


Innovation all for the patients



CHUGAI PHARMACEUTICAL CO., LTD.

 A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2022.12 2Q Financial Results

July 21, 2022

Event Summary

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[Participants]		
[Number of Speakers]	5	
	Dr. Osamu Okuda	President & CEO
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	Shinji Hidaka	Executive Vice President, Head of Marketing & Sales Division
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Presentation

Sasai: Ladies and gentlemen, thank you very much for attending today's financial results briefing for Q2 of the fiscal year ending December 31, 2022. I am Sasai of Corporate Communications, and I will be chairing today's meeting. Thank you.

To prevent the spread of the coronavirus, today's session will be conducted as a combined on-site lecture and Zoom webinar.

Conference on FY2022.12 2Q Financial Results

Agenda



01

FY2022 Q2 Overview

Dr. Osamu Okuda

President & CEO

02

FY2022 Q2 Consolidated Financial Overview (Core) Toshiaki Itagaki

Director, Executive Vice President & CFO

03

Overview of Development Pipeline

Tetsuya Yamaguchi

Executive Vice President, Head of Project & Lifecycle Management Unit

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The agenda for today's meeting can be found on the audience screen, on the web screen, and on page three of the presentation materials. Our presentations will be as described here.

Questions will be taken after all presentations have been completed. The question-and-answer session is expected to last approximately 30 minutes. Please note that your audio will be muted during the presentation.

First, Dr. Okuda will give an overview of Q2 of FY2022.

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Financial Overview

- Significant increases in revenues and profits as expected due to the contribution of RON, in addition to strong sales of new products and exports to Roche, etc.
- The impact of yen depreciation* is expected on some second-half year costs denominated in foreign currencies, but the company will continue aiming to achieve its initial forecast

Core (billions of JPY)	2021 Jan - Jun actual	2022 Jan - Jun actual	Growth		2022 Jan - Dec forecast	Progress (%)
Revenues	390.2	504.3	+114.1	+29.2%	1150.0	43.9%
Domestic sales	203.4	273.8	+70.4	+34.6%	646.3	42.4%
Overseas sales	100.7	179.0	+78.3	+77.8%	385.2	46.5%
ROOI	86.1	51.4	-34.7	-40.3%	118.5	43.4%
Operating profit	165.8	201.4	+35.6	+21.5%	440.0	45.8%
Operating margin	42.5%	39.9%	-2.6pts		38.3%	-
Net income	121.7	144.7	+23.0	+18.9%	312.5	46.3%
EPS (yen)	73.99	87.97	+13.98	+18.9%	190.00	46.3%

ROOI: Royalty and other operating income RON: Ronapreve HEM: Hemlibra ACT: Actemra

*Supply of RON to the Japanese government (denominated in Swiss francs) in the second half of the year is not hedged against exchange rates at the beginning of the fiscal year, therefore cost of sales is expected to be higher than the initial assumption due to yen depreciation.

- Despite the impact of the NHI drug price revision and other factors, domestic sales grew as expected due to contributions from new products. RON was not delivered to the government in April-June as initially expected.
- Overseas sales increased significantly mainly due to HEM and ACT exports to Roche as initially expected.
- Significant decrease in ROOI associated with initial shipping inventory of HEM
- Russia/Ukraine situation had no negative impact on performance and limited impact on development activities

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Okuda: I would now like to give a summary of Q2.

Please see slide five.

Revenues increased approximately 30% YoY, and operating profit and quarterly net income each grew approximately 20%. H1 ended with significant increases in both revenues and income. New products in Japan and exports to Roche have been strong.

Although the impact of yen depreciation is expected in H2 of the fiscal year, we will aim to increase both sales and income for the full year as planned at the beginning of the fiscal year.

Ronapreve had no government deliveries from April to June, as expected. In addition, there is no change in our assumption from the beginning of the period regarding the volume of deliveries until the end of December of this fiscal year.

There is no significant negative impact of the situation in Ukraine on our business performance.

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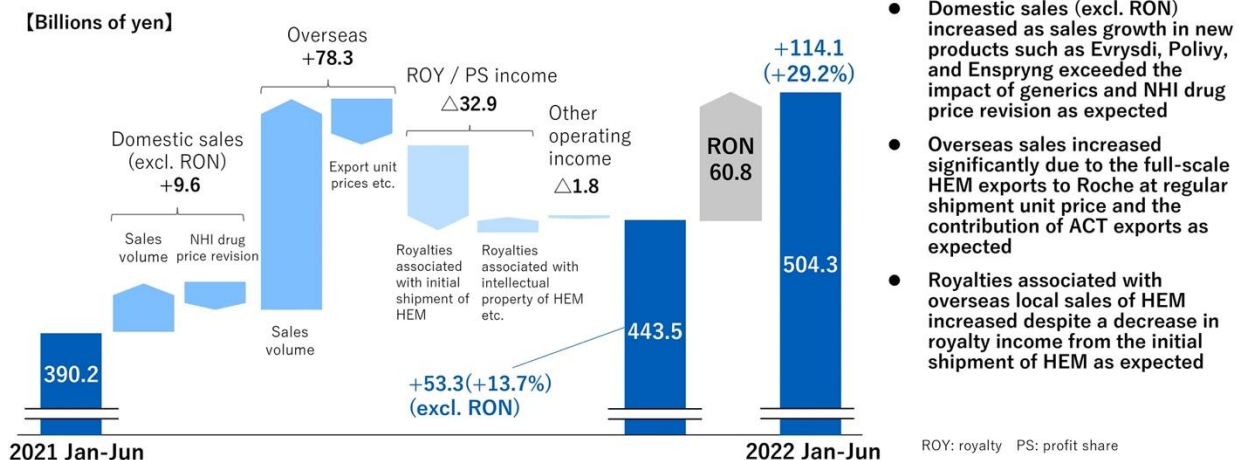
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Topline Overview

- Domestic sales (excl. RON) increased due to an increase in new products and sales volume
- Overseas sales increased significantly as volume growth exceeded the decline in export unit prices
- A decrease in royalty income was offset by an increase in overseas sales as expected



- Domestic sales (excl. RON) increased as sales growth in new products such as Evrysdi, Polivy, and Enspryng exceeded the impact of generics and NHI drug price revision as expected
- Overseas sales increased significantly due to the full-scale HEM exports to Roche at regular shipment unit price and the contribution of ACT exports as expected
- Royalties associated with overseas local sales of HEM increased despite a decrease in royalty income from the initial shipment of HEM as expected

Next, the top-line results.

In the core area of sales in the domestic market, excluding Ronapreve, we have seen a steady penetration of new products such as Evrysdi and Polivy, as well as the increase in volume, offset the negative effects of the price revision and other factors. As a result, sales have increased.

Overseas, export sales increased significantly due to the full-scale export of Hemlibra at regular shipment unit price, as well as the export of Actemra.

Royalty-related revenues declined on a YoY basis due to lower royalty income from the initial shipment of Hemlibra. Combined domestic and international sales and royalties increased by 13.7%, or JPY53.3 billion.

In addition, overall sales increased significantly in H1, as expected, with the addition of the contribution of Ronapreve.

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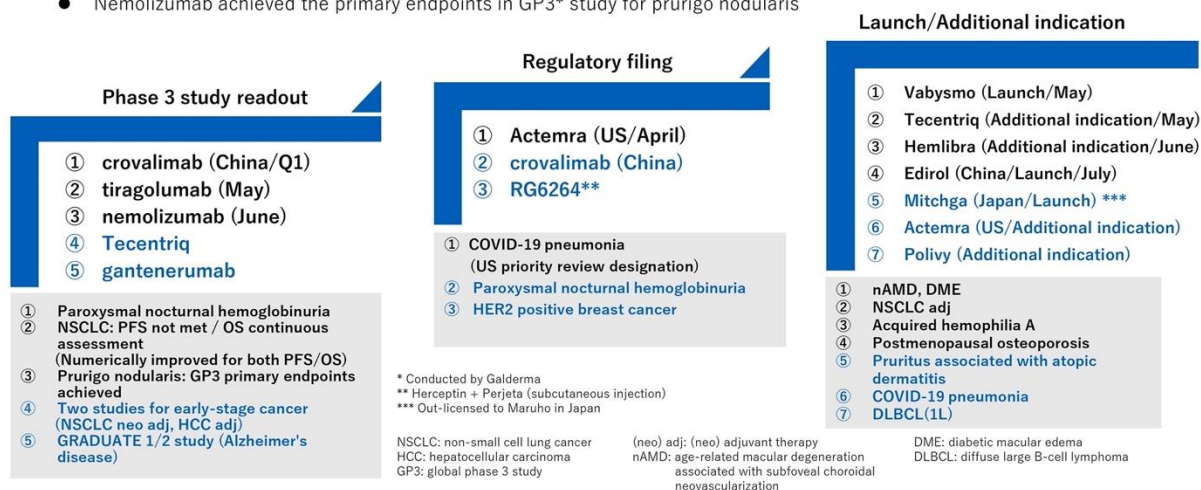
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R&D Overview

■ Progress of the projects with high market potential is expected to contribute to future sales growth

- A full-scale entry into the ophthalmology field by launching Vabysmo in May 2022
- Tecentriq obtained an additional indication for NSCLC adj as the first immunotherapy in Japan
- Nemolizumab achieved the primary endpoints in GP3* study for prurigo nodularis

Letters in blue: Planned this year



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Next, I will talk about R&D. The black figures indicate actual results for H1, and the blue figures indicate forecast results for the remainder of the year.

First, on the far left, is the readout of the Phase III study. Crovalimab met its primary endpoint in a Phase III study of paroxysmal nocturnal hemoglobinuria in China. In a trial for PD-L1-high expression non-small cell lung cancer, tiragolumab did not achieve the PFS endpoint. We are continuing our evaluation and look forward to the overall survival results.

The global Phase III study of nemolizumab conducted by Galderma, for prurigo nodularis met its primary endpoints. Results from a Phase III trial of the same design currently underway are expected by the end of the year. In addition, the results of several trials on Tecentriq and gantenerumab are expected by the end of the year.

In the middle column, regulatory filings, Actemra received priority review designation for COVID-19 pneumonia in the United States. Crovalimab is scheduled to be filed for approval in China before the end of the year, ahead of the rest of the world. RG6264 is a subcutaneous injection formulation of Herceptin and Perjeta. The administration time, which is normally more than one hour, is reduced to just over five minutes, reducing the burden on both medical professionals and patients.

As for new products, Chugai launched Vabysmo in May, marking the Company's first full-scale entry into the ophthalmology field. Tecentriq is the first cancer immunotherapy in Japan to have adjuvant therapy for non-small cell lung cancer added to its indications. In addition, we launched Ediol in China. The domestic launch of Mitchga and the addition the first-line indication for DLBCL for Polivy are expected by the end of the year.

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Strategic Policies for 2022 -Main Progress in the First Half-

Continuous creation of R&D output	<ul style="list-style-type: none"> Approval/Launch: Actemra (COVID-19 (Japan)), Vabysmo (nAMD/DME), Tecentriq (NSCLC adj), Hemlibra (acquired hemophilia A (Japan)), Ediol (postmenopausal osteoporosis (China)), etc. Regulatory filing: Actemra (COVID-19 (USA)), Gazyva (chronic lymphocytic leukemia) Start of clinical study(in-house product): crovalimab (P2 SCD), GYM329 (P2/3 SMA)
Maximize the value of growth drivers	<ul style="list-style-type: none"> Accelerating market penetration of growth drivers in Japan and overseas <ul style="list-style-type: none"> Hemlibra: Strong performance in Japan, the US, Europe, and the rest of the world. Expected to add non-inhibitor (mild to moderate) indications in Europe Tecentriq: Sales declined due to the market expansion re-pricing in August last year and supply restrictions on the combination drug Enspryng: Approved in a total of 72 countries (as of July 2022). Steady market penetration in Japan and overseas Polivy, Evrysdi: Steady market penetration as new products Introducing new products and additional indications to the market <ul style="list-style-type: none"> Vabysmo: Chugai is fully prepared to meet highly specialized information needs. Solid start after Launch on May 25 Tecentriq (NSCLC adj): Reinforcing "patient-centric safety countermeasure activities" by enhancing cooperation of Value Delivery 3 divisions¹
Strengthen business foundation	<ul style="list-style-type: none"> Received DX Grand Prix 2022 Awards for the first time as a leading company in promoting DX Established and held a Special Committee at the request of the revised Corporate Governance Code Continuous selection for major ESG indices (GPIF selected domestic equity ESG index including FTSE Blossom Japan Sector Relative Index)



1: Marketing / Medical Affairs / Safety; 2: Research & Early Development
SCD: sickle cell disease, SMA: spinal muscular atrophy

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Next, I will describe the progress made against the priority policies for FY2022.

As I have just explained, R&D is progressing smoothly.

With respect to value maximization as a growth driver, our mainstay product, Hemlibra, continues to perform well in Japan, Europe, and the United States. The situation with Tecentriq is as expected. Other new products, Enspryng, Polivy, and Evrysdi, are also making steady market penetration.

In the area of business infrastructure reinforcement, all of the five ESG indices for Japanese equities adopted by the GPIF, including the FTSE Blossom Japan Sector Relative Index which was launched in March of this year, have been selected since the start of operations.

