

Innovation all for the patients



CHUGAI PHARMACEUTICAL CO., LTD.

 A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2022.12 Financial Results

February 2, 2023

Event Summary

[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.	
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[Participants]		
[Number of Speakers]	<div>5</div> <div> <div>Osamu Okuda</div> <div>Toshiaki Itagaki</div> <div>Tetsuya Yamaguchi</div> <div>Shinji Hidaka</div> <div>Toshiya Sasai</div> </div> <div> <div>President & CEO</div> <div>Director, Executive Vice President & CFO</div> <div>Executive Vice President, Head of Project & Lifecycle Management Unit</div> <div>Executive Vice President, Head of Marketing & Sales Div.</div> <div>Head of Corporate Communications Dept.</div> </div>	
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*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

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Presentation

Sasai: Thank you very much for taking time out of your busy schedule today to attend the CHUGAI PHARMACEUTICAL CO., LTD. financial results briefing for the fiscal year ended December 31, 2022. My name is Sasai, from Corporate Communications, and I will be facilitating today's session. Thank you.

Due to the coronavirus pandemic, today's session will be conducted as a combination of an on-site session and an online Zoom webinar. The agenda for today's meeting is displayed on the screen, and on page three of the presentation materials. Our presentations will be in line with these materials. Questions will be taken after all presentations have been completed. The Q&A session is expected to last approximately 30 minutes.

Now without further ado, President and CEO Osamu Okuda will give FY2022 overview and FY2023 forecast. Over to you.

FY2022 Overview and FY2023 Forecast



2022 Financial Performance

- Due to significant increase in sales, the company achieved YoY increase in revenues and profits, exceeding its full-year forecast
- Revenues exceeded 1 trillion JPY for the first time, achieving the record-high revenues and profits for six consecutive fiscal years

Core (billions of JPY)	2021 Jan - Dec actual	2022 Jan - Dec actual	Growth		2022 Jan - Dec forecast	Progress (%)
Revenues	999.8	1,168.0	+168.2	+16.8%	1,150.0	101.6%
Domestic sales	518.9	654.7	+135.8	+26.2%	646.3	101.3%
Overseas sales	283.9	384.6	+100.7	+35.5%	385.2	99.8%
ROOI	196.9	128.8	-68.1	-34.6%	118.5	108.7%
Operating profit	434.1	451.7	+17.6	+4.1%	440.0	102.7%
Operating margin	43.4%	38.7%	-4.7pts	-	38.3%	-
Net income	311.5	317.7	+6.2	+2.0%	312.5	101.7%
EPS (yen)	189.35	193.11	+3.76	+2.0%	190.00	101.6%

- Domestic sales significantly increased mainly due to the supply of Ronapreve to the government, in addition to the steady market penetration of new products (Evrysdi, Polivy, Enspryng, Vabysmo), and the favorable growth of mainstay products (Hemlibra, Kadcyra), despite the impact of NHI drug price revision and generics
- Overseas sales significantly increased in sales of Hemlibra and Actemra
- ROOI significantly decreased in royalty income for initial shipping inventory of Hemlibra
- Due to the significant increase in sales, the company achieved YoY increase in revenues and profits

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Okuda: Okuda here. I will provide FY2022 overview and FY2023 forecast. Please see slide five.

For the full year of 2022, revenues exceeded JPY1 trillion for the first time, at JPY1.168 trillion, an increase of 16.8% compared to the previous fiscal year. Operating profit was JPY451.7 billion, up 4.1% year on year.

The results for both revenues and profits exceeded the full-year forecast, mainly due to a significant increase in sales. For the sixth consecutive fiscal year, we achieved record-high revenues, operating profit, and net income.

Domestic sales saw growth of 26.2%. Although affected by NHI drug price revision and generics, there was steady market penetration of new products and strong sales of mainstay products. Sales of new products grew, including Evrysdi, Polivy, Enspryng and Vabysmo. In addition, government deliveries of Ronapreve contributed significantly to the large increase.

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Overseas sales increased by 35.5%. We saw a YoY decrease in exports of Alecensa to Roche but increases in Hemlibra and Actemra made a significant contribution.

ROOI was down 34.6% due to a significant decrease in royalty income related to the initial shipments inventory of Hemlibra.

These total results exceeded the full-year forecast, resulting in YoY increases in both revenues and profits.

FY2022 Overview and FY2023 Forecast

2023 Forecast



- Revenues and profits are expected to decrease to 1,070.0 billion JPY (-8.4%, YoY) and 415.0 billion JPY (-8.1%, YoY) in 2023, respectively
- The decline in sales and profit is due to lower sales revenues from COVID-19-related drugs such as Ronapreve
- Excluding the COVID-19-related temporary impact, revenues are expected to increase, and profits are expected to increase slightly

Core (billions of JPY)	2022 Jan - Dec actual	2023 Jan - Dec forecast	Growth (year on year)	
Revenues	1,167.8	1,070.0	-97.8	-8.4%
Domestic sales	654.7	541.7	-113.0	-17.3%
Overseas sales	384.6	378.3	-6.3	-1.6%
Other revenues	128.6	150.0	+21.4	+16.6%
Operating profit	451.7	415.0	-36.7	-8.1%
Operating margin	38.7%	38.8%	+0.1pts	-
Net income	317.7	306.0	-11.7	-3.7%
EPS (yen)	193.11	186.00	-7.11	-3.7%

- Domestic sales are expected to decrease due to the decrease in the supply of Ronapreve to the government and the impacts of generics despite the growth of new and mainstay products both in Oncology and Speciality fields. Domestic sales excluding Ronapreve expect steady growth to 460.5 billion JPY (+2.1%)
- Overseas sales are expected to decrease slightly due to a decrease in export volume reflecting the Roche Group's optimization of Hemlibra inventory levels and decrease of Actemra COVID-19-related demand
- Other revenues are expected to increase due to the increase of Hemlibra-related royalty and profit-sharing income and one-time income

"Royalties and Other Operating Income," which has previously been reported under "Revenues," will be changed to "Other Revenues," while income from disposal of product rights will be excluded therefrom. Figures in the green color of the above table apply the aforementioned change.

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Here is the forecast for 2023. Forecast revenues are JPY1.07 trillion, a decrease of 8.4%. Core operating profit is expected to be JPY415 billion, a decrease of 8.1%. We are forecasting a decrease in revenues and profit. The main reason for the decrease is decline in COVID-19 related therapies such as Ronapreve.

Excluding these temporary effects, however, we expect revenues to increase and operating profit to rise slightly.

Domestic sales are expected to decrease. While new products and mainstay products in both the oncology and specialty areas are expected to grow, the Company anticipates negative factors such as a decrease in government deliveries of Ronapreve and the impact of generics.

The forecast for domestic sales for 2023, excluding Ronapreve, is JPY460.5 billion. This is shown on the right. This is expected to increase by 2.1%.

Overseas sales will be affected by the optimization of inventory levels at Roche for Hemlibra. Also, a slight decrease is expected due to lower COVID-19-related demand for Actemra.

From FY2023, "Royalties and other operating income", which has previously been reported under revenues will be changed to "other revenues", while income from disposal of product rights will be excluded therefrom.

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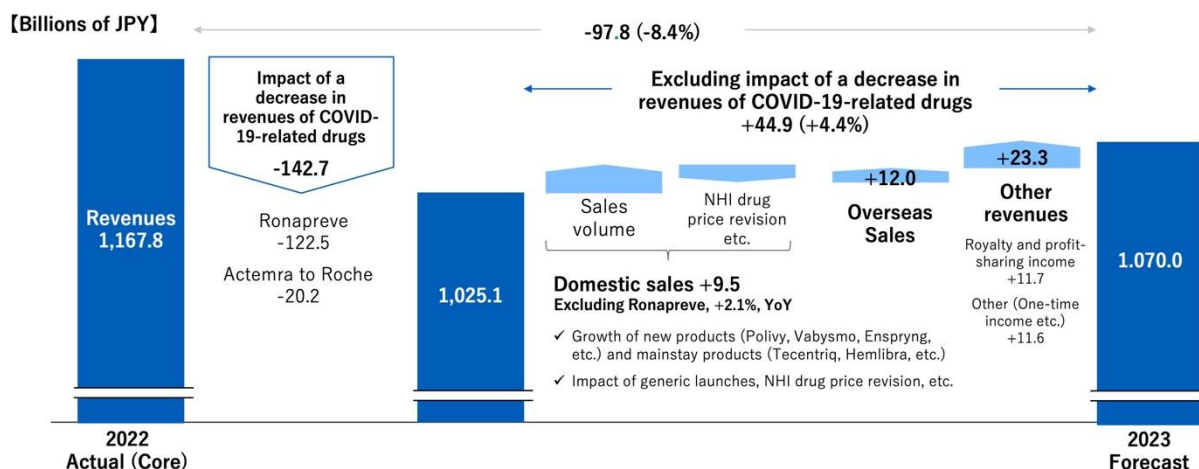
As for the new item, other revenues, we expect an increase in revenues due to higher royalty and profit-sharing income from Hemlibra, as well as an increase in one-time income.

FY2022 Overview and FY2023 Forecast



Topline Analysis of 2023 Forecast

- Expected growth of core businesses in Japan and overseas
- Increased revenues (+44.9 billion JPY, +4.4%, YoY) excluding the impact of a decrease in revenues of COVID-19 related drugs (-142.7 billion JPY, YoY)



On the next slide, we see the change in revenue excluding the impact of the decline in sales of COVID-19-related therapies such as Ronapreve.

First, on the left side, sales of COVID-19-related drugs are forecast to decrease by JPY142.7 billion, including JPY122.5 billion for Ronapreve and JPY20.2 billion for Actemra to Roche. Subtracting these figures from the actual revenues in FY2022, we arrive at JPY1.0251 trillion.

And compared to the JPY1.07 trillion in revenues forecast in FY2023, which is on the far right here, this would mean an increase in revenues of JPY44.9 billion, or 4.4%.

Thus, excluding the decrease in sales of COVID-19 related drugs, the core businesses are expected to grow, both in Japan and overseas.

The breakdown of the variance is shown in this waterfall chart.

Domestic sales are expected to increase by JPY9.5 billion, as volume growth outweighs the expected impact of generics and NHI drug price revision.

Forecast overseas sales are plus JPY12 billion. Of other revenues, royalties and profit-sharing income are expected to be positive JPY11.7 billion.

In Mr. Itagaki's financial presentation, we will discuss in more detail the impact of lower COVID-19-related sales on operating profit.

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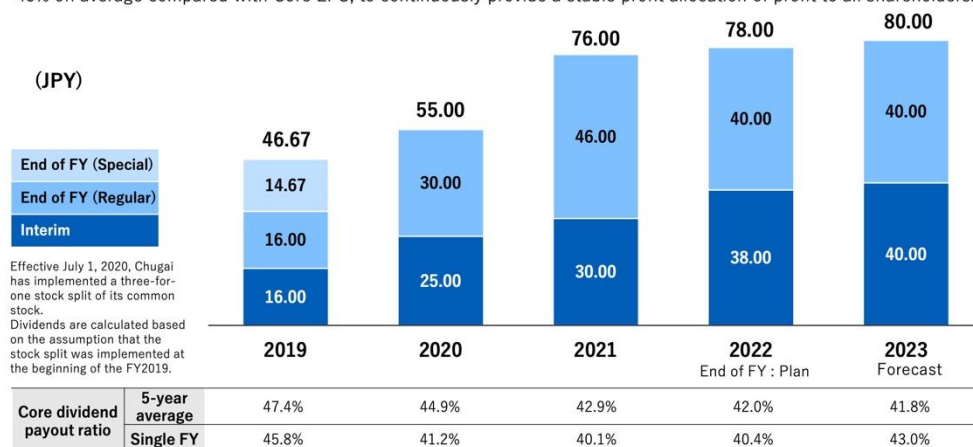


Contribution to Shareholders

- The 2022 year-end dividends are increased to 40 JPY to reflect favorable financial performance. For 2023, we expect annual dividends of 80 JPY

- 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 explain about dividends. Considering our strong financial performance in FY2022, we have changed our original dividend forecast and year-end dividends for the fiscal year ended December 31, 2022 are planned to be JPY40 per share. As a result, annual dividends will be JPY78 per share.

In FY2023, although revenues and profits are expected to decline, we forecast an annual dividend of JPY80, an increase of JPY2 from 2022, in line with our basic policy of providing shareholders with stable dividends on an ongoing basis. Both interim and year-end dividends are expected to be JPY40 per share.

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Review of Strategic Policies for 2022 (1/2)

Continuous creation of R&D output	● Mid-size molecule project: LUNA18 and subsequent mid-size molecule projects are on track
	● Progress of in-house projects is slightly behind the plan <ul style="list-style-type: none"> Slight delay in the PC transition of new projects P1 study preparation/progress are on track: DONQ52, RAY121, ALPS12 (study started in Jan. 2023), etc. Progress of GP3 is favorable: Expansion of indications such as crovalimab, Enspryng, and Alecensa
	● Partial change in plan for regulatory filings <ul style="list-style-type: none"> Filed (4): RG6264*, crovalimab [PNH/China], Gazyva [CLL]**, Actemra Development Discontinued/Changed (7): Development, including Tecentriq/tiragolumab, was discontinued due to failure of primary endpoints in P3. Filing year changed for Tecentriq [HNC (adjuvant)] .
	● Steady progress in Approval/Launch <ul style="list-style-type: none"> Approval/Launch (12): Tecentriq, Hemlibra, Vabysmo, Polivy, etc.

(): number of projects *PER/HER fixed-dose subcutaneous combination ** Gazyva was filed for the treatment of CLL in March 2022, and obtained approval in December 2022



Next, we look back at the key policies for FY2022. First, regarding the continuous creation of R&D output, LUNA18 and subsequent mid-size molecule projects are progressing well.

Phase I trials for the in-house project were prepared and initiated, and progress was favorable for the expansion of indications and late-stage development trials.

However, PC transition of new projects was slightly delayed.

In addition, the failure of Phase III trials, including Tecentriq and tiragolumab, led to the suspension of development and changes in the schedule for filing.

On the other hand, 12 projects were approved and launched as planned.

The picture of the number of projects at the bottom of the slide summarizes the project changes at each of the above development stages.

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Review of Strategic Policies for 2022 (2/2)

Maximize the value of growth drivers	<ul style="list-style-type: none"> ● Tecentriq: Early market penetration in expanded indications such as eNSCLC ● Vabysmo: Successful entry into the ophthalmology field, and established product position ● Hemlibra: Steady market penetration in Japan and overseas* ● Establishment of new distribution system: Established an efficient distribution system for specialty products
Strengthen business foundation	<ul style="list-style-type: none"> ● Chugai Life Science Park Yokohama: Completed in October 2022; transfer of research function started in November 2022 ● Steady progress in the drug discovery process using AI technology ● Utilization and consideration of development and application strategies utilizing RWD ● Initiate and expand new value delivery channels: Remote/Digital MSLs, On-line MRs ● Employee awareness survey: A high positive "employee engagement" response rate was maintained. However, issues were found in the "environment for maximizing employees" ● Implement human resource management reform as part of the transformation of affiliates, and build an autonomous business management system ● Digital plants: Initiate digital infrastructure to support new production operations at Ukima Plant

*Hemlibra: Trends of domestic hemophilia A patient share

	'18 Q4	'19 Q4	'20 Q4	'21 Q4	'22 Q1	'22 Q2	'22 Q3	'22 Q4
Share	2.2%	14.4%	20.0%	24.7%	26.3%	27.3%	28.5%	29.2%

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Next are the main results on maximizing the value of growth drivers. Tecentriq, Vabysmo, Hemlibra, Polivy, and others, each of which achieved steady market penetration.

