Innovation all for the patients

CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2023.12 Q2 Financial Results

July 27, 2023

Event Summary

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[Participants]	
[Number of Speakers]	5

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Toshiaki Itagaki	Director, Executive Vice President & CFO
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Kae Miyata	Head of Corporate Communications Dept.

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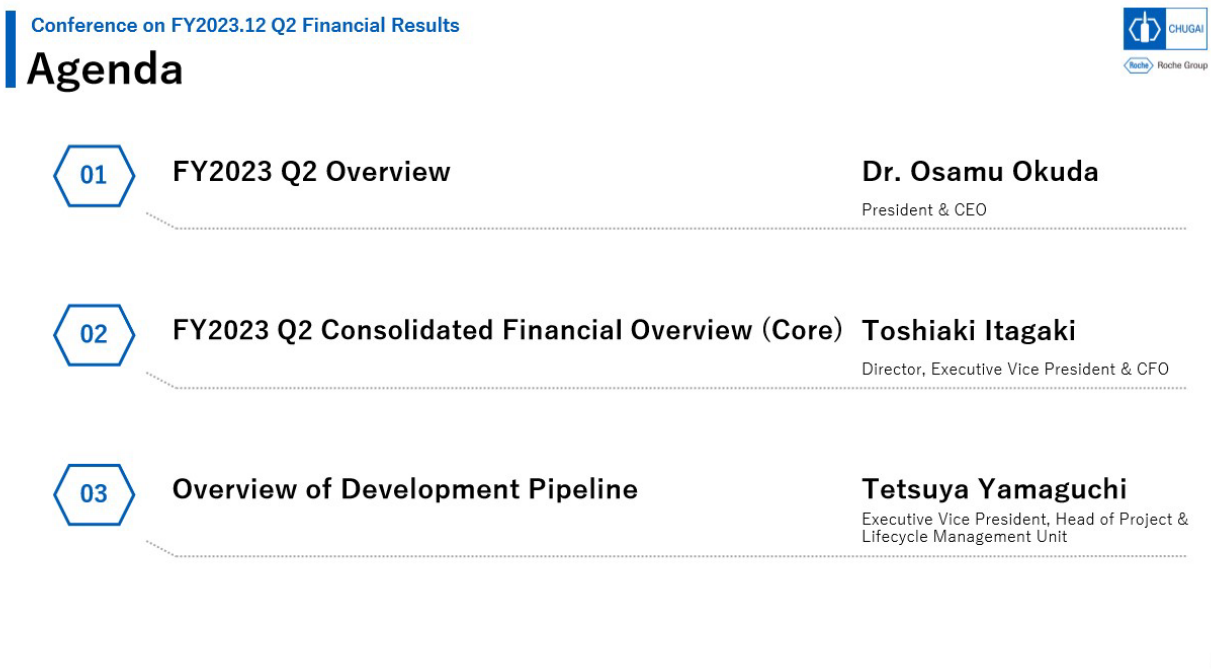
*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

Presentation

Miyata: Thank you very much for attending today's financial results briefing for Q2 FY2023.

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

Today's session will be conducted as a joint on-site presentation and Zoom webinar.



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

There will be time for screen capture before each presentation.

Questions will be taken after all presentations have been completed. The Q&A session is expected to last 30 minutes, so we hope you will be proactive and ask questions.

Please note that your audio will be muted during the presentation.

Now, Dr. Okuda will give an overview of Q2 FY2023. Thank you.

FY2023 Q2 Overview

Financial Overview

- **Increases in revenue and profits were mainly driven by good penetration of new/mainstay products and steady growth of exports to Roche**
- **Excluding the impact of COVID-19-related sales decrease, full-year revenue and profits are expected to increase YoY, with no changes to the initial forecast**

Core (billions of JPY)	2022 Jan -Jun actual*	2023 Jan -Jun actual	Growth		2023 Jan - Dec forecast	Progress (%)
Revenue	**504.0**	**579.7**	**+75.7**	**+15.0%**	**1,070.0**	**54.2%**
Domestic sales	273.8	313.6	+39.8	+14.5%	541.7	57.9%
Overseas sales	179.0	209.4	+30.4	+17.0%	378.3	55.4%
Other revenue	51.2	56.6	+5.4	+10.5%	150.0	37.7%
Operating profit	**201.4**	**232.0**	**+30.6**	**+15.2%**	**415.0**	**55.9%**
Operating margin	40.0%	40.0%	-	-	38.8%	-
Net income	**144.7**	**171.4**	**+26.7**	**+18.5%**	**306.0**	**56.0%**
EPS (yen)	**87.97**	**104.19**	**+16.22**	**+18.4%**	**186.00**	**56.0%**

* Starting from FY 2023, Chugai has excluded income from disposal of product rights from revenue. In conjunction with this change, the results for FY 2022 have been restated accordingly.

- Domestic sales grew due to the good market penetration of new/mainstay products and the supply of Ronapreve to the government despite the impact of NHI drug price revision and generics.
- Overseas sales significantly increased mainly due to Alecensa and Hemlibra exports to Roche.
- Other revenue increased mainly due to the increase of milestone income.

Hemlibra: Patient Share in Hemophilia A in Japan

Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023
27.3%	28.5%	29.2%	30.0%	30.8%

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Okuda: My name is Okuda, and I am the President and CEO of Chugai Pharmaceutical.

I will now provide a summary of the Q2 period of FY2023. Let's start with slide five.

