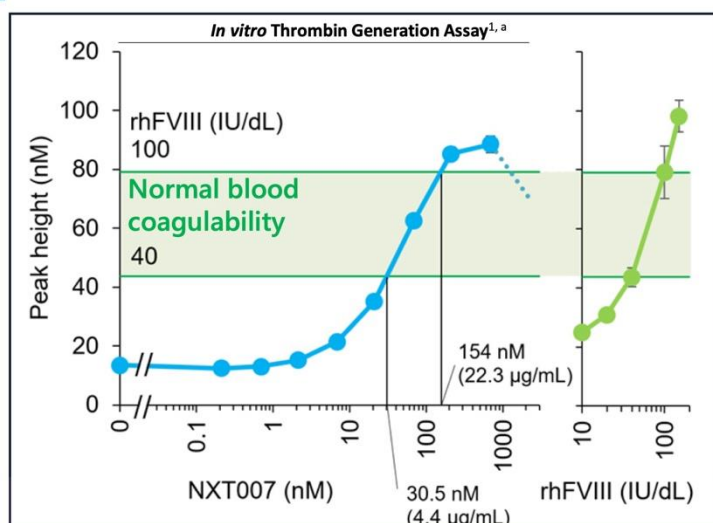
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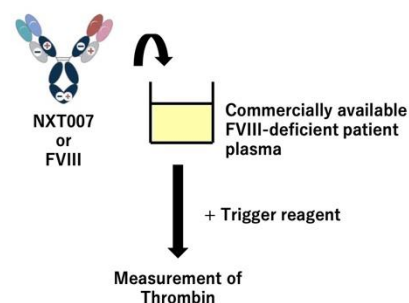
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## NXT007 Demonstrated Possibility of Maintaining Blood Coagulability Equivalent to Healthy Individuals in People with Hemophilia A



### Non-clinical research data (*in vitro*)



<sup>1</sup> Yuri Teranishi-Ikawa et. al. *Journal of Thrombosis and Haemostasis* 2023 (partially modified)  
<sup>a</sup> tissue factor triggered

26

Next, we would like to introduce the data from the non-clinical study of NXT007, which we published in November last year.

This is the result of a thrombin generation test in which various concentrations of NXT007 are added to plasma from hemophilia A patients to measure blood coagulation ability.

The range shown in green on the graph indicates normal blood coagulability with a factor VIII activity of 40 to 100 IU/dL. NXT007, shown in the blue graph, reaches the range of normal blood coagulability as the concentration is increased, indicating the possibility of maintaining blood coagulability equivalent to that of healthy individuals.

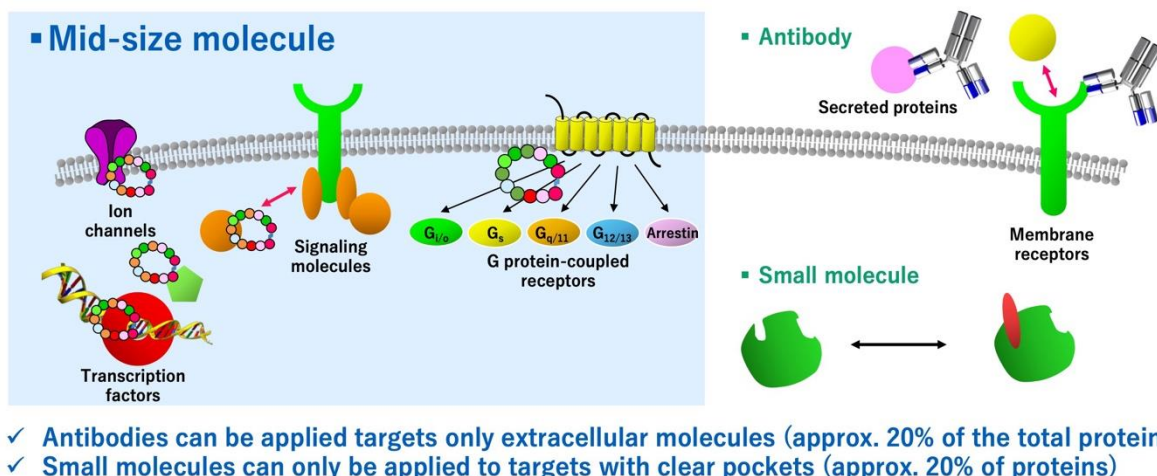
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## Chugai's Mid-Size Molecule Can Address Intracellular Tough Targets Undruggable by Small Molecules and Antibodies



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The next slides cover the mid-size molecule platform. The Chugai mid-size molecule platform was explained at the R&D briefing at the end of last year, and I will review the key points in two slides.

First, the antibody shown in the upper right corner of the slide has a high affinity for the target, but the molecule is too large to enter the cell. Extracellular proteins are said to comprise approximately 20% of total proteins.

On the other hand, the small molecule shown in the lower right corner of the slide can enter cells but requires a clear pocket on the target molecule.

Therefore, the many proteins that are present in the cell and have no clear pocket, such as in the case of intracellular protein-protein interactions, represent a vast untapped field of drug discovery that cannot be approached by small molecules or antibodies.

Mid-size molecules are a new drug discovery modality that can approach these so-called tough targets, which have been difficult to discover with small molecules and antibodies.

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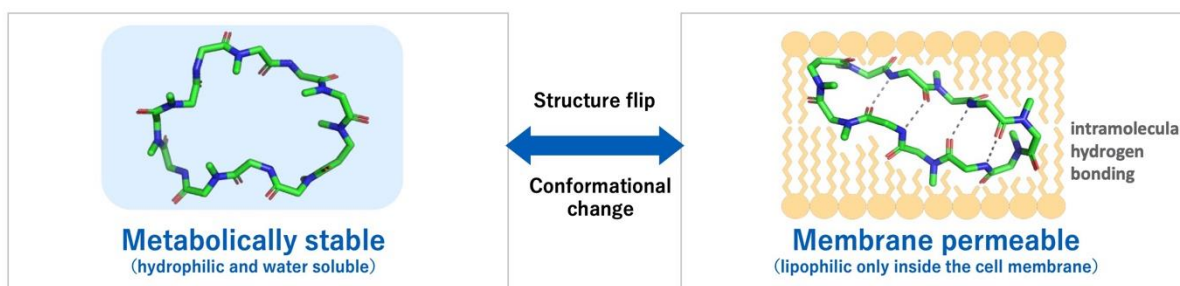
## Chugai has Established Unique Mid-Size Molecules Technology

“Chugai Criteria” to create drug-like mid-size molecule beyond “Rule of 5”



**Oral bioavailability    Intracellular targeting    High affinity binding**

**Cyclic peptides with 9-11 amino acids, more than half should be N-alkylated**



Ohta et al, JACS. 2023 28

The next slide shows our approach to mid-size molecules: a cyclic peptide with a molecular weight of about 500 to 2,000, consisting of 9 to 11 amino acids, the majority of which are N-alkylated.

As you can see on the right side of the slide, the cyclic peptide flips inside the cell membrane, and the lipophilic moiety is positioned on the outer side, allowing it to pass through the cell membrane.

On the other hand, on the left side, inside or outside the cell, the hydrophilic moiety is positioned toward the outside of the molecule, making it more stable against metabolism.

Mid-size molecules can be administered orally and still enter the cell and exert protein-protein interactions with high affinity. It is a modality that combines the good features of antibodies and small molecules.

Furthermore, through the integration of biotechnology and chemistry, we have created a drug discovery platform that will provide commercial value. At present, we have 30 mid-size molecule projects.

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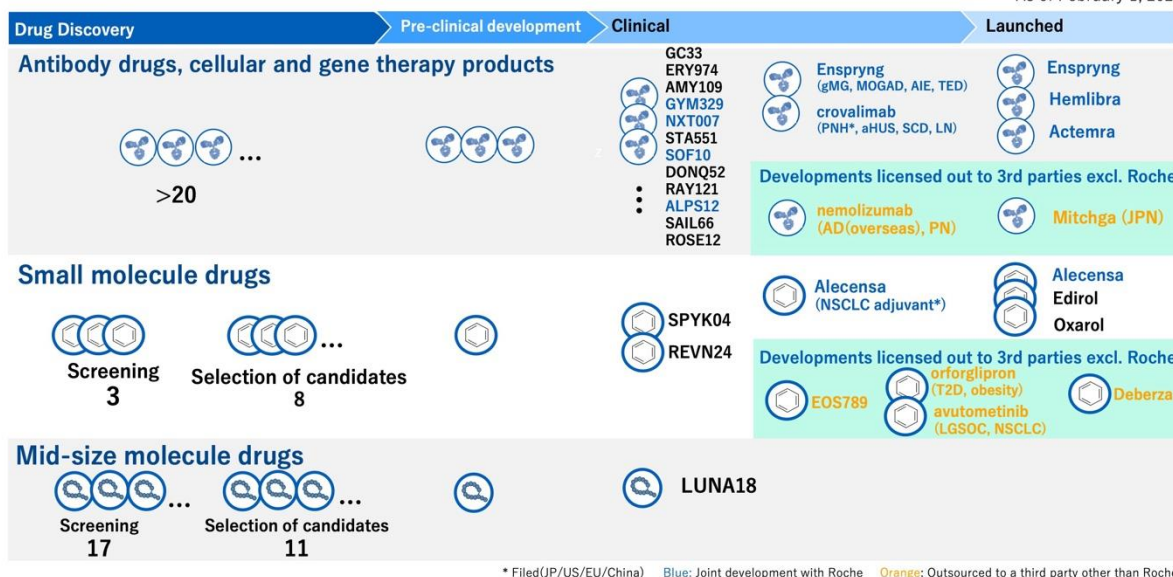
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## Portfolio of Each Modality