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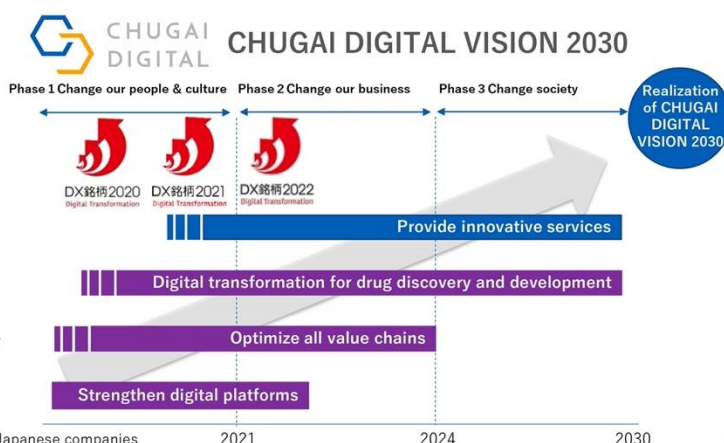
DX Promotion for the Realization of "TOP I 2030"

- The efforts for promoting DX so far have been highly recognized, and Chugai has been selected as a DX stock* consecutively and received DX Grand Prix 2022 Awards
- Continue to promote company-wide efforts toward the realization of "CHUGAI DIGITAL VISION 2030"



DXグランプリ2022
Digital Transformation

Growth strategy "TOP I 2030" is well linked with "CHUGAI DIGITAL VISION 2030," the company's vision for promoting DX, and its achievements in a series of initiatives for drug discovery and manufacturing processes, as well as those for healthcare professionals and patients. These comprehensive efforts were highly recognized.



* The DX Stocks are jointly selected by METI and TSE to accelerate DX of Japanese companies

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Next, the topic of DX, one of the key drivers for the realization of TOP I 2030.

We have been promoting the acceleration of DX across the entire value chain, leveraging artificial intelligence, digital, and robotics. Molecular design of antibodies using AI technology, digital plant construction, and proof of value of drugs using digital biomarkers are all areas where DX integration has accelerated considerably.

In recognition of our achievements in these efforts, we have been selected as a DX stock for three consecutive years. Chugai is the only company in the pharmaceutical industry to gain this accolade. Furthermore, this year we were awarded the Grand Prize as the company with the most outstanding DX initiatives.

We will continue to promote DX throughout the Company to realize TOP I 2030.

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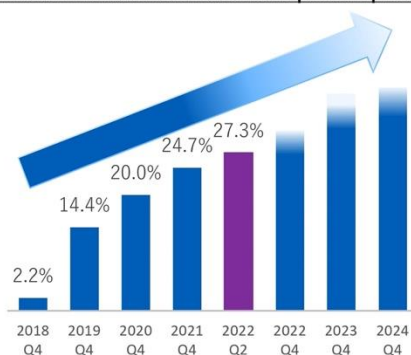
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Situations on Hemlibra

- The patient share continues to increase steadily and can be further expanded
- Hemlibra may continue to be selected even in the presence of competitors due to the accumulation and penetration of long-term efficacy and safety data, in addition to convenience of administration

Hemlibra: Trends of domestic hemophilia A patient share*¹, *²

*¹ Past patient shares are recalculated to reflect the latest survey results
 *² Charts for Q4 2022 and beyond are growth images

Major competitors in the late development stage*³

Modality	Company	Developing product	Route of administration / interval	Developing stage
Half-life extended FVIII	Sanofi	BIVV001	IV, QW	P3
Bispecific antibody	Novo Nordisk	Mim8	SC, QW/QM	P3
Gene therapy	Biomarin	Roctavian	IV(one-time)	Filing* ⁴
Gene therapy	Pfizer	SB-525	IV(one-time)	P3
siRNA	Sanofi	Fitusiran	SC, QM	P3
Antibody	Novo Nordisk	Concizumab	SC, Daily	P3
Antibody	Pfizer	Marstacimab	SC, QW	P3

*³ Based on public information of each company (as of July 21)

*⁴ The European Medicines Agency's Drug Evaluation Committee recommends conditional approval (US: preparing for resapplication)

IV: intravenous injection, SC: subcutaneous injection, QW: weekly administration, QM: monthly administration

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Next, I will talk about Hemlibra.

Hemlibra, a growth driver, is performing well domestically and internationally. The graph on the left shows the market share in Japan. The product is steadily penetrating the market and its use is expected to expand further.

As shown to the right, there is a wide range of competing products for Hemlibra in late-stage development. However, in addition to the convenience of reducing the burden on patients and their families, Hemlibra has a solid foundation of long-term efficacy and safety data accumulated to date. We believe we can continue to maintain our competitive advantage.

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Partial Revision of the Basic Alliance Agreement with Roche

■ Background

- Under the previous Basic Alliance Agreement (BAA), Roche has agreed to cooperate in maintaining Chugai's listing on the first section of the Tokyo Stock Exchange.
- Following the revision of the market classification on the Tokyo Stock Exchange, new listing criteria were established for the Prime Market, which commenced operations on April 4, 2022.
- Chugai and Roche have made relevant revisions in light of the current situation while inheriting the basic spirit of the agreement.

■ Revised content

- The main revisions to the BAA are as follows:
 - ✓ Roche will cooperate in maintaining Chugai's listing on the Prime Market¹ of the Tokyo Stock Exchange.
 - ✓ In the event that Chugai issues shares, etc., Roche has the pre-emptive right* in order to maintain its current and future shareholding ratio in Chugai².

1: Revised from "first section"

2: Revised from "50.1%"

* Right to acquire the shares at the same price and under the same conditions as a third party

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Next, I will explain the partial revision of the basic agreement regarding the strategic alliance with Roche.

Under the previous Basic Alliance Agreement, Roche was to cooperate in our listing on the First section of the Tokyo Stock Exchange. In April of this year, the TSE market classification was reviewed, the TSE First section was abolished, and the Prime market began operations.

Accordingly, after discussion between the two companies, a revision was made to specify an arrangement whereby Roche will continue to cooperate in maintaining the listing of the Company's shares on the Prime market. In addition, the conditions under which Roche may invoke its pre-emptive rights for the Company's shares have been revised in line with the current situation, while maintaining the basic spirit of the previous policy.

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Summary



- **First half results:** Significant increase in revenues and profits due to strong sales of new products and exports to Roche
- **Full-year results:** Aiming to increase revenues and profits for the sixth consecutive year, although there are concerns about the impact of foreign exchange on profits
- **R&D:** Steady progress of the projects with high market potential is expected to contribute to the future sales growth
- **DX promotion:** Efforts to realize "TOP I 2030" were highly recognized. Expect to continue the company-wide initiatives moving forward
- **HEM:** Expect sustainable growth by maintaining competitive advantage of clinical evidence and high convenience
- **Governance:** Partially revised the Basic Alliance Agreement with Roche

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Finally, a summary.

H1 results, new products, and exports to Roche led to a significant increase in sales and profit.

Despite concerns about the impact of the yen's depreciation, we are aiming for a sixth consecutive year of full-year growth in both sales and income.

In R&D, we expect steady progress in development products with high market potential to contribute to future sales growth.

In the promotion of DX, our efforts to date have been highly recognized. We will continue to promote company-wide initiatives moving forward.

We anticipate that Hemlibra will maintain its competitive advantage and sustained growth thanks to its solid base of real-world clinical evidence, and its high convenience.

In governance, we have partially revised the basic agreement on strategic alliances based on the trust relationship with Roche.

That is all from me.

Sasai: Thank you very much.

Mr. Itagaki will continue with an overview of the consolidated financial results for Q2 of FY2022.

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IFRS and Core Results Jan – Jun

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenues	596.2		-91.9	504.3
Sales	452.8			452.8
Royalties and other operating income	51.4			51.4
Other revenue	91.9		-91.9	-
Cost of sales	-194.2	+0.6		-193.7
Operating expenses	-115.0	+0.2	+5.6	-109.2
M&D and G&A	-47.3		+3.9	-43.4
Research and development	-67.7	+0.2	+1.8	-65.8
Operating profit	286.9	+0.7	-86.3	201.4
Financial account balance	-0.0			-0.0
Income taxes	-82.8	-0.2	+26.3	-56.7
Net income	204.2	+0.5	-59.9	144.7
EPS (JPY)	124.08			87.97

Non-Core items

(Billions of JPY)

Intangible assets

Amortization	+0.6
Impairment	+0.2

Others

Lump-sum income related to settlement agreement with Alexion Pharmaceuticals, Inc., etc.	-90.7
Restructuring expenses, etc.	+4.5

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Itagaki: Thank you.

Please see page 14. First of all, just for confirmation, there is a big difference between IFRS results on a full basis and core results.

As we have already announced in the presentation of Q1 financial results, we have settled the lawsuit with Alexion, for which we will receive USD775 million. The litigation-related income and expenses were excluded from other income in the amount of JPY91.9 billion because the transactions were classified as non-core transactions. In addition, we have excluded the business tax related to the settlement payment, which had been included in general and administrative expenses, because it amounted to about JPY1.2 billion.

As shown on the right, the reconciliation is JPY90.7 billion (net of revenues and enterprise taxes), which is a non-core adjustment.

In addition, as shown on the right, the full operating profit is JPY286.9 billion, and the core operating profit is JPY201.4 billion, after adjusting for amortization of intangible assets, impairment losses of intangible assets, and restructuring expenses. All of the slides that follow will be explained in terms of these core results.

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P/L Jan - Jun (Year on Year)

(Billions of JPY)	2021	2022	Growth	
Revenues	390.2	504.3	+ 114.1	+ 29.2%
Sales	304.1	452.8	+ 148.7	+ 48.9%
Domestic	203.4	273.8	+ 70.4	+ 34.6%
Overseas	100.7	179.0	+ 78.3	+ 77.8%
Royalties and other operating income	86.1	51.4	- 34.7	- 40.3%
Royalty and profit-sharing income	83.3	50.4	- 32.9	- 39.5%
Other operating income	2.8	1.0	- 1.8	- 64.3%
Cost of sales	-121.9	-193.7	- 71.8	+ 58.9%
(cost to sales ratio)	40.1%	42.8%	+2.7%pts	-
Operating expenses	-102.5	-109.2	- 6.7	+ 6.5%
M&D and G&A *	-42.7	-43.4	- 0.7	+ 1.6%
Research and development	-59.9	-65.8	- 5.9	+ 9.8%
Operating profit	165.8	201.4	+ 35.6	+ 21.5%
(operating margin)	42.5%	39.9%	-2.6%pts	-
Financial account balance	0.6	-0.0	- 0.6	-
Income taxes	-44.7	-56.7	- 12.0	+ 26.8%
Net income	121.7	144.7	+ 23.0	+ 18.9%
EPS (JPY)	73.99	87.97	+13.98	+ 18.9%

Domestic sales

Significant 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

Increase due to impact of yen depreciation on costs denominated in foreign currencies and progress of development projects, etc.

Operating profit

Growth mainly due to increase in sales

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

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The next page, page 15, shows profit/loss results, comparing H1 results with the same period of the previous year.

Revenue was JPY504.3 billion, an increase of 29.2%.

This is a breakdown. Sales in the domestic market increased 34.6% thanks to strong sales of new products and mainstay products. Overseas sales also grew by 77.8%, thanks to a significant increase in exports of Hemlibra and Actemra.

Royalty and profit-sharing income were down 39.5% due to a decrease in royalty income for initial shipment of Hemlibra, the so-called Royalty 2. In addition, other operating income was only JPY1 billion to a decrease in one-time income from fewer events during H1 of the fiscal year.

Cost-to-sales ratio was 42.8%, a 2.7 percentage point rise year on year, reflecting a change in the product mix and other factors.

Each of the expenses is affected by the increase due to the depreciation of the yen. In addition, R&D expenses increased by 9.8% due to steady progress in development projects.

As a result, operating profit was JPY201.4 billion, an increase of 21.5%. The operating margin was 39.9%.

After subtracting financial account balance and income tax, the net income was JPY144.7 billion, an increase of 18.9%.

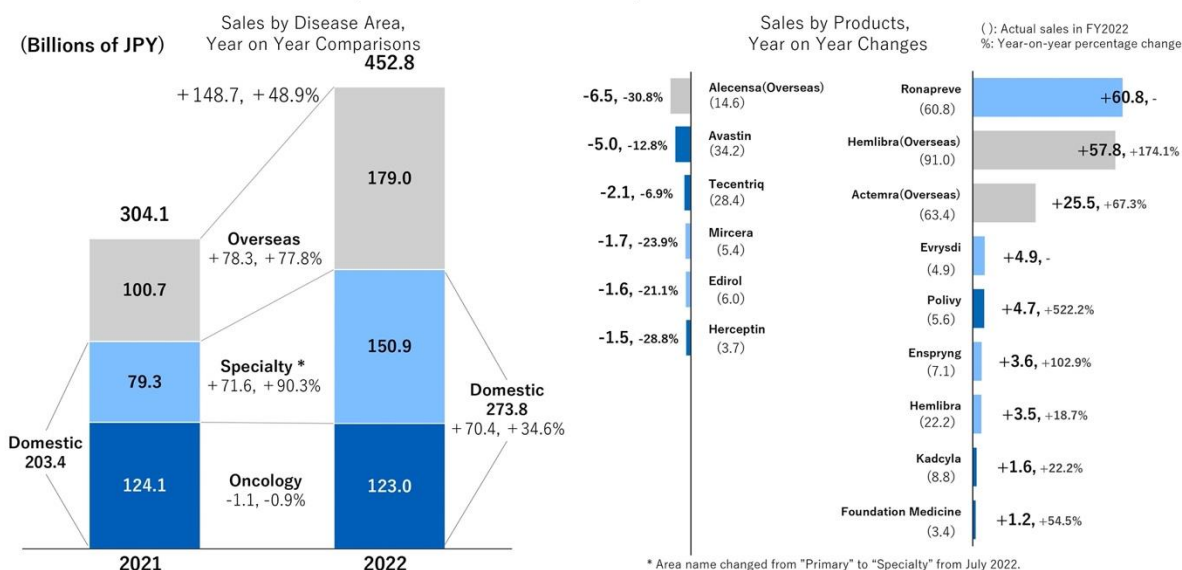
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Sales Jan - Jun (Year on Year)



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The next page shows the breakdown of changes in sales.