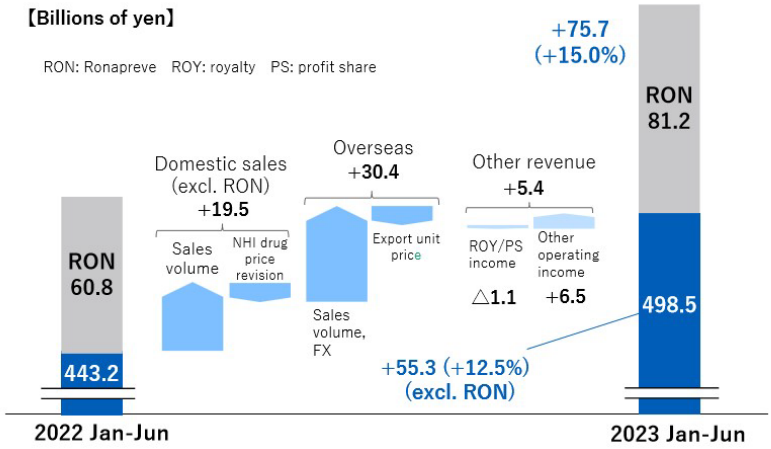
This quarter saw an increase in both revenue and profit. Revenue increased 15% YoY. Operating profit increased 15.2%, and net income increased 18.5%. New and mainstay products in the domestic market, and export of in-house products to Roche continue to be favorable.

The trend has remained unchanged since Q1, with steady growth in both domestic and overseas based businesses. Excluding the impact of COVID-19-related sales, we expect both revenue and profits to increase for the full year.

FY2023 Q2 Overview

Topline Overview

- **Domestic sales (excl. RON) increased due to the steady penetration of new/mainstay products despite the impact of NHI drug price revision, etc.**
- **Overseas sales increased due to the impacts of foreign exchange and sales volume, surpassing the decrease in export unit price**
- **Other revenue increased as other operating income compensated for the decline in royalty income**



- Domestic sales (excl. RON) increased due to growth of the new products such as Polivy and Vabysmo, as well as the favorable sales of the mainstay products including Hemlibra, Enspryng, and Tecentriq, absorbing the negative impacts of NHI drug price revision and the erosion of generic drugs, as expected.
- Overseas sales increased significantly by FX and sales volume, surpassing the decline in export unit price.
  Export of Alecensa significantly increased and export of Hemlibra progressed well.
  Generally progressed as expected.
- Other revenue increased overall primarily due to a significant increase in milestone income, despite the termination of royalty income from initial shipments of Hemlibra as expected.

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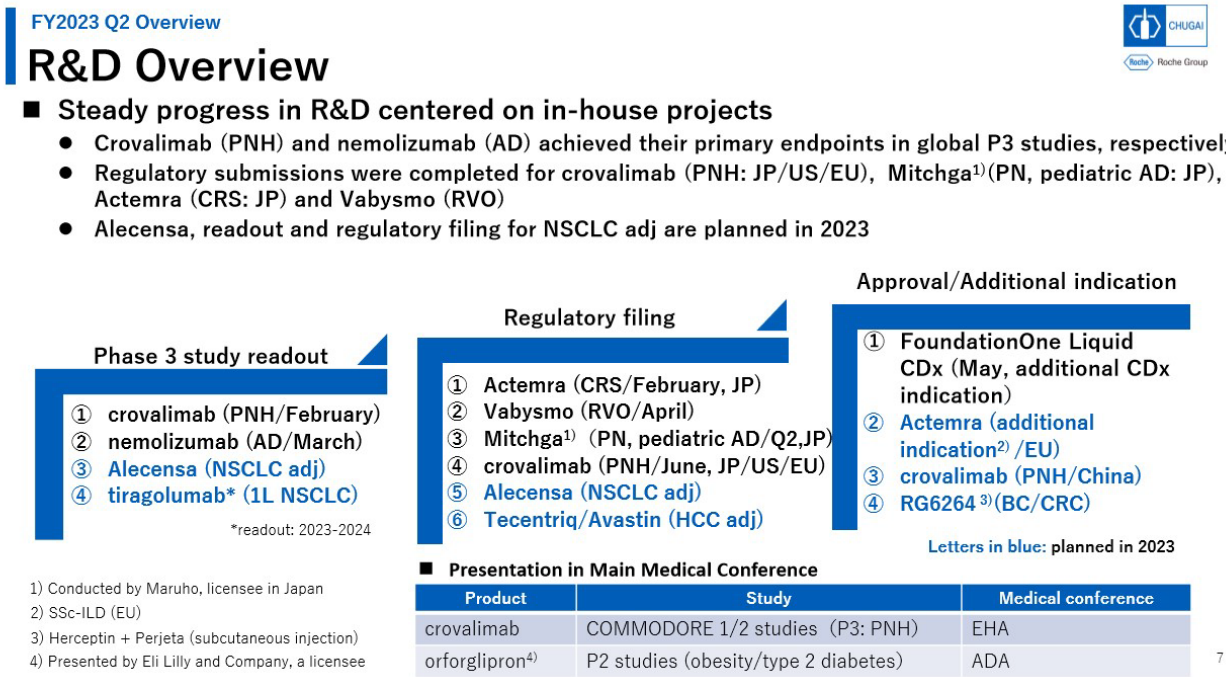
Next, I will discuss the topline results. This graph shows the factors contributing to the increase in revenue in H1 compared to the preceding year, excluding Ronapreve sales.

Sales in the domestic market increased due to steady penetration of new products such as Polivy and Vabysmo, and mainstay products such as Hemlibra, Enspryng, and Tecentriq. The segment saw increased volume, absorbing the negative impacts of NHI drug price revision and other factors.