As of February 1, 2024



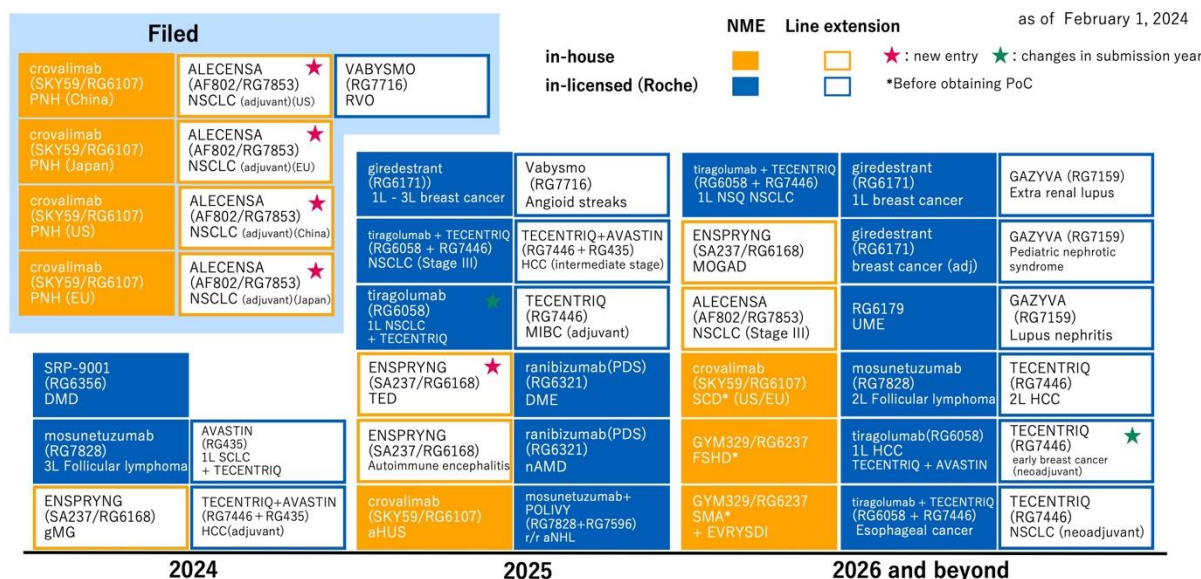
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The next slide shows the status of the portfolio for each modality. We have an abundance of in-house created projects, and we believe that we are making good progress.

## Projected Submissions (Post PoC NMEs and Products)



as of February 1, 2024



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Finally, this slide covers the upcoming application schedule. As always, red stars indicate new additions and green stars indicate changes in the year of application. The following slides are for your reference. That is all from me.

**Miyata:** Thank you very much. Next, Mr. Itagaki will provide an overview of the consolidated financial results for the fiscal year ended December 31, 2023.

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

(Billions of JPY)	IFRS results	Non-core items		Core results	Non-core items	(Billions of JPY)
		Intangible assets	Others		Intangible assets	
<b>Revenue</b>	<b>1,111.4</b>			<b>1,111.4</b>		
Sales	974.5			974.5		
Other revenue	136.9			136.9		
Cost of sales	-413.3	+1.2	+0.1	-412.0	Amortization	+1.6
Research and development	-174.9	+5.4	+6.7	-162.8	Impairment	+5.1
Selling, general and administration	-112.6		+10.6	-102.0		
Other operating income (expense)	28.6		-12.5	16.1	<b>Others</b>	
<b>Operating profit</b>	<b>439.2</b>	<b>+6.6</b>	<b>+4.9</b>	<b>450.7</b>	Restructuring expenses, etc. including gain on disposal of assets	-5.5
Financial account balance	4.6			4.6	Early retirement incentive program	+10.3
Income taxes	-118.3	-2.0	-1.4	-121.8		
<b>Net income</b>	<b>325.5</b>	<b>+4.6</b>	<b>+3.5</b>	<b>333.6</b>		
<b>EPS (JPY)</b>	<b>197.80</b>			<b>202.71</b>		

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**Itagaki:** Thank you very much. Please turn to page 44.

This is a non-core adjustment, which means that the adjustment transactions listed on the right are almost the same as before, but there are certain trends that are different. In the Others section, the top row, which used to be titled business office restructuring expenses, etc. now includes the phrase including gain on disposal of assets.

Until now, the cost side had been incurred in the form of accelerated depreciation or removal costs for Gotemba and Kamakura, and so on. However, we have now decided to transfer a portion of Gotemba and Kamakura, and a gain on sale has been recorded in Q4.

As a result, the gain on sale was larger than the closure-related expenses, and the offsetting result was JPY5.5 billion on the revenue side. This means that JPY5.5 billion of revenue was subtracted in this non-core adjustment.

The amount of JPY10.3 billion has been fixed for early retirement incentives, which includes additional retirement benefits and outplacement expenses. After adjusting for these non-core transactions, operating profit on a core basis was JPY450.7 billion, and net income was JPY333.6 billion.

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## P/L Jan – Dec (Year on Year)

(Billions of JPY)	2022	2023	Growth	
<b>Revenue</b>	<b>1,167.8</b>	<b>1,111.4</b>	<b>- 56.4</b>	<b>- 4.8%</b>
Sales	1,039.2	974.5	- 64.7	- 6.2%
Domestic	654.7	558.0	- 96.7	- 14.8%
Overseas	384.6	416.5	+ 31.9	+ 8.3%
Other revenue	128.6	136.9	+ 8.3	+ 6.5%
Cost of sales	-475.0	-412.0	+ 63.0	- 13.3%
(cost to sales ratio)	45.7%	42.3%	-3.4%pts	-
Research and development	-143.7	-162.8	- 19.1	+ 13.3%
Selling, general and administration	-98.8	-102.0	- 3.2	+ 3.2%
Other operating income (expense)	1.4	16.1	+ 14.7	12 times
<b>Operating profit</b>	<b>451.7</b>	<b>450.7</b>	<b>- 1.0</b>	<b>- 0.2%</b>
(operating margin)	38.7%	40.6%	+1.9%pts	-
Financial account balance	-2.1	4.6	+ 6.7	-
Income taxes	-131.8	-121.8	+ 10.0	- 7.6%
<b>Net income</b>	<b>317.7</b>	<b>333.6</b>	<b>+ 15.9</b>	<b>+ 5.0%</b>
<b>EPS (JPY)</b>	<b>193.11</b>	<b>202.71</b>	<b>+9.60</b>	<b>+ 5.0%</b>

### Domestic sales

Decrease in the supply of Ronapreve to the government

### Overseas sales

Significant increase in sales of Hemlibra and Alecensa

### Other revenue

Increase in income of Hemlibra and one-time income

### Cost of sales

Cost to sales ratio improved due to product mix, etc.

### Research and development expenses

Increase due to investments in research and early development, including start of operations at Chugai Life Science Park Yokohama and progress of development projects

### Selling, general and administration expenses

Increase in various expenses

### Other operating income (expense)

Increase in income from disposal of product rights and gain on sales of property, plant and equipment, etc.

### Net income

Increase due to decrease in income taxes and improvement in financial account balance, etc.

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I will now explain the full-year results on a core basis. Please see page 45.

First of all, revenue exceeded JPY1 trillion for the second consecutive year. Operating profit exceeded JPY450 billion for the third consecutive year, with the operating profit margin returning to above the 40% level.

Looking at the breakdown, first of all, revenue itself was JPY1.1114 trillion, a 4.8% decrease because of the impact of Ronapreve.

In Japan, decreased by JPY96.7 billion, but excluding Ronapreve, sales would have increased.

Overseas, Hemlibra and Alecensa continued to perform well, growing 8.3%.

Other revenue also grew by 6.5%, mainly due to royalty and one-time revenue from Hemlibra.

The cost ratio of manufactured goods was 42.3%. The improvement was mainly due to changes in the product mix, which improved by 3.4 percentage points.

As for expenses, SG&A expenses increased only JPY3.2 billion, while R&D expenses increased JPY19.1 billion, in line with the RED SHIFT strategic policy.

Other operating profit totaled JPY16.1 billion, including a gain on the sale of Bonviva.

As a result, operating income was JPY450.7 billion, on par with the previous year's record high. The operating margin increased 1.9 percentage points to 40.6%.

In addition, financial income and expenses improved due to gains on foreign exchange derivatives and a decrease in items such as corporate income tax burden, resulting in a 5% increase in net income to JPY333.6 billion, a record high for the seventh consecutive year.

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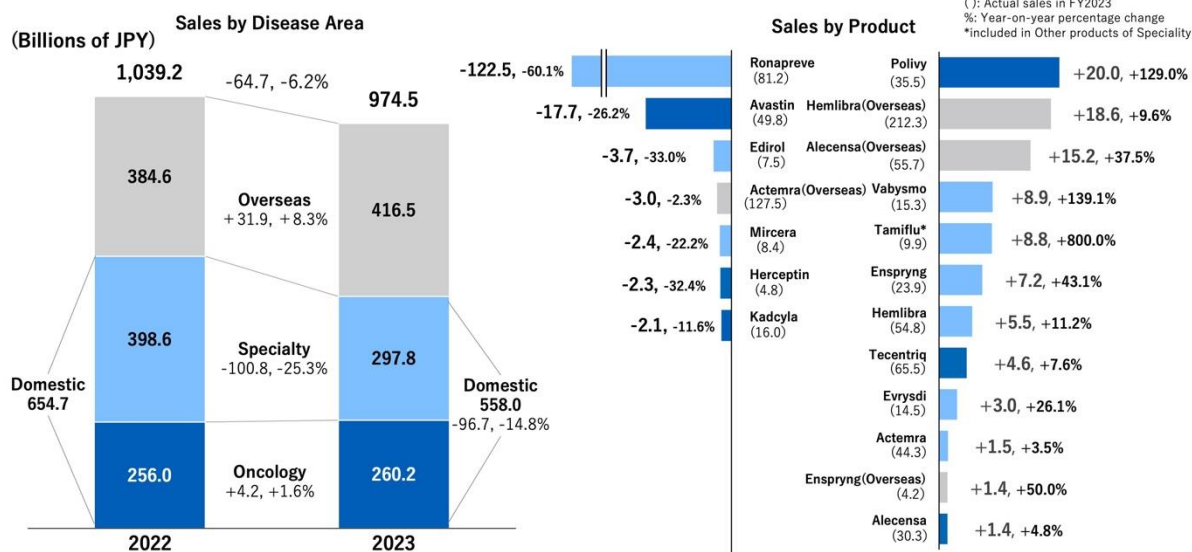
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# Sales Jan – Dec (Year on Year)



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Page 46 is a breakdown of changes in manufactured goods.