Looking at the results by area, from the bottom, domestic oncology declined slightly, by 0.9%. The products shown in dark blue on the right are Polivy, which was launched in May last year, Kadcyla, which is performing well due to its expanded indications, and Foundation Medicine, to which FoundationOne Liquid has been added. Sales are increasing in these areas.

On the other hand, looking at areas with a decrease in sales, Avastin and Herceptin were affected by biosimilars. Tecentriq's price dropped by about 11% due to the re-pricing for market expansion in August last year. This has had a negative impact on our sales.

This is the second row from the bottom left. We used to call it the primary area, but we have renamed it as the specialty area from this time. Here we saw a 90.3% increase in sales. Looking at individual products, sales of Ronapreve totaled JPY60.8 billion. Since there were no sales in H1 of last year, these results mark the first sales. In addition, Evrysdi, which was launched in August of last year, has also seen an increase in sales, with sales of JPY4.9 billion. Sales of Enspryng and Hemlibra, in-house products are also increasing steadily.

Mircera and Edirol saw a decrease in sales.

Finally, overseas sales were also very strong, increasing 77.8%. The inventory of Hemlibra overseas for initial shipments has almost run its course. As shipments at ordinary supply prices began in earnest around the second half of last year, the H1 sales increased by 174.1%, 2.7 times increase. Actemra's overseas sales also increased, by 67.3%. We will look at the details on the next page.

As for Alecensa's overseas sales, Roche's safety stock buildup practically came to an end last year, and the export volume for H1 of this year has decreased. In addition, the unit price of exports has also declined, resulting in a JPY6.5 billion decrease in revenue.

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Export of Actemra to Roche

(Billions of JPY)

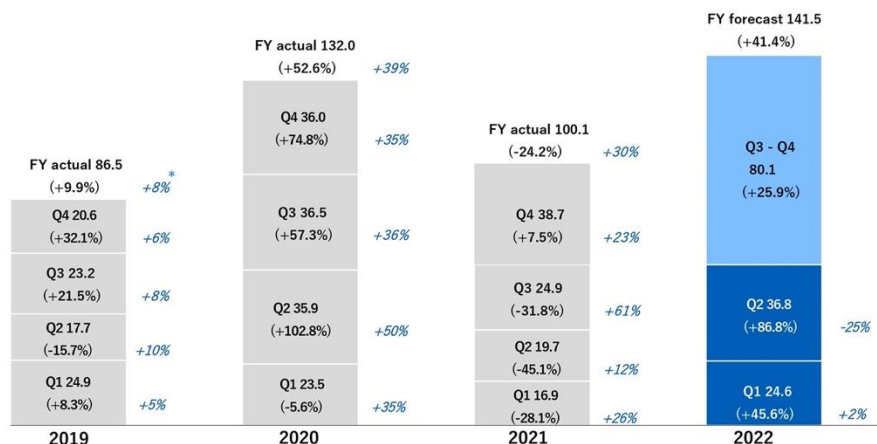


%, year on year growth

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.



17

Now, on page 17, we have a slide on export of Actemra to Roche.

First, the percentage change in global sales by Roche, which is shown in blue text by each bar. First of all, if you look at the bottom right-hand side, Q1 2022, sales of Actemra in Roche territory grew by 2%. Sales in Q2 declined by 25%. Roche also announced its financial results today.

On the other hand, our exports to Roche are growing, with increases of 45.6% in Q1 and 86.8% in Q2 2022. The first reason for this is that last year's Q1 and Q2 figures were very small in comparison. Since August of last year, with the coronavirus pandemic, there was a problem with Actemra's production capacity. As a reaction to the low level of exports, we had expanded our production capacity toward the end of last year. As the market itself was a little low on Actemra stock and we have been told that there is a shortage of products, this year we are steadily filling the gap. This is why our exports of Actemra to Roche have grown so much.

In fact, as you can see in the blue text above, global demand due to COVID-19 is calming down a bit, but the overall shortage, particularly with regard to inventory for rheumatoid arthritis patients, is extremely important. We are working to bring that inventory back to an appropriate level, and the demand for our exports is still firm.

Therefore, the JPY80.1 billion written at the top right is the balance of the full-year forecast announced at the beginning of the fiscal year, minus H1 results. We believe that we can achieve the JPY80.1 billion figure.

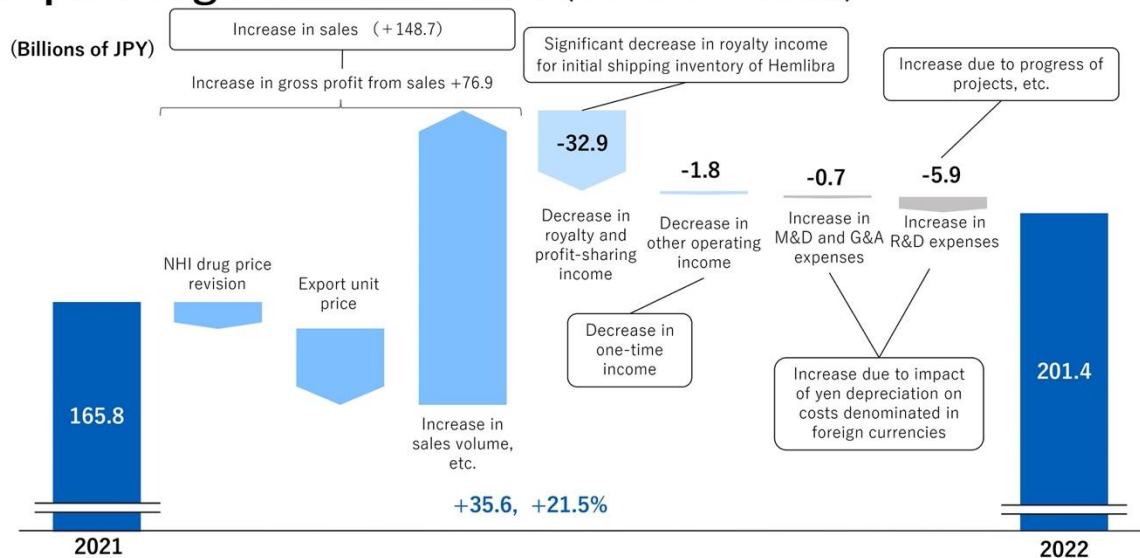
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Operating Profit Jan - Jun (Year on Year)



18

On page 18, we have a breakdown of the increase in operating profit.

The second, third, and fourth bars on the left show the increase in gross profit, and the breakdown of the factors shows that the price revision caused the decrease. It has fallen due to a drop in the unit price of exports. As sales volume increased, net sales increased by JPY148.7 billion and gross profit increased by JPY76.9 billion.

The royalty and profit-sharing income decreased by JPY32.9 billion, of which JPY40.2 billion is the decrease in royalties related to the initial shipment of Hemlibra, the so-called Royalty 2.

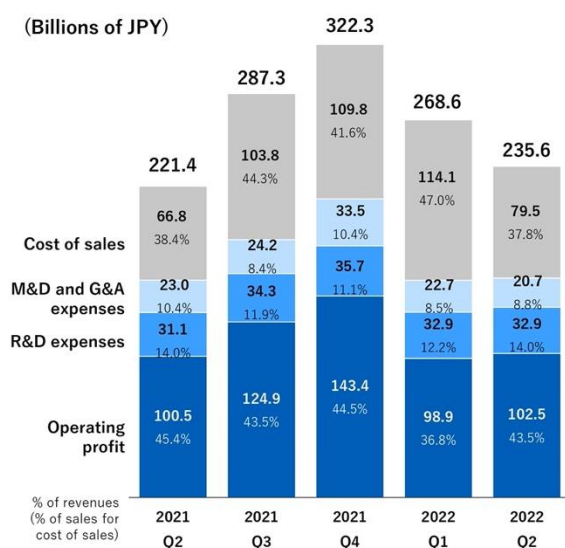
Other operating income, M&D and G&A expenses, and R&D expenses are as shown here.

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Structure of Costs and Profit by Quarter



vs. Year on Year (2021 Q2)

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

M&D and G&A expenses: decrease due to gain on sales of property, plant and equipment, etc.

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

Operating profit: increase of +2.0 (+2.0%)

vs. Previous Quarter (2022 Q1)

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

M&D and G&A expenses: decrease due to gain on sales of property, plant and equipment, etc.

Operating profit: increase of +3.6 (+3.6%)

19

Starting on page 19, there are three more slides showing quarterly trends. First of all, here is the first slide, which looks at the cost structure.

On the right side, comments on Q2 results compared to last year's Q2 are on the top row, and then comments compared to this year's Q1 are on the bottom row. As you can see from the comparison, the cost of sales ratio improved, M&D and G&A expenses decreased, and operating profit increased, but I would like to make two additional points.

First of all, regarding the cost of sales ratio, as you can clearly see from the graph on the left, Q2 last year and Q2 of this year were in the 30% range, but the three periods in between all have cost of sales ratios above 40%. This is because supply to Ronapreve's government started in Q3 of last year. There was also Q4, and Q1 this year. There were no government supplies of Ronapreve in Q2 of last year or Q2 this year, so the cost of sales ratio increased significantly for the three periods when Ronapreve was supplied.

And the second point is M&D and G&A expenses. The absolute amount of M&D and G&A expenses is JPY20.7 billion for Q2 of this fiscal year. As you can see in the comment on the right, we have leased back some of the land and buildings we own. The proceeds from this sale are actually included in Q2 as a reversal of M&D and G&A expenses, or perhaps it is called a reversal of M&D and G&A expenses, because it is revenue.

Another point is the business tax related to the Alexion settlement that I explained earlier. This was left in Q1 and was put back in Q2, which also appears to have reduced M&D and G&A expenses by JPY1.2 billion. The total of the profit from the sale of the leaseback and the business tax is JPY2.3 billion, which is the same as last year and slightly higher than Q1.

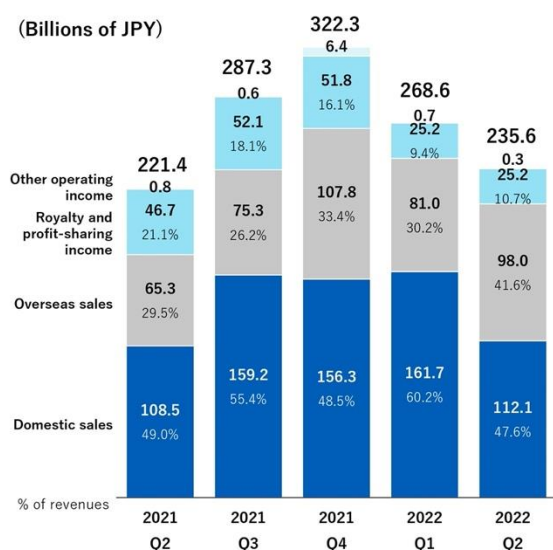
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Structure of Revenues by Quarter



vs. Year on Year (2021 Q2)

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

vs. Previous Quarter (2022 Q1)

Domestic sales: decrease due to the absence of supply of Ronapreve to the government

Overseas sales: significant increase in sales of Actemra

20

The next page, page 20, is a look at the revenue structure over the course of each quarter.

The reasons for the changes in amounts are as noted on the right.

I would like to add a few words about the composition ratio. First of all, as for the composition of sales in the domestic market, in Q3 and Q4 of last year, and in Q1 of this year, the relatively high composition of sales in the domestic market is due to the fact that government supplies of Ronapreve were made during this period.

The export composition itself has been gradually rising due to the start of full-scale regular shipments of Hemlibra in H2 of last year. Although it is a little heterogeneous when looking at the per-quarter figures. As a result, in the most recent Q2, the percentage of exports rose to 41.6%.

Since the beginning of this year, the composition ratio of royalty and profit-sharing income at the top of this chart has dropped dramatically to about 10%.

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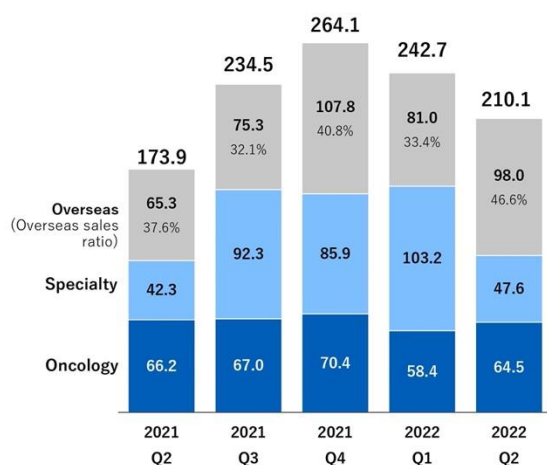
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Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2021 Q2)

Oncology	Polivy:	+2.0	Kadcyla:	+0.8
	Avastin:	-2.7	Tecentriq:	-1.4
Specialty	Evrysdi:	+2.8	Hemlibra:	+2.2
	Enspryng:	+1.7	Edirol:	-2.0
Overseas	Hemlibra:	+21.6	Actemra:	+17.2

vs. Previous Quarter (2022 Q1)

Oncology	Tecentriq:	+1.6	Avastin:	+1.2
	Alecensa:	+1.1		
Specialty	Ronapreve:	-60.8	Hemlibra:	+2.1
	Vabysmo:	+0.9		
Overseas	Actemra:	+12.0	Alecensa:	+4.2
	Hemlibra:	+1.6		

21

Page 21 shows the overall composition of products by product category.