Overseas, export of Alecensa and Hemlibra increased significantly as the impact of foreign exchange rates and volume growth outweighed the impact of lower export unit prices.

Other revenue increased overall due to a significant increase in milestone income, despite the termination of royalty income from initial shipments of Hemlibra.

As a result, even excluding the contribution of Ronapreve, the foundation business is growing steadily. Sales increased in H1 as expected.



Next, I would like to present some key points of progress in R&D. The black letters indicate actual results for H1, and the blue letters represent our plan for the rest of the year.

Here on the left is the main Phase III trial readout. Crovalimab and nemolizumab met their primary endpoints in global Phase III studies in paroxysmal nocturnal hemoglobinuria and atopic dermatitis, respectively. Phase III trial results for Alecensa and tiragolumab are expected to be obtained by the end of the year.

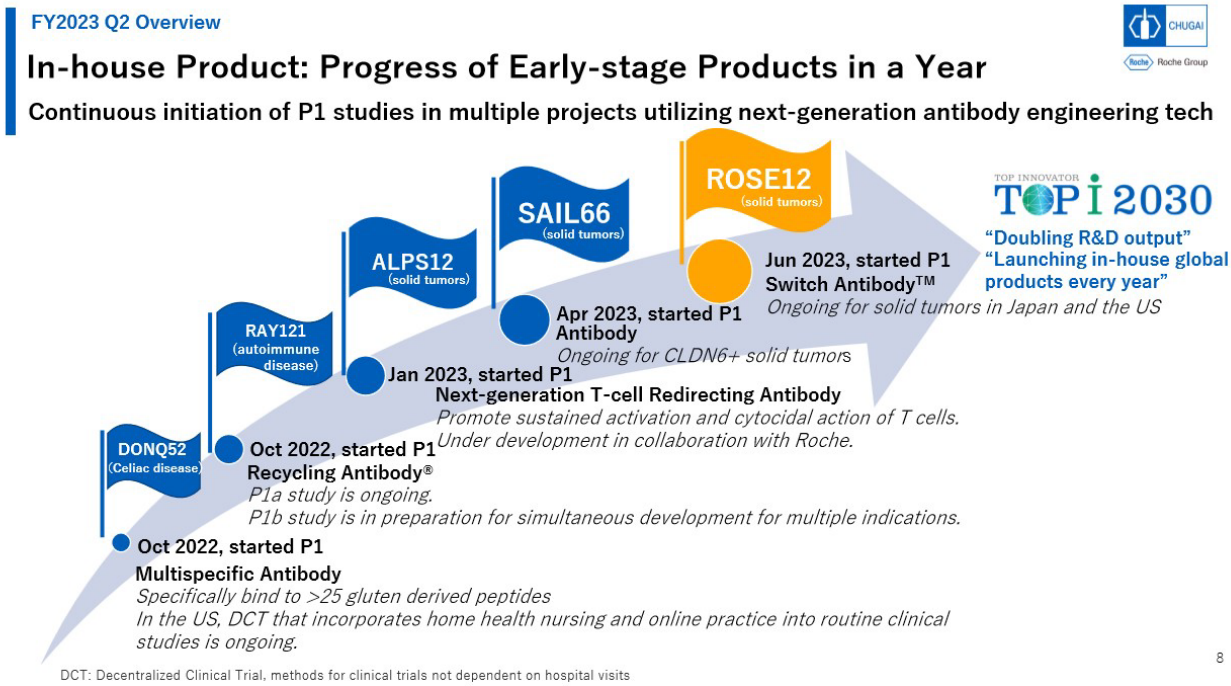
In the middle, in terms of regulatory filing, applications for approval were filed for crovalimab in Japan, the US and Europe in June. In addition, an application was filed in Q2 by Maruho, a licensee in Japan, for additional indications of Mitchga for the indications of prurigo nodularis and atopic dermatitis in children.

Approvals and additional indications include FoundationOne Liquid CDx, cancer genome profile with companion diagnostic capabilities for the MET inhibitor capmatinib. We are also aiming for approval of RG6264, a subcutaneous injection formulation of Herceptin and Perjeta, by the end of the year.

This is a list of major conference presentations.

Global Phase III studies results for crovalimab and two Phase II studies for orforglipron, which is being developed globally by Eli Lilly and Company, were presented. Global Phase III studies on this are currently underway.

Although not mentioned here, Mr. Yamaguchi will later present the development status of our mid-size molecule LUNA18.