First is the oncology area in Japan, where sales increased by 1.6%. The decrease in sales of Avastin, Herceptin, and Kadcyla, which have been affected by NHI price revisions, biosimilars, and competitor products, was absorbed by the increase in sales of Polivy, Tecentriq, and Alecensa.

Specialty sales were down 25.3%. This was due to a JPY122.5 billion decline in sales of Ronapreve. Excluding the decrease in revenue from Ronapreve, the increase would be JPY25.8 billion in domestic sales. Vabysmo, Enspryng, Hemlibra, Evrysdi, Actemra, and many others have seen increases in sales. In addition, due to the influenza pandemic, Tamiflu recorded an increase of JPY8.8 billion, the first time in a long time that the product showed an increase in sales.

Overseas growth was 8.3%, with Hemlibra, Alecensa, and Enspryng posting solid export growth.

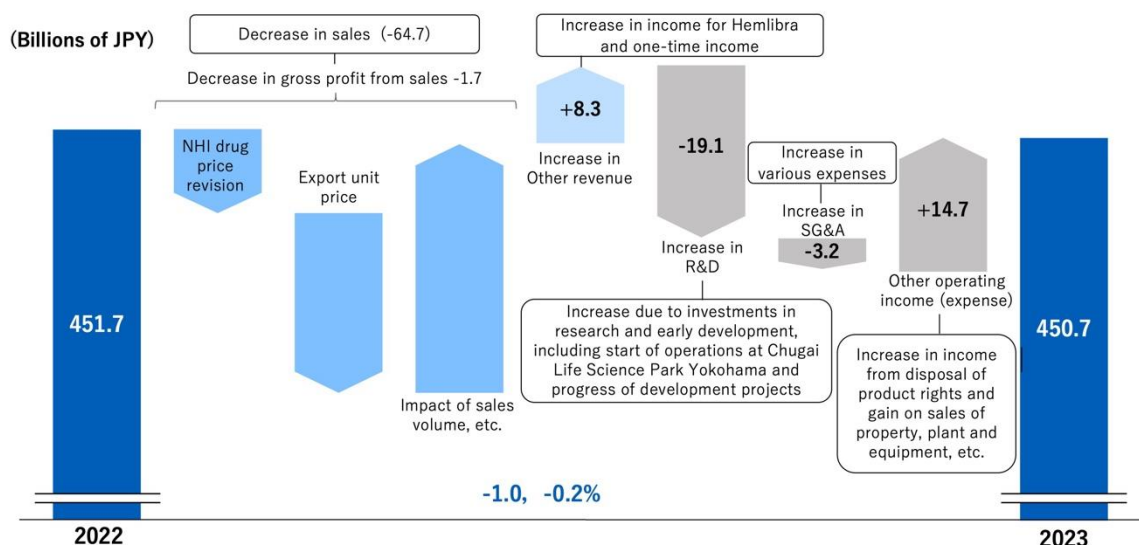
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# Operating Profit Jan – Dec (Year on Year)



47

Next, on page 47, is a breakdown of the increase in operating profit.

From the left, first, gross profit decreased by JPY1.7 billion. As you can see, we were not able to absorb 100% of the negative impact of the price revision and export unit price by increasing exports. The arrow is pointing upward due to the impact of the volume here, but the growth was sluggish due to the impact of the drop in Ronapreve and other factors.

The increase in other revenue was JPY8.3 billion. This includes, of course, the impact of the Hemlibra Royalty 2, which ended in FY2022. The negative impact of loss of Royalty 2 of JPY11.2 billion is included here. Excluding this, other revenue increased by JPY19.5 billion.

The cost aspect has already been explained.

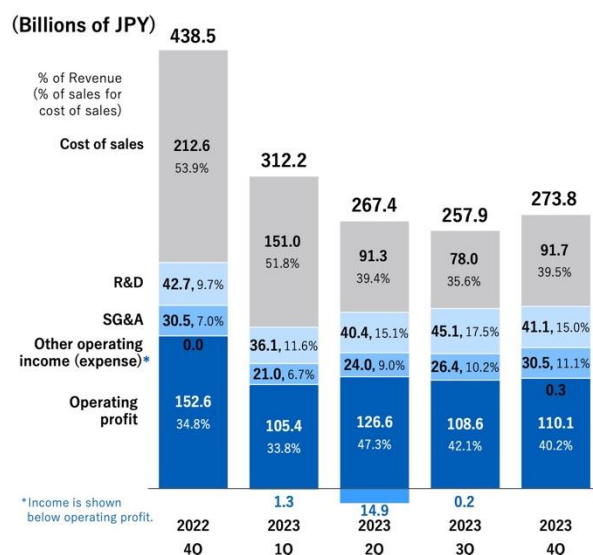
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## Structure of Costs and Profit by Quarter



### Year on Year (vs. 2022 Q4)

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

**R&D:** difference from the timing of incurred expenses

**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:** -42.5 billion JPY, -27.9%

### Quarter on Quarter (vs. 2023 Q3)

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

**R&D:** difference from the timing of incurred expenses

**SG&A:** increase due to the annual upward trend of cost

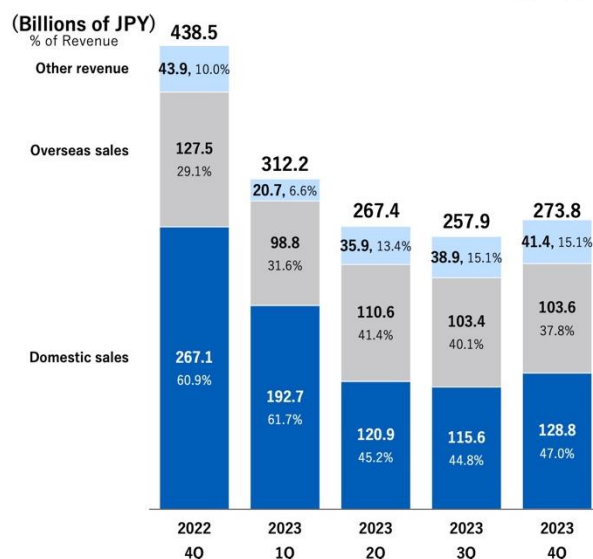
**Other operating income (expense):** same level as the previous quarter

**Operating profit:** +1.5 billion JPY, +1.4%

48

On page 48, we show the quarterly profit and loss. One of the reasons for the bumpy quarter is whether or not Ronapreve was delivered to government. The second reason is the timing of exports.

## Structure of Revenue by Quarter



### Year on Year (vs. 2022 Q4)

**Domestic sales:** decrease due to the absence of Ronapreve supplied to the government

**Overseas sales:** decrease in sales of Hemlibra and Actemra

**Other revenue:** decrease in royalty income of Actemra, etc.

### Quarter on Quarter (vs. 2023 Q3)

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

**Overseas sales:** increase in sales of Actemra and Alecensa, offsetting the decrease in sales of Hemlibra due to the timing of shipment

**Other revenue:** increase in royalty income of Hemlibra, etc.

49

Page 49. First of all, the figure for Ronapreve in Q4 of FY2022 was JPY142.8 billion. In addition, JPY81.2 billion in government deliveries were also recorded in Q1, so it can be seen that sales of domestically manufactured goods are inflated by that amount, especially during these two periods on the far left.

Next, if you look at the overseas sales of products, you will see an increase in FY2022 Q4. The figure in the next quarter, Q1 of the following year, has declined. This shows the impact of export timing here.

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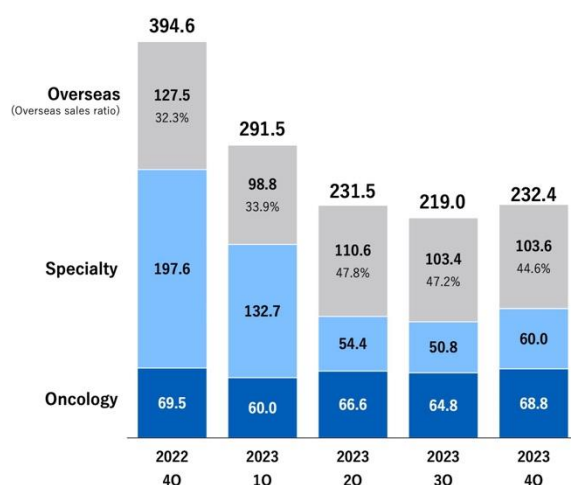
Changes for individual products are shown on the next page.

## FY2023 Consolidated Financial Overview (Core)



# Structure of Sales by Quarter

(Billions of JPY)



## Year on Year (vs. 2022 Q4)

Oncology	Avastin:	-5.1	Polivy:	+3.6
	Phesgo:	+0.7		
Specialty	Ronapreve:	-142.8	Tamiflu*:	+3.6
	Enspryng:	+1.9	Vabysmo:	+1.4
Overseas	Hemlibra:	-18.2	Actemra:	-9.3
	Alecensa:	+4.3		

## Quarter on Quarter (vs. 2023 Q3)

Oncology	Tecentriq:	+1.3	Alecensa:	+0.7
	Phesgo:	+0.7		
Specialty	Tamiflu*:	+3.0	Enspryng:	+1.1
	Actemra:	+0.9	Vabysmo:	+0.6
Overseas	Actemra:	+19.5	Alecensa:	+11.3
	Hemlibra:	-27.4	Enspryng:	-3.3

\*Included in Other products of Specialty

50

As shown in detail on the right side of this page, the quarterly comparisons show a three-digit increase or decrease in overseas Ronapreve, Hemlibra, Actemra, and Alecensa.