Again, with or without the supply of Ronapreve to the government, there is some variability, with the absolute value of the specialty area going up or down.

Oncology has absorbed the downside of biosimilars and remains almost flat with new products.

In addition, overseas, Hemlibra and Actemra are leading the way in terms of revenue growth.

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P/L Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Jun	2022 Jan - Dec	Progress	Progress*
Revenues	504.3	1,150.0	43.9%	39.0%
Sales	452.8	1,031.5	43.9%	37.9%
Domestic	273.8	646.3	42.4%	39.2%
Overseas	179.0	385.2	46.5%	35.5%
Royalties and other operating income	51.4	118.5	43.4%	43.7%
Royalty and profit-sharing income	50.4	114.0	44.2%	44.5%
Other operating income	1.0	4.5	22.2%	28.6%
Cost of sales	- 193.7	- 460.0	42.1%	36.3%
(cost to sales ratio)	42.8%	44.6%	-	-
Operating expenses	- 109.2	- 250.0	43.7%	44.5%
M&D and G&A	- 43.4	- 100.5	43.2%	42.5%
Research and development	- 65.8	- 149.5	44.0%	46.1%
Operating profit	201.4	440.0	45.8%	38.2%
(operating margin)	39.9%	38.3%	-	-
Net income	144.7	312.5	46.3%	39.1%
EPS (JPY)	87.97	190.00	46.3%	39.1%

Domestic Sales

Overall progress nearly in line with forecast
(2021 progress: low level as Ronapreve supply to the government scheduled for H2)

Overseas sales

Progress nearly in line with forecast
(2021 progress: low level as full-scale export of Hemlibra to Roche at ordinary supply prices started from middle of second quarter)

Royalty and profit-sharing income

Progress nearly in line with forecast

Other operating income

Progress nearly in line with forecast

Cost of Sales

Cost to sales ratio nearly in line with H1 forecast

Operating expenses

Progress nearly in line with forecast

Operating profit

Progress nearly in line with forecast

* Jan - Jun progress versus Jan - Dec

22

Next, on page 22, we show the progress of the full-year forecast announced at the beginning of the fiscal year, and the actual progress in H1 of last year as a reference.

As shown in the comments to the right, cost of sales, expenses, and profit are all generally progressing as expected. However, if you can compare our progress results with last year's progress results, there are a few things that we are making better progress on this year.

First, sales in the domestic market. Progress to full-year forecast in the domestic area this year is 42.4%, and last year's progress was 39.2%. This does not mean that progress is good this year. Since we are at the turnaround point, we are at just over 40% progress, which we consider normal. This is also due to the fact that Ronapreve has been a little bit of a problem. In the first half of previous year, there was no contribution from Ronapreve. If we exclude the sales of Ronapreve, the progress rate of this year at 47.6% is almost the same as the previous fiscal year at 46.1%.

Next is overseas, which also has some variability, with 46.5% this year and 35.5% last year. This is more characteristic of the very low progress made last year, which also means that export of Hemlibra at a regular shipping price is now in full swing for H2 of last year. This is the reason why, looking at the full year, H1 progress was particularly low last year. As a result of this year's results, for example, the progress rate of operating profit at 45.8% is as expected for this year's full year forecast.

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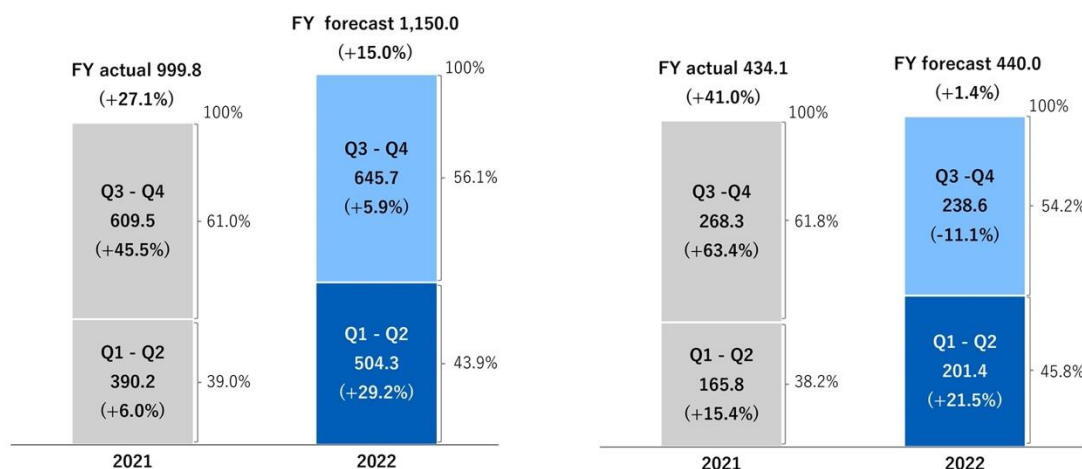
H1 Actual and Remaining Year Forecast (Year on Year)

(billions of JPY)

(): Year-on-year percentage change

<Revenues>

<Operating profit>



23

Page 23 gives a slightly different perspective. The left half shows revenue, and the right half shows core operating profit. Each shows comparison year on year.

First of all, in terms of points of interest, the operating profit on the far right shows a 21.5% increase compared to the previous year in H1 of this year, as shown in the parentheses. So, what will happen in H2 of this year? The forecast for H2, which is the full-year forecast minus H1 results, is now written in the upper right-hand column. JPY238.6 billion is a decrease of JPY11.1 billion compared to H2 of last year, which is a decrease in profit. That's a profit increase in H1 and a profit decrease in H2.

The trend appears to have flipped, but this is actually another problem with last year, which we are comparing with, and the composition ratios for H1 and H2 of the year are written on the right. For example, if we assume that the full year of this year is 100, the ratio of operating profit in H1 is 45.8%, and the remaining 54.2% is in H2.

The reason is, first of all, that the supply of Ronapreve to the government still came in in a big way in H2 of last year. Then, in H1 for Actemra, we made inventory adjustments, but in H2, there was still a shortage, so we began to gradually increase shipments in H2. The situation last year was a bit unbalanced, as export at a regular shipping price of Hemlibra increased dramatically in H2. Last year, profits were higher in H2. In this year, H1 is about 46%, and H2 is 54%, that is rather normal.

For both FY2019 and FY2020, the actual results are 46% for H1 and 54% for H2, so the balance for this year is within that trend. The forecast balance of JPY238.6 billion for H2 has not changed, there is no discrepancy, and we will continue to run toward achieving the full-year forecast.

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Sales Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021	(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Jun	2022 Jan - Dec	Progress	Progress *		2022 Jan - Jun	2022 Jan - Dec	Progress	Progress *
Sales	452.8	1,031.5	43.9%	37.9%	Specialty	150.9	385.8	39.1%	30.8%
Domestic	273.8	646.3	42.4%	39.2%	Ronapreve	60.8	199.0	30.6%	0.0%
Oncology	123.0	260.5	47.2%	47.5%	Hemlibra	22.2	51.8	42.9%	45.0%
Avastin	34.2	69.4	49.3%	48.5%	Actemra	20.6	41.9	49.2%	47.0%
Tecentriq	28.4	62.0	45.8%	49.0%	Enspryng	7.1	16.7	42.5%	36.1%
Perjeta	15.6	33.7	46.3%	48.8%	Edirol	6.0	10.8	55.6%	34.1%
Alecensa	13.7	28.7	47.7%	47.3%	Mircera	5.4	10.2	52.9%	49.3%
Polivy	5.6	16.2	34.6%	13.2%	Evrysdi	4.9	8.8	55.7%	0.0%
Kadcyla	8.8	16.0	55.0%	45.9%	CellCept	3.8	7.4	51.4%	48.8%
Herceptin	3.7	8.3	44.6%	53.1%	Bonviva	3.6	7.0	51.4%	50.0%
Gazyva	2.1	5.4	38.9%	46.7%	Oxarol	2.8	5.1	54.9%	48.4%
Rituxan	2.2	4.1	53.7%	47.1%	Vabysmo	0.9	4.6	19.6%	-
Foundation Medicine	3.4	9.1	37.4%	43.1%	Other	12.8	22.5	56.9%	46.6%
Other	5.2	7.5	69.3%	49.1%	Overseas	179.0	385.2	46.5%	35.5%
					Hemlibra	91.0	186.0	48.9%	29.1%
					Actemra	63.4	144.4	43.9%	36.9%
					Alecensa	14.6	34.1	42.8%	42.1%
					Enspryng	1.7	4.6	37.0%	60.0%
					Neutrogen	4.6	8.8	52.3%	52.7%
					Other	3.7	7.4	50.0%	48.4%

* Jan - Jun progress versus Jan - Dec

24

Page 24 shows the progress of sales forecasts for individual products.

This comment is also in line with our expectations, but we are making progress of about 40% or more. There are a few products here and there that are below 40%.

If you look first at oncology, you will see things like Polivy, Gazyva, and Foundation Medicine. In the specialty area on the right, Ronapreve and Vabysmo are seen. All of the products you have just mentioned are new products or growing products, and we expect that they will continue to rise steadily in H2. Since this is the case, naturally, progress in H1 is weaker than that of other products.

Overseas exports depend on the timing of shipments. Therefore, it is difficult to judge simply because progress is high or low, but to begin with, shipments at the beginning of the period are in line with expectations. They were essentially included in the scope of firm order transactions at the time the plan was prepared.

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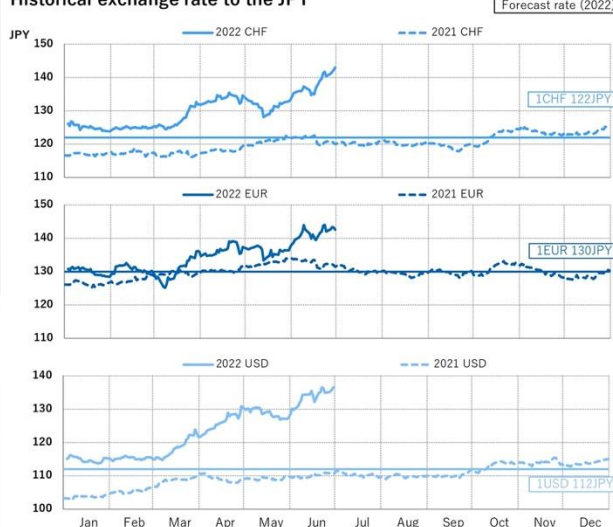
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Impact from Foreign Exchange Jan - Jun

(billions of JPY)	vs. 2021 Actual	vs. 2022 Assumption
Revenues	+13.3	+2.2
Sales	+9.5	+0.9
Royalties and other operating income	+3.8	+1.3
Cost of sales	-5.8	-0.1
Operating expenses	-1.8	-0.9
Operating profit	+5.7	+1.2

Market average exchange rate(JPY)	2021 Actual	2022 Assumption	2022 Actual
1CHF	118.60	122.00	130.15
1EUR	129.76	130.00	134.35
1USD	107.63	112.00	122.87

Historical exchange rate to the JPY



25

The next slide is on page 25, the impact from foreign exchange. Since March of this year, the foreign exchange market has been moving very sharply, especially with the depreciation of the yen. This slide shows how it has affected our profit and loss.

The upper left-hand side of the chart shows that in the past, we only included information on how the actual results compared to the assumed rate at the beginning of the period, but this time we have included the impact compared to the previous year's rate. In terms of the actual exchange rate of the previous year, the depreciation of the yen had a positive effect of JPY5.7 billion on operating profit compared to this year's H1 P&L. The forecasted rate was a positive JPY1.2 billion against operating profit.

Our foreign currency transactions like this, mainly sales to Roche, income from Roche, or purchases from Roche, are denominated in Swiss francs, which are quite voluminous, but in the previous year, about 80% of our annual transactions are hedged against foreign exchange. We are using the hedged exchange rate as the planned rate for this year while referring to the hedged exchange rate, so if we do it throughout the year, 80% of the time there will be no difference from the plan. The remaining 20% exposure is to market exchange rate movements and volatility.

However, in H1, almost 100% of the transactions are actually hedged. Since hedges have been taken frequently over the last year, there are some fluctuations in the individual hedged items themselves. In H1, many of the hedges were taken at a slightly weaker-than-expected yen, which resulted in an increase in operating profit of JPY1.2 billion. This is the reason for the JPY1.2 billion increase in operating profit.

The remaining 20% of our exposure would normally be our revenue, sales, royalties from Roche, and purchases from Roche, net of our revenue side, net position, and revenue side is larger. However, for this year only, in addition to the positive exposure, the Ronapreve purchase was not hedged at the beginning of the period.