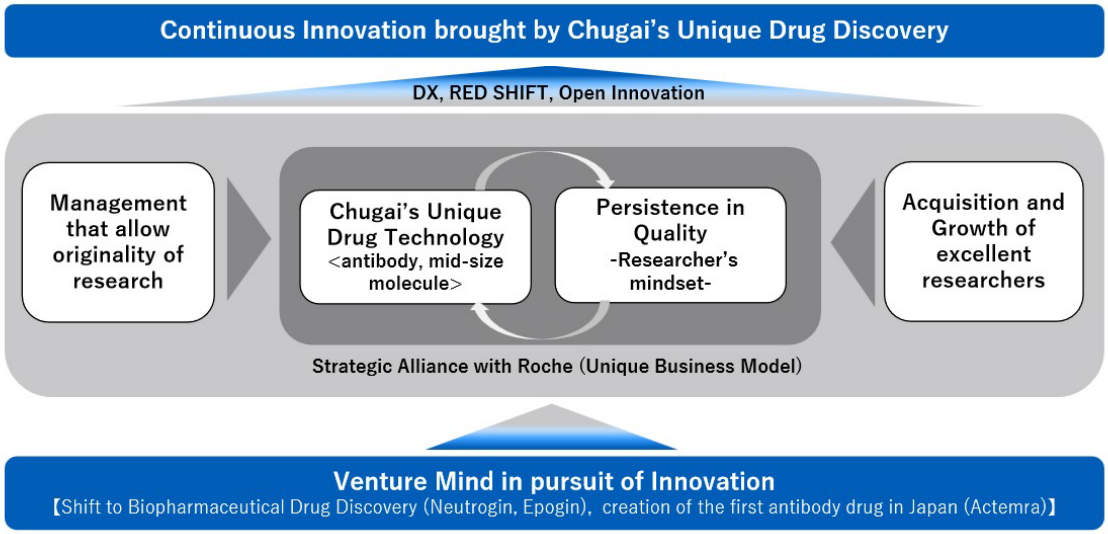
This slide shows our in-house projects for which clinical trials have started in the last year.

A total of five new antibody projects using next-generation antibody engineering technologies have entered clinical trials. In June, ROSE12, our second Switch Antibody, entered Phase I trials in Japan and the US for solid tumors. Mr. Yamaguchi will explain the details later.

Through the continuous creation of innovative in-house projects, we will strive to double our R&D output and achieve the goal of launching in-house global products every year as stated in "TOP I 2030."

FY2023 Q2 Overview

Innovation Development Model in Chugai



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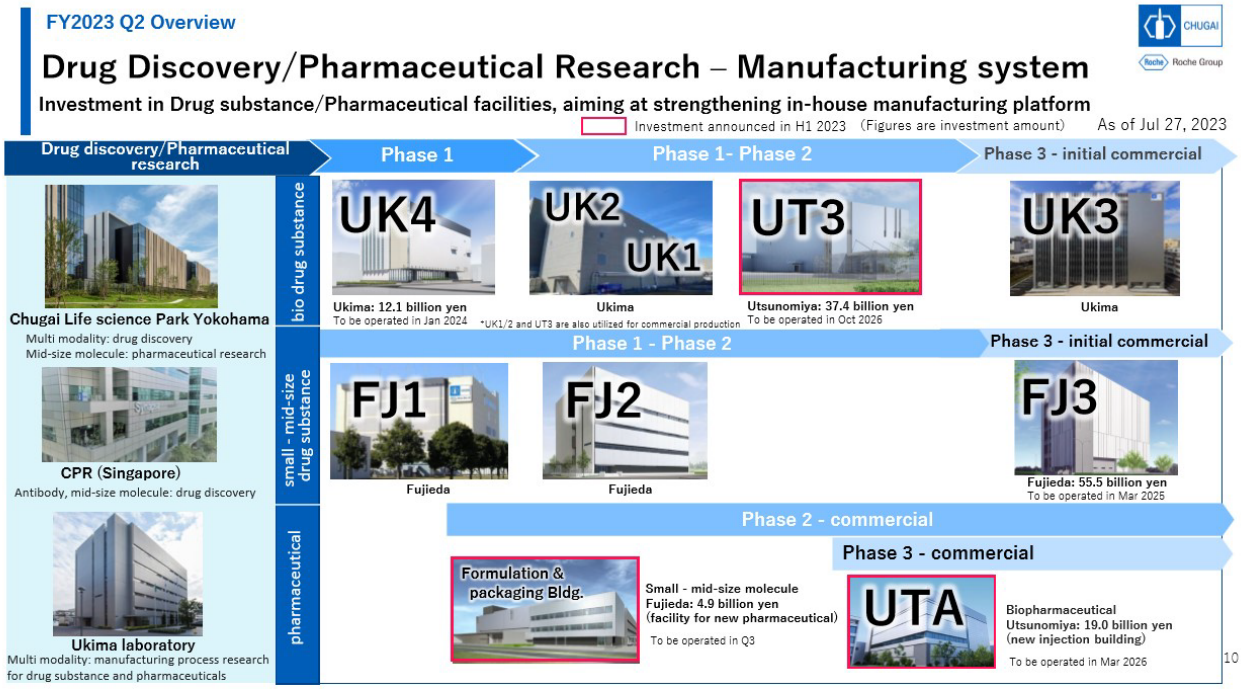
We are often asked how we are able to create these innovative in-house projects continuously. This slide sums up our answer to that question, presenting our strengths and highlighting Chugai's unique innovation development model.

We were one of the first in the industry to take on the challenge of drug discovery using biotechnology. This venture mindset led to the later creation of Actemra, as well as the establishment of antibody engineering technology and our expansion into the field of mid-size molecule technology.

Through our strategic alliance with Roche, a cycle was created in which human resources grew, drug discovery capabilities were strengthened, and even more talented people were attracted by benchmarking with world-class companies such as Roche and Genentech.

In addition, based on a stable revenue base through the domestic development and sales of Roche products, management has allowed and supported researchers' free conception of research activities. This has led to the development of a researcher's mindset focused on quality and the establishment of Chugai's unique drug discovery technologies. These interrelate to create drug discovery innovations that only Chugai can deliver.



In order to deliver breakthrough new drugs created in this way to patients as quickly as possible, we are aggressively investing in production facilities to strengthen our own supply base.

This slide shows our facility system from drug discovery/formulation research to production.

From left to right**:** drug discovery/pharmaceutical research facility, then Phase I through Phase III, and the initial commercial API production facility.