I think it would be good for you to look at the overall situation, not the quarterly increase or decrease. In the case of Actemra, there was an explosion of temporary demand relating to COVID-19. While that demand has largely settled, the excess inventory in the market has almost been corrected as of the end of the fiscal year. In addition, there were concerns about the impact of biosimilars last year, but I believe that Actemra exports last year remained mostly calm, without any impact from biosimilars.

Hemlibra was affected by the adjustment of Roche's safety stock, which probably had an impact of about JPY20 billion on our exports. On the other hand, our exports are growing significantly, driven by strong market demand in the Roche territory.

The effects of the inventory buildup that occurred approximately two years ago have largely been eliminated, and our exports are growing in parallel with market penetration.

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## P/L Jan – Dec (vs. Forecast)

(Billions of JPY)	2023		+/-	Achiev.
	Forecast	Actual		
<b>Revenue</b>	<b>1,070.0</b>	<b>1,111.4</b>	<b>+ 41.4</b>	<b>103.9%</b>
Sales	920.0	974.5	+ 54.5	105.9%
Domestic	541.7	558.0	+ 16.3	103.0%
Overseas	378.3	416.5	+ 38.2	110.1%
Other revenue	150.0	136.9	- 13.1	91.3%
Cost of sales	- 405.0	- 412.0	- 7.0	101.7%
(cost to sales ratio)	44.0%	42.3%	-1.7pts	-
Research and development	- 165.0	- 162.8	+ 2.2	98.7%
Selling, general and administration	- 100.0	- 102.0	- 2.0	102.0%
Other operating income (expense)	15.0	16.1	+ 1.1	107.3%
<b>Operating profit</b>	<b>415.0</b>	<b>450.7</b>	<b>+ 35.7</b>	<b>108.6%</b>
(operating margin)	38.8%	40.6%	+1.8pts	-
<b>Net income</b>	<b>306.0</b>	<b>333.6</b>	<b>+ 27.6</b>	<b>109.0%</b>
<b>EPS (JPY)</b>	<b>186.00</b>	<b>202.71</b>	<b>+ 16.71</b>	<b>109.0%</b>

### Domestic sales

Various products outperformed the forecast (see next slide)

### Overseas sales

Sales of Hemlibra, Actemra and Alecensa exceeded the forecast

### Other revenue

One-time income and income for Hemlibra were lower than the forecast

### Cost of sales

Cost to sales ratio improved compared to the forecast due to the impact of product mix, etc.

### Research and development expenses

Mostly in line with the forecast

### Selling, general and administration expenses

Mostly in line with the forecast

### Other operating income (expense)

Mostly in line with the forecast

51

On page 51, we show how well the Company met the full-year forecast that was announced at the beginning of the fiscal year. Revenue was 103.9% of the target, operating profit was 108.6% of the target, and net income was 109% of the target. We exceeded the target for all of these figures.

Revenue exceeded the forecast both domestically and internationally, but the achievement rate for other revenue was only 91.3%. There are two reasons for this: some milestone revenues that we thought would be recorded in Q4 were shifted to the following Q1.

The other reason is that royalty income from Roche was slightly below the initial forecast. The royalties we receive are based on the conversion of all of Roche's global sales into Swiss francs, multiplied by a percentage.

Although sales of Hemlibra in Roche territory were very strong, the Swiss franc was strong against other currencies, especially against the US dollar, the largest market, last year, and we did not expect it to be that strong at the beginning of the period. This had an impact on our royalty income, which was lower than we had expected at the beginning of the period.

The cost to sales ratio improved by 1.7 percentage points from the beginning of the period. Exports of our original products, which have a low cost to sales ratio, were much higher than expected.

Although there were some positive and negative factors in terms of expenses, overall, we were able to keep within the total budget through cost control.

In light of the above, the fact that operating profit exceeded the forecast by JPY35.7 billion can be summed up in one phrase: sales in the domestic market and overseas exports were stronger than expected.

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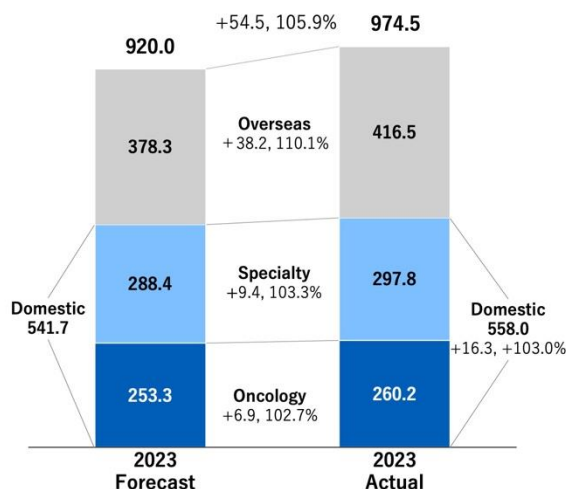
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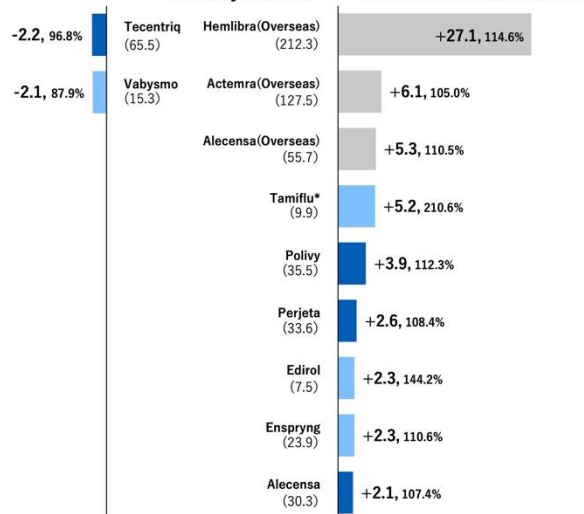
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# Sales Jan – Dec (vs. Forecast)

Sales by Disease Area  
(Billions of JPY)



Sales by Product



52

Now, let's look at the ratio of individual product sales to the forecast. See page 52.

Oncology, specialty, and overseas areas all exceeded forecasts. Looking at the results on an individual basis, first of all, Tecentriq and Vabysmo fell slightly short of the plan. This is because the forecast itself was bullish, as we had already explained during the term.

Many other products exceeded expectations, as you can see here. In oncology, Polivy, Perjeta, and Alecensa, and in specialty, Edirol and Enspryng each landed in the double-digit billion yen range.

Next, Tamiflu. Tamiflu, included in other products of Speciality, exceeded the forecast by JPY5.2 billion, which is the largest increase among domestic products, so it is listed separately. In fact, we had expected a figure of JPY4.7 billion, but the actual result was JPY9.9 billion.

Overseas, exports of Hemlibra, Actemra, and Alecensa exceeded expectations, pulled by strong demand.

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# Impact from Foreign Exchange Jan – Dec

(Billions of JPY)	vs. 2022 Actual rate	vs. 2023 Forecast rate* <sup>1</sup>
<b>Revenue</b>	<b>+51.9</b>	<b>+10.3</b>
Sales	+41.4	+8.9
Other revenue	+10.5	+1.4
<b>Cost of sales</b>	<b>-26.1</b>	<b>-0.6</b>
<b>Other than above*<sup>2</sup></b>	<b>-4.6</b>	<b>-2.8</b>
<b>Operating profit</b>	<b>+21.2</b>	<b>+7.0</b>

Exchange rate (JPY)	2022 Jan - Dec Actual rate* <sup>3</sup>	2023 Jan - Dec Actual rate* <sup>3</sup>
1CHF	125.17	140.31
1EUR	137.67	151.38
1USD	116.27	134.21

\*<sup>1</sup> Foreign Exchange effect from Jan-Dec Forecast rate(2023)

\*<sup>2</sup> Total of R&D, SG&A and other operating income (expense)

\*<sup>3</sup> Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

Historical exchange rate to the JPY

◀ : Full-year Forecast rate(2023)



53

This is the impact from foreign exchange rates.

We hedge about 80% of our foreign currency transactions in the previous year. This means that the remaining 20% is exposure, and this is where the impact on the plan will be.

As you can see in the graph on the right, the exchange rate has been moving in the direction of yen depreciation over the past two years. The net position is strongly on the profit side because the yen depreciation is positive for earnings and negative for expenses against the assumed exchange rate in the table on the left. As a result, operating profit contributed JPY7 billion to the plan.

In addition, comparing the actual rate in 2022 with last year's settlement rate, there was a considerable contribution from the yen's depreciation, which means that there was a JPY21.2 billion foreign exchange contribution in operating profit.