Regarding the strengthening of our business foundation, we have completed construction of the Chugai Life Science Park Yokohama, started digital infrastructure to support more efficient production operations at the Ukima Plant, and are making steady progress in our AI-based drug discovery process.

On the other hand, there are some challenges in terms of human resources regarding environment for maximizing employees. We will accelerate our efforts to address the gap from our goals in the future.

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TOP I 2030 Progress to Date

■ Generally steady progress for two years

Drug Discovery	<ul style="list-style-type: none"> ✓ Steady progress in the clinical study of the mid-size molecule project "LUNA18" ✓ Improvement of digital research infrastructure by introducing AI drug discovery (MALEXA) and experimental robots ✓ Completion of Chugai Life Science Park Yokohama
Development	<ul style="list-style-type: none"> ✓ Progress in simultaneous development of in-house products for multiple diseases (Expanded indications of Enspryng, crovalimab, and GYM 329, and projects out-licensed to third-party) ✓ Obtain regulatory approval of HER/PER mCRC using RWD
Pharmaceutical Technology	<ul style="list-style-type: none"> ✓ Establishment of manufacturing system for mid-size molecule projects (Completion of FJ2, promotion of FJ3 construction, etc.) ✓ Strengthen cost competitiveness by operating a Production operation digital platform in UK3 ✓ Start of new CPMC organization in line with domestic affiliate reforms
Value Delivery	<ul style="list-style-type: none"> ✓ Start new information provision channels (remote/digital MSLs, online MRs, central SEs) ✓ Disseminate the internal value delivery model by changing the marketing structure and using the cross-functional information platform ✓ Prioritized resource allocation for new areas and products
Foundation for Growth	<ul style="list-style-type: none"> ✓ While employee engagement is high, we are only halfway to increasing active employees ✓ Strengthen the foundation of sustainability, including steady progress in environmental measures such as reducing CO₂ emissions ✓ Achieved total 150,000 hours reduction through RPA ✓ Received highest rating in pharmaceutical sector in the DJSI2022 World

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Two years have passed since the start of TOP I 2030. The main results of the past two years are shown on this slide, using the five reforms as a starting point.

While there are challenges that have partially changed trajectories and gaps from targets, overall, we are making good progress.

The entire company is united in our RED SHIFT initiative. We will continue to work toward doubling our R&D output and launching global in-house products every year as targeted in TOP I 2030.

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Updates on Mid-term Milestones

- Although some track changes and gaps remain, we are generally on track to achieve TOP I 2030

Drug Discovery	<p>● Progress on schedule However, for “Creation and Promotion of Innovative Drug Discovery Projects by Strengthening Biology,” the goals are clarified as follows (Before change) Development of a system for utilizing human clinical samples to improve the accuracy of non-clinical research <2024> (Revised) Speeding up access to inaccessible human clinical samples as part of improving the accuracy of non-clinical research <2024></p>
Development	● Progress on schedule
Pharmaceutical Technology	● Progress on schedule
Value Delivery	<p>● Progress is almost on schedule Since it is necessary to reconstruct the plan for the “Introduction of assays for monitoring the therapeutic effects of molecular target drugs,” new goals and options are being considered.</p>
Foundation for Growth	<p>● Progress is almost on schedule However, there are gaps between the target and two items for human resources (HR). We will accelerate our response to the issues and aim to achieve the target. (HR) Increase the number of active employees based on the results of the employee awareness survey • Percentage of active employees: Achieve the same level as high-performing global companies <2024> (HR) Acceleration and penetration of D&I • Positive response rate to the employee awareness survey innovation questions (Quantitative target exists) <2024> In addition, one item was added to human resources from 2023. (HR) Employee's Health</p>

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Next are the mid-term milestones. I would like to add to the point I made on the previous slide where I mentioned that there are some trajectory changes and gaps from the goals.

As you can see, in drug discovery and value delivery, there are items for which we are clarifying and reconsidering targets.

In addition, the employee awareness survey conducted in 2022 revealed a gap with the target in terms of the proportion of active employees. We will accelerate our response to these challenges.

Other items are generally progressing as planned.

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Strategic Policies for 2023

1) Strengthening of RED Function Enhancement and development of in-house development portfolio	2) Maximize the value of growth drivers Promotion of development/VD and evolution of operations	3) Strengthen business foundation Innovation, efficiency, and ESG
<ul style="list-style-type: none"> ➤ Promotion and expansion of development of mid-size molecule projects <ul style="list-style-type: none"> • Promotion of P1 for LUNA18 ➤ Continuous creation of new projects and construction of technology infrastructure <ul style="list-style-type: none"> • Development of next-generation antibody technology ➤ Proof of value of in-house pre-PoC projects and strengthening of Foundation <ul style="list-style-type: none"> • Accelerated development of in-house products ➤ Accelerating Open Innovation <ul style="list-style-type: none"> • Establishment of system for promotion 	<ul style="list-style-type: none"> ➤ Enhance value of post-PoC projects <ul style="list-style-type: none"> • Achievement of approval/application plan ➤ Maximizing value of new products and growth drivers <ul style="list-style-type: none"> • Penetration of mainstay products in Japan and overseas (Hemlibra, Tecentriq, Enspryng, Vabysmo, Polivy, etc.) ➤ Operation Model Evolution <ul style="list-style-type: none"> • Efficient production system and late-stage development operations 	<ul style="list-style-type: none"> ➤ Foster an organizational culture that continues to produce innovation <ul style="list-style-type: none"> • Change human resource behavior and promote D&I ➤ Resource creation by business process reform <ul style="list-style-type: none"> • Promotion of ASPIRE program* and business transformation (Bx) ➤ Sophistication of risk management functions <ul style="list-style-type: none"> • Improvement of risk compliance system ➤ Promotion of autonomous management of affiliated companies <ul style="list-style-type: none"> • Sophistication of group management ➤ Measures to address Mid-Term Environmental Goals <ul style="list-style-type: none"> • Continuous initiatives for environmental protect

*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

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As I have just reviewed, in TOP I 2030, we are making steady progress. In 2023, as in the years through 2022, we have proceeded with three key policies.

We will focus on enhancing our in-house development portfolio and making progress in development, maximizing the value of our growth drivers, and further strengthening our foundation by fostering an organizational culture that continues to generate innovation. We aim to improve business processes, and upgrade risk management functions.

As for business process reforms, we will implement changes to global standard operations and standard-based business processes in conjunction with the ERP update, the next-generation core business infrastructure.

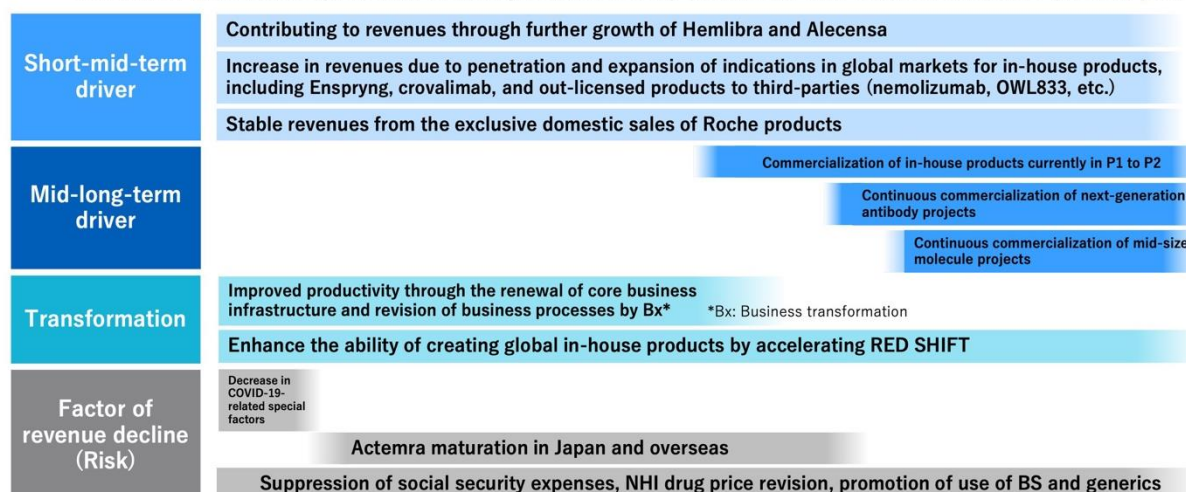
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Outlook of Mid- to Long-term Growth after 2023

- Steady progress in domestic and overseas core business despite uncertainties and ambiguities
- Innovative drug discovery is the key to growth. Double R&D output in 10 years, establish a system to launch innovative global in-house products every year, and aim at a sustainable growth path



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I will continue with an explanation of our medium- to long-term growth outlook for 2023 and beyond.

Regardless of uncertainties in the external environment or the success or failure of individual products or development projects, we anticipate steady progress in our domestic and overseas core businesses. Key factors along the way are listed in categories.

In the short- to medium-term, we expect Hemlibra and Alecensa to contribute to earnings through further growth. We anticipate sales growth for Enspryng and crovalimab, our next global products, as well as the global launch and market penetration of nemolizumab and OWL833, which were licensed out to third parties.

In the mid- to long-term, we anticipate that the commercialization of in-house products, which are currently in Phase I to Phase II, will contribute to earnings. In addition, as a long-term driver, we expect that the next generation antibody project, in addition to LUNA18 and other mid-molecule projects, will go on to become global products.

In each value chain, we are strengthening our infrastructure in parallel. We believe that building such a system will lead to higher productivity and long-term growth.

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Sustainability Management

- The Chugai Group views sustainability as the sustainable development of both our company and society
- Accelerate to promote sustainability throughout the company - deliberation and decision-making by the Board of Directors Meeting, Executive Committee, and Management Advisory Committees



- Four advisory bodies (the EHS Committee, Compliance Committee, Risk Management Committee, and Corporate Communications Committee) will deliberate specific matters within their field of expertise, and then the Executive Committee deliberates and approves plans and policies related to sustainability
- Mr. Yano chairs the EHS Committee, and Mr. Ebihara chairs both the Compliance Committee and the Risk Management Committee. Mr. Itagaki, who chairs the Corporate Communications Committee, will have overall responsibility for all ESG communications
- In addition to the ELT promotion system outlined above, managers, including the heads of each unit, division, and department, will work together to promote sustainability throughout the company

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Next, I would like to talk about sustainability management. For the Chugai Group, sustainability means the sustainable development of both our company and society. The entire company works together to accelerate the proactive promotion of sustainability, while the Board of Directors, the Executive Committee, and the Management Advisory Committee deliberate and make decisions.

I am responsible for sustainability overall, and executive responsibility is shared by eight members of the Executive Committee, which includes myself.

In addition to financial growth, TOP I 2030 aims to place our company as a global role model for leading solutions to social issues. We will also aim to be a leading company in sustainability with respect to ESG and SDGs.

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Summary

- In 2022, Chugai achieved record-high revenues and profits for the sixth consecutive year. Domestic and overseas core business has been steadily growing, even after excluding the Ronapreve effect.
- All five reforms to realize TOP I 2030 made generally steady progress. Strategic policies for 2023 consist of Strengthening of RED function, Maximize the value of growth drivers, and Strengthen business foundation. We will continue to promote RED SHIFT going forward.
- Despite the anticipated decline in revenues and profits in 2023, we expect our core businesses to grow, excluding COVID-19-related temporary impact.
- Backed by steady progress in R&D based on abundant pipelines and proprietary technologies, Chugai aims to achieve sustainable growth by strengthening its strategy and foundation towards the realization of TOP I 2030.

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This last slide is a summary. This concludes my presentation.

Sasai: Next, Mr. Itagaki will give an overview of the consolidated financial results for the fiscal year ending December 31, 2022. Over to you.

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	
Revenues	1,259.9		-91.9	1,168.0	Amortization	+1.7
Sales	1,039.2			1,039.2	Impairment	+0.6
Royalties and other operating income	128.8			128.8		
Other revenue	91.9		-91.9	-	Others	
Cost of sales	-476.3	+1.2		-475.0	Lump-sum income related to settlement agreement with Alexion Pharmaceuticals, Inc., etc.	-90.7
Operating expenses	-250.4	+1.1	+8.0	-241.3	Restructuring expenses, etc.	+6.8
M&D and G&A*	-100.8		+3.1	-97.6		
Research and development	-149.6	+1.1	+4.8	-143.7		
Operating profit	533.3	+2.3	-83.9	451.7		
Financial account balance	-2.1			-2.1		
Income taxes	-156.7	-0.7	+25.6	-131.8		
Net income	374.4	+1.6	-58.3	317.7		
EPS (JPY)	227.57			193.11		

* M&D: Marketing and distribution, G&A: General and administration

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Itagaki: I would like to present the financial results in further detail. Please see page 24. First of all, in terms of IFRS results, revenue exceeded JPY1 trillion, and operating profit was over JPY500 billion. Core results are calculated by adding or subtracting non-core adjustments to or from the full base results.

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The adjustment items are the same as before and consist of updating the amount by the Q4 amount. Looking at the operating profit level, core operating profit was JPY451.7 billion, a decrease of JPY83.9 billion.

FY2022 Consolidated Financial Overview (Core)

P/L Jan – Dec (Year on Year)



(Billions of JPY)	2021	2022	Growth	
Revenues	999.8	1,168.0	+ 168.2	+ 16.8%
Sales	802.8	1,039.2	+ 236.4	+ 29.4%
Domestic	518.9	654.7	+ 135.8	+ 26.2%
Overseas	283.9	384.6	+ 100.7	+ 35.5%
Royalties and other operating income	196.9	128.8	- 68.1	- 34.6%
Royalty and profit-sharing income	187.2	123.2	- 64.0	- 34.2%
Other operating income	9.8	5.6	- 4.2	- 42.9%
Cost of sales	-335.5	-475.0	- 139.5	+ 41.6%
(cost to sales ratio)	41.8%	45.7%	+3.9%pts	-
Operating expenses	-230.2	-241.3	- 11.1	+ 4.8%
M&D and G&A	-100.4	-97.6	+ 2.8	- 2.8%
Research and development	-129.8	-143.7	- 13.9	+ 10.7%
Operating profit	434.1	451.7	+ 17.6	+ 4.1%
(operating margin)	43.4%	38.7%	-4.7%pts	-
Financial account balance	-2.5	-2.1	+ 0.4	- 16.0%
Income taxes	-120.1	-131.8	- 11.7	+ 9.7%
Net income	311.5	317.7	+ 6.2	+ 2.0%
EPS (JPY)	189.35	193.11	+3.76	+ 2.0%

Domestic sales

Increase due to sales growth of new products as well as mainstay products

Overseas sales

Significant increase in sales of Hemlibra and Actemra

Royalty and profit-sharing income

Significant decrease in royalty income for initial shipping inventory of Hemlibra

Other operating income

Decrease in one-time income

Cost of sales

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

Operating expenses

Despite decrease in various expenses, increase in R&D expenses due to progress of development projects and impact of yen depreciation on costs denominated in foreign currencies, etc.