The lower section summarizes investments in major formulation facilities. The red boxes indicate investments announced in H1. For biopharmaceuticals, we decided to invest over 50 billion yen in total in the first half of this year.

FY2023 Q2 Overview

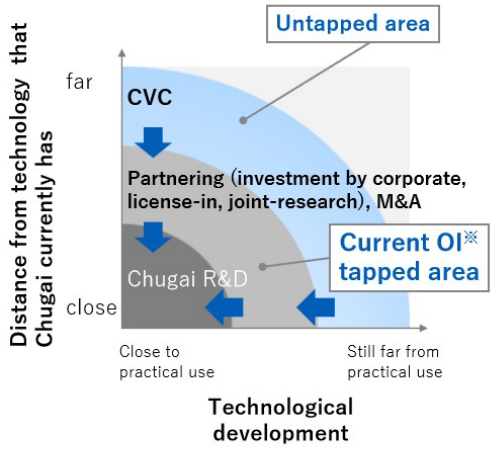
Establishment of Corporate Venture Capital（CVC）

Overview

- Name: Chugai Venture Fund, LLC
- Aiming at combining Chugai's strengths with external technologies
- Investment: up to 200 million USD
- Location: in the Boston area, MA, U.S.A.
- Investment area: primarily in the U.S., Europe, and Japan

Scope

1 Target	Novel therapeutic target, and technologies related to deep cultivation of disease biology that identifies the target, and to analyze large-scale data, etc.
2 Tech-nology	Technologies that can ensure and/or enhance Chugai's core technologies Novel technologies that are new to Chugai and complementary to Roche
3 Digital	Digital and AI technology that can assist drug discovery and translational research



※OI: Open Innovation

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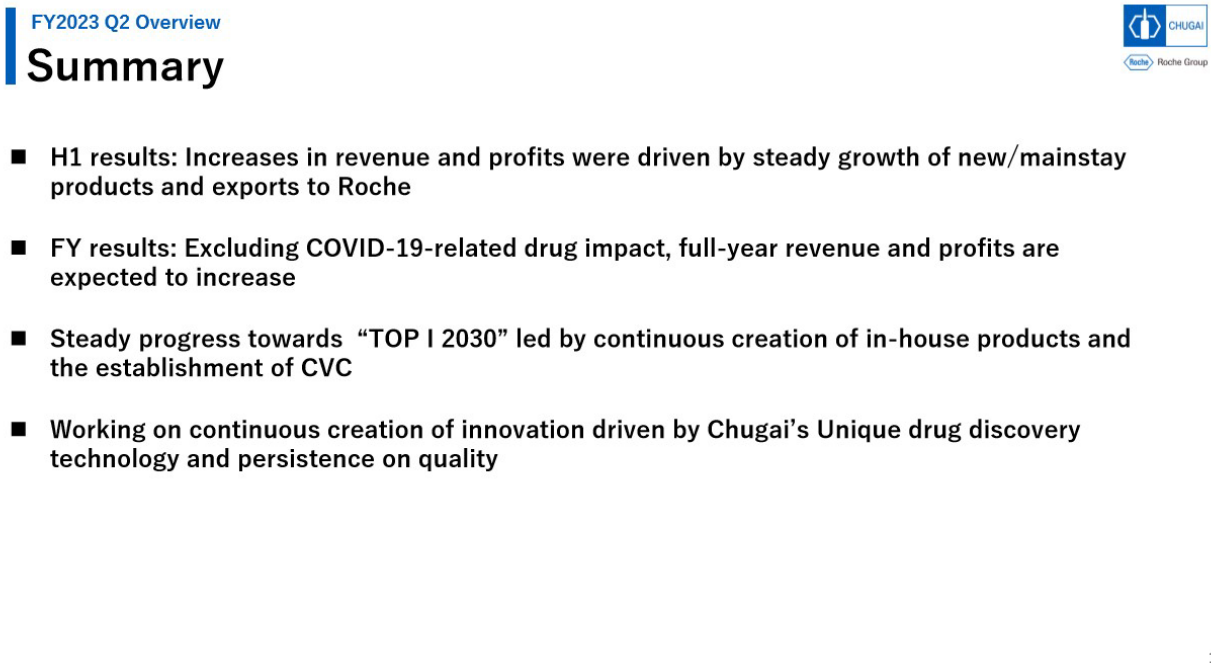
I would like to continue with an overview of our recent decision to establish corporate venture capital in order to further accelerate innovation.

We are establishing a corporate venture capital, or CVC, in the Boston area for the purpose of investing in drug discovery start-ups and other companies to accelerate innovation opportunities centered on innovative new drugs.

Beyond our own R&D and existing partnering framework, we aim to further promote open innovation by strengthening access to talented entrepreneurs and high-potential technologies in the US, Europe, and Japan.



Finally, a summary.

We have seen increases in both revenue and profits in H1 and excluding the impact of COVID-19 related drugs, we expect this trend to continue in the full year results, as forecast.

Progress toward "TOP I 2030" is on track, and we will continue our efforts to generate continuous innovation.

That is all from me.

Miyata: Thank you very much.

Next, Mr. Itagaki will provide an overview of the consolidated financial results for Q2 FY2023. Thank you.