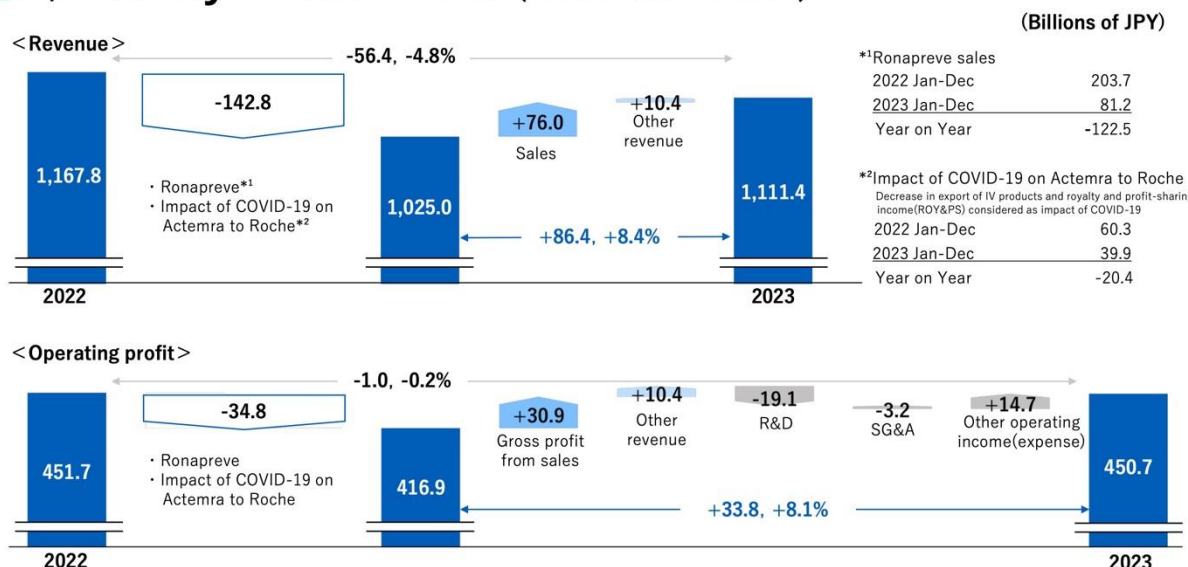
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# P/L Analysis Jan – Dec (Year on Year)



54

Page 54. This figure is adjusted for the impact of COVID-19-related revenues and earnings.

For Ronapreve, last year the figure was JPY81.2 billion, and the year before that it was over JPY200 billion, so the difference in earnings here is JPY122.5 billion.

In addition, there was a JPY20.4 billion downside in revenues related to IV Actemra for Roche. Adjusting for these factors, the 4.8% decrease in revenue on a core basis before any adjustments was an 8.4% increase in revenue for the base business. In terms of operating profit, adjusted for the same factors, the increase was 8.1%, which means that both sales and profit in the base business were up in the 8% range last year.

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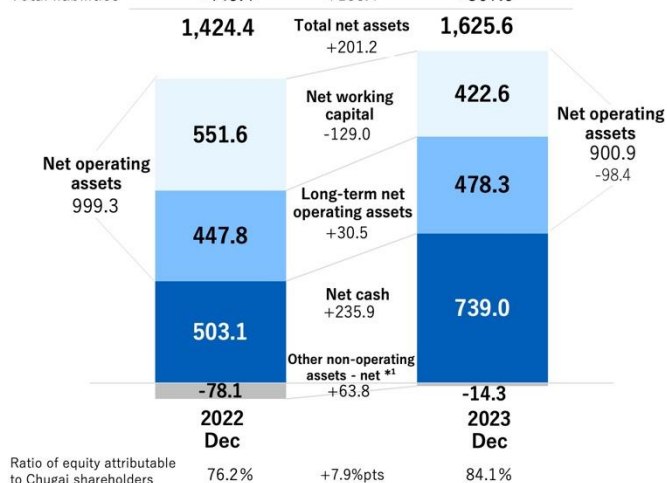
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# Financial Position (vs. 2022 Year End)

(Billions of JPY)

Total assets	1,869.8	+62.7	1,932.5
Total liabilities	-445.4	+138.4	-307.0



## Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

## Increase in long-term net operating assets

Increase in property, plant and equipment mainly due to the investment in manufacturing building for active pharmaceutical ingredients(FJ3) at Fujieda Plant

## Increase in net cash

(See next slide)

## Increase in other non-operating assets – net

Decrease mainly due to a decrease in accrued corporate tax

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

55

Moving from P&L to a slide on the balance sheet.

Total net assets here amounted to JPY1.6256 trillion, an increase of JPY201.2 billion from the end of the previous year. The ratio of shareholders' equity to total assets is 84.1% and the Company is in a very robust financial position.

The breakdown of the JPY129 billion decrease in net working capital is as follows. Net working capital decreased due to the collection at the beginning of last year of Ronapreve accounts receivable that are due to the government at the end of FY2022, and the collected cash was added to the net cash balance. As a result, net cash increased by JPY235.9 billion to JPY739 billion at the end of last year.

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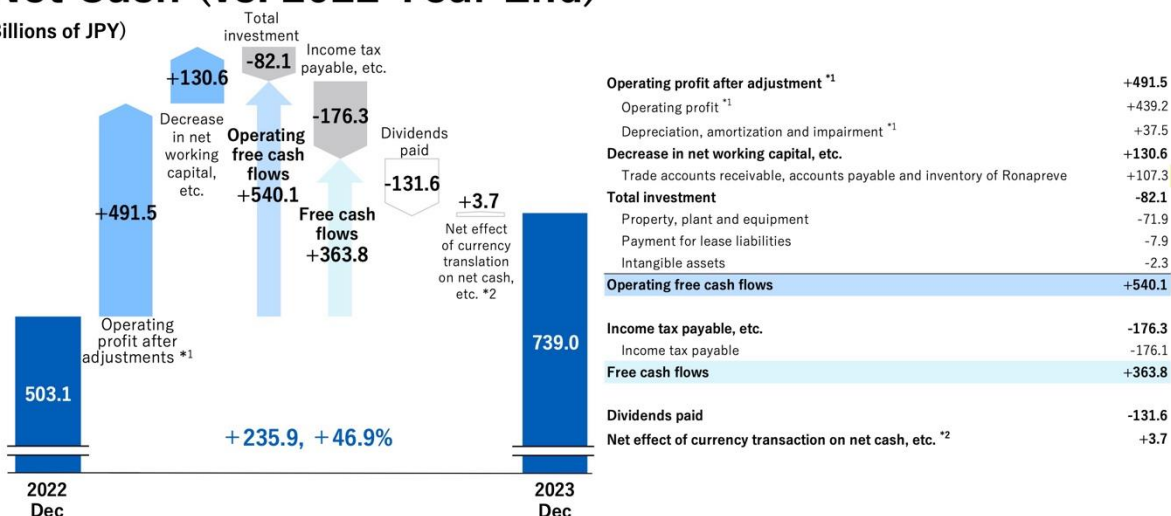
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# Net Cash (vs. 2022 Year End)

(Billions of JPY)



\*1 Including Non-Core (IFRS results)

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

\*3 Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on IAS 7 and IAS 21)

56

The net cash movement there is shown on page 56, and the cash inflow from operating activities and the decrease in net working capital will also increase cash. Even if we subtract investments and dividends paid for corporate income tax, the net cash inflow last year exceeded JPY200 billion.

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# Current Status / Plan for Major Investments

		~2022	2023	2024	2025	2026	2027	2028~	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	47.3	billion JPY	2021	2024
	Ukima site	UK4: Manufacture bio-APIs for early-stage clinical development							12.1	10.7	billion JPY	2021	2023
	Utsunomiya plant	UT3: Manufacture bio-APIs for middle to later- stage clinical development and early commercial use							37.4	5.6	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use							19.0	5.3	billion JPY	2023	2025
	Ukima plant	UK3(modification): Manufacture bio-APIs							20.3	-	billion JPY	2024	2027
Research and development	CPR	Accelerate creation of clinical candidates utilizing proprietary antibody technologies							758	558	million SGD	2012	2026
		of which, capital investment:							82	77			
		Move and renovate facilities to enhance research functions							60	-	million SGD	2024	2026
	Chugai LSP Yokohama	Building of state-of-the-art R&D site to create innovative new drug candidates							128.8	124.9	billion JPY	2019	2022
		- Land of 43.0 billion JPY excluded										- Start of operation: Apr. 2023	
	IFReC	Funding to IFReC per comprehensive collaboration agreement							10.0	6.8	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030							109.5	2.9	billion JPY	2022	2033
		estimated total amount											

\* Incl. part of Chugai LSP Yokohama and UK3(modification)

57

On page 57, there are two new projects that have been added to the list of major investments.

First, UK3 at the Ukima plant at the bottom of the manufacturing system. UK3 is a production building for biopharmaceuticals, which has already been built and is in operation. We are planning to improve and expand this building. The amount is JPY20.3 billion, including some investments such as CFC compliance.

Also, under R&D we have CPR. The R&D function is written here, and this is the part that Dr. Okuda just explained. There is a plan to relocate the facility in accordance with the expansion of our research functionality. Accordingly, we expect to invest SGD60 million.

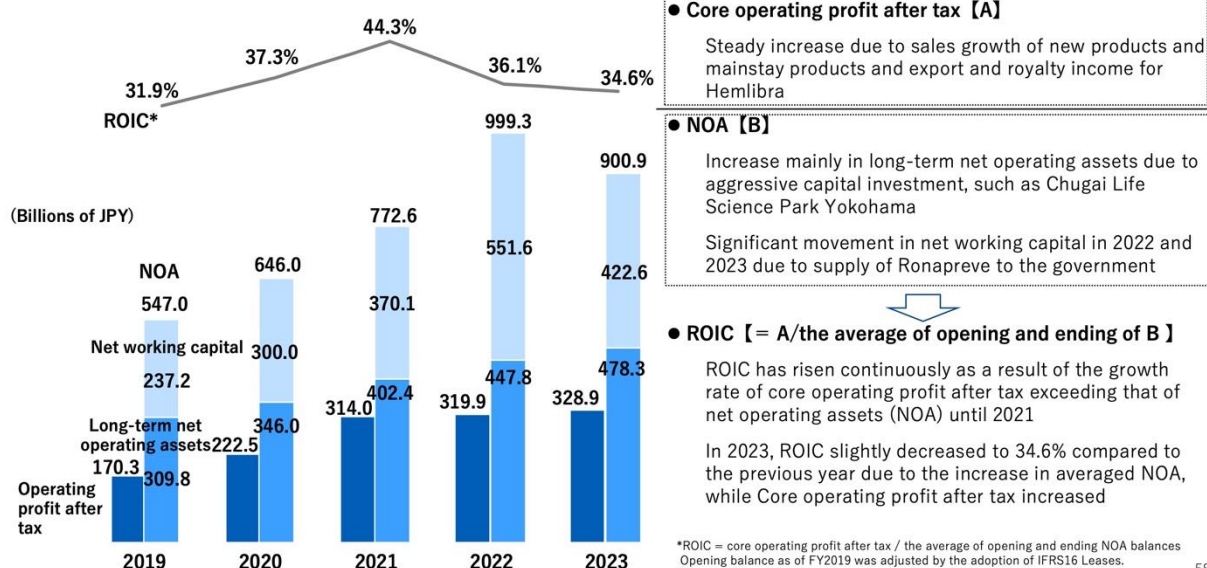
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# ROIC



58

Next, we have ROIC. This one is a capital efficiency indicator, which we look at over the medium to long term.