Operating profit

Growth mainly due to increase in sales

25

Now, I would like to talk about core performance. Page 25 shows sales revenue. Last year's result was JPY1.168 trillion, an increase of 16.8% on the previous fiscal year.

Sales in the domestic market grew 26.2% due to strong sales of new and mainstay products. Overseas sales also grew 35.5% due to significant increases in Hemlibra and Actemra.

Royalty and profit-sharing income is down 34.2% due to a significant decrease in royalties related to the initial shipment of Hemlibra, the so-called Royalty 2. Other operating income also decreased by JPY4.2 billion due to lower one-time income.

The cost of goods sold increased by 3.9% to 45.7%, mainly due to changes in the product mix.

Expenses increased by 4.8%, due in part to the progress of development projects and the depreciation of the yen.

As a result, operating profit increased 4.1% to JPY451.7 billion, and the operating margin was 38.7%.

After subtracting financial income/expenses and corporate income tax, net income increased by JPY317.7 billion, or 2%. This is a record high result for the sixth consecutive fiscal year.

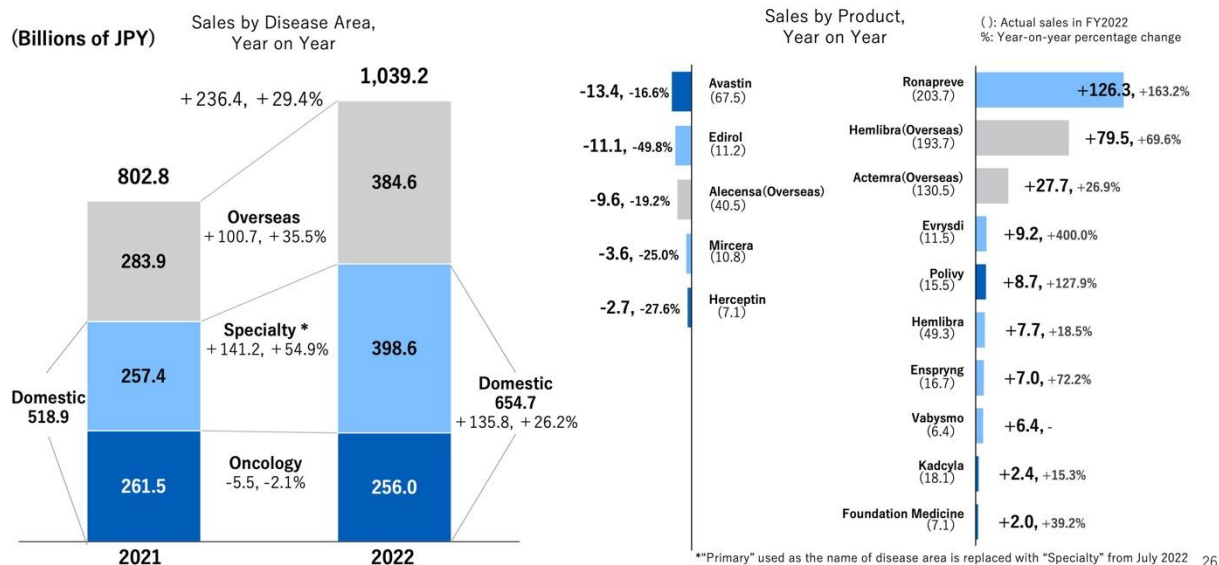
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Sales Jan – Dec (Year on Year)



Next, on page 26, is a breakdown of the change in sales of manufactured goods. First, sales in the oncology area in Japan declined by 2.1%. By product, sales of Avastin and Herceptin declined due to the penetration of biosimilars.

On the other hand, sales of Polivy, which was launched in May 2021, Kadcyla, whose indications were expanded, and Foundation Medicine, to which FoundationOne Liquid was added, are increasing.

Specialty areas saw a 54.9% increase in revenues, while sales of Ronapreve increased by JPY126.3 billion. Evrysdi is increased by JPY 9.2 billion which is launched in August 2021. Sales of our own products, Hemlibra and Enspryng, are also growing steadily.

Vabysmo, which was launched in May of last year, has steadily penetrated the market with sales of JPY6.4 billion.

Products that saw a decrease in sales included Edirol and Mircera.

Overseas sales remained strong with a 35.5% increase in total sales. Overseas sales of Hemlibra grew by about 70%, or JPY79.5 billion. Similarly, overseas sales of Actemra increased by 26.9%, or JPY27.7 billion.

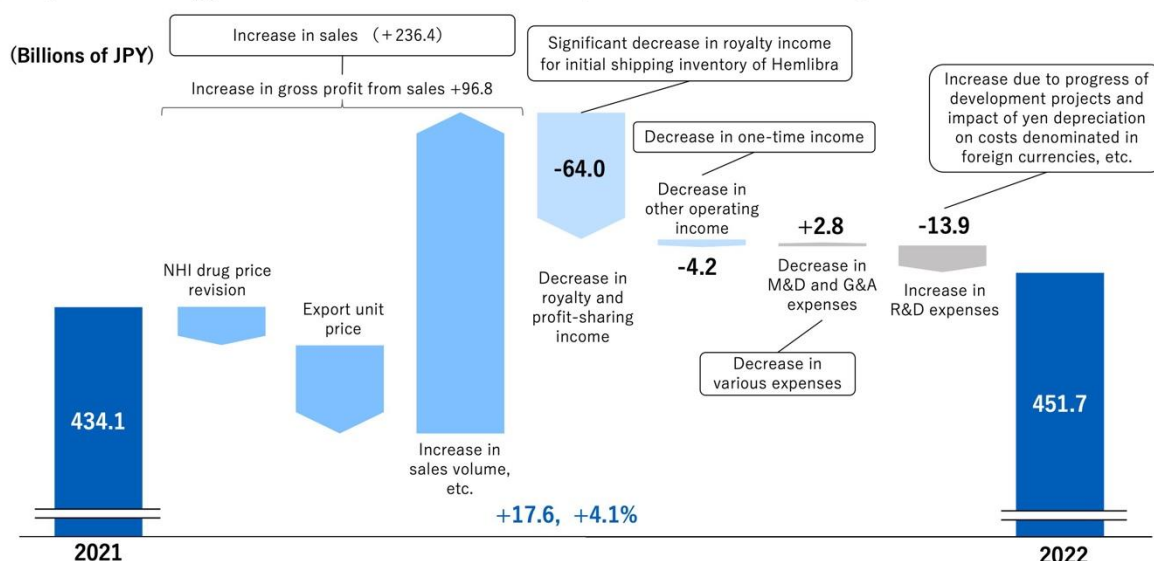
Overseas sales of Alecensa decreased YoY by JPY9.6 billion, partly because Roche's stock buildup had run its course.

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Operating Profit Jan – Dec (Year on Year)



27

Page 27 shows the breakdown of the increase in operating profit. As you can see, there is a downside due to price revision and the decline in export unit prices, but these factors are absorbed by the increase in volume, resulting in a net increase in gross profit of JPY96.8 billion.

Next, royalty and profit-sharing income decreased by JPY64 billion from the same period last year. There is a decrease in Royalty 2 here. In FY2021, the Royalty 2 was JPY97.4 billion, and last year, it was JPY11.2 billion. That is a decrease of JPY86.2 billion. If we subtract that decrease, other royalties increased by JPY22.2 billion.

Other operating revenues, SG&A and R&D expenses are as shown.

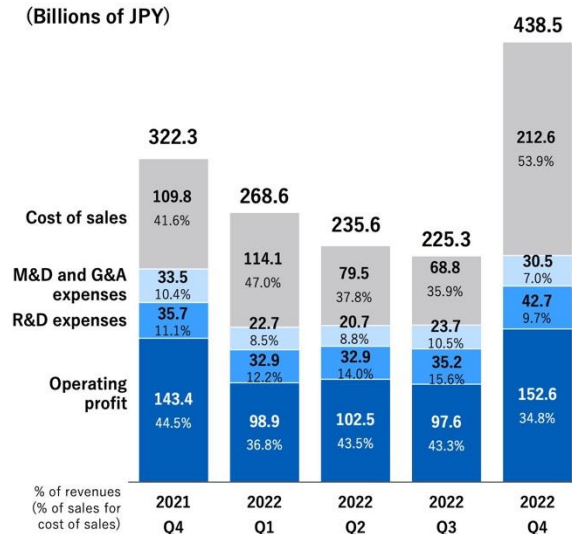
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Structure of Costs and Profit by Quarter

(Billions of JPY)



Year on Year (2021 Q4)

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

M&D and G&A expenses: decrease in various expenses

R&D expenses: increase due to completion of Chugai Life Science Park Yokohama and progress of development projects, etc., as well as impact of yen depreciation on costs denominated in foreign currencies

Operating profit: +9.2, +6.4%

Quarter on Quarter (2022 Q3)

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

M&D and G&A expenses: increase due to the annual upward trend of costs

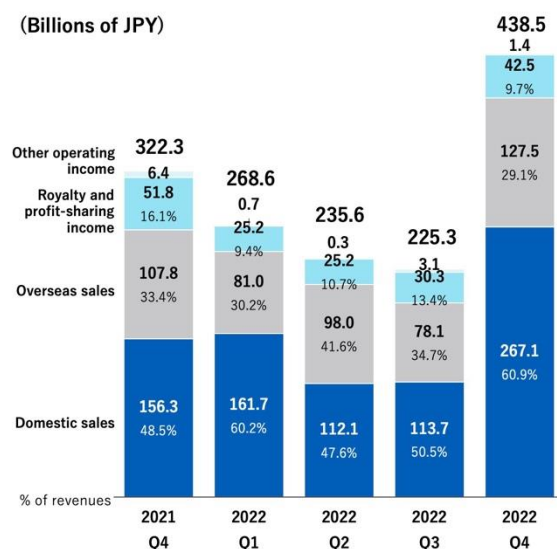
R&D expenses: increase due to completion of Chugai Life Science Park Yokohama and progress of development projects, etc.

Operating profit: +55.0, +56.4%

28

Structure of Revenues by Quarter

(Billions of JPY)



Year on Year (2021 Q4)

Domestic sales: significant increase due to sales growth of new products as well as mainstay products

Overseas sales: increase in sales of Actemra and Hemlibra

Royalty and profit-sharing income: decrease in royalty income for initial shipping inventory of Hemlibra

Quarter on Quarter (2022 Q3)

Domestic sales: significant increase due to sales growth of new products as well as mainstay products

Overseas sales: significant increase in sales of Actemra and Hemlibra

Royalty and profit-sharing income: Increase in royalty income related to intellectual property rights of Hemlibra

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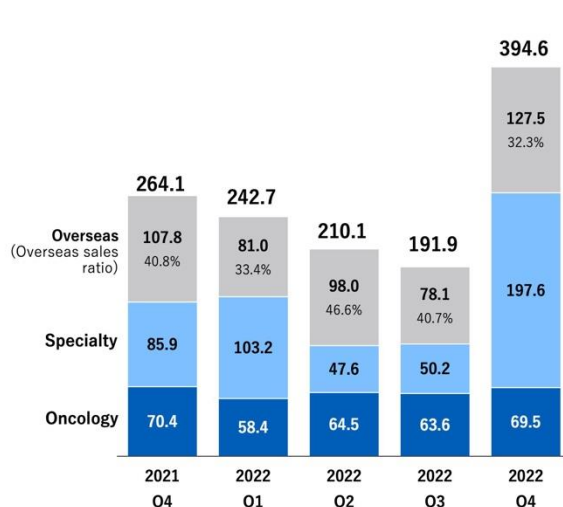
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Structure of Sales by Quarter

(Billions of JPY)



Year on Year (2021 Q4)

Oncology	Avastin:	-4.5	Herceptin:	-0.6
	Polivy:	+3.1	Tecentriq:	+1.0
Specialty	Ronapreve:	+108.2	Vabysmo:	+3.2
	Hemlibra:	+1.8	Enspryng:	+1.7
	Evrysdi:	+1.6	Edirol:	-2.3
Overseas	Actemra:	+11.0	Hemlibra:	+6.2
	Alecensa:	+1.7		

Quarter on Quarter (2022 Q3)

Oncology	Polivy:	+2.9	Tecentriq:	+1.6
Specialty	Ronapreve:	+142.8	Hemlibra:	+1.0
Overseas	Actemra:	+33.5	Hemlibra:	+14.7
	Alecensa:	+1.1		

30

From page 28, the next three slides cover quarterly changes. The volume, or the percentage of Q4 composition, has changed significantly due to the very large impact of the Ronapreve delivered to the government in December.

Aside from this, there is no particular movement that needs to be mentioned. Since time is limited today, I will skip a detailed explanation of this quarterly trend.

P/L Jan – Dec (vs. Forecast)

(Billions of JPY)	2022		+/-	Achiev.
	Forecast	Actual		
Revenues	1,150.0	1,168.0	+ 18.0	101.6%
Sales	1,031.5	1,039.2	+ 7.7	100.7%
Domestic	646.3	654.7	+ 8.4	101.3%
Overseas	385.2	384.6	- 0.6	99.8%
Royalties and other operating income	118.5	128.8	+ 10.3	108.7%
Royalty and profit-sharing income	114.0	123.2	+ 9.2	108.1%
Other operating income	4.5	5.6	+ 1.1	124.4%
Cost of sales	- 460.0	- 475.0	- 15.0	103.3%
(cost to sales ratio)	44.6%	45.7%	+1.1%pts	-
Operating expenses	- 250.0	- 241.3	+ 8.7	96.5%
M&D and G&A	- 100.5	- 97.6	+ 2.9	97.1%
Research and development	- 149.5	- 143.7	+ 5.8	96.1%
Operating profit	440.0	451.7	+ 11.7	102.7%
(operating margin)	38.3%	38.7%	+0.4%pts	-
Net income	312.5	317.7	+ 5.2	101.7%
EPS (JPY)	190.00	193.11	+ 3.11	101.6%

Domestic Sales

Various products outperformed the forecast (see next slide)

Overseas sales

Despite higher sales from foreign exchange impact etc., export of Actemra was delayed due to manufacturing timing

Royalty and profit-sharing income

Exceeded the forecast due to the impact of foreign exchange, etc.

Cost of Sales

Cost to sales ratio higher from the forecast due to the impact of foreign exchange, etc.