FY2023 Q2 Consolidated Financial Overview (Core)

P/L Jan – Jun (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenue	**579.7**			**579.7**
Sales	523.0			523.0
Other revenue	56.6			56.6
Cost of sales	-243.0	+0.6	+0.1	-242.3
Research and development	-87.4	+5.1	+5.7	-76.5
Selling, general and administration	-54.3		+9.3	-45.0
Other operating income (expense)	16.0		+0.2	16.2
Operating profit	**210.9**	**+5.8**	**+15.3**	**232.0**
Financial account balance	2.7			2.7
Income taxes	-57.0	-1.8	-4.6	-63.3
Net income	**156.7**	**+4.0**	**+10.7**	**171.4**
EPS (JPY)	**95.23**			**104.19**

Non-core items (Billions of JPY)

Intangible assets

Amortization	+0.9
Impairment	+4.9

Others

Restructuring expenses, etc.	+4.9
Early retirement incentive program	+10.4

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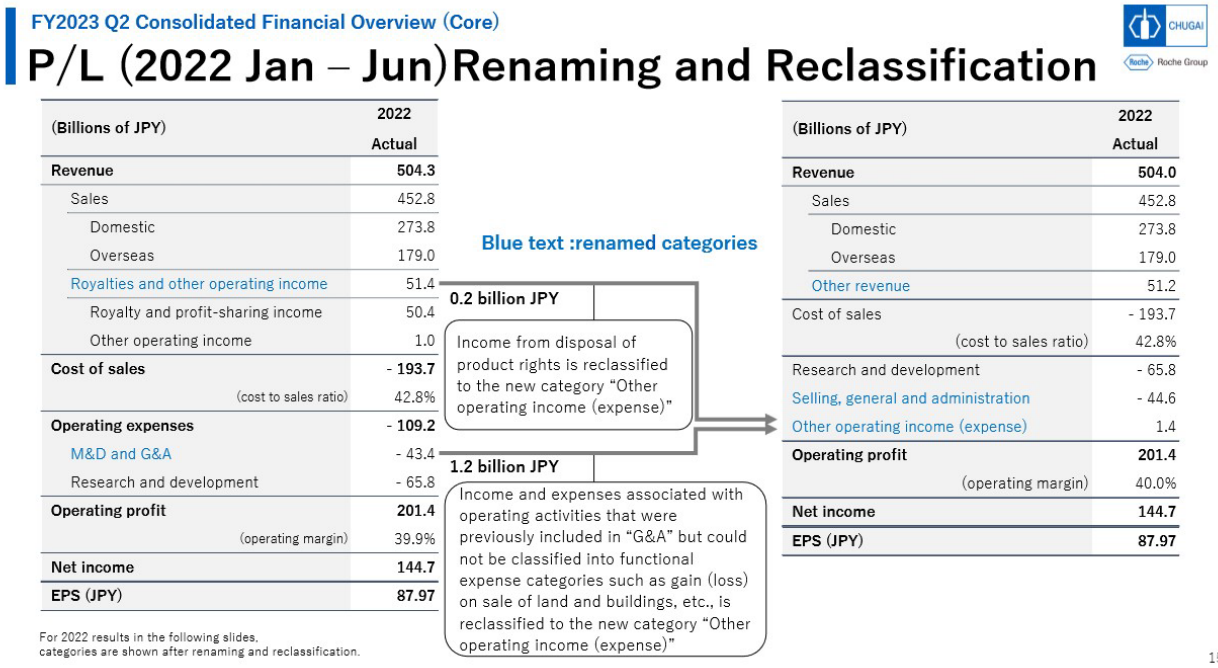
Itagaki: I would like to provide some detail about the financial figures.

Page 14 shows core results. First, the four items on the right, which we call non-core transactions, are added to or subtracted from the full IFRS results to calculate the core results.

For the three items other than the early retirement incentive program, we have updated the actual amounts from Q1 and there are no major events that require special explanation.

The amount of JPY10.4 billion for early retirement incentive program includes additional retirement benefits for the 374 employees who chose this preferential treatment as of the end of June, as well as support costs for those who wish to reenter the workforce.

With these adjustments, JPY21.1 billion was added back to the operating profit level, resulting in JPY232 billion on a core basis. Subsequent slides will be presented in terms of core results.



This page shows the changes and reclassifications made to the P&L from this year. For comparison purposes, we can see what happens when the changes are applied to last year's results.

Revenue is shown as JPY300 million less, but operating profit and net income remain the same. The subsequent slides will also be explained using the previous year's core results after the reclassification here.

FY2023 Q2 Consolidated Financial Overview (Core)

P/L Jan – Jun (Year on Year)

(Billions of JPY)	2022	2023	Growth	
Revenue	**504.0**	**579.7**	**+ 75.7**	**+ 15.0%**
Sales	452.8	523.0	+ 70.2	+ 15.5%
Domestic	273.8	313.6	+ 39.8	+ 14.5%
Overseas	179.0	209.4	+ 30.4	+ 17.0%
Other revenue	51.2	56.6	+ 5.4	+ 10.5%
Cost of sales	-193.7	-242.3	- 48.6	+ 25.1%
(cost to sales ratio)	42.8%	46.3%	+3.5%pts	-
Research and development	-65.8	-76.5	- 10.7	+ 16.3%
Selling, general and administration	-44.6	-45.0	- 0.4	+ 0.9%
Other operating income (expense)	1.4	16.2	+ 14.8	12 times
Operating profit	**201.4**	**232.0**	**+ 30.6**	**+ 15.2%**
(operating margin)	40.0%	40.0%	-	-
Financial account balance	-0.0	2.7	+ 2.7	-
Income taxes	-56.7	-63.3	- 6.6	+ 11.6%
Net income	**144.7**	**171.4**	**+ 26.7**	**+ 18.5%**
EPS (JPY)	**87.97**	**104.19**	**+16.22**	**+ 18.4%**

Domestic sales
Increase due to growth of new and mainstay products

Overseas sales
Increase in sales of Alecensa and Hemlibra

Other revenue
Increase mainly in milestone incomes

Cost of sales
Cost to sales ratio higher due to impacts including increasing foreign exchange rate

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

Selling, general and administration expenses
Same level as the same period of the previous year

Other operating income (expense)
Increase in income from disposal of product rights and gain on sales of property, plant and equipment, etc.