The contract with the government was not made at the beginning of the period, and therefore, hedging is not possible. If we start a new contract now, the yen has depreciated significantly against the assumed rate at the

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beginning of the fiscal year, so the profit against the plan will be hit by that amount. We are currently forecasting a large increase in negative cost of sales at the assumed rate for the full year.

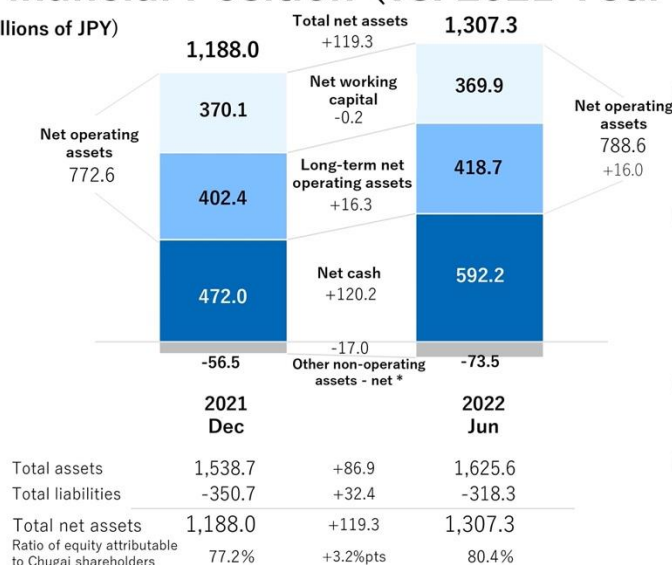
This concludes the section on profit and loss.

FY2022 Q2 Consolidated Financial Overview (Core)



Financial Position (vs. 2021 Year End)

(Billions of JPY)



Decrease in net working capital

Same level as the end of Dec 2021, mainly due to decrease in accounts receivable offset by payment for API manufacturing building (FJ3) at Fujieda plant

Increase in long-term net operating assets

Increase in property, plant and equipment due mainly to the following investments
 - Chugai Life Science Park Yokohama
 - Biopharmaceutical API manufacturing building(UK4) at Ukima Branch

Increase in net cash

(See next slide)

Decrease in other non-operating assets – net

Increase mainly in foreign exchange contracts liabilities, etc.

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

26

Page 26 is on the balance sheet.

If you look at the second line from the bottom on the left, you will see the total amount of net assets. At the end of June, the balance stood at JPY1.3073 trillion, an increase of JPY119.3 billion from the end of last year.

Two lines above that is a breakdown. First of all, assets increased by JPY86.9 billion over the past six months. The liabilities figure is positive, but the absolute amount is different, so positive means that it is decreasing. The liabilities are decreasing by about JPY32.4 billion. The bottom line is the ratio of shareholders' equity to total assets, which increased by 3.2 percentage points to 80.4%.

As you can see from the graph above, there are pluses and minuses, but the largest increase was in net cash, which increased by JPY120.2 billion. A breakdown of this is shown on the next page.

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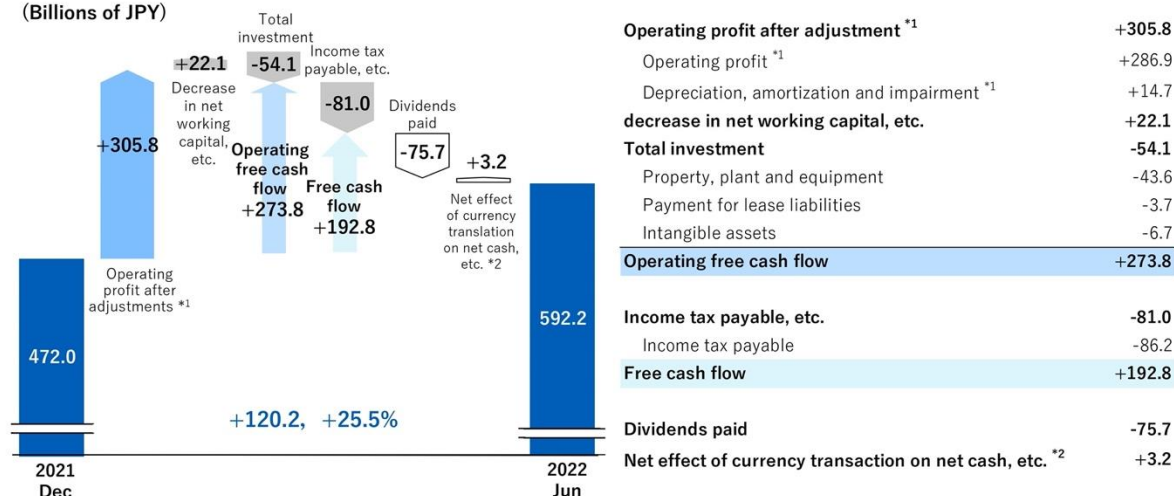
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Net Cash (vs. 2021 Year End)

(Billions of JPY)

^{*1} Including Non-Core (IFRS results)^{*2} Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + 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)

27

The second graph on the left, adjusted operating profit, showed a cash inflow of JPY305.8 billion. This is not on a core basis, but on a full basis. The one-time income from Alexion is around JPY90 billion, included in the cash.

After subtracting changes in net working capital and investments, operating free cash flow was positive JPY273.8 billion, and after-tax payments, income taxes, and last year's year-end dividend payment, net cash increased by JPY120.2 billion to JPY592.2 billion at the end of June.

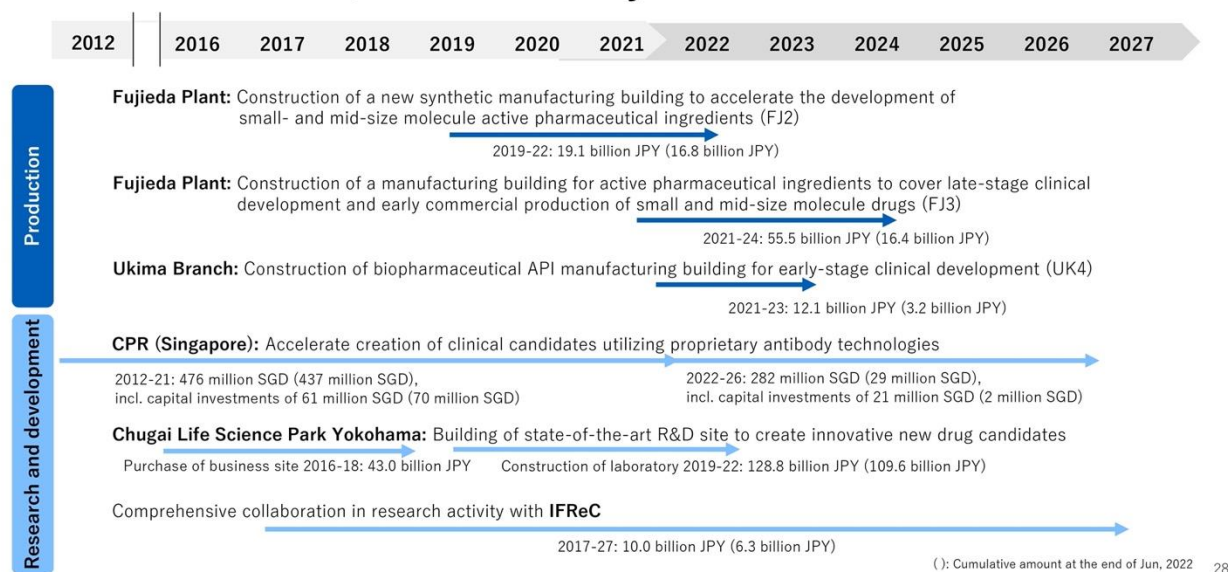
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Current Status / Plan for Major Investments



Last is the current plan for major investments.

There are no new matters to report this time from those disclosed in the previous fiscal year's financial statements. It is the same. The actual amounts have been updated.

Construction of the Fujieda facility, FJ2 at the top, and the R&D facility, Chugai Life Science Park Yokohama in the middle, will be completed this year as scheduled. The construction of manufacturing facilities, such as FJ3 in Fujieda and UK4 in Ukima, are also progressing smoothly.

That is all from me. Thank you very much.

Sasai: Next, Mr. Yamaguchi will discuss the status of our development pipeline.

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

As of July 21, 2022

Launched	Vabysmo	Age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema	May 2022
	Edirol	Postmenopausal osteoporosis (China)	July 2022
Approved	Tecentriq	PD-L1-positive NSCLC (adjuvant)	May 2022
	FoundationOne® CDx Cancer Genomic Profile	<ul style="list-style-type: none"> • dacomitinib hydrate: NSCLC (Activated <i>EGFR</i> alterations) • brigatinib: NSCLC (<i>ALK</i> fusion genes) • encorafenib, binimetinib: Malignant melanoma (<i>BRAF</i>V600E and V600K alterations) 	June 2022
	Hemlibra	Acquired hemophilia A	June 2022
	Avastin	Additional dosage and administration in ovarian cancer: every 2 weeks (public knowledge-based application)	June 2022
	Neutrogin	Relapse or refractory acute myeloid leukemia in combination with other anticancer agents (public knowledge-based application)	June 2022
Readout in pivotal study	Rituxan	Prevention of recurrence of NMOSD (including neuromyelitis optica)	June 2022
	RG6058/tiragolumab	NSCLC P3 (SKYSCRAPER-01) PFS: did not meet / OS: continuously evaluate	May 2022
	RG7446/Tecentriq	Renal cell carcinoma (adjuvant) P3 (IMmotion010) DFS: did not meet	June 2022
	CIM331 / nemolizumab	Prurigo nodularis P3 (OLYMPIA 2 conducted by Galderma) Primary endpoints were met	June 2022

NSCLC: non-small cell lung cancer; NMOSD: neuromyelitis optica spectrum disorder
PFS: Progression-free Survival; OS: Overall Survival; DFS: Disease-free Survival

30

Tetsuya Yamaguchi: Thank you.

The presentation starts from slide 30. First, here is a slide showing some of the topics since the last financial announcement.

As already announced, Vabysmo was launched in May for the two indications of age-related macular degeneration and diabetic macular edema. In addition, Edirol was launched in China on July 15 for the indication of postmenopausal osteoporosis.

In terms of approvals, Tecentriq is now approved for adjuvant therapy in PD-L1-positive non-small cell lung cancer, and FoundationOne CDx is approved for non-small cell lung cancer and as a companion diagnostic to four drugs for malignant melanoma. Hemlibra has been extended for use in acquired hemophilia A, and Avastin and Neutrogin have received partial changes in their approved items and approval, respectively, through public knowledge filings. In addition, the indications of Rituxan were extended for the prevention of recurrence of neuromyelitis optica spectrum disorders.

As for the top-line anti-TIGIT antibody tiragolumab in late-stage development, PFS has not been achieved for non-small cell lung cancer, and OS is still under evaluation. Tecentriq has not met its primary endpoint in renal cell carcinoma, and nemolizumab has met its primary endpoints in a Phase III trial for prurigo nodularis. I will discuss tiragolumab and nemolizumab in further detail later.

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Q2 Topics (2/2)



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

As of July 21, 2022

Medical conference	Evrysdi	FIREFISH study, three-year data presented at European Paediatric Neurology Society Congress	April 2022
	OWL833 (LY3502970)	P1 study, PK data in healthy volunteers presented at American Diabetes Association*	June 2022
	Hemlibra	HAVEN 6 study, data in mild-moderate hemophilia A without inhibitors presented at ISTH	July 2022
	Hemlibra	AGEHA study, data in acquired hemophilia A presented at ISTH	July 2022
	Vabysmo	TENAYA & LUCERNE studies, two-year data in nAMD presented at ASRS	July 2022
New to pipeline	Perjeta	APHINITY study in combination with Herceptin, eight-year data in HER2 positive early BC at ESMO Virtual Plenary	July 2022
	RG7159/Gazyva	Lupus nephritis	domestic P3 (June 2022)
	GYM329 (RG6237)	Spinal Muscular Atrophy (MANATEE study) in combination with Evrysdi	P2/3 (June 2022)
	RG6396/pralsetinib	NSCLC (2nd line)	domestic P2 (June 2022)
Development discontinued	RG6058/tiragolumab	SCLC (1st Line), SKYSCRAPER-02 study in combination with Tecentriq	
	RG7446/Tecentriq	Ovarian cancer (1st Line), IMagyn050 study in combination with Avastin	
	RG7880/efmarodocokin alfa	Inflammatory bowel disease	

NSCLC: non-small cell lung cancer; BC: breast cancer; nAMD: neovascular age-related macular degeneration; ISTH: International Society on Thrombosis and Haemostasis; ASRS: American Society of Retina Specialists Annual Scientific Meeting; ESMO: European Society for Medical Oncology
* Conducted by Eli Lilly, the overseas licensee

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Coming to the next slide, we have a conference presentation. The second item, OWL833, is the result of a clinical pharmacology study conducted by Eli Lilly and Company. It has been shown that once-daily oral administration of OWL833 resulted in pharmacokinetics similar to those of injectable GLP-1. All other results presented were similarly positive.

In the pipeline entry, Gazyva has started Phase III trials in Japan for lupus nephritis. In addition, GYM329 has started Phase II/III study in combination with Evrysdi in pediatric SMA. These two trials will be explained later. In addition, we have initiated a domestic Phase II study of pralsetinib, an RET inhibitor, for second-line non-small cell lung cancer.