Operating expenses

Total expenses are lower than forecast partly due to spending controls throughout the fiscal year

Operating profit

Actual profit exceeded the forecast by +11.7(+2.7%)

* Jan - Dec progress versus Jan - Dec

31

I would like to ask you to turn to slide 31. This is the status of actual achievement against the full-year forecast.

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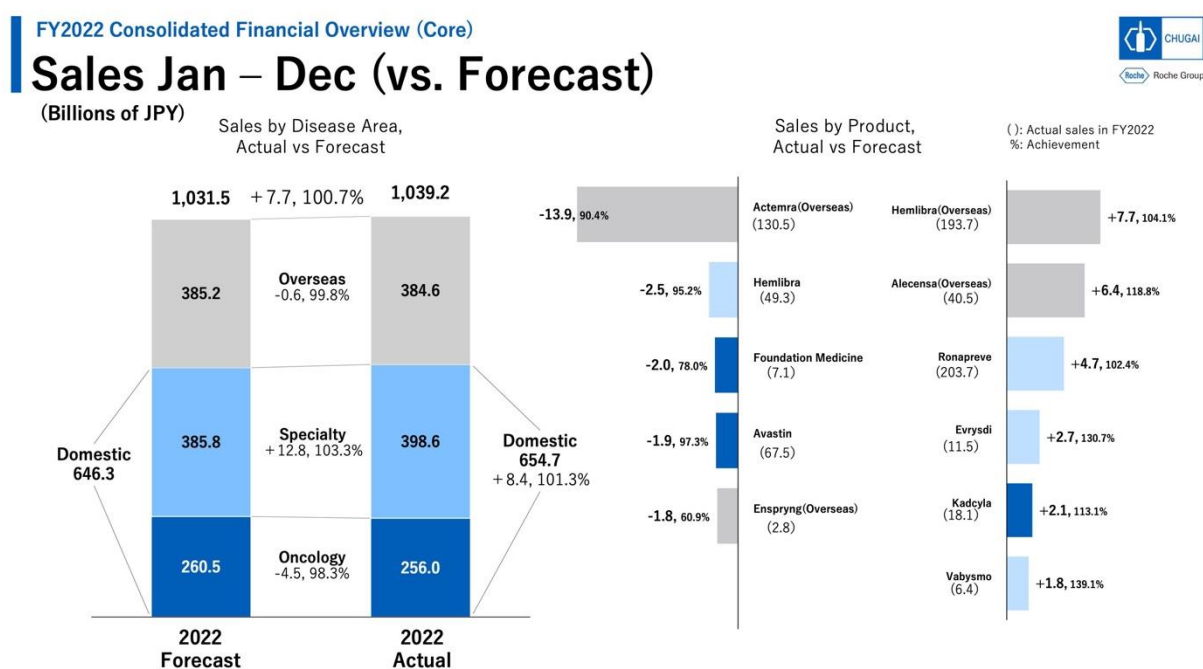
Sales revenue exceeded the forecast by JPY18 billion. Only overseas sales have not reached the forecast, but this is due to the delay in Actemra shipments of approximately JPY15 billion that occurred in Q3.

However, Hemlibra and Alecensa grew steadily, and the positive effect of the yen's depreciation was about JPY12 billion, so when combined with this, overall overseas sales fell short by only JPY0.6 billion.

There is a forecast variance in royalties and cost of sales, respectively, which is due to the impact of foreign exchange rates.

As for expenses, we had already incurred some unspent expenses during the term, and we made efforts to control costs in consideration of this year's budget measures for the next term. We ended last year's term with an underspend of JPY8.7 billion.

As a result, operating profit and net income exceeded the forecast by 2% to less than 3%.



32

Next is the ratio of individual product sales to the forecast. Looking at oncology, specialty, and overseas sales, results were generally in line with the forecast, within the range of plus or minus 3%. Looking at individual products, as shown on the right, the picture is less uniform.

The difference with the forecast was particularly large for three export products. As explained earlier, Actemra fell short of expectations, while Hemlibra and Alecensa made up for this.

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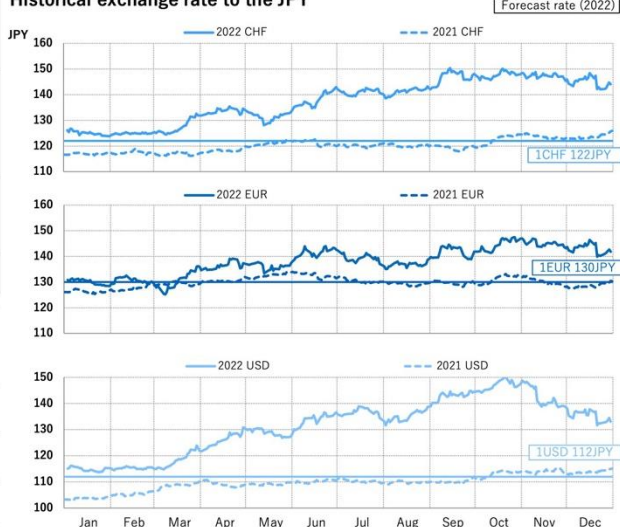
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Impact from Foreign Exchange Jan - Dec

(billions of JPY)	vs. 2021 Actual	vs. 2022 Assumption
Revenues		
Sales	+39.2	+19.6
Royalties and other operating income	+27.9	+12.0
	+11.3	+7.6
Cost of sales	-18.1	-17.6
Operating expenses	-5.3	-3.7
Operating profit	+15.7	-1.7

Market average exchange rate(JPY)	2021 Actual	2022 Assumption	2022 Actual
1CHF	120.10	122.00	137.62
1EUR	129.83	130.00	138.21
1USD	109.75	112.00	131.40

Historical exchange rate to the JPY



33

These overseas sales figures include some foreign exchange effects, and I would like to take a look at that for a moment in the next slide. This is page 33.

The yen weakened during the last year, which had a positive effect of JPY39.2 billion on revenue and a JPY23.4 billion increase in costs and expenses on the expense side. The net effect was positive JPY15.7 billion in operating profit.

As for the contrast to the forecast, the part of the sales revenue that is not hedged by foreign exchange, which we call exposure, was affected by market fluctuations in foreign exchange rates. As a result, there is the upside effect of JPY19.6 for revenues.

On the other hand, on the cost side, the depreciation of the yen has a negative impact on the cost of sales of JPY17.6 billion and an increase in expenses of JPY3.7 billion.

Of the JPY17.6 billion impact on cost of sales, about 75% is attributable to the purchase of Ronapreve delivered to the government in Q4. This was not hedged at the beginning of the period and is directly impacted by the yen's depreciation.

The total unfavorable variance in operating profit was JPY1.7 billion.

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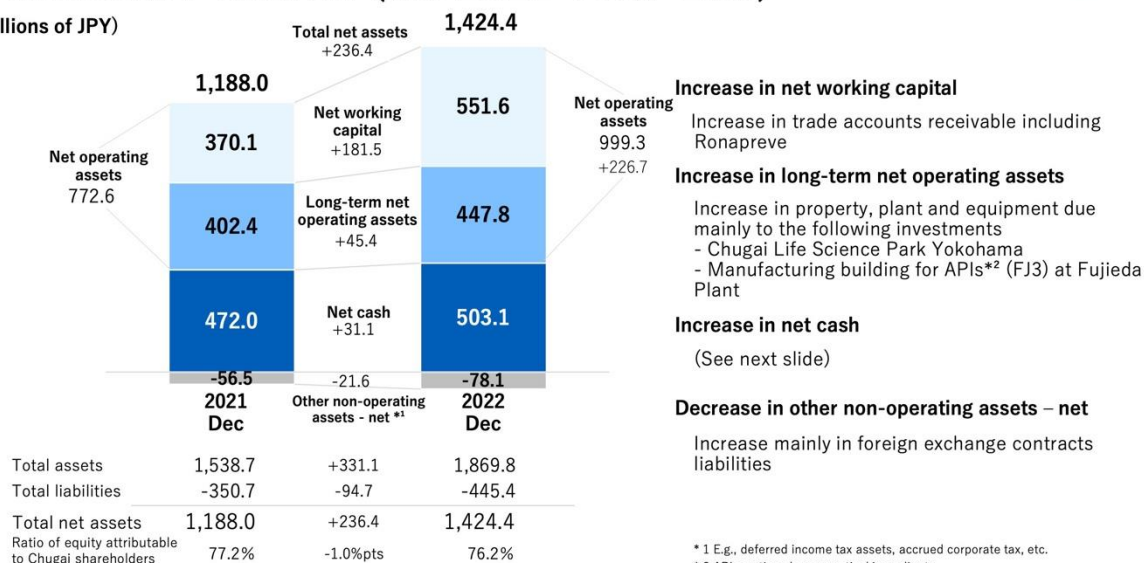
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Financial Position (vs. 2021 Year End)

(Billions of JPY)



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Page 34 is the balance sheet. If you look at the second line from the bottom on the left, total net assets, at the end of last year, were JPY1.4244 trillion, an increase of JPY236.4 billion from the previous period.

And if you look at the line below that, we continue to maintain a robust financial position with a shareholder equity ratio of 76.2%.

Net cash, shown in the middle of the chart, increased by JPY31.1 billion and exceeded JPY500 billion for the first time at the end of the fiscal year.

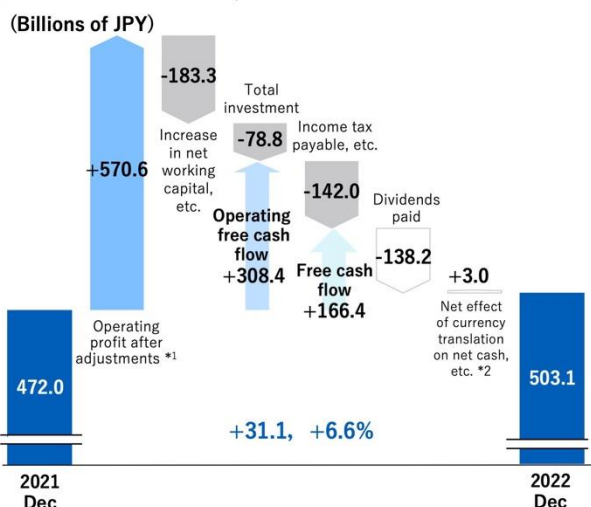
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Net Cash (vs. 2021 Year End)



Operating profit after adjustment *1	+570.6
Operating profit *1	+533.3
Depreciation, amortization and impairment *1	+32.1
Increase in net working capital, etc.	-183.3
Trade accounts receivable, accounts payable and inventory of Ronapreve	-92.0
Total investment	-78.8
Property, plant and equipment	-62.6
Payment for lease liabilities	-7.6
Intangible assets	-8.6
Operating free cash flow	+308.4
Income tax payable, etc.	-142.0
Income tax payable	-152.1
Free cash flow	+166.4
Dividends paid	-138.2
Net effect of currency transaction on net cash, etc. *2	+3.0

*1 Including Non-Core (IFRS results)

*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(*3)

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

35

The next page shows a breakdown of this change in net cash. This is cash flow-in from operating activities. As noted in the second column from the left, there was a cash inflow of JPY570.6 billion after adding back depreciation to operating profit.

The cash flow here is on a full basis, so this includes JPY96.2 billion in cash inflows from the Alexion settlement, converted into yen. Subtracting from this the increase in net working capital, as well as investments in new laboratories and manufacturing facilities, operating free cash flow was positive JPY308.4 billion. After subtracting taxes and dividends, net cash increased by JPY31.1 billion from the previous period to JPY503.1 billion at the end of last year.

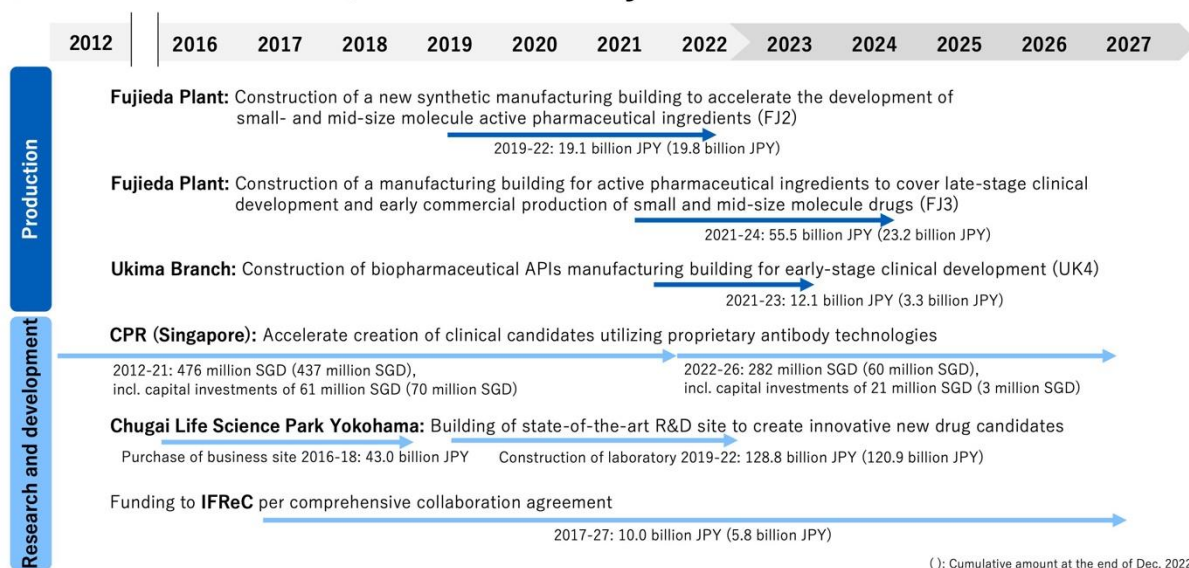
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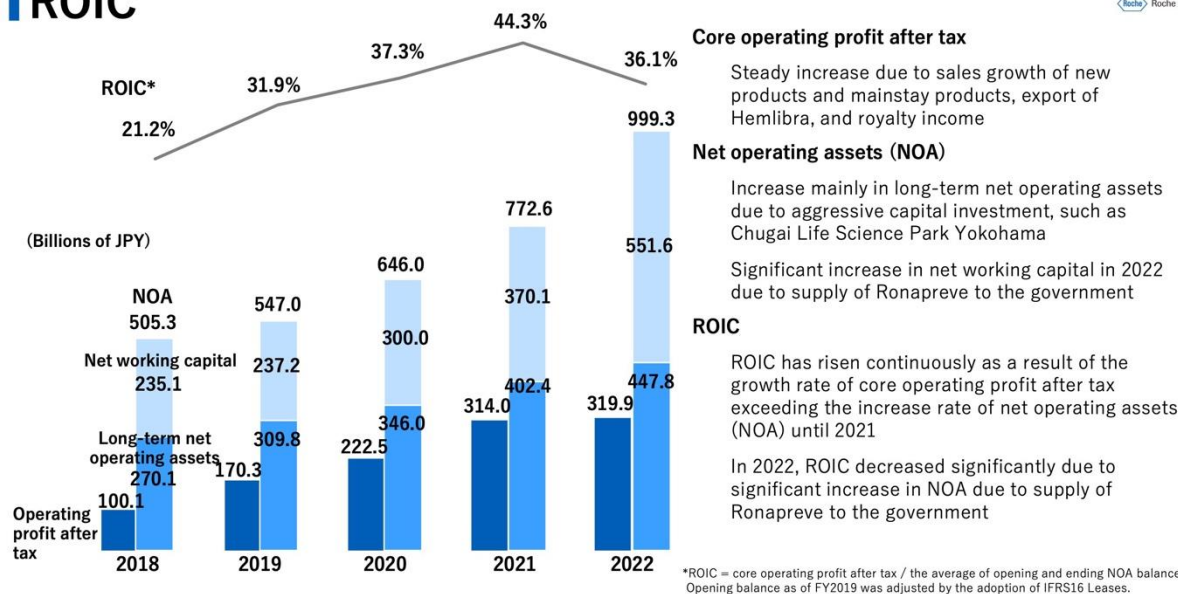
Current Status / Plan for Major Investments



36

Page 36 shows the status of investments. We have updated the actual amount here, and there are no new projects added. The construction of manufacturing facility, FJ2 in Fujieda was completed on August 30 last year. The Chugai Life Science Park Yokohama was completed on October 15, and we are on schedule for full utilization in April. Construction of manufacturing facilities FJ3 and UK4 in Ukima is also progressing smoothly.