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Now, let us turn to page 16. This chart compares P&L results for H1 of the fiscal year with the previous year.

First, revenue was JPY579.7 billion, an increase of 15%.

Domestic sales grew 14.5% due to strong sales of new and mainstay products, including Ronapreve, and international sales grew 17% due to increases in sales of Alecensa and Hemlibra.

Other revenue grew by 10.5%, mainly due to an increase in milestone income.

The cost to sales ratio increased by 3.5 percentage points, mainly due to the effect of foreign exchange rates. The figure was 46.3%.

We saw a 16.3% increase in R&D expenses due to investments in drug discovery and early development, including the full-scale start of operations at Chugai Life Science Park Yokohama, as well as the progress of development projects.

On the other hand, SG&A expenses increased only slightly by 0.9%.

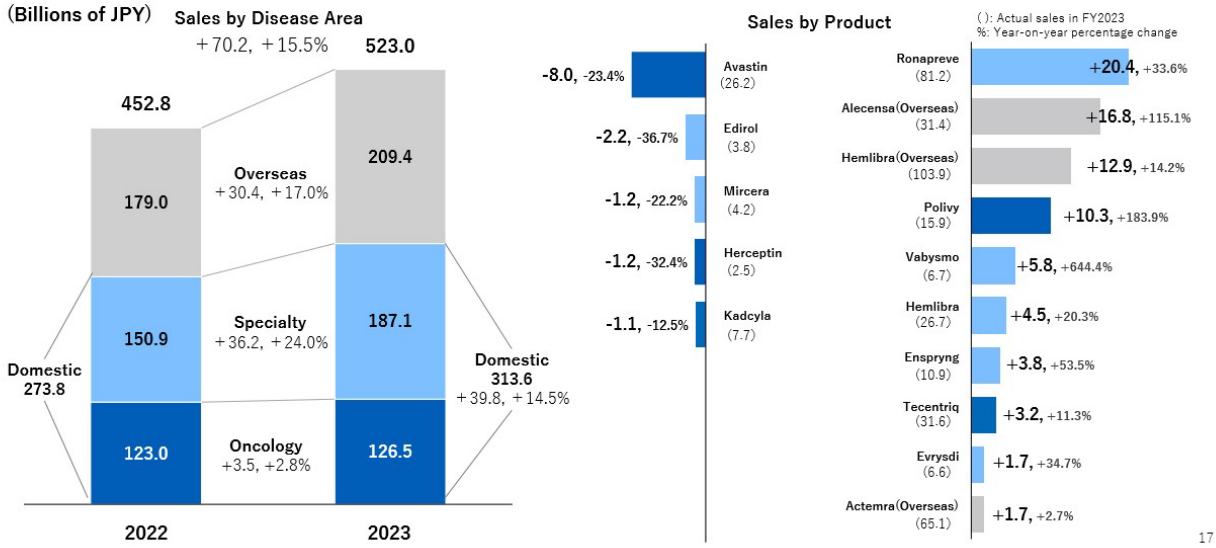
Other operating income totaled JPY16.2 billion. This included proceeds from the product transfer of Bonviva and the sale of tangible fixed assets, mainly land.

As a result, operating profit was JPY232 billion, an increase of 15.2%. The operating margin was exactly 40%.

In addition, there was a financial income of JPY2.7 billion due to gains on foreign exchange derivatives, resulting in a net income of JPY171.4 billion. This represents an increase of 18.5%. This is the best H1 performance ever for revenue, operating profit, and net income.

FY2023 Q2 Consolidated Financial Overview (Core)

Sales Jan – Jun (Year on Year)