The three products under development discontinued are tiragolumab for small cell lung cancer, Tecentriq for ovarian cancer, and RG7880, the active IL-22 protein, for inflammatory bowel disease.

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Nemolizumab

Galderma announced the phase III OLYMPIA 2 trial met all primary endpoints in patients with PN

- Prurigo nodularis (PN) is a chronic skin disorder with hard dome-like or wart-like nodules and intense pruritus
- No treatments for PN is approved despite negatively affecting QOL
- Nemolizumab is a Chugai originated first in class antibody designed to inhibit IL-31 signal which is involved in PN pathology

<Data from OLYMPIA 2 trial*>

- **Meet two primary endpoints by nemolizumab monotherapy**.** Safety profile was consistent with the phase II trial.
 - Skin lesions (IGA score): 38% of nemolizumab group reached clearance or almost-clearance of skin lesions, compared to 11% of placebo group. (p<0.0001)
 - Itch (PP-NRS score): 56% of nemolizumab group achieved an at least four-point reduction, compared to 21% of placebo group. (p<0.0001)
- **Data confirm early onset of action on itch, skin lesions and sleep disturbance as the trial also met all key secondary endpoints.**
- **Favorable results of OLYMPIA 2 reproduce the data of the P2 study, granted breakthrough therapy designation by the US FDA in December 2019**

* OLYMPIA 2 is a randomized, double-blind, placebo-controlled phase III clinical trial, to assess the efficacy and safety of nemolizumab monotherapy compared with placebo in patients at least 18 years of age with prurigo nodularis after a 16-week treatment period. 274 patients with moderate-to-severe prurigo nodularis joined the trial. A second phase III trial investigating the efficacy of nemolizumab in patients with prurigo nodularis, named OLYMPIA 1, is ongoing. The OLYMPIA 1 trial has a similar design to OLYMPIA 2.

** without background topical corticosteroids or topical calcineurin inhibitors

IGA: Investigator's Global Assessment, PP-NRS: Peak Pruritus Numerical Rating Scale

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Please proceed to the next page, 32. From here, individual projects will be explained.

The first is nemolizumab.

Galderma's Phase III study, OLYMPIA 2, for prurigo nodularis, met its primary endpoints. Prurigo nodularis is a skin disease characterized by hard dome-shaped nodules and intense itching that interferes with daily life.

Nemolizumab is an antibody developed in-house against IL-31 receptor A. It is expected to directly suppress itching by blocking the signal of IL-31, a cytokine that induces itching.

The two primary endpoints, the IGA score for skin lesions and the PP-NRS score for itching, were achieved with single-agent nemolizumab.

All primary secondary endpoints were also met, confirming an early effect on itching, skin lesions, and sleep disturbances.

These results replicate the results of a Phase II study that received a Breakthrough Therapy Designation (BTD) from the US FDA in 2019. The application will be submitted with the results of the other ongoing Phase III study, OLYMPIA 1.

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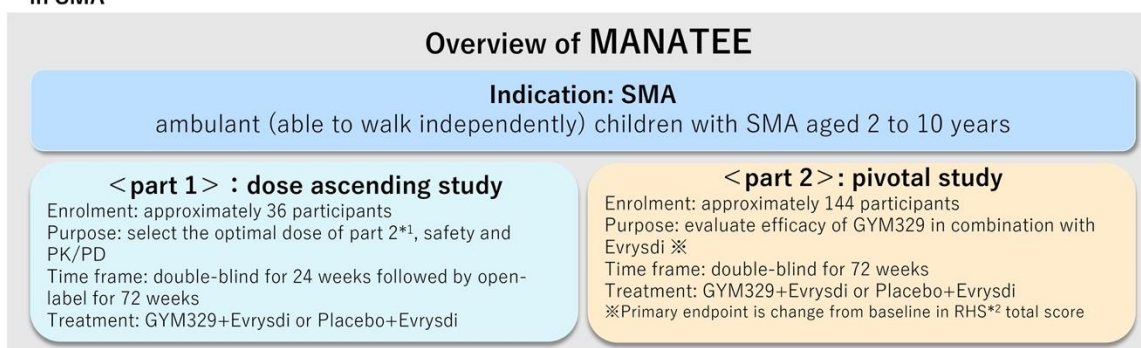
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GYM329: Global P2/3 study (MANATEE)

Study in combination with Evrysdi in pediatric patients with Spinal Muscular Atrophy (SMA)

- Evrysdi increases and sustains the production of the survival motor neuron (SMN) protein which is critical for maintaining healthy motor neurons and movement.
- GYM329 inhibits latent myostatin which suppresses muscle growth and is expected to control progression of loss in muscle strength in neuromuscular disease
- Combination therapy of these drugs is expected to further improve motor movement and clinical outcome in SMA



^{*1} administration of GYM329: Q4W, SC ^{*2} RHS: Revised Hammersmith Scale (Scale for evaluation of motor function in children with SMA)

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The next slide, page 33, is on GYM329. I am pleased to introduce the Phase II/ III (MANATEE) study that Roche has initiated.

The MANATEE trial will be a combination of GYM329 and Evrysdi for spinal muscular atrophy (SMA).

Evrysdi is an oral SMN2 splicing modifier that was launched in Japan last year for the treatment of SMA.

GYM329 is a sweeping antibody against myostatin precursor, created by Chugai, which removes myostatin, which inhibits muscle growth, before it is activated. This results in increasing muscle mass and strength.

We expect further improvement in motor function in SMA with this combination. In subjects aged 2-10 years who are ambulatory, part one will be a dose-finding study and part two will be a pivotal study to evaluate the efficacy of combination GYM329 on the primary endpoint of change in RHS of motor function assessment scale.

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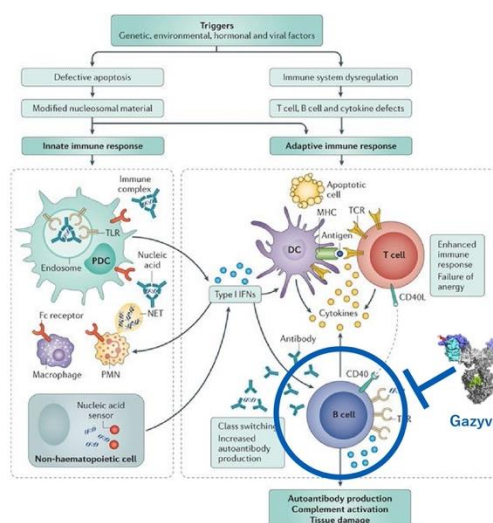
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Gazyva (Obinutuzumab) for Lupus Nephritis

Gazyva provides enhanced B cell depletion which could bring benefit to LN patients, local Phase 3 initiated

- **Lupus Nephritis (LN):** An autoimmune disease, frequent complication in people who have systemic lupus erythematosus which leads to impaired kidney function or kidney failure caused by activation of self-reactive T cells and B cells and tissue deposition of immune complexes formed by autoantibodies produced by B cells
- **Humanized anti-CD20 monoclonal antibody that binds to the CD20 antigen, engineered to induce greater ADCC and direct cell death^{*1}**
- **Positive results of Phase 2 study in Lupus nephritis confirmed^{*2}**



^{*1} launched for CD20-positive follicular lymphoma in August 2018 in Japan

^{*2} Ann Rheum Dis 2022;81:100–107

Next on page 34 is an introduction to the domestic Phase III study of Gazyva for lupus nephritis.

Lupus nephritis is a renal disorder that appears in about half of all cases of lupus erythematosus. It is believed that renal damage is caused by activation of autoreactive T and B cells and deposition of immune complexes formed by autoantibodies produced by B cells in the renal glomerular tissue.

Gazyva is a glycoengineered anti-CD20 monoclonal antibody, which is already in use in Japan as a therapeutic agent for CD20-positive follicular lymphoma. It is characterized by its strong B-cell-disrupting ability by enhancing ADCC and inducing direct cell death through glycosylation. The strong B-cell-disrupting effect of Gazyva is expected to suppress the disease activity of lupus nephritis and reduce organ damage.

Phase II clinical trials conducted in the US and Europe have already confirmed its high efficacy for lupus nephritis, and we have obtained BTM from the US FDA.

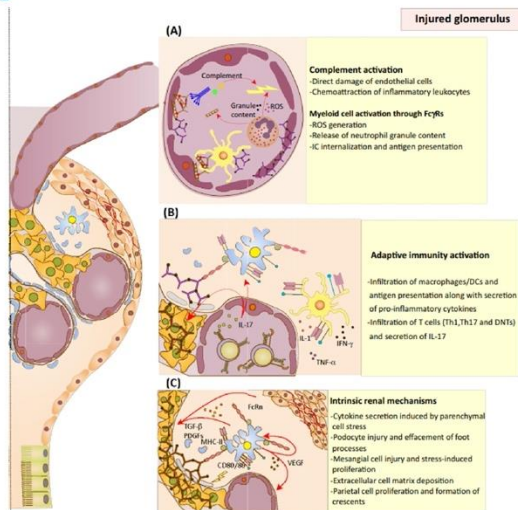
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Crovalimab for Lupus Nephritis (LN)

Inhibiting terminal complement pathway could prevent cell damage in glomerulus and inflammation: P1 study to be initiated



■ Recycling antibody created by Chugai, targeting complement C5 and inhibits cleavage of C5 into C5a and C5b

■ Expected to prevent cell damage in glomerulus and inflammation by inhibiting terminal complement pathway. Phase 1 study of crovalimab in LN is to be initiated

□ Complement activation following immune complex deposition in glomerulus is reported to be associated with pathophysiology of LN

- C5a causes migration of macrophage and neutrophils to glomerulus and subsequent activation
- MAC (Membrane-attack complex) attacks endothelial cells

■ Synergy with Gazyva in renal disease area (lupus nephritis) is expected

an excerpt from Giovanna Flores-Mendoza et al., Trends in Molecular Medicine, April 2018, Vol. 24, No. 4

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The next slide is on crovalimab. This is Roche's new trial for lupus nephritis.

Crovalimab is a recycling antibody that targets complement C5 and inhibits the cleavage of C5 to C5a and C5b.

In lupus nephritis, immune complexes are deposited on the glomerular membrane and mesangium, where complement is activated and causes tissue damage. By inhibiting complement activity, the drug is expected to reduce glomerular damage and inflammation.

Since the mechanism of action is different from that of Gazyva, which was introduced earlier, we expect synergistic effects between the two drugs in the future.

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Tiragolumab: Development Status

Exploring the role of new cancer immunotherapy in ongoing multiple global P3 studies in combination with Tecentriq

- 1L SCLC (SKYSCRAPER-02): did not meet its co-primary endpoint of PFS. OS is unlikely to reach statistical significance
- 1L NSCLC (SKYSCRAPER-01): did not meet its co-primary endpoint of PFS. OS will be assessed continuously. A numerical improvement was observed in both primary endpoints
- No new safety signals were identified in both studies in combination therapy with tiragolumab and Tecentriq
- Other global P3 studies for NSCLC (stage III) and esophageal cancer are ongoing

< Global P3 study participating from Japan >

* A numerical improvement was observed in both PFS and OS.

Study	Indication	Design	Primary endpoint	Filing
SKYSCRAPER-01 (NCT04294810)	1L NSCLC (PD-L1-high)	Tecentriq ± tiragolumab	PFS*: did not meet OS*: continuous assessment	2023
SKYSCRAPER-02 (NCT04256421)	1L SCLC	Tecentriq + chemo ± tiragolumab	PFS: did not meet OS: unlikely to meet	Development discontinued
SKYSCRAPER-03 (NCT04513925)	NSCLC (stage III)	Tecentriq + tiragolumab vs. durvalumab	PFS	2024
SKYSCRAPER-07 (NCT04543617)	esophageal cancer	Tecentriq ± tiragolumab vs. placebo	PFS/OS	2024

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Next, on page 36, I would like to discuss the development status of tiragolumab.

Tiragolumab is an antibody against the immune checkpoint receptor TIGIT on T cells and NK cells and is considered a strong candidate for combination cancer immunotherapy.

The Phase II trial in non-small cell lung cancer has shown favorable results, and multiple Phase III trials are currently underway in combination with Tecentriq.

The SKYSCRAPER-02 study for first-line treatment of small-cell lung cancer has failed to meet its PFS primary endpoint, and the decision has been made to discontinue development. Of all lung cancers, small-cell lung cancer has a particularly aggressive course. Unfortunately, efficacy was not observed with the tiragolumab combination.

On the other hand, in the SKYSCRAPER-01 trial for first-line treatment of non-small-cell lung cancer in the read-out in May, PFS was not achieved and OS was continued to be assessed, but numerical improvements were observed in both cases. We expect to obtain good results in the OS interim and final analyses.

Both studies showed no new safety concerns with the combination of tiragolumab and Tecentriq, demonstrating once again the ease of use of the TIGIT antibody as a concomitant drug.

In addition, Japan is participating in Phase III trials for non-small-cell lung cancer (Stage III) and esophageal cancer, as shown in the bottom row. The results of these Phase III studies are awaited.