ROIC



37

Page 37 shows capital efficiency indicators. This is the trend in ROIC. Last year, the denominator of the ROIC calculation was a little heavier due to the fact that the portion of government deliveries from Q4 remained as accounts receivable. As a result, the ROIC has dropped a little to 36.1%. Despite this, we can say that we are still maintaining a very high level of capital efficiency.

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P/L - Renaming and Reclassification

(Billions of JPY)	2022 Actual		(Billions of JPY)	2022 Actual
Revenues	1,168.0		Revenues	1,167.8
Sales	1,039.2		Sales	1,039.2
Domestic	654.7		Domestic	654.7
Overseas	384.6		Overseas	384.6
Royalties and other operating income	128.8		Other revenue	128.6
Royalty and profit-sharing income	123.2		Cost of sales	- 475.0
Other operating income	5.6		(cost to sales ratio)	45.7%
Cost of sales	- 475.0		Research and development	- 143.7
(cost to sales ratio)	45.7%		Selling, general and administration	- 98.8
Operating expenses	- 241.3		Other operating income (expense)	1.4
M&D and G&A	- 97.6		Operating profit	451.7
Research and development	- 143.7		(operating margin)	38.7%
Operating profit	451.7		Net income	317.7
(operating margin)	38.7%		EPS (JPY)	193.11
Net income	317.7			
EPS (JPY)	193.11			

Blue text :rename categories

0.2 billion JPY

Income from disposal of product rights is reclassified to the new category "Other operating income (expense)"

1.2 billions JPY

Income and expenses associated with operating activities that were previously included in "G&A" but could not be classified into functional expense categories such as gain (loss) on sale of land and buildings, etc., is reclassified to the new category "Other operating income (expense)"

38

First of all, there will be a change in the presentation and reclassification of P&L, which I will briefly explain.

First of all, transfer of products, I mean Bonviva will be transferred to Taisho Pharmaceutical in this fiscal year. The income related to the transfer of products, or the profit and loss associated with the sale of land and buildings, which were previously included in the above sales revenue, will now be included in a new account line item called, other operating income and expenses, under SG&A expenses.

Last year, for these items, JPY200 million and JPY1.2 billion respectively, or a total of JPY1.4 billion, was transferred there.

For those accounts that contained each of these items, we have slightly changed the names to the corresponding accounts.

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P/L 2023 Forecast

(Billions of JPY)	2022 Actual	2023 Forecast	Growth	
Revenues	1,167.8	1,070.0	- 97.8	- 8.4%
Sales	1,039.2	920.0	- 119.2	- 11.5%
Domestic	654.7	541.7	- 113.0	- 17.3%
Overseas	384.6	378.3	- 6.3	- 1.6%
Other revenue	128.6	150.0	+ 21.4	+ 16.6%
Cost of sales	- 475.0	- 405.0	+ 70.0	- 14.7%
(cost to sales ratio)	45.7%	44.0%	-1.7%pts	-
Research and development	- 143.7	- 165.0	- 21.3	+ 14.8%
Selling, general and administration	- 98.8	- 100.0	- 1.2	+ 1.2%
Other operating income (expense)	1.4	15.0	+ 13.6	11times
Operating profit	451.7	415.0	- 36.7	- 8.1%
(operating margin)	38.7%	38.8%	+0.1%pts	-
Net income	317.7	306.0	- 11.7	- 3.7%
EPS (JPY)	193.11	186.00	- 7.11	- 3.7%

Domestic sales

Decrease in supply of Ronapreve to the government

Overseas sales

Decrease in sales of Actemra and Hemlibra, increase in sales of Alecensa

Other revenue

Increase in income for Hemlibra and one-time income

Cost of sales

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

Research and development

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

Other operating income (expense)

Mainly income from disposal of product rights

Operating profit

Despite increase in other revenue and income from disposal of product rights, etc., operating profit decreased due to decrease in supply of Ronapreve to the government and increase in R&D expenses, etc.

39

I will now discuss the full-year forecast for FY2023. Sales are projected to decrease by 8.4%, or JPY1.07 trillion.

There are three reasons for the decrease in revenues. The first point is that sales of Ronapreve are forecast to decrease by JPY122.5 billion. This is the cause of the forecast decrease in domestic sales. Other than the above, we expect growth of JPY9.5 billion, absorbing the impact of price revision and other factors.

The second reason for the decrease in revenues is related to Actemra exports. The demand for Actemra for patients with severe cases of coronavirus and pneumonia has settled down, and our exports of Actemra to Roche will be reduced.

The third point is the export of Hemlibra, which is affected by Roche's optimization of safety stock levels. This will also reduce our exports. The combined effect of Hemlibra and Actemra is negative JPY6.3 billion.

Regarding the cost of sales ratio, we will see a change in the product mix with a reduction in sales of Ronapreve. If you calculate it, while the top line decreased by 8.4%, the gross profit level has decreased by 4% YoY.

However, since we plan to continue to aggressively increase R&D spending, this time by JPY21.3 billion, the degree of decrease in operating profit grows slightly to the 8% level. We are projecting an operating profit of JPY415 billion. However, this is against an operating profit margin of 38.8%, which is higher than last year.

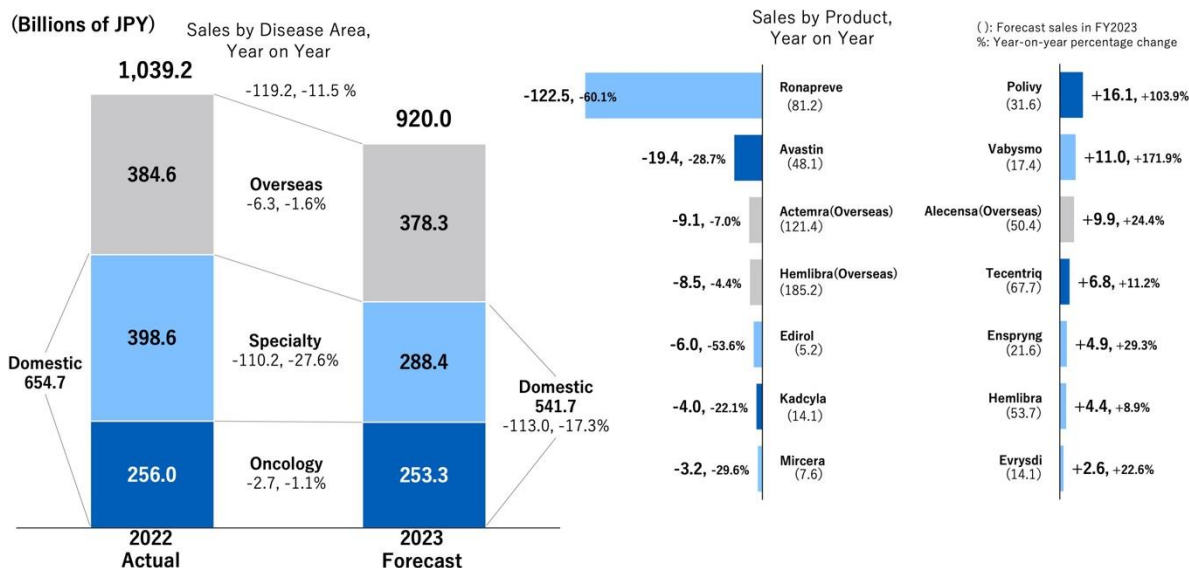
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Sales 2023 Forecast



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I mentioned earlier the three items that triggered the decrease, and on page 26, on the graph of last year's results, on the top right side of the increase, there was Ronapreve, Actemra export, and Hemlibra export. However, when we look at the forecast for this year, this has changed. We anticipate that these three items will see the largest YoY decrease.

As for other products, biosimilars and generics are listed on the lower revenue forecast side, while new products, new drugs, and growth drivers are listed on the higher revenue side.

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Export of Actemra to Roche

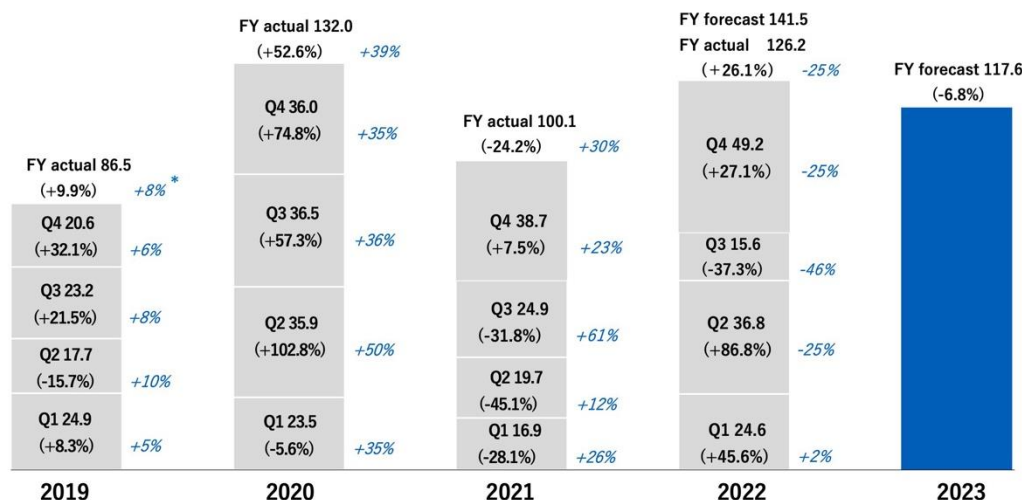
(Billions of JPY)


 CHUGAI
 Roche Group

%: year on year growth
 black: Chugai sales to Roche

blue*: Roche sales excluding Japan (for reference)

*Growth rates in blue are calculated with the effects of exchange rate fluctuations eliminated.



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Page 41 shows Actemra's exports to Roche in chronological order.

In 2022 and the year before that, demand was very strong and there was a shortage of supply on the market side, which was embedded in H1 of last year. However, there were delays in Q3 due to supply chain problems. The impact was approximately JPY15 billion, which means that we fell short of our initial forecast by JPY15 billion.

The Q3 portion was delayed to Q4, and what was expected and planned for Q4 has been delayed to this year.

Nevertheless, since there is no problem on the Roche side in terms of inventory volume, we believe that the impact of the change in exports relating to coronavirus has now temporarily ceased.

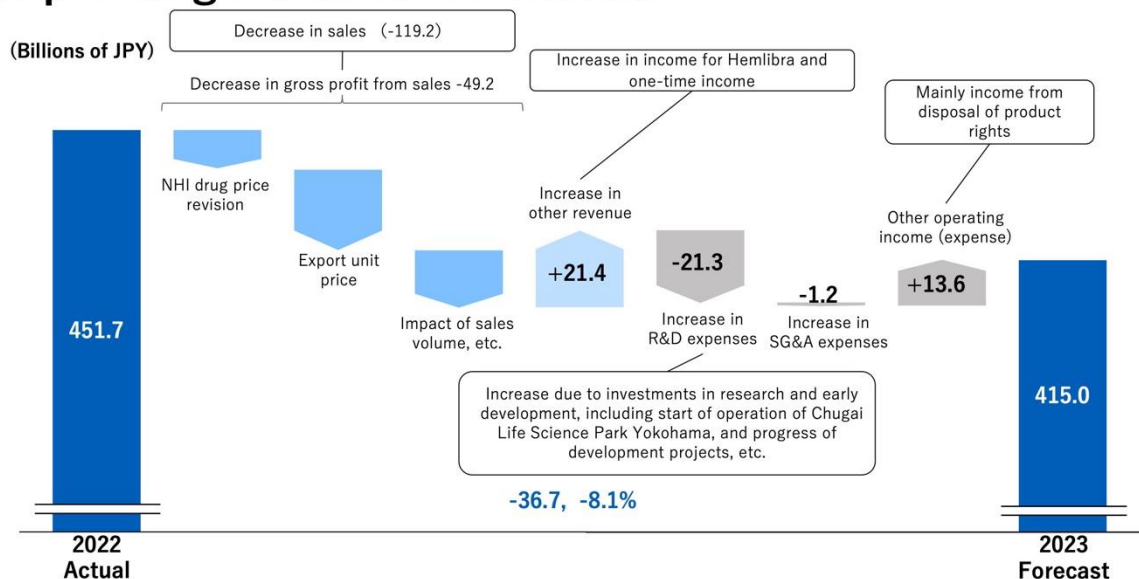
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Operating Profit 2023 Forecast



On page 42, here is a waterfall chart of changes in projected operating profit from the previous year.

There will be another negative impact due to price revision this year. Then there is the impact of falling export unit prices.

In past years, the trend has been to absorb this in volume, resulting in a large increase in gross profit, but for the current fiscal year, the impact of volume has also turned downward.

The main reason for this is that Ronapreve and the export of Actemra, as mentioned earlier, as well as Hemlibra exports, are expected to be on the downside in terms of volume.

Other revenue, which has been renamed, mainly consists of royalties and profit sharing. This includes the Hemlibra Royalty 2, which came to an end last year. The negative impact of the absence of this year's royalty 2 is a negative JPY11.2 billion, but ordinary royalty income is expected to increase, for a total increase of JPY21.4 billion.

In terms of expenses, we are shifting toward R&D investment, with an increase of JPY21.3 billion, while keeping SG&A expenses low.

Other operating income (expense) are expected to be recognized as income, JPY13.6 billion.