ROIC is the operating profit after tax divided by NOA, which is the net operating assets. The denominator, NOA, is an average of the end of the period and the beginning of the period, and as such, changes during the year, such as those relating to Ronapreve sales or inventory, do have an impact, and have resulted in an apparent decrease in recent years. Last year, however, the NOA was 34.6%, and our cost of capital, which we have announced to the public, was 6% level. Considering the recent increase in interest rates, I think it has gone up a bit more, to about 7%, but I believe we have maintained a very high level of capital efficiency compared to that.

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# P/L 2024 Forecast

(Billions of JPY)	2023 Actual	2024 Forecast	Growth	
<b>Revenues</b>	<b>1,111.4</b>	<b>1,070.0</b>	<b>- 41.4</b>	<b>- 3.7%</b>
Sales	974.5	922.0	- 52.5	- 5.4%
Domestic	558.0	454.9	- 103.1	- 18.5%
Overseas	416.5	467.1	+ 50.6	+ 12.1%
Other revenue	136.9	148.0	+ 11.1	+ 8.1%
Cost of sales	- 412.0	- 337.5	+ 74.5	- 18.1%
(cost to sales ratio)	42.3%	36.6%	-5.7pts	-
Research and development	- 162.8	- 171.0	- 8.2	+ 5.0%
Selling, general and administration	- 102.0	- 102.0	0	0.0%
Other operating income (expense)	16.1	0.5	- 15.6	- 96.9%
<b>Operating profit</b>	<b>450.7</b>	<b>460.0</b>	<b>+ 9.3</b>	<b>+ 2.1%</b>
(operating margin)	40.6%	43.0%	+2.4pts	-
<b>Net income</b>	<b>333.6</b>	<b>335.5</b>	<b>+ 1.9</b>	<b>+ 0.6%</b>
<b>EPS (JPY)</b>	<b>202.71</b>	<b>204.00</b>	<b>+ 1.29</b>	<b>+ 0.6%</b>

## Domestic sales

Decrease in supply of Ronapreve to the government, the NHI price revisions and market penetration of generic drugs

## Overseas sales

Significant increase in sales of Hemlibra, decrease in sales of Actemra

## Other revenue

Increase in income for Hemlibra and one-time income

## Cost of sales

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

## Research and development

Increase due to investments in research and early development and progress of development projects, etc.

## Selling, general and administration expenses

The same level as the previous year

## Other operating income (expense)

Income from disposal of product rights to decrease

Exchange rate (JPY)	2023 Actual	2024 Assumption
1CHF	140.31	159.00
1EUR	151.38	157.00
1USD	134.21	136.00

59

Now, our forecast for FY2024. The forecast is for sales of JPY1.070 trillion, a decrease of 3.7%.

While overseas and other revenue are expected to increase, we forecast a JPY103.1 billion decrease in domestic sales. Even excluding the negative impact of Ronapreve to the tune of JPY81.2 billion, sales in the domestic market are expected to decrease by JPY21.9 billion. This is due to the continued impact this year of NHI price revisions and generics.

Regarding the cost of sales, the cost of sales ratio has improved due to the elimination of Ronapreve and the growth of exports of our own products. We are forecasting a cost of sales ratio of 36.6%, the first time in 16 years that the ratio has been 30% level.

R&D expenses plan to increase by 5% to JPY171 billion, while depreciation and amortization expenses of Chugai LSP Yokohama are neutral since the facility is operating at full capacity as in the previous year, and SG&A expenses will be kept flat.

In other operating income, there was a one-time payment for product transfers last year, but there was no such event this year, so the figure is JPY500 million.

As a result, Core operating profit is projected to reach a record high of JPY460 billion, with an operating margin of 43%. Core net income is projected to reach a record high of JPY335.5 billion for the eighth consecutive year.

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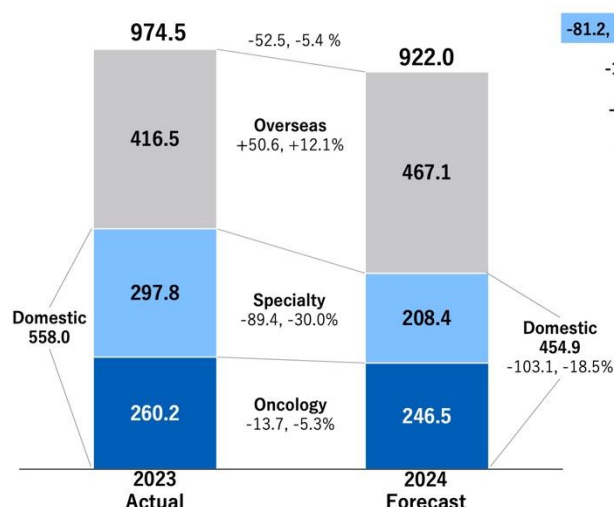
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# Sales 2024 Forecast

(Billions of JPY)

Sales by Disease Area

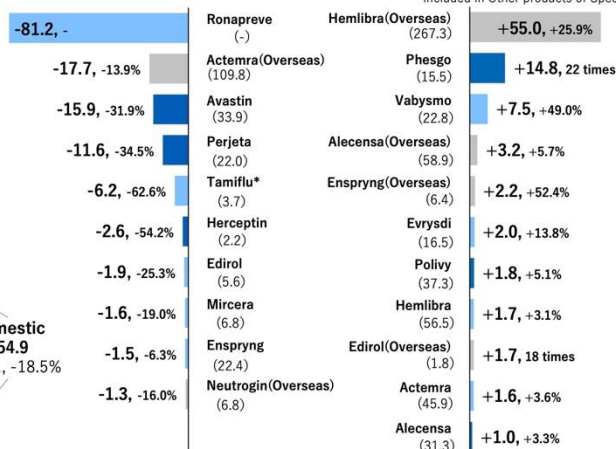


Sales by Product

(): Forecast sales in FY2024

%: Year-on-year percentage change

\*included in Other products of Speciality



60

As for the forecast for individual products, which is on page 60, sales of Ronapreve are forecast to decrease by JPY81.2 billion because government deliveries will be zero. We anticipate that Tamiflu sales will decrease by JPY6.2 billion because we do not currently assume that the influenza season will continue into the next season.

As for Actemra overseas, we have assumed a JPY17.7 billion decrease in exports, factoring in the possibility that biosimilars may finally have an impact.

We anticipate a decrease in sales for Perjeta associated with a switch to Phesgo.

Other products that will see a decrease in sales are those affected by drug price revisions and generics.

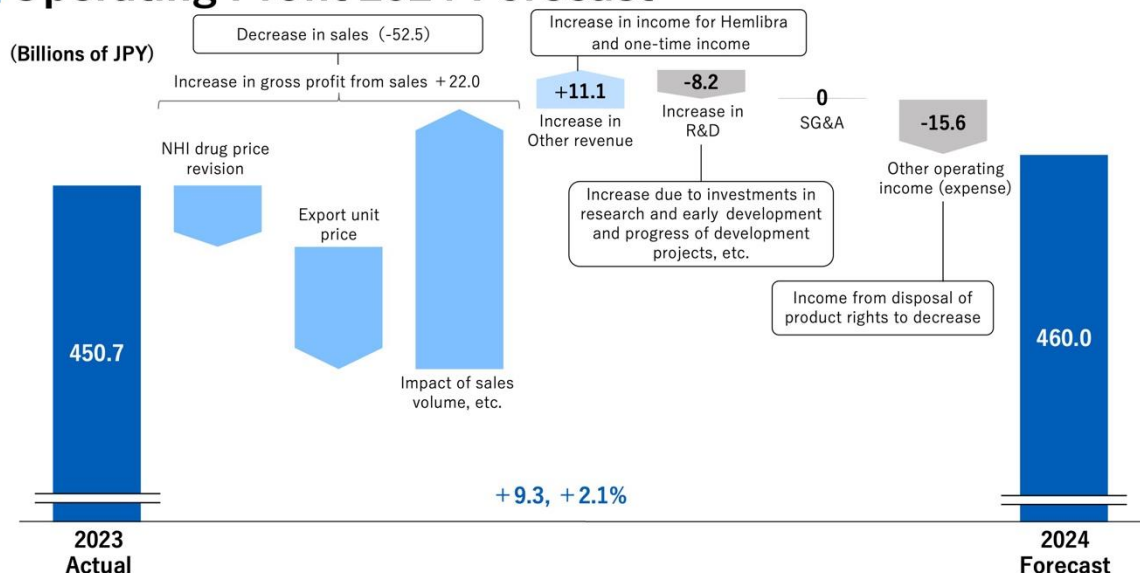
As for the increase in revenues, we expect a 25.9% increase to JPY267.3 billion in Hemlibra overseas due to the continued strong performance of three overseas products.

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# Operating Profit 2024 Forecast



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Next, our profit forecast. We expect gross profit to be JPY22 billion, a record high.

Other revenue is also forecast to increase by JPY11.1 billion.

We will increase R&D expenses as I mentioned earlier and there will be no one-time income from other operating income, so there is a minus, but it is a record high and we will continue to grow without adjusting the profit side of COVID-19 related income. This means that we will continue to maintain a strong business base.

That is all. Thank you very much.