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2022: Key R&D Milestones

	Product	Indication/Study name	Progress
Projects to be approved	Actemra	COVID-19 pneumonia (Japan)	✓
	Mitchga	Atopic dermatitis (Japan)	✓
	Hemlibra	<u>Acquired hemophilia A (Japan)</u>	✓
	Herceptin/Perjeta	HER2 positive colorectal cancer	✓
	Vabysmo	Neovascular age-related macular degeneration (nAMD)	✓
	Vabysmo	Diabetic macular edema (DME)	✓
	Tecentriq	<u>Non-small cell lung cancer (NSCLC) [adjuvant]</u>	✓
P3/Pivotal readouts	Polivy	Previously untreated diffuse large B-cell lymphoma (DLBCL)	
	Alecensa	ALINA Study: NSCLC [adjuvant]	2023
	crovalimab	<u>COMMODORE 3 study (China): PNH</u>	✓
	nemolizumab	<u>OLYMPIA 2 study: Prurigo nodularis</u>	✓
	gantenerumab	GRADUATE 1/2 study: Alzheimer's disease	
	Tecentriq	IMpower030 study: NSCLC [neoadjuvant]	
	Tecentriq	<u>IMmotion010 study: RCC [adjuvant]</u>	✗
	Tecentriq	<u>IMvove010 study: HNC [adjuvant]</u>	Continuous assessment
	Tecentriq + Avastin	IMbrave050 study: HCC [adjuvant]	
	<u>Tecentriq + tiragolumab</u>	<u>SKYSCRAPER-01 study: NSCLC [1st line]</u>	Continuous assessment
	<u>Tecentriq + tiragolumab</u>	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 April 25, 2022

PNH: Paroxysmal nocturnal hemoglobinuria; RCC: renal cell carcinoma; HNC: head and neck carcinoma; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung cancer; SCLC: small cell lung cancer

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On page 37, we summarize the progress of this year's major R&D events.

As for approvals, we have made steady progress and have already obtained approvals for seven items. The remaining major approvals are DLBCL first-line treatment for Polivy, which was introduced earlier.

In the bottom row, in the pivotal readout, the positive points are crovalimab for PNH in China and nemolizumab achieving the primary endpoints in one study of prurigo nodularis overseas. The remaining major readouts are gantenerumab and Tecentriq for preoperative adjuvant non-small cell lung cancer and adjuvant hepatocellular carcinoma by the end of the year.

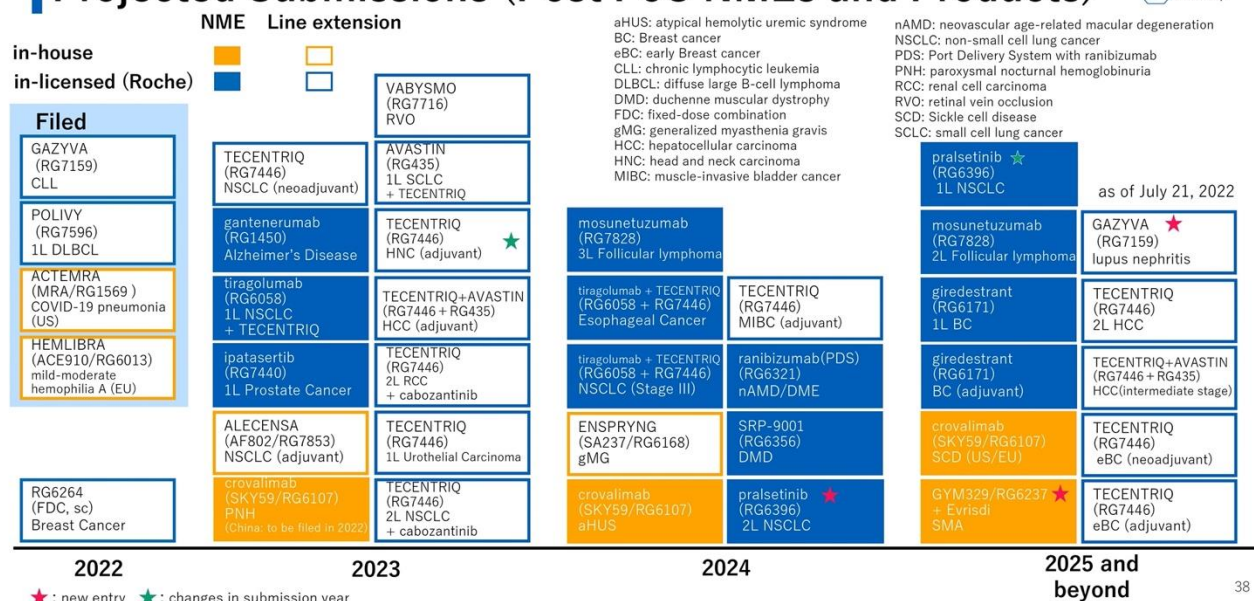
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Projected Submissions (Post PoC NMEs and Products)



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The next page, page 38, as usual, shows the schedule of future applications, with red stars indicating those added at this time and green stars indicating those with changes in the year of application, both as explained.

The following pages are for reference. On pages 39 and 40 are the status of our development pipeline, followed by third-party out-licensing projects and the progress of major items. Pages 42 and 43 provide information on the companion diagnostic function of FoundationOne CDx and FoundationOne Liquid CDx. The last section shows publicly available information on our major in-house developed products, although it is not possible to give a specific explanation because they have not yet started clinical trials. We hope you will refer to this page as appropriate.

That is all from me.

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Question & Answer

Sasai [M]: Okay, we will now move on to the Q&A session.

Mr. Hidaka, Executive Vice President, Head of Marketing & Sales Division, will also be present for the Q&A session.

We apologize for the inconvenience, but in order to encourage as many people as possible to ask questions, please limit the number of questions to two per person.

Please note that an audio recording of your questions, along with the presentation, will be posted on our website at a later date.

First, we will take questions from the audience, followed by those participating in the Zoom webinar. If you have any questions, please raise your hand and a staff member will hand you the microphone.

Now, if you have any questions, please do not hesitate. Please raise your hand.

Sakai [Q]: My name is Sakai from Credit Suisse. Let me ask a question first to Mr. Itagaki.

Regarding the Ronapreve sales, I agree that while not a major factor, it affected the overall results somewhat. I think you mentioned on page 25 that the impact of the exchange rate on Ronapreve will be significant in H2 of the fiscal year. You explained that the depreciation of the yen in the area of purchases will increase the payment of Swiss francs. I think this is what was meant.

However, I think Ronapreve already has a plan for this year, and since it is a government contract, it will come out almost without a blip. If 80% of the assets are hedged, as you mentioned, I think we can calculate the impact of exchange rate fluctuations in the second half of the year.

Or is this something we can't calculate? I'm not sure about cost ratios and such, so I'm sure that would be a bit of a blur.

Itagaki [A]: Thank you, Mr. Sakai.

You are right. The plan announced at the beginning of the fiscal year includes sales of Ronapreve to be supplied to the government. This is denominated in yen, so there is a foreign exchange impact. It is necessary to purchase Ronapreve from Roche for this purpose. This is also because the plan at the beginning of the period was based on certain foreign exchange assumptions. In the plan at the beginning of the period, we thought that we could purchase, for example, at JPY122 to the CHF. When we decided to hedge or book the exchange rate, the yen had already depreciated, so it would come out between the plan and the purchase price. The logic is that the cost of goods will increase versus the plan.

We have already decided how much to stock, of course. Since it is the cost that is affected, it can be calculated if the cost amount is multiplied by the exchange rate. For example, if the exchange rate was thought to be JPY122 and now it is JPY142, that is a 16% increase. We have the result of calculation at hand, but by saying this, we are talking about cost, so I won't say how much.

However, I still think that guidance is necessary, and a profit plan will be affected by the difference between purchase cost of Ronapreve and such a plan. On the other hand, as I said before, there is considerable

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exposure to other transactions. It is a plus this time around. Netting this will unfortunately result in some negatives. However, the project is not as large as the JPY10 billion scale.

Since we have not revised our full year forecast, we are working to achieve the forecast. I think it is fine to think that the exchange rate has that level of impact.

Sakai [Q]: I understand. Thank you very much.

Then the other question is Hemlibra, the table on page 10. This is informative to learn various development products and competitors. I would like to ask you two questions. First, the global market share of Hemlibra is just under 30%. The point is that we thought, or rather expected to some extent, that factor VIII would be switched at a faster pace at the beginning of the launch.

We know that there is a need for doctors and patients using factor VIII who do not want to switch, but how do we cut through this need in the future? Is there something you can do, or do you just let nature take its course?

Another concern is this Sanofi drug. The results were good, as I recall. It is long-acting, which means more and more presence in factor VIII, maybe cannibalism happens in Sanofi, so there may not be a sudden influence on Hemlibra. Please let me know what you think about this area.

Okuda [A]: Okay, let me start.

According to Roche, the share of Q2 for the US and the EU5 is 35%, that's up 1% point from the previous quarter. It was 34% before that and 33% before that, I think. The number is increasing steadily. We see further room for growth there.

As shown in the graph today, Japan has been affected by the coronavirus pandemic to some extent. It is true that this is slower than expected, but as you can see in this graph, the patient share is steadily increasing. We believe that there is still room for growth here, too.

After all, Hemlibra is administered subcutaneously once a week, once every two weeks, or once every four weeks, making it very easy to use and more convenient than the intravenous formulation. In the pediatric population, of course, it can be difficult securing veins, so the product penetrated quite quickly. The benefit for adult patients is the convenience, which can have a big impact on lifestyle. As people recognize these benefits, the market share is continuing to grow.

As you know, the hemophilia market is a market where, once patients are satisfied with a certain formulation, it is difficult to switch. So, as you said, I wonder if perhaps that contributed to the slower-than-expected switch. However, as far as I can see here, there is still room for growth.

On the other hand, as our market share increases in this way, we will face a number of competitors. It is also a market from which it is difficult to switch back, or rather, switch from one to another. Thank you.

Sakai [M]: Thank you very much.

Sasai [M]: Thank you.

Next question, please.

Kohtani [Q]: My name is Kohtani from Nomura Securities.

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Two questions from me. The first is on Hemlibra. Recently, at the ISTH conference, I was listening to data and presentations from competitors, and I was wondering if there are three things that everyone is trying to use to differentiate themselves from each other.

One possibility is that with Hemlibra thrombin production is only about 20% of that of a healthy person, so there are questions about whether it would be a factor VIII for sporty and active people.

Second, it seems that Hemlibra is painful when injected subcutaneously, and some patients are a little concerned about this.

The third point is that the majority, about 70%, are administered once every two weeks, so the drugs that will appear in the future will be administered once a month or once every two months.

In the future, I think we will see Fitusiran, Mim8, efanesoctocog alfa, which I think are shown on page 10, come out with differentiation, especially in terms of dosing intervals and activity. What I would like to ask specifically is whether these issues are such a big issue in today's actual clinical practice. For Hemlibra, or NXT007, which is about to come out, are these products able to sustain solid growth? This is the first question.

Hidaka [A]: Thank you for your question. I am Hidaka, Head of Marketing & Sales Division. Let me explain a little about the domestic situation.

Some people, especially those who play sports, are concerned, but this also depends very much on the patient, so it depends on the situation. In fact, we are currently conducting clinical research on Hemlibra to see how much the data will change if a patient is more active. We would like to get the results of such research as well.

The dosing interval also depends on the patient's preference, so I believe that the use of different dosing intervals will probably be determined according to this and other factors. We would like to make sure that we are not only presenting data from clinical trials, but also data from clinical studies, in order to make a strong differentiation point for our products.

Kohtani [Q]: Why is the dosing interval once every two weeks in about 70% of cases? Once-a-month dosing is also available. It seems that the sooner shifting to the longer interval, the better it will be against the competition. Is there any reason why that dosing regimen is not spreading?

Hidaka [A]: One thing I would like to say is that there is a sense of security, or perhaps a sense of uneasiness if too much space is left between doses, so I am aware that the current situation is not one where very long dosing intervals are widely used.

Kohtani [Q]: I understand.

The second question is about Enspryng. I believe the presentation was done before and talked about prolonging the survival of plasmablasts that produce IL-6 and AQP4 antibodies. Recently, a very interesting paper by your researcher and a professor from Yamaguchi University was published in the journal Neurology, showing a mechanism whereby administration of IL-6R antibody inhibits the breakdown of the blood-brain barrier.

Recently, you have started Phase III studies for various autoimmune diseases, such as myasthenia gravis, MOG antibody disease, and autoimmune encephalitis. If IL-6R antibodies are used to inhibit this mechanism, it seems they will be effective in a wide range of diseases. Is my understanding correct? If so, I think a clinical trial would be started in areas with a larger number of patients, such as CNS lupus. Thank you.

Tetsuya Yamaguchi [A]: Thank you.

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We are currently studying the mechanism of action of Enspryng in various ways, and while there may be a way of thinking as you have just described, our current thinking is that it is not necessarily the only way.

Regarding lupus, we are now in the process of selecting the applicable diseases, including the positioning of lupus with crovalimab.

Kohtani [M]: I understand. Thank you very much.

Sasai [M]: Next question.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities. Thank you for your detailed explanation of Actemra's exports to Roche on page 17.

In your statement, Mr. Itagaki, I think you mentioned that you believe the JPY80.1 billion forecast for H2 is achievable. In light of the current global sales situation from Roche, is it not a bit challenging? I would appreciate your comments given Roche's results.

Also, you explained again today that the previous year and the current year both had various special factors that made it difficult to interpret the figures. I would appreciate it if you could comment again on how we should think about this situation in the next fiscal year. Of course, it would be helpful if you could give us specific figures on how much it is likely to increase or decrease, but we would appreciate it if you could give us a summary of the points that we should keep in mind in our thinking.

Itagaki [A]: Thank you, Mr. Hashiguchi.