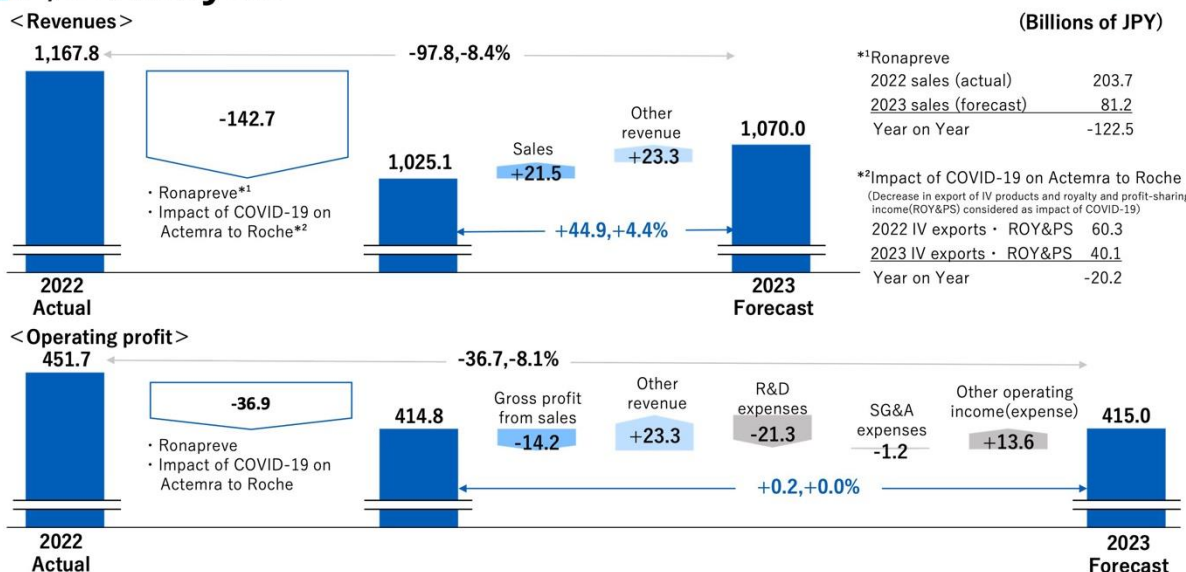
So, if you look at this overall figure, the negative volume impact, the part that points downward, is a very significant factor in the decrease in profit, and this is the decrease in sales of COVID-19 drugs.

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P/L Analysis



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On the last page, we present the results of our analysis, which also includes this perspective.

The top line, revenue, which is also in the section that Dr. Okuda just showed on the slide, and furthermore, in the same way, the bottom line is what this would look like in terms of operating profit.

First of all, the impact of the decrease in sales of COVID-19-related items in terms of sales revenue was JPY142.7 billion. As you can see on the right, first of all, the decrease in Ronapreve alone amounts to JPY122.5 billion.

In addition, as indicated by asterisk two on the right, the impact and fluctuation of COVID-19 demand is linked to the export of IV products, that is, Actemra. One of the reasons for this is that the increase or decrease in Actemra IV exports will still be affected by demand relating to COVID-19.

We also receive royalties from Roche on the sales of IV drugs. Also, profit sharing. The change in this amount was also be affected by the export of IV products in 2022 and the amount of royalties and profit share received from Roche for IV products, which is JPY60.3 billion. The forecast for this year is JPY40.1 billion, so the difference of JPY20.2 billion will have an impact, and if you combine it with the Ronapreve total mentioned earlier you get JPY142.7 billion.

This is the reason for the decrease in revenue from last year to this year's forecast. If we take this out of the equation, what is happening in 2023 forecast? There is an increase of JPY44.9 billion, as described earlier.

This is exactly the same, and if we now move to operating profits, we see that operating profits have decreased by JPY36.9 billion, which corresponds to the JPY142.7 billion decrease in sales of COVID-19 therapeutics.

If we eliminate this, we see that there is a JPY200 million increase otherwise. However, if you look at the breakdown of the JPY200 million, even though we plan to invest JPY21.3 billion in R&D, we still have a flat JPY200 million in 2023 forecast, and although I have not mentioned it here, there was also the impact of inventory adjustments on the Roche side for the export of Hemlibra. Even after absorbing such things, we

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were able to achieve a profit of JPY200 million. So, the last two messages that I would like to convey on this qualitative side, because of the fact that the other profit phases are constant. The base business is solid. The second point is that we will not slacken our efforts in R&D toward achieving TOP I 2030. This concludes my presentation.

Sasai: Now, Mr. Yamaguchi will give an update on the status of the development pipeline. Over to you.

Overview of Development Pipeline

Q4 Topics



As of February 2, 2023

Launched	Edirol tablet	Osteoporosis (Additional dosage form)	December 2022
Approved	Gazyva	CD20-positive CLL (including small lymphocytic lymphoma)	December 2022
	Actemra/RG1569	COVID-19 in hospitalized adult patients (US)	December 2022
	Hemlibra/RG6013	Moderate hemophilia A (EU)	January 2023
Filed	FoundationOne Liquid CDx cancer genomic profile	Capmatinib hydrochloride hydrate: NSCLC (<i>MET</i> exon14 skipping alterations)	December 2022
New to pipeline	Alecensa/RG7853	Stage III NSCLC (maintenance treatment after chemoradiotherapy)	P3(November 2022)
	tiragolumab	Non-squamous NSCLC (1L)	P3(November 2022)
	RAY121	Autoimmune disease	P1(October 2022)
	ALPS12/RG6524	Solid tumors	P1(January 2023)
Medical conference	cevastamab	r/r MM	P1(November 2022)
	crovalimab/RG6107	COMMODORE 3 study (PNH), efficacy and safety data: ASH	December 2022
	Hemlibra/RG6013	HAVEN 7 study (infant with hemophilia A), interim analysis: ASH	December 2022
	Polivy	POLARIX study (DLBCL), PFS and OS data at 3 years: ASH	December 2022
Others	AMY109	Non-clinical efficacy data including MOA: The 44th Annual Meeting of the Japanese Society of Endometriosis	January 2023
	OWL833/orforglipron	Announcement of P2 study results for obesity* and type 2 diabetes	December 2022
Development discontinued	Tecentriq	NSCLC (2L) (CONTACT-01 study in combination with cabozantinib)	
	Tecentriq	UC (1L) (IMvigor130 study)	
	gantenerumab	Alzheimer's disease (GRADUATE1/2 study)	

Letters in orange : in-house projects (global development)

Letters in blue : in-licensed from Roche (development and distribution in Japan)

* preliminary data

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Tetsuya Yamaguchi: Thank you. We start on page 45. First, here is a summary of Q4 topics.

The launch, approval, and filing parts have already been announced.

Coming to the pipeline entry, first of all, Alecensa and tiragolumab have started a new Phase III trial.

We are not disclosing the mechanism of action or target disease for RAY121, which is an in-house developed antibody applying recycling antibody technology, but we will aim to develop for multiple diseases simultaneously.

The results of the COMMODORE 3 trial for crovalimab, which was filed in China, were presented at ASH. I will explain in detail later.

In addition, non-clinical efficacy data including mode of action for AMY109, developed in-house, was presented at the Japanese Society of Endometriosis. AMY109 is an antibody that inhibits IL-8.

In addition, it was confirmed that AMY109 induced improvement in monkeys with surgically induced endometriosis.

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ALPS12/RG6524

The first next-generation T-cell redirecting antibody applying Chugai's proprietary Dual-Ig® technology. Phase 1 study for solid tumors initiated.



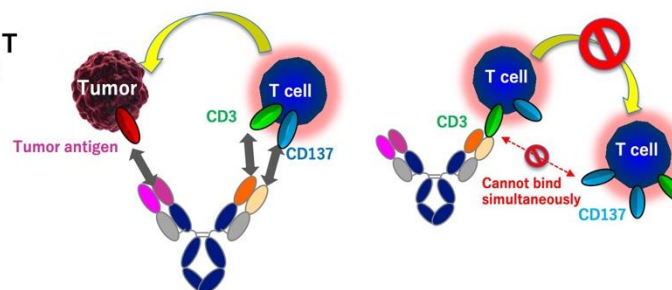
■ Characteristics of Dual-Ig®:

- Dual-Ig® binds to CD3 and CD137 with T cell binding Fab. It is designed to avoid binding to CD3 and CD137 simultaneously.
- This would result in CD3-mediated activation and CD137-mediated costimulation of T cell only in the presence of tumor antigen.

■ Effect of CD137 signal*:

- T cell proliferation and survival
- Th1 cytokine production
- Prevention of T cell exhaustion

* Adrienne L, Nat Med. 2015 Jun; 21(6): 581–590.



Conceptual illustration: Dual-Ig®

- * Tumor antigen is not disclosed
- * Actual molecular shape of ALPS12 is different from the molecular shape of Dual-Ig® used in this conceptual illustration.
- * Out-licensed to Roche

Source: Slides partly modified from Chugai R&D Meeting (Dec, 2021) 46

I would like to start with an explanation of ALPS12, a Chugai originated product.

ALPS12 is a next-generation T-cell redirecting antibody that uses our proprietary Dual-Ig technology.

Unfortunately, I cannot disclose the target tumor antigen at this time. However, we believe that the application of Dual-Ig technology will give us an advantage over our competitors.

In other words, the Dual-Ig technology allows this antibody to bind not only to CD3 but also to CD137. This would result in CD3-mediated activation and CD137-mediated costimulation of T cell in the presence of tumor antigen.

While reducing systemic side effects, the drug is expected to have an anti-tumor effect by activating T cells more potently and continuously at the tumor site.

We have already out-licensed ALPS12 to Roche in the pre-clinical stage, and our intention is to promptly conduct Phase I study for solid tumors in collaboration with Roche.

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Cevostamab : Relapsed or Refractory Multiple Myeloma

Antitumor efficacy is expected via cytotoxic T cell activation against myeloma cells. Local Phase 1 study initiated.

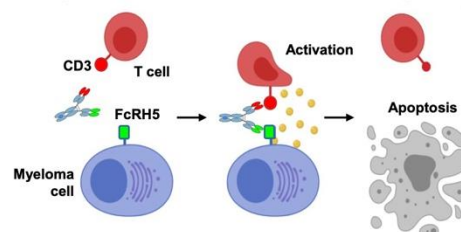
- Multiple myeloma is a tumor of plasma cells differentiated from B cells, and causes abnormal monoclonal immunoglobulin (M protein) production, hematopoietic disorders (mainly anemia), renal disorders, osteolytic lesions, etc.
- Fc receptor-homolog 5 (FcRH5) has been shown to be selectively expressed in B cell lineages, including plasma cells^{*1}.

FcRH5 expression level: myeloma cells > B cells

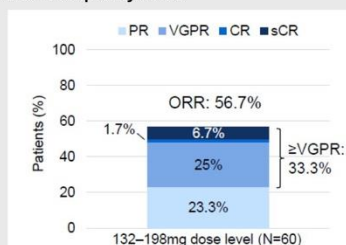
- Cevostamab is a humanized bispecific monoclonal antibody against FcRH5/CD3 that binds to FcRH5 on myeloma cells and CD3 on T cells to activate cytotoxic T cell-mediated immunity and kill myeloma cells^{*1,2}.
- Anti-tumor activity has been demonstrated in the ongoing Global P1 study conducted by Roche^{*2}.

1. Li et al. Cancer Cell 2017;31:383–95, 2. Suzanne Trudel et al. ASH2021

ORR: over all response rate, VGPR: very good partial response, PR: partial response; sCR: stringent complete response, CR: complete response



Results of global P1 study (single agent) for previously treated multiple myeloma



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Next, I will talk about cevostamab. This is an antibody introduced from Roche. Multiple myeloma is a tumor in which plasma cells that have differentiated from B cells become cancerous. It is most common among the elderly, accounting for about 10% of all blood cancers.

Cevostamab is an antibody that bispecifically binds to FcRH5, which is expressed on B cell lineages including plasma cells, and CD3 on T cells. It is expected to induce anti-tumor effects via cytotoxic T cells.

As already shown in the graph, a response rate of 56.7% has been achieved in Phase I monotherapy study overseas.

FcRH5 is Roche's exclusive target, currently the only product in development targeting FcRH5 is cevostamab.

We expect to provide a new treatment option for patients with this type of disease who repeatedly relapse with existing drugs.

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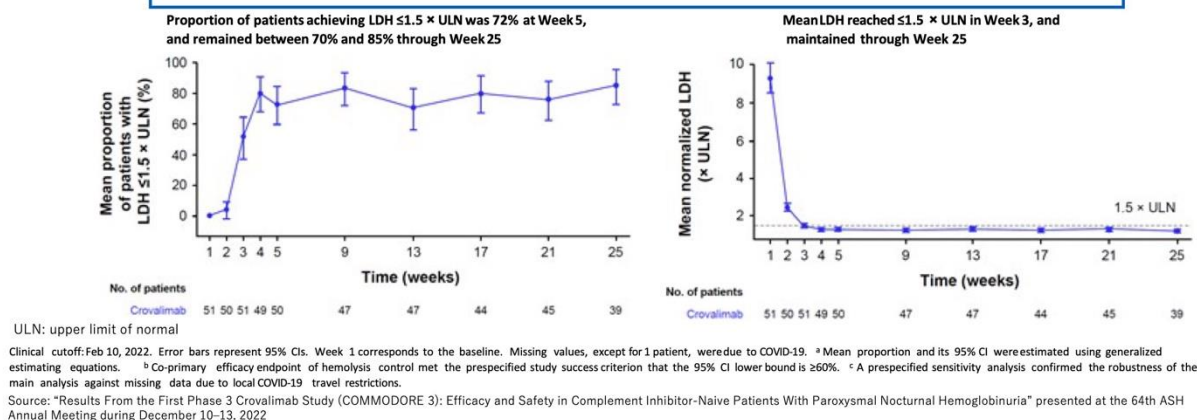
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Crovalimab: Data from COMMODORE 3 Study (China) (1/2)

Phase 3 single-arm study in PNH (complement inhibitor-naïve patients) met co-primary endpoints (hemolysis control and transfusion avoidance)

■ Achieved rapid and stable hemolysis control

Mean proportion of patients achieving hemolysis control ($LDH \leq 1.5 \times ULN$) from Week 5 through Week 25 was 78.7% (95% CI: 67.8, 86.6)^{a-c}



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The next two slides show the results of the COMMODORE 3 study for crovalimab.

COMMODORE 3 is a Phase III single-arm study conducted in China in patients with PNH who have not been treated with a complement inhibitor.

The first primary endpoint, hemolysis control, is defined as hemolysis control with LDH levels below 1.5 times the upper limit of normal.

As shown in the graph on the left, the percentage of patients who achieved hemolysis control remained between 70% and 85% from the 5th week to the 25th week of treatment.

The graph on the right side shows the mean LDH group. It reached less than 1.5 times during the third week of treatment and was maintained for 25 weeks thereafter. This is interpreted as rapid and stable hemolysis control achieved with crovalimab treatment.