**Miyata:** Thank you.

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## Question & Answer

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**Miyata [M]:** We will now move on to the Q&A session. For the Q&A session, please be advised that Mr. Hidaka, Executive Vice President, Supervisory responsibility for Marketing & Sales, is also present. Please limit the number of questions to two per person. Please note that the audio of your questions will be posted on our website at a later date, along with the presentation.

**Sakai [Q]:** My name is Sakai from UBS. First of all, regarding Actemra-BS, the timing of entry and the number of entrants were not disclosed in the past, but this time they are included in the guidance. Since your Company is a party to the settlement, I think we don't know at what point they will come in, because there are other parties, but for example, in terms of the details of the settlement, what is the earliest they could come in, and how many companies are you expecting this quarter?

**Okuda [A]:** Thank you for your question, Mr. Sakai. Your question is about Actemra biosimilars. I would like to include updated information.

The first company is called Fresenius Kabi. They are developing both IV and SC formulations. It was launched in Europe on November 1. In the US, for the IV and SC, the FDA accepted the application in August 2022, but we have not received any information that it has been approved at this time.

Then there is the alliance of Biogen and Bio-Thera, which developed IV formulations. The information is that the SC is under development.

In China, the product has already been approved and launched.

In Europe, the EMA has accepted the application, but we have not yet received any information that it has been approved.

Then there is the US, where it was approved as an IV formulation on September 29 last year. However, the timing of the market launch is unknown. We have not received any information that the product has been placed on the market yet.

To return to the beginning, we know that the Fresenius Kabi product was launched last year on November 1, but we do not yet have a clear idea of how much sales have been achieved since then.

There was another company, Celltrion, which was developing IV and SC formulations. There was a press release on January 28 stating that an application was filed with the FDA.

The first two, Fresenius Kabi, and Biogen and Bio-Thera, have been settled, with our Company and Roche.

Because of confidentiality obligations regarding the details of the settlement, we are unable to respond to the timing or conditions of the market launch.

The decrease in Actemra exports compared to last year that I mentioned earlier is, to some extent, our estimate, and there may be some impact from biosimilars. However, it is difficult to predict when or how soon they will be launched, so we will keep a close eye on the market and pay attention to it. That is all.

**Sakai [Q]:** I understand. Thank you very much. Regarding Enspryng, I think we finally have gMG, and this is probably the first, the biggest or the central indication for the development of this product. I assume this is after looking at the global Phase III data, but could you please explain the process again? How large a market

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could we be looking at? I know this does not mean that all 174,000 patients are covered, but I would like to know what percentage I should consider. Thank you.

**Tetsuya Yamaguchi [A]:** Thank you. As for gMG, as you have pointed out, we have had clinical and non-clinical data suggesting the involvement of IL-6, and we are proceeding with this study. Also, recently in China, there have been some good results for gMG with IL-6 signaling blockages.

Under these circumstances, we have been working with the Roche Group on a global Phase III study, the Luminesce study, and we will soon have a readout of the results. If this readout proves to be very good, we are looking into the possibility of taking this to the application process this year.

On the other hand, unfortunately, we do not disclose potential sales. We have been watching tocilizumab and other drugs in this area, but the competition has become very fierce, and it is in this context that we introduced the positioning mentioned earlier.

This means that no further disclosures or sales can be made now.

**Sakai [Q]:** I understand. Am I correct in assuming that this is a simultaneous global application with Roche?

**Tetsuya Yamaguchi [A]:** Yes. Basically, that is the kind of timeline we are looking at.

**Sakai [M]:** I understand. Thank you very much.

**Miyata [M]:** Thank you very much. Next question please.

**Hashiguchi [Q]:** Hashiguchi, Daiwa Securities. I have two questions. The first is about how you intend to communicate with stakeholders about the status of your medium- and long-term initiatives. I am looking at the slides from last year and the year before, and I believe that in the year before last, the three-year mid-term plan was abolished and a mid-term milestone was set. There was information about communicating using this milestone last year, and there was an explanation of the actual situation and the milestones that were actually reviewed.

I have the slides this time, but I think Dr. Okuda hardly touched on it, so I wonder how you will communicate this with us in the future. Could you please explain a little more about your thoughts on how you think this progress is going so far and what the challenges are?

**Okuda [A]:** Thank you for your question, Mr. Hashiguchi. Regarding the explanation this time around, we have attached it to the Appendix. As you indicated, the amount of information is somewhat less than last year. This time, we have only shown you our progress on what we have achieved in 2023. This is mostly what is written here in the overall picture, but it appears to be progressing well.

On the other hand, we just started TOP I 2030 in 2021, three years ago. The 2030 goal is now only seven years away, and we are now thinking about whether and how we can achieve the 2030 goal in these seven years. We are seriously reviewing our mid-term milestones. We were not able to ready the information in time for this presentation, but we will be able to present our revised mid-term milestones at the mid-term closing in July. Please wait a little longer.

**Hashiguchi [Q]:** So it is my understanding that there will be no need to revise the 2030 target at this time?

**Okuda [A]:** Yes. We have been working on various mid-term milestones, and things are generally going well there. It's been three years, so our goal for the next seven years is slightly easier to envision. Under such circumstances, we are now reviewing whether we can really meet this mid-term milestone.

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**Hashiguchi [Q]:** Understood. Thank you very much. The other point I would like to make is regarding your forecast for this fiscal year. In your explanation of the last fiscal year, you mentioned that the plan was a bit ambitious and challenging with regard to domestic sales. You mentioned several times that you were replenishing inventory or adjusting inventory with regard to exports.

We would like to know if you have any information on your forecast for the current term, such as if your forecast is somewhat high or conservative. If possible, please share with us information about inventory adjustments relating to export, and if such factors are affecting exports.

**Itagaki [A]:** I have never said I was bullish or bearish from the beginning of the term, but rather, I would say that I was watching the trends. I think those comments came out last year during the term.

On the other hand, as for inventory adjustment, our exports last year were based on orders from Roche. I think we said from the beginning of the fiscal year that we would make a safety stock adjustment of JPY20 billion for Hemlibra last year in our communication, and that is how we ended up with such results. However, there is no such inventory adjustment in this year's plan. We have also confirmed with Roche.

**Hashiguchi [Q]:** You have mentioned many times that Actemra's overseas sales trends are highly uncertain and difficult to forecast. Or is the forecasting process not that different from others?

**Itagaki [A]:** As I mentioned earlier, the order forecast from Roche has come in for a few months, about half of this term's plan. The rest is free, so although it is variable, we always look at it on a monthly, rolling basis.

We have been making plans since October and November of last year, working towards January, and then to our announcement today. A few months have passed, and our forecasts have been steadily updated in that time. We have had no major changes in that time. Roche is doing the same thing, and this is what we have been doing. Roche has also come out with a forecast in anticipation of the impact of biosimilars.

It is difficult to say what is conservative or risky, but as we are in the same position, we have a view of the market, and based on that view, we have included our most recent estimates here.

**Hashiguchi [M]:** Thank you very much. That is all.

**Miyata [M]:** Thank you very much. Next question, please.

**Hyogo [Q]:** My name is Hyogo and I am an analyst at Mitsubishi UFJ Trust and Banking Corporation. Thank you very much for your time today.

I'm sorry, this is a bit of a continuation of Mr. Hashiguchi's question, but I'm looking at the FY2022 documents regarding the positioning of mid-term milestones, and I think the original idea was to confirm the validity of the plan with a 2030 target, mid-term milestones, and single-year plans. The part that Dr. Okuda just mentioned is that the mid-term milestone is supposed to be reviewed, and the definition of mid-term milestone is written as three to five years depending on the strategy, and it is updated or changed according to environmental changes. Is it correct to say that we will be able to see the changes to be made in July?

**Okuda [A]:** Thank you for your question, Mr. Hyogo. I think that understanding is correct. We had originally set medium-term milestones that varied over three or five years, but now we are reviewing them again, this time in an agile manner every year, and we are taking some time to reconfirm and re-set milestones looking ahead to the next seven years. Thank you.

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**Hyogo [Q]:** I understand that you have reached this point and that visibility has increased, but what was the biggest trigger, changes in the external environment or internal factors such as the increase of things that are going well in your company?

**Okuda [A]:** As I explained earlier, we are doing quite well on various milestones. The biggest factor is, of course, changes in the environment, but the question is how to set goals internally seven years from now. If we raise the visibility of goals that can be achieved realistically, is this really enough? This is an effort to increase the accuracy of internal target setting.

**Hyogo [M]:** I am looking forward to July, so I am waiting with raised expectations. Thank you very much.

**Wakao [Q]:** My name is Wakao from JP Morgan. Thank you. I would like to ask about page 12. While you mentioned that you are now reviewing the medium-term milestones, I understood from the summary and outlook you used last year that you are rather more certain about the growth potential this time around, but is that overly optimistic? I think we have a much better idea of the timing of Actemra biosimilars, and so on. Hemlibra is entering a stable growth phase, so it may be easier to make predictions.

From today's message, I wonder if you could tell us roughly what kind of growth rate we can anticipate. I know that you are aiming for single digit growth this fiscal year, but I would appreciate it if you could tell me if you can achieve at least single digit growth, in terms of operating profit, or from that perspective as well.

**Okuda [A]:** Thank you for your question, Mr. Wakao. The first question was whether the certainty of the medium- to long-term growth outlook has increased compared to the same period last year.

There have been some positive development results in FY2023, so in that sense, I think we can say that the accuracy of the results has improved.

Regarding Actemra biosimilars, as I explained the situation earlier, we had expected that there would not be much of an impact in FY2023. As for FY2024, there will be some impact. It was also difficult to foresee the precise situation.

As you can see here, for example, the ALINA results for adjuvant Alecensa are positive, Enspryng will be even more certain this year when the gMG results I mentioned earlier comes out. For crovalimab, the global Phase III is positive for PNH, and so on. It is certain that we are seeing results that will pull growth in the medium term.

However, it is difficult to predict what the growth rate will be, and we would like to continue with our current attitude.