This is about Actemra, right? This can be achieved. The results in H2. As I said earlier, of course, it is assumed that COVID-19 is a bit of an unknown. Of course we do not know, but even without that, there is still a shortage of both IV and SC, although the movement of rheumatoid arthritis patients is shifting from IV to SC. We believe that while we need to fill this area, at present this is attainable.

It has not been easy to give guidance for the next fiscal year as of this Q2, and we have not yet made firm forecasts. We would like to focus on what possibilities exist at present.

Also, there was the situation that we were discussing the Royalty 2 cliff. We cleared that last year or this year. This time, we may talk about the Ronapreve cliff, because we will have Ronapreve sales this year, but there might not be next year.

First of all, regarding Ronapreve, we have last year's results and this year's full-year forecast. Not to mention the fact that we also have this year's Q1 results. The ones that were supplied last year and in Q1 this year are for the first contract, which was contracted last year. If we exclude Q1 results from this full year, last year's contract and the remainder of this year's forecast are nearly equal.

Regarding the second contract, there will be some in Q1 of next year, so while we first keep in mind that Ronapreve will still have some next year, compared to this year's figures, there will probably be less next year. One thing about what kind of deals we are talking about for next year is that Ronapreve will probably go down a bit.

We will also make efforts with Actemra this year to fill the market inventory from the current demand, but again, there is the unknown of the coronavirus. If it were zero, there would obviously be a downside.

Hemlibra's Royalty 2 have gone down. We have JPY9.5 billion as of H1, but even for the full year it is about JPY10 billion or so, so it is already down, but this will be zero next year, so there is a downside.

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In terms of R&D investment, we are proceeding the RED shift, and we intend to do quite a bit next year as well. This is a negative factor compared to this year against profit.

On the other hand, what is positive is that the domestic market will grow. Tecentriq, Polivy, and Hemlibra are the obvious ones, but there is also Enspryng, Vabysmo. Of course Avastin and Actemra, which are a bit of a headwind. In net calculations, these are growing domestically.

Exports will grow considerably for Hemlibra, Enspryng, and Alecensa, excluding Actemra. Then Hemlibra will lose Royalty 2, but will get quite a bit of regular Royalty 1. Also, I can't talk about the contents of one-time payments, but we can expect to receive a large lump-sum payment next year.

In addition, with the depreciation of the yen, if it stays at the current level, if there is no purchase of Ronapreve, the whole positive effect comes in. There are quite a few of these pluses. I guess the question is how much of a plus, and although I haven't scrutinized it now, I don't think there will be a cliff next year. This is the guidance at this point.

Hashiguchi [M]: Thank you very much.

Sasai [M]: Next question.

Hasegawa [Q]: My name is Hasegawa from Iyaku Keizaisha.

Regarding Vabysmo, I believe it was JPY0.9 billion. Please comment on the start-up and tell us about your current sales strategy. Also, I believe that there are advantages in terms of dosing intervals and so on. Please tell us how they are considered in the field.

Hidaka [A]: Thank you for your question. I am Hidaka from Marketing & Sales.

I think we got off to a very good start. In particular, the extended dosing intervals you mentioned, especially the 16-week interval, which is possible in about 60% of the cases in the clinical trial data, have been seen as very attractive.

However, since patients have only been administering the drug for a short period of time, I believe that we will not be able to get a real sense of the clinical effect until now.

The other point is the mechanism of action, which is to suppress Ang-2 in addition to VEGF. This could be used to treat patients for whom no treatment responded to date, and to give new patients the benefit of a long dosing interval. With this in mind, we feel that the start has been very positive.

Hasegawa [Q]: Thank you.

I would like to ask you about Ronapreve, what kind of impact do you expect the current spread of infection to have in the future? Also, I understand that you are concerned that BA.5 might reduce its effectiveness, and I would appreciate your comments on this point as well.

Tetsuya Yamaguchi [A]: Thank you.

Today, the package insert has been slightly revised to describe the degree of neutralizing activity of Ronapreve against Omicron strains. BA.1 was attenuated by a factor of 1,000 or more, but BA.2, BA.4, and BA.5 were all attenuated by a factor of 200 to 300, which means that the current mainstream strains are not as attenuated as they were at first.

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Based on this, I believe that the package insert states that the treatment is for when there is no other treatment available, and that usage for prevention should be carefully selected. Therefore, we believe that as the current mutant strain expands, there will be some treatment sites that will also consider certain usage for Ronapreve.

On the other hand, there are reports that other companies are expanding the indications for antibody cocktails, so I think that treatment methods will continue to expand.

Hasegawa [M]: Thank you very much.

Sasai [M]: Thank you.

Now, we would like to continue and take questions from those participating online.

Let me move on to the first question. JPMorgan Securities, Mr. Wakao, please go ahead.

Wakao [Q]: My name is Wakao from JPMorgan. Thank you very much.

What will offset the deterioration in Ronapreve's cost of sales for the current fiscal year? Now that the cliff is not coming in the next fiscal year, I am sure that if domestic products continue to be strong, your company will be able to secure an increase in profit next year, and I am very glad to hear your comments on that.

On the other hand, I was a little unsure of what would offset the deterioration in the cost of Ronapreve this year. Am I correct in assuming that Actemra's exports will eventually swing upward? Looking at the progress up to the first half of the year, I think it was almost as expected, so I couldn't quite pinpoint what the upside was, so please tell me again. This is the first question.

Itagaki [M]: Itagaki here. Your question is about this year's results.

Wakao [M]: Yes.

Itagaki [M]: Was the question about how to address the cost of Ronapreve going up compared to the plan?

Wakao [M]: Yes.

Itagaki [A]: Well first off, domestic is fine. The fact that domestic is fine, and as I said before, effect of yen depreciation for Ronapreve will be partially offset by a positive effect of yen depreciation on exposure, so when we say it is not JPY10 billion, you may think it is quite large, but it is not that much. That part can be absorbed quite well by items with strong domestic sales, and to a lesser extent, the cost of goods can be a bit better with different product mix.

We are also looking at the possibility that we may not spend this much on expenses, and we believe that we can absorb some of the increase in the cost of purchasing Ronapreve to some extent through other items.

Wakao [Q]: I understand. In your answer to my earlier question, I had the impression that Actemra would swing upward in the second half of the year since SC is also doing well, but is that not the case?

Itagaki [A]: No, it's more like we will be able to reach about the second half forecast remaining that I indicated earlier, and I have not made any further comments.

Wakao [Q]: I understand.

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Second, I too would like to know about Hemlibra. As to what points of clinical differentiation are important for Hemlibra, including next generation products, Mr. Kohtani just gave us some of them. My understanding is that your company also told us that zero-bleed is important. How important is zero-bleed in actual clinical practice?

Also, how should I interpret the zero-bleed numbers for HAVEN 6? They appear to be slightly lower than the pooled analysis numbers for HAVEN 1 through HAVEN 4, which I believe were about 70 to 80, while HAVEN 6's numbers were just under 70. Is it safe to assume that with these figures, your company can maintain a competitive advantage over other companies' products in terms of zero-bleed?

That is all.

Tetsuya Yamaguchi [A]: Yamaguchi here.

Zero-bleed is of course very important, and to finally achieve a daily life at the same level as a healthy person, we need a drug like NXT007. In other words, we want to bring coagulation activity to the level of a normal person, and we recognize that there are cases where people are restricted in their lives due to zero-bleed, so this is a very important part of the process.

Furthermore, we have a long-term strategy of not only focusing on major bleeding but also on micro-bleeding to prevent joint destruction and other disorders caused by long-term inflammation due to joint hemorrhage. Therefore, I believe that zero-bleed will be a very important point.

On the other hand, HAVEN 6 is not considered to be significantly inferior in any way. However, it is true that the figures were numerically lower. That is our understanding at this stage.

As you said, I would like to check the analysis again a little bit to see if that is what happened where the severity was relatively minor. Thank you.

Wakao [Q]: Thank you very much. Am I correct in understanding that even with the zero-bleed figures of HAVEN 6, your company can maintain superiority over the competing products you have presented on this 10th slide?

Tetsuya Yamaguchi [A]: Yes. Among the products mentioned in this report, gene therapy and siRNA are quite novel to begin with, and it will take some time for them to penetrate the market.

On the other hand, we believe that the extended half-life type is used as an extension of factor VIII, so we hope that the current market penetration will continue in the areas of bispecific antibodies and SC, which are the characteristics of Hemlibra.

As I mentioned earlier, once a patient has chosen treatment, it is difficult for a switch to occur among patients who are relatively satisfied with the treatment. We are now thinking of establishing our presence in the market as much as possible.

Wakao [M]: Thank you very much. Understood. That is all.

Sasai [M]: Thank you.

Next, Mr. Yamaguchi, Citigroup Securities, please go ahead.

Hidemaru Yamaguchi [Q]: Thank you very much.

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The first question is not directly related to the financial results, but the CEO of Roche will be replaced by Thomas Schinecker from Roche Diagnostics in March next year. I would like to ask you first whether you are maintaining this relationship and whether it will remain unchanged after next year.

Okuda [A]: Thank you for your question, Mr. Yamaguchi.

Roche announced today that Roche's CEO will be replaced. Thomas Schinecker, who is now CEO of Roche Diagnostics, has just announced that he will now become CEO of Roche as a whole.

The relationship between Chugai and Roche has been a very strong win-win relationship since 2002, when the two companies started a strategic alliance. The Roche management team and various members of Roche share this sentiment, and we do not see this relationship as something that will change immediately because of a change in CEO.

The current CEO of Roche Pharma is Bill Anderson. We have received a great deal of recognition from Roche for maintaining this strong relationship, or even more so, for improving the R&D capabilities and capacity of Chugai. We expect that this relationship will be further strengthened and developed.

Hidemaru Yamaguchi [Q]: Thank you very much.

The second question is simple. The partial revision of the basic agreement on strategic alliances was mentioned today. Where things have changed is that the TSE First Section has changed to Prime market, and while I believe the current figure is approximately 60%, it has changed from 50.1%. Is nothing different in terms of content? Or did you use this kind of wording to include the possibility of some kind of share movement?

Okuda [A]: Thank you for your question.

Regarding your question about partial revision of the basic contract, basically, the content has not changed. Since the TSE First Section has been eliminated, we have revised it to the Prime market and changed the related areas in keeping with the spirit of the original basic agreement.

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

Sasai [M]: Thank you.

Now, due to time constraints, we will close the session after the next question. Thank you.

Next, Mr. Muraoka, Morgan Stanley MUFG Securities, please go ahead.

Muraoka [Q]: Hello. Morgan Stanley, Muraoka. Thank you very much.

Earlier, Mr. Itagaki explained to us some of the elements of your thinking for the next fiscal year. Perhaps I was just misunderstanding this, but regarding Actemra, do you think that the decrease in exports due to the biosimilar launch or the risk of inventory adjustment within Roche are not points for to keep an eye on in the next fiscal year? There was no mention of this point, so let me confirm whether I am mistaken in my thinking.

Itagaki [A]: Indeed, the downside risk of the loss of coronavirus-related demand, and of course there are several biosimilars that are now in Phase III by several companies, so that is a downside risk. We do not yet know how much of an impact this will have, but even after factoring those things in, we do not currently anticipate any major net cliffs in the next fiscal year, if we include the positive factors I mentioned earlier.

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Muraoka [Q]: In other words, even if there is some demand movement on an end-to-end basis, is it correct to assume that the shortage situation will continue for another year, even if we do not yet see the risk of a major inventory adjustment, or even within Roche?

Itagaki [A]: These are comments based on the limited information we have at this point, so we will have to work out and scrutinize the supply-demand relationship with Roche and the export demand for our company in the future, but that is where we are at this point.

Muraoka [Q]: I understand. Thank you very much.

Also, regarding this revision of the alliance with Roche, I understand that it has not essentially changed, but I believe that in the previous agreement, there was a clause that allowed Roche to increase its shareholding ratio without agreement between the two companies after 2012. Is this still in place?

In addition, given the current exchange rate and the decline in your company's stock price from its peak, in Swiss franc terms, your company looks very cheap. It would be helpful if you could help us sort out our thinking in that area as well.

Okuda [A]: With the creation of the Prime market, the TSE's requirement for the ratio of liquid shares has changed. In short, what used to be a 5% liquid stock ratio is now required to be 35% in the Prime market. This is the big difference.

Roche now owns 59.9% of Chugai's shares. Since Roche will cooperate in maintaining the listing exactly as it was revised, Roche will have less freedom to increase its purchases.

Therefore, the contract was revised in accordance with our listing on the Prime market, in accordance with the basic spirit of the original contract. When the ratio was 50.1%, we had decided to give Roche a pre-emptive right in the event of dilution below 50.1% when new shares were issued by Chugai. Roche's intention was to maintain that ratio at 59.9% at this time, so we have decided to give the preference right in that form.

Muraoka [Q]: In other words, with the item of maintaining prime, there is still an item that Roche can raise without agreement, but is it okay to understand that this is automatically disabled?

Okuda [A]: Yes. Your understanding is correct. In reality, the benefits of having the Company in the Prime market are self-evident, so if such a situation should arise, we would of course have to discuss it, but we assume that such a situation would be unlikely to occur.

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

Sasai [M]: Thank you very much.

This concludes our Q2 financial results briefing.

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For those who were not able to ask questions due to time constraints, please contact Corporate Communications separately. Contact information can be found at the end of the presentation materials.

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

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