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Crovalimab: Data from COMMODORE 3 Study (China) (2/2)

Phase 3 single-arm study in PNH (complement inhibitor-naïve patients) met co-primary endpoints (hemolysis control and transfusion avoidance)

- Patients with transfusion avoidance reached 51.0% from baseline through Week 25, a statistically significant improvement compared with 0% during 24 weeks prior to screening
- The overall safety data were consistent with the known safety profile of C5 inhibitors and the underlying disease. No new safety signals were identified with crovalimab and it was well tolerated
- No neutralizing antibodies against crovalimab were detected during the first 24 weeks of study treatment

	Crovalimab (N=51)	
	Prior to screening ^a	from baseline through week 25
Patients with transfusion avoidance, n (%)	0	26 (51.0)
95% CI	0.0, 8.7	36.8, 65.1
Difference in proportions (95% CI), %	51.0 (34.3, 65.1)	
P value ^b	<0.0001 ^c	
pRBC units transfused per patient, mean (SD)	10.8 (6.6)	4.6 (6.7)
Among patients who did not achieve transfusion avoidance (n=25) ^e	13.4 (6.5)	9.4 (6.8)

Clinical cutoff: Feb 10, 2022. ^a Within 24 weeks prior to screening. ^b Paired McNemar test. ^c Statistically significant at two-sided type I error level of 0.05. ^d Post-hoc subgroup analysis. Source: "Results From the First Phase 3 Crovalimab Study (COMMODORE 3): Efficacy and Safety in Complement Inhibitor-Naïve Patients With Paroxysmal Nocturnal Hemoglobinuria" presented at the 64th ASH Annual Meeting during December 10–13, 2022

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The next slide shows the results of the second primary endpoint, transfusion avoidance. Transfusion avoidance is defined as the percentage of patients who avoided transfusion from baseline through week 25.

Within 24 weeks prior to screening, no patients avoided transfusions, but by 25 weeks after treatment, 51%, or about half of the patients, avoided transfusions, a statistically significant improvement.

In addition to this, several secondary endpoints were met, no new safety issues were identified, and the drug was well tolerated.

In China, the main treatments for PNH remain blood transfusions and symptomatic treatment. In this study, patients with relatively severe PNH were enrolled. We believe that there is currently a very high unmet medical need for PNH.

China has designated crovalimab for priority review, and we expect approval in H1.

Meanwhile, the global Phase III trials for PNH are being conducted in Japan, the US, and Europe. The readouts of the two Phase III trials, COMMODORE 1 and COMMODORE 2, are scheduled to be conducted during this quarter. This antibody drug is expected to be our next growth driver.

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2022: Key R&D Milestones

	Product	Indication/Study name	Progress
Projects to be approved	Actemra	COVID-19 pneumonia (Japan)	✓
	Actemra	COVID-19 pneumonia (US)	✓
	Mitchga	Atopic dermatitis (Japan)	✓
	Hemlibra	Acquired hemophilia A (Japan)	✓
	Herceptin/Perjeta	HER2 positive CRC	✓
	Vabysmo	nAMD	✓
	Vabysmo	DME	✓
	Tecentriq	NSCLC [adjuvant]	✓
	Polivy	Previously untreated DLBCL	✓
	Gazyva	CD20-positive CLL (including small lymphocytic lymphoma)	✓
P3/Pivotal readouts	Alecensa	ALINA Study: NSCLC [adjuvant]	<u>2023</u>
	crovalimab	COMMODORE 3 study (China): PNH	✓
	nemolizumab	OLYMPIA 2 study: Prurigo nodularis	✓
	gantenerumab	GRADUATE 1/2 study: Alzheimer's disease	✗
	Vabysmo	BALATON/COMINO study: RVO	✓
	Tecentriq	IMpower030 study: NSCLC [neoadjuvant]	<u>2024</u>
	Tecentriq	IMmotion010 study: RCC [adjuvant]	✗
	Tecentriq	IMvove010 study: HNC [adjuvant]	<u>2023</u>
	Tecentriq + Avastin	IMbrave050 study: HCC [adjuvant]	✓*
	Tecentriq + tiragolumab	SKYSCRAPER-01 study: NSCLC [1st line]	<u>2023</u>
	Tecentriq + tiragolumab	SKYSCRAPER-02 study: SCLC	✗

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan)
Underlined are new progress since October 24, 2022 * January 2023

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Now, coming to the next slide, page 50, I will summarize the major R&D events of 2022 and their results.

The progress from the Q3 financial results is underlined. If you look at the Phase III readout, unfortunately, gantenerumab did not meet its primary endpoint in Alzheimer's disease.

On the other hand, in two trials for retinal vein occlusion, Vabysmo met the primary endpoints in both trials.

Several other trials on Tecentriq have been continued.

In addition, looking at 2022 as a whole, some studies, particularly for Tecentriq, failed to meet their primary endpoints. This is as expected, as we take some calculated risks as we move forward in development.

As we continue to aggressively pursue clinical development, we will continue to take certain risks in terms of competition and novelty.

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2023: Key R&D Milestones



	Product	Indication/Study name	Progress
Projects to be approved	Actemra Hemlibra crovalimab RG6264 (PER/HER FDC)	SSc with ILD (EU) <u>Moderate hemophilia A (EU)</u> PNH (China) HER2 positive BC and CRC	✓
P3/Pivotal readouts	Alecensa crovalimab <u>Tecentriq + Avastin</u> Tecentriq Tecentriq Tecentriq + tiragolumab mosunetuzumab + Polivy delandistrogene moxeparvec	ALINA study: NSCLC [adjuvant] COMMODORE 1/2 study: PNH <u>IMbrave050 study: HCC [adjuvant]</u> IMpassion030: eBC [adjuvant] IMvove010 study: HNC [adjuvant] SKYSCRAPER-01 study: NSCLC [1st line] SUNMO study*: r/r aNHL EMBARC study	✓

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

Underlined are new progress since January 1, 2023 *readouts expected in 2023/24

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The next slide shows major R&D events for the year 2023. The progress made since January is also underlined.

There are four approvals, including the approval for Hemlibra in moderate hemophilia A in Europe.

The bottom row, readouts, has eight points. Of these, an adjuvant treatment trial of Tecentriq in combination with Avastin for hepatocellular carcinoma met its primary endpoint of recurrence-free survival at the interim analysis.

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Potential Market Sales* of Post PoC Projects

As of February 2, 2023

In-house projects	Indications	Global sales** (billion JPY)	Peak Sales Year
Hemlibra	Hemophilia A, acquired hemophilia A	400-800	-2030
Alecensa	NSCLC, ALCL, NSCLC (adjuvant), etc.	200-400	-2030
Enspryng	NMOSD, gMG, AIE, MOGAD, etc.		2031 and beyond
crovalimab	PNH, aHUS, SCD, etc.	100-200	-2030

In-licensed (Roche)	Indications	Domestic sales (billion JPY)	Peak Sales Year
Tecentriq	Lung cancer, BC, HCC, Urological cancer, HNC, etc.	120-240	2031 and beyond
Polivy	DLBCL	30-60	-2030
Vabysmo	nAMD, DME, RVO		2031 and beyond
Evrysdi	SMA	15-30	-2030
RG6264 (PER/HER FDC)	MBC, eBC, CRC		-2030
tiragolumab	NSCLC, Esophageal cancer, etc.		2031 and beyond
giredestrant	MBC, eBC		2031 and beyond
Gazyva	FL, LN, etc.	< 15	-2030

*Not considering probability of success

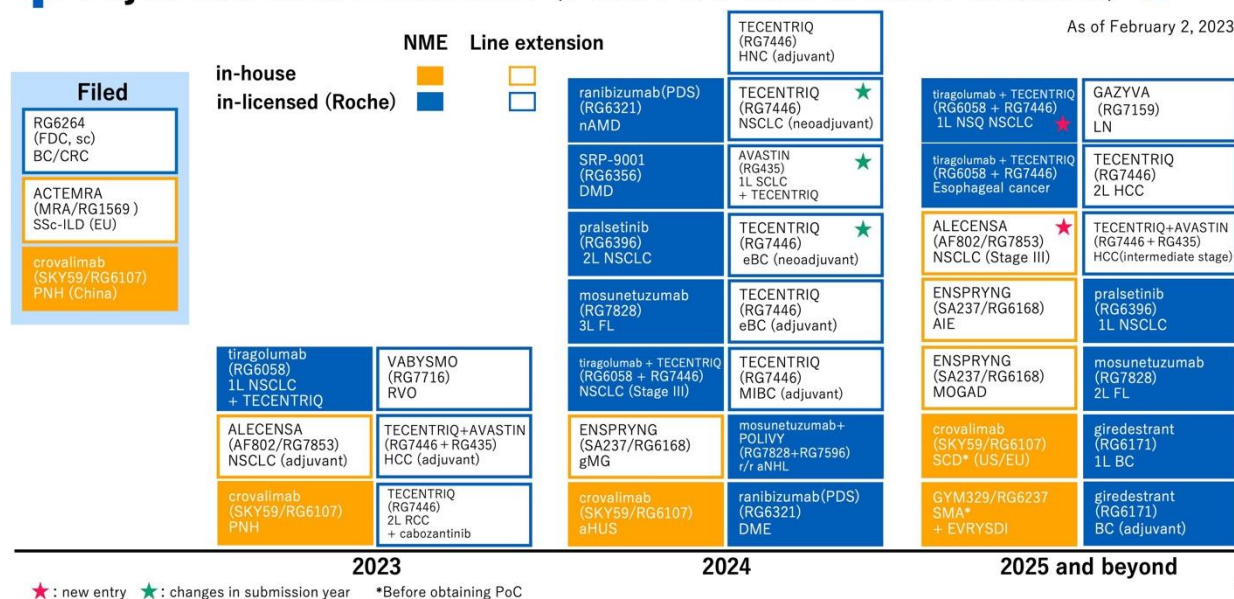
**Global sales are calculated at 1 CHF = 138 JPY

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The next slide shows the updated market sales forecast for the projects after the proof of concept. The range of expected peak sales has been clarified by doubling each level. On top of that, these figures are in the nature of current estimates and projections that do not take into account the probability of success.

Projected Submissions (Post PoC NMEs and Products)

As of February 2, 2023



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Moving on to the next slide, this is the schedule for future applications. As always, red stars indicate new additions, and green stars indicate projects whose year of application has changed.

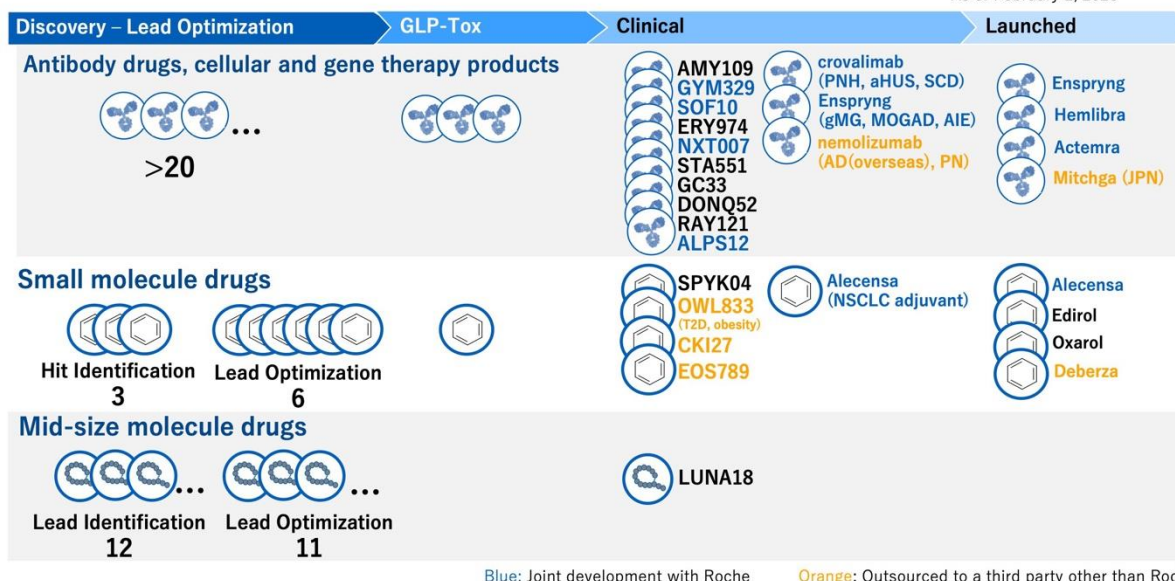
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Research Portfolio of Each Modality

As of February 2, 2023



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The next slide shows the status of the research portfolio for each modality. We believe that development is progressing very well.

The following slides are for reference only, and as always, we have included slides showing the development pipeline and the progress of third-party licensing projects, and so on. Please refer to them as necessary. That is all from me.

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Question & Answer

Sasai [M]: We will now move on to the Q&A session. Mr. Hidaka, Executive Vice President, Head of Marketing & Sales Div., will also be present for the Q&A session.

We would like to limit each person to one question today. We would appreciate your cooperation as another company's financial results presentation is scheduled after this meeting. If we can't answer your question today, we would be happy to take your questions at another time.

Please note that the audio of your questions will be posted on our website at a later date, along with the presentation. Now, I would like to begin by taking questions from the audience. We would appreciate it if you could tell us your company name and name when asking a question. Thank you. Now, the person at the front.

Sakai [Q]: Thank you very much. My name is Sakai from Credit Suisse. I would like to ask for a comment on an individual product. I understand that Actemra's coronavirus-related sales will decrease this fiscal year, but I think there is a possibility that a Fresenius Kabi's biosimilars (BS) will be launched. Personally, I only have a little information about that. How much information do you have about the development of this BS?

Please let me confirm that the risk of Fresenius coming in has not been factored into the forecast for the current fiscal year.

Okuda [A]: Thank you for your question, Mr. Sakai. I will answer your question. First of all, we have received information that several companies are developing Actemra BS. For Fresenius Kabi, the regulatory authorities have announced that the FDA and EMA have accepted the applications for approval for the SC and IV formulations. I think this was last August.

We have entered into a settlement agreement with Fresenius Kabi regarding Actemra patents. Due to confidentiality reasons, we are unable to state when the Actemra BS will be launched. However, we expect the impact on sales in Europe and the United States in FY2023 to be limited.

Another company that is making progress is Biogen/Bio-Thera. Bio-Thera is a Chinese company. Information has emerged that Bio-Thera received approval for its IV formulation in China on January 16, 2023, just a few days ago.

Biogen has the rights outside of China, and it was announced that the EMA accepted the application for the IV formulation on September 30, 2022, and the FDA accepted the application on December 9, 2022.

The timing of the market launch is unknown. However, even if the product is launched in 2023, we believe that its impact on Actemra's US and European sales in 2023 will be limited. Thank you.

Sakai [M]: Thank you.

Sasai [M]: Thank you very much. Next question, please. Mr. Hashiguchi.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities. I was wondering if we can expect that the optimization of inventory level of Hemlibra at Roche will be almost completed in the current fiscal year, and that the next fiscal year will see growth in reaction to that. In relation to this, on page 52, you show a forecast for peak sales, and the lower limit for Hemlibra is JPY400 billion, which is almost the same as the actual results for FY2022. Could you tell us how likely you consider the lower limit scenario to be?