**Wakao [Q]:** I understand. Thank you very much. Secondly, I wonder if you could tell us about royalties in this term. You mentioned that the milestones for the previous fiscal year were shifted to this fiscal year, but even so, the plan for this fiscal year looks a little low.

**Itagaki [A]:** The exchange rate for what we receive from Roche is hedged, and it is still hedged at a further depreciation of the yen, as you can see in our forecast for this year, so we are rather on the positive side there.

On the other hand, as I said earlier, even if there is an impact of a stronger or weaker Swiss franc on the Roche side, we are not assuming at this point that the impact there will be an even stronger franc than this year. This will simply be a growth in the Hemlibra part of Roche side sales. Actemra will be affected by biosimilars, so Actemra royalties will go down. These factors, plus and minus, are included in the planned figures.

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**Wakao [Q]:** As I understand it, the figure for the beginning of the last fiscal year was JPY150 billion, and the forecast for this fiscal year is JPY148 billion, but I thought it could be a little higher than JPY148 billion because of the shift and the increase in royalties from Hemlibra, if sales are growing.

**Itagaki [A]:** The milestone is a one-time payment, so of course it is positive, but there are many other one-time payments, and the impact will depend on the amount of the one-time payment between last year and this year.

**Wakao [M]:** I understand. Thank you very much. That is all.

**Miyata [M]:** Thank you very much. Next, Mr. Yamaguchi, Citigroup Global Markets, please go ahead.

**Hidemaru Yamaguchi [Q]:** Thank you very much. Regarding Phesgo, the sales forecast is in and it will be in the style of a switch from Perjeta and Herceptin, but there are a few bumps in the road. How do you see this assumption? I think it's a pretty good product and will move rapidly, but on the other hand, we still have Perjeta and Herceptin, so could you give us a little idea of your thinking in this area? This is my first question. This is the forecast for the current fiscal year.

**Hidaka [A]:** Thank you for your question, Mr. Yamaguchi. As for Phesgo, we are trying to switch as quickly as possible, since it is a very convenient drug for patients, requiring only eight minutes for the first injection and five minutes for the second and subsequent injection. However, of course, it is possible that the sum of Perjeta and Phesgo may temporarily appear larger than before, depending on the patients who can switch promptly and those who cannot, as well as on the circumstances of the hospital.

I believe that eventually things will settle down in that way, and we would like to proceed in such a way that it will permeate the system.

**Hidemaru Yamaguchi [Q]:** Is it conceivable that this would result in a return from generic Herceptin?

**Hidaka [A]:** Yes, that's right. As you say, a large percentage of Herceptin has gone to biosimilars, and I believe that this amount will be returned as the penetration of Phesgo continues.

**Hidemaru Yamaguchi [Q]:** I understand. Thank you very much. Also, one more thing. I think you may have explained this before, but the previous year's forecast was easy to understand because sales excluding COVID-19 were clearly stated, but do you have any idea what will happen if the forecast for the current year is revised in the same way?

**Itagaki [A]:** If we assume that there will be no more COVID-19 impact on IV Actemra in this fiscal year, that part will be only Ronapreve. Therefore, if we disclose the profit, one may know profit for Ronapreve, so we do not disclose the profit. Even without that adjustment, the profit will increase.

**Hidemaru Yamaguchi [M]:** I understand. Thank you very much. That is all.

**Miyata [M]:** Thank you very much. Next, Mr. Muraoka, Morgan Stanley Securities, please go ahead.

**Muraoka [Q]:** Hello. Morgan Stanley, Muraoka. Thank you very much. Sorry, the line went down a bit in the middle and I missed some of what I heard, but please let me know. I would like to ask about GYM329. In Roche's presentation today it says that Phase Ib of the obesity trial will begin this year. I am looking at GYM329, very excited that we are finally at GYM329 and obesity, but I think we will see the results in no time, because it says it only requires three administrations.

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With the MANATEE in combination with Evrysdi for SMA coming out this year, can we expect to see two indications of GYM329 at about the same time?

On the same idea, Regeneron is going to do myostatin antibodies, which you mentioned the other day. Again, I think you have explained this before, but can you tell us the advantages of GYM329 over the competition, especially in obesity?

**Tetsuya Yamaguchi [A]:** First of all, as you mentioned, Roche is starting a Phase I trial for obesity, which I understand is a single-agent trial for a very small number of patients. It is due to start in Q2 of this year, and should not be a long trial, so I think you are about right on the timing.

Whether or not the obesity treatment will be continued in the future depends on whether it will be used by itself for obesity, or whether it will be necessary to use incretin and other concomitant therapies. Also, there is the time required for Phase II and Phase III trials.

On the other hand, the combination study with risdiplam started in Q2 of FY2022, so you are right that we will see the results of this study as well. I believe that we will be moving a little faster in the area of neuromuscular diseases, including FSHD that Roche is working on.

Regarding GYM329, first of all, it binds specifically to latent myostatin, and we believe that it has a very high affinity for the target protein, so we expect it to be highly active.

In terms of convenience, the four-weekly subcutaneous injection will be a great advantage, especially in the treatment of obesity.

I think that is what we can currently explain.

**Muraoka [Q]:** Thank you very much. Another obesity question, which is also quite forward-looking, is that Roche bought injectable GLP-1 at the end of last year. I assume that it will probably be used in combination with GYM, but when it finally appears that it can be commercialized in the future, I am not sure if your company will be doing this in Japan.

I have a feeling that Eli Lilly will probably not sell orforglipron in Japan, considering the way they have been doing things in Japan, so I am assuming that they will ask Chugai to do it for them. I am imagining that there will need to be a choice between doing orforglipron or injections. Could you comment on this?

**Tetsuya Yamaguchi [A]:** Thank you. There are very high expectations for incretins for obesity in the pharmaceutical industry, and the three incretins from Roche's Carmot that you have just introduced are currently in Phase I or Phase II studies.

As for this asset, Chugai has the First Refusal Right for Roche products, so we will conduct a thorough due diligence on each project and introduce the asset if we choose to do so. We also expect that there may be pathways such as using it in combination with GYM329.

On the other hand, the oral GLP-1 was licensed to Eli Lilly, including in Japan. Naturally, Lilly has a strong presence in Japan, especially in the area of incretin, which is not limited to obesity, but also has a franchise in Japan for diabetes.

In this context, we are very pleased that Eli Lilly has already started Phase III clinical trials of orforglipron, which was out-licensed at the preclinical stage in 2018, and that Eli Lilly has already started six studies for diabetes and 3 studies for obesity. We believe that the speed and high expertise of Eli Lilly are such that we were able to out-license the drug to the right company. We hope to get a return on our investment under the

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current collaboration agreement. With regard to Carmot, as I mentioned earlier, I believe that we will be able to include Carmot if there are opportunities in Japan on a project-by-project basis. Thank you.

**Muraoka [M]:** I understand. Thank you very much. That is all.

**Miyata [M]:** Thank you very much. The next question will be our last. Ms. Sogi of Alliance Bernstein, thank you for your time.

**Sogi [Q]:** Thank you very much. I have two questions. First, regarding the Swiss Franc exchange rate. With the yen weakening against the Swiss franc considerably, I would like to know your perspective on overseas sales for this fiscal year and, as you asked earlier, on royalties.

You explained earlier that although the Swiss franc itself is rising, the appreciation of the Swiss franc against the US dollar is too high, so in the end Roche's sales are not rising that much, so the Swiss franc is simply getting more expensive. What impact does this have on the royalty payments?

**Itagaki [A]:** Let me give you a hypothetical example: Roche sold Chugai products in the US. Suppose they sold USD100 worth. It would be fine if USD100 remained equal to CHF100, but a stronger Swiss franc would mean that the USD100 sold would be replaced by CHF70, for example. So, even if it is the same thing, if the Swiss franc strengthens, Roche's sales in Swiss francs will decrease when converted to Swiss franc-denominated sales.

We receive a royalty rate multiplied by 70 instead of 100, which means that our base sales in Swiss francs will first be affected by the exchange rate. That is uncontrollable.

What we can control is that we will hedge the following year's royalties, whether they are 70 or 100, from Roche in the previous year. This is the relationship between the yen and the Swiss franc.

So, as for the hedged portion, the plan is as it is, so whether the yen weakens or strengthens against the Swiss franc during the period, that portion is neutral. This is the kind of relationship we are talking about.

**Sogi [Q]:** Thank you very much. Even considering this, with the Swiss franc so high, I think that overseas sales and royalties should be a little higher, but I wonder if there are any conservative estimations in your Company regarding this.

**Itagaki [A]:** That is not the case.

**Sogi [Q]:** I understand. Another question is regarding Dual-Ig. I understand that the first products related to CLDN6 are currently undergoing clinical trials, but I understand that this is a platform that can be used for targets other than CLDN6 as well. Please tell me if my understanding is correct and by what rationale you are starting with CLDN6 in the first place.

**Tetsuya Yamaguchi [A]:** Regarding Dual-Ig, as you understand, this antibody can be used for various drug discovery targets as a so-called T-cell engaging antibody.

There are a number of T-cell engagers on the market that use CD3 and cancer antigens, but the activated T cells are considerably exhausted by CD3 stimulation, and the effectiveness of the T-cell engagement is diminished. CD137 stimulation can maintain T-cell activation or cause proliferation. If this concept is confirmed, we believe that this platform has considerable potential.

CLDN6 was selected because it is specifically expressed in tumor cells, and also because we have achieved antibodies with a very high affinity for this target.

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We are already using this technology in our ALPS project. If this technology is successful, we expect that it will become a promising method for antibody engineering technology.

**Sogi [M]:** Thank you very much.

**Miyata [M]:** Thank you very much. This concludes the presentation of Chugai's financial results for the fiscal year ended December 31, 2023. For questions that we were unable to answer due to time constraints, please contact the Corporate Communications Department separately. Phone numbers and email addresses are listed on the last page of the presentation materials.

Thank you very much for joining us today. Thank you.

[END]

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