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Okuda [M]: Thank you for your question, Mr. Hashiguchi. Mr. Itagaki will say a few words on the optimization of inventory levels, and then I will talk about the status of growth after this fiscal year.

Itagaki [A]: First of all, the scale of the inventory level optimization by Roche is about one month's worth. Therefore, in terms of our export value, we are now looking at about JPY20 billion. We have just exchanged forecasting with Roche in the form of rolling forecasting, and at this point, we believe that the impact of inventory optimization on our company will be almost complete this year.

Okuda [A]: Regarding the future growth potential of Hemlibra, Roche announced last year that local sales of Hemlibra increased by 27% YoY. The main driver of this growth has been the significant growth in regions outside of the US and Europe.

As I mentioned earlier in my explanation, Hemlibra's market share in Japan is steadily progressing and growing. Considering these factors, we believe there is still room for growth in the Hemlibra revenues.

On the other hand, the range of JPY400 billion to JPY800 billion is quite broad, so while JPY400 billion is at the bottom of the range, in fact that has already been exceeded. The possibility of peak sales of JPY400 billion is, as you can imagine, not very high. It is assumed that the figure will still grow in the future.

Hashiguchi [Q]: It may vary from item to item, but in the main scenario, is it correct to say that the median value is about the same in all cases, and that there are no major deviations?

Okuda [A]: I will refrain from mentioning whether this is the median or not, but I hope you understand that this is the range that Chugai is currently looking at.

Hashiguchi [M]: Thank you very much.

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

Kohtani [Q]: My name is Kohtani from Nomura Securities. On page 52, regarding nemolizumab, I think it was previously stated that the peak sales is JPY200 billion. I suppose this is no longer the case. Is this because of increased competition reducing the potential for sales?

Also on the same page, regarding crovalimab, the COMMODORE 3 trial is very difficult to evaluate from an outsider's point of view. The biggest event of the year is, after all, your company's COMMODORE 1 trial for crovalimab, so I would like to ask you to explain a little more about this area.

The reason is that the 301 trial of ravulizumab is a potential comparison, and although we really shouldn't be comparing clinical trials, the number of patients who avoided transfusion was 74% in their trial, and 51% for your company, so at a glance, it seems that it is not very effective.

However, I don't think your company explained the baseline, but actually, in their trial, the LDH value was about 1,600, and yours was 2,300, which is almost a lethal hemolysis. In this case, is it more important to look at the change in LDH?

If so, can we expect the COMMODORE 1 trial to do well in this severely ill patient population, with something like an 80% reduction in LDH? Or, would it be fair to say that this treatment is quite similar to ravulizumab?

Okuda [M]: I will pass this question to Mr. Yamaguchi. Also, the first part, the reason for not including nemolizumab. Mr. Yamaguchi will reply to you about that as well.

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Tetsuya Yamaguchi [A]: First of all, as you know, Galderma is currently developing and will market nemolizumab on a global basis, but they are not disclosing information about it. Because of this, we have refrained from announcing the progress of clinical development or market sales forecasts.

On the other hand, there is nothing wrong with the development itself, and sales will depend on the data that will be released soon. We believe that it has the potential to become a blockbuster, so I hope you understand that we are not disclosing this information because we are entering a somewhat sensitive year for the client companies.

On the other hand, if someone took a superficial look at the clinical trial results, I could understand there being questions about the potential of crovalimab. As you say, the patients who were enrolled in China this time had very advanced disease and were severely ill. This is almost certainly the main reason for the difference.

Of course, we should not make comparisons between studies, but in China, where PNH was severe for a very long period of time, C5 antibodies were not available, so in that sense, patients received only conventional treatment, and many of them had a very high bleeding rate, and some had comorbidities.

We believe that crovalimab is a drug that can compete with or even exceed the convenience of drugs such as Alexion's Soliris or ravulizumab, which you just mentioned.

Kohtani [Q]: I'm sorry, am I correct in understanding that if there is some change here, then the figure for peak sales will be reviewed?

Tetsuya Yamaguchi [A]: The current peak sales range is between JPY100 billion and JPY200 billion. We are considering these figures as the base case. It is very difficult for us to provide a peak sales range for this market, and we only show the market share based on the number of patients and expected TPP in the development model. So I think you are right that there is naturally a way to view that it will rise further.

Kohtani [M]: Understood. Thank you very much.

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

Hasegawa [Q]: My name is Hasegawa from Iyaku Keizaisha. I would like to ask you about Ronapreve. I know that the administration of Ronapreve is not recommended overseas due to the outbreak of the Omicron variant, but I think that Ronapreve purchases are still planned in 2023. I would like to know the reasons for this and what kind of discussions are going on with the MHLW, to the extent that you can disclose this information.

Okuda [A]: Thank you for your question, Ms. Hasegawa. The contract with the government is for FY2022, basically, from April of last year to March of this year. This is in line with the government fiscal year.

Last year, we supplied to the government what we reported earlier. We have the remaining portion of that contract, and according to that contract, we promised to supply to the government in Q1 of this year, and we will supply according to that promise.

Hasegawa [Q]: Basically, is it correct to say that Ronapreve will not be supplied in Q2 and beyond?

Okuda [A]: After Q2, the next fiscal year begins for the government. There are no plans or assumptions at this time regarding contracts for the next fiscal year.

Hasegawa [M]: Okay. Thank you very much.

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

Mochizuki [Q]: This is Mochizuki from Mix. I don't have an accurate grasp of the figures, but I think Chugai is number one in terms of domestic sales in this fiscal year, and I would like to know how you intend to continue as a leading company in the future, as well as what your plans are for domestic sales. In addition, given that the TOP I strategy mentions new sales channels, I would like to know what your thoughts are about domestic sales as well. Thank you.

Hidaka [A]: Thank you very much, Mochizuki. I will answer your question. I think you have asked a very difficult question about how we will proceed as a leading company, but I believe that our most core element, a patient-centered vision, will continue to be important in the future.

Of course, we would like to focus on product sales, but since we handle a large number of specialty products, we would like to focus more on how we can bring benefits to patients through our therapies.

Mochizuki [Q]: In the TOP I strategy; I think it was on page 11 that you mentioned utilizing new sales channels. In the value delivery section, it says that you will start a new information delivery channel. What kind of information delivery system will you use to convey this value?

Hidaka [A]: Yes, of course, all companies are working on digitalization, but we have established our own unique channels, especially in the use of digitalization. We would like to make them unique. Our goal is to create our own unique channels, especially in the use of digital technology.

In particular, I would like to see how we can integrate digital technology with MRs, not only by providing information digitally but also by integrating with MRs to make a solid contribution to patients, as I mentioned earlier. Thank you.

Mochizuki [Q]: Thank you. If possible, could Dr. Okuda say a few words on this topic?

Okuda [A]: Yes, I am proud to say that we have become a leading company in Japan, and in fact, at the sales promotion level, we have been number one since last year and the year before. Last year, we celebrated the 20th anniversary of our strategic alliance with Roche.

This strategic alliance has been very successful, and this scheme will allow Chugai to develop and market innovative new drugs from Roche to the Japanese market. Furthermore, in the Japanese market, Chugai's drug discovery capabilities are becoming stronger and stronger, so it is possible to develop and launch groundbreaking new drugs. In this sense, I believe that by continuing to introduce new drugs on a sustained basis, we can further secure and maintain our position as a leading company in Japan.

At the same time, we aim to be a top innovator in the healthcare field not only in Japan but also worldwide. We will further strengthen our drug discovery capabilities and deliver our innovative medicines to patients around the world toward 2030.

Sasai [M]: Thank you very much. Now, we would like to take questions from those participating online. Firstly, Mr. Wakao from JPMorgan, please go ahead.

Wakao [Q]: My name is Wakao from JPMorgan. Thank you. Regarding Hemlibra, I think the actual export sales are slightly above the plan. I was wondering if you could tell me more about the factors behind this and the background behind reaching JPY800 billion, which was described as the peak sales figure.

The reason I ask is that, given the way the current market share is growing, it seems to me that this JPY800 billion figure is something that would be difficult to achieve if we only look at the bottom. In the last fiscal

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year, I think it was about 34% at the end of FY2021, and then last year, it went up 2% to 36% at the end of the last fiscal year, so looking at just this share, I'm not sure how much further it has to grow.

In addition, I think competitor products may be approved in February and March, respectively, so while there is a bit of a range, I'm not quite seeing a narrative about how it reaches the top of the range. Could you spell this out for me?

Okuda [A]: First of all, the range is from JPY400 billion to JPY800 billion, and we expect peak sales to occur somewhere between these two figures. Theoretically, if you take the entire share of hemophilia, I think it would be higher, but JPY800 billion may indeed be the highest point.

On the other hand, looking at sales trends here in Europe, the United States, Japan, and the rest of the world, it appears that there is still plenty of room for growth.

Therefore, considering this, we are expecting steady growth beyond the growth in local sales and inventory adjustment optimization this year. Mr. Itagaki, do you have anything to add?

Itagaki [A]: The fact that the result exceeded last year's forecast is, after all, a result of the depreciation of the yen. Neither exports nor purchases are 100% hedged. Since the figure is 80%, the part of the exposure is the effect of the yen's depreciation.

Wakao [Q]: Okay. I would like to ask you to comment only on the competition. I think that the growth of new patients will slow down if a competing product is introduced in the US. What do you think about the impact of competing products in the near future, such as this fiscal year or next fiscal year?

Okuda [M]: Mr. Yamaguchi will take this question.

Tetsuya Yamaguchi [A]: From my point of view, in the short term, in the current and next fiscal year, I do not think there will be a very large competitive impact.

Hemlibra, as a bispecific antibody, is in a unique position. Even if competitor such as a long-acting Factor 8 enters the market, or BIVV, there will not be much erosion from the positioning segment of Hemlibra. In the positioning segment of Hemlibra, it is our view that there will not be much erosion.

Wakao [M]: Okay. Thank you very much.

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

Muraoka [Q]: Thank you very much. I would like to ask about R&D expenses. The budget for this fiscal year has increased quite noticeably. Should we assume that spending of these expenses will start out strong from Q1? Or is it more a case of having the money on hand in case it's needed? Thank you.

Itagaki [A]: In FY2023, we forecast an increase of JPY21.3 billion from the previous year. About a quarter of the increase is mainly attributable to depreciation and amortization at Chugai Life Science Park Yokohama. I also mentioned that in TOP I 2030, one of the key drivers is RED SHIFT. The goal here is to target the variable cost of our drug discovery and increase innovative research. Of course, we will also increase the headcount. The budget for cost increase has been factored in, including the steady progress of development projects.

Also, R&D costs are denominated in foreign currencies, and unfortunately, the impact of the yen's depreciation means that increased foreign exchange costs and increased energy costs are also included in this category. This is why the nearly 15% breakdown of research activities is what it is.

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Depreciation for Chugai Life Science Park Yokohama started on October 15 last year, but this year it will be a full year and will start on January 1. The other expenses will increase gradually, so we expect that the increase of JPY21.3 billion will be allocated toward the end of the fiscal year.

Muraoka [M]: Okay. Thank you very much.

Sasai [M]: Thank you very much. Next, Mr. Yamaguchi from Citigroup Global Markets.

Hidemaru Yamaguchi [Q]: Thank you very much. In the President's review of key policies at the beginning of the meeting, on page nine, there was talk of minor delays in the progress of in-house projects, and slight delays in PC transitions of new projects.

After that, I don't think the R&D portion touched on that part in particular, but could you comment on the factors that led to this, the policy for improvement, and so on?

Okuda [M]: I'll pass this to Mr. Yamaguchi.

Tetsuya Yamaguchi [A]: Yes, first of all, with regard to the PC transition, there were some projects that took a long time to complete in the pre-clinical phase. We had an aggressive timeline to begin with, but there was a slight delay. As you can see in the appendix, we have a very substantial number of projects.

On the other hand, in late-stage clinical development, we have been taking risks in expanding indications, combination therapy, combination with existing therapies, and immune doublets such as tiragolumab, focusing mainly on Tecentriq.

In the past, had been proceeding with a demonstration, or rather, a smaller-scale verification before entering Phase III. However, because of the emphasis on speed in the midst of competition, we would have to take a bit of a risk. Even so, it is a characteristic of this industry that some development trials do not meet our expectations.

Hidemaru Yamaguchi [Q]: Thank you very much. So, the PC transition and the slight delay, as you mentioned, is due to the fact that it was pulling back a bit aggressively and that it took a bit of time in the pre-clinical phase, and once those issues are resolved, we should see a re-acceleration of that part of the process, is that correct?

Tetsuya Yamaguchi [A]: Thank you. In reality, there are many cases in which preclinical projects end up not making it to the clinical stage, but at least in the previous year, the part of the project that we had hoped for is still progressing, and we are expecting that it will probably make it to the clinical stage this year or so.

Hidemaru Yamaguchi [M]: Thank you very much.

Sasai [M]: Thank you very much. Sanford Bernstein, Sogi, please go ahead.

Sogi [Q]: My name is Sogi from Sanford Bernstein. Thank you. I have a question regarding crovalimab. Crovalimab will be approved in China in H1, and AstraZeneca's Soliris was approved in November of last year. We expect that the market for treatment itself will change dynamically.

I have two questions regarding this. First, I would like to know what the process is and how long it takes to actually start prescribing in China after approval. The other thing is that Soliris has already been approved and is probably on the market right now, but with your company and Soliris being approved and on the market with almost no time difference, are there any differences in the popularity of the target? What do you think is the difference in the target population of crovalimab?

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Tetsuya Yamaguchi [A]: I will take this question. First of all, in terms of product penetration in the Chinese market, we understand that products that are not covered by insurance can be launched immediately after approval.

However, I understand that the volume of these drugs will not be generated until they are listed on the National Reimbursement Drug List, or NRDL, and reimbursed to a certain extent.

On the other hand, in the NRDL listing, we are obliged to allow a considerably low drug price, and we have to make a decision and negotiate with the Chinese government on this matter.

The NRDL listing used to be once every four years, but now it is becoming an annual listing, so I think it will be possible to launch the product under the NRDL listing within a year or so.

We are paying attention to whether AstraZeneca's Soliris will be listed in the NRDL or not, and we believe that only after it is listed in such places will the C5 antibody be widely used and penetrated. This is the situation.

In terms of the segment, we believe that the two are not so different, but crovalimab is very convenient because it can be administered by subcutaneous injection and only needs to be administered once every four weeks in the maintenance period.

Soliris is IV, intravenous, once a week, or once every two weeks. I think crovalimab has a significant advantage in terms of convenience.

Sogi [M]: Thank you very much.

Sasai [M]: Thank you very much. Now that we are out of time, I would like to conclude the financial results briefing. As always, if you were unable to ask a question due to time constraints, please contact the Corporate Communications Department.

Thank you very much for taking time out of your busy schedule to join us today. Thank you.

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