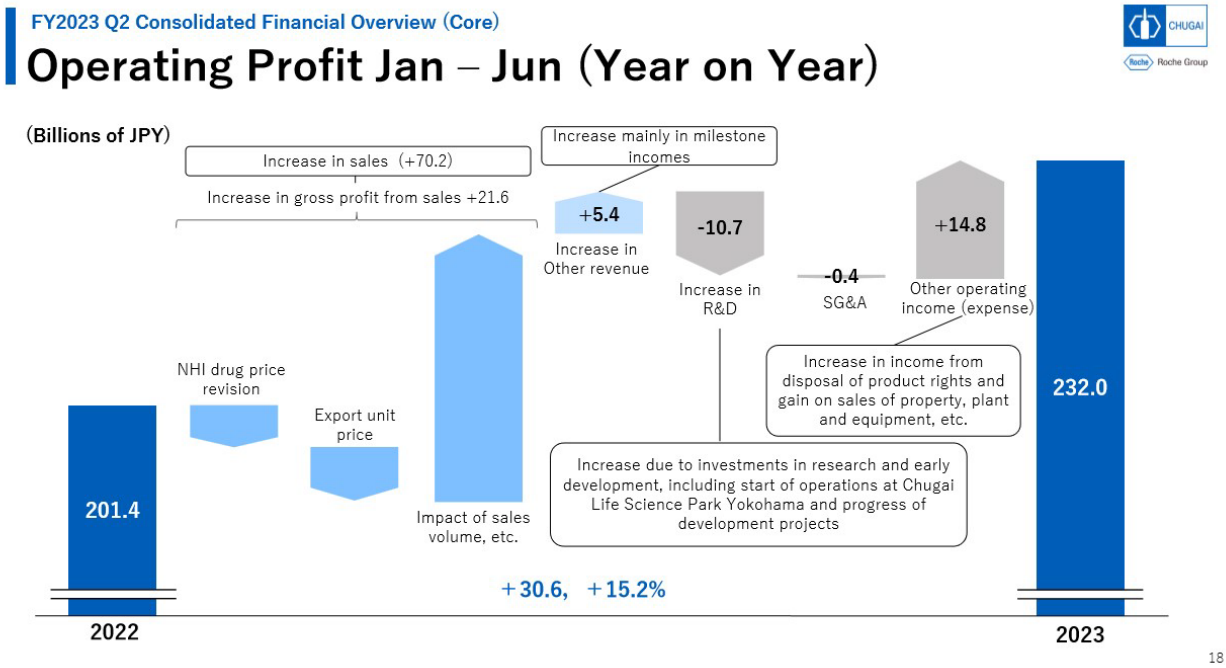


The next page, page 17, shows the breakdown of changes in sales.

The dark blue block on the lower left, the domestic oncology area, showed a 2.8% increase in sales. As you can see in the dark blue area of individual products on the right, sales of Avastin, Herceptin, and Kadcyla decreased due to price revision, biosimilars, and competitors' products. In the case of Polivy and Tecentriq, these effects were absorbed, and positive growth was achieved.

Next is the light blue block, the specialty area, which shows a 24% increase in sales. Excluding the increase in sales of Ronapreve, sales in the specialty area increased by JPY15.8 billion, or 17.5%. In terms of individual products, sales increased for Vabysmo, Hemlibra, Enspryng, and Evrysdi.

The gray block, the overseas area, also continued to perform well with a 17% increase in sales. Sales overseas of Alecensa, Hemlibra, and Actemra are all growing.



Next, page 18. The second to fourth bars on the left show the breakdown of the increase in operating profit.

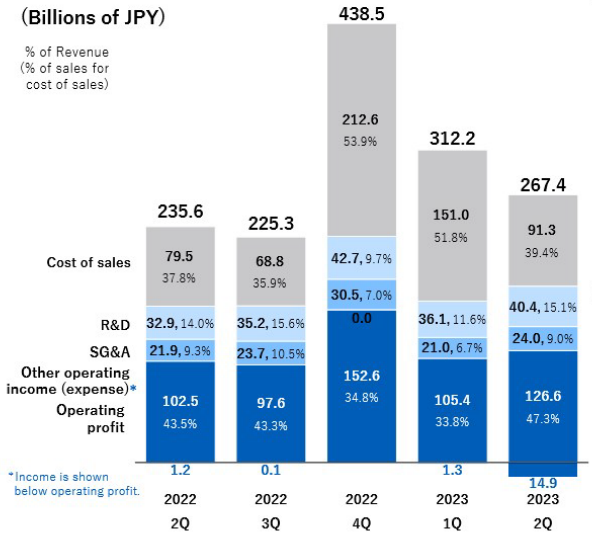
Although there is a negative impact from price revision and a decline in unit prices for exports, this was absorbed by the increase in volume and the effect of the yen's depreciation.

The increase in other sales revenue of JPY5.4 billion includes a negative JPY9.5 billion impact from royalties related to the initial shipment of Hemlibra, which expired last year. This JPY14.8 billion increase includes an JPY8.4 billion increase in royalties and profit sharing, and a JPY6.5 billion increase in milestone income.

Research and development expenses, SG&A expenses, and other operating income are as explained earlier.

FY2023 Q2 Consolidated Financial Overview (Core)

Structure of Costs and Profit by Quarter



Year on Year (vs. 2022 Q2)

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

R&D: increase due to investments in research and early development, including start of operations at Chugai Life Science Park Yokohama and progress of development projects

SG&A: increase due to various sales activities

Other operating income (expense): increase in income from disposal of product rights

Operating profit: +24.1 billion JPY, +23.5%

Quarter on Quarter (vs. 2023 Q1)

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

R&D: increase due to progress of development projects, etc.

SG&A: increase due to various sales activities

Other operating income (expense): increase in income from disposal of product rights

Operating profit: +21.2 billion JPY, +20.1%

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Beginning on page 19, there are three more slides showing quarterly trends.

The transition in this quarter will be bumpy, depending on whether or not there were government deliveries of Ronapreve. Ronapreve sales were recorded at JPY142.8 billion in Q4 last year and JPY81.2 billion in Q1 of this year. Since we have limited time today, I am going to skip ahead to slide 22.

FY2023 Q2 Consolidated Financial Overview (Core)

P/L Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual 2023 Jan - Jun	Forecast 2023 Jan - Dec	Progress	2022 Progress*
Revenue	**579.7**	**1,070.0**	**54.2%**	**43.2%**
Sales	523.0	920.0	56.8%	43.6%
Domestic	313.6	541.7	57.9%	41.8%
Overseas	209.4	378.3	55.4%	46.5%
Other revenue	56.6	150.0	37.7%	39.8%
Cost of sales	- 242.3	- 405.0	59.8%	40.8%
(cost to sales ratio)	46.3%	44.0%	-	-
Research and development	- 76.5	- 165.0	46.4%	45.8%
Selling, general and administration	- 45.0	- 100.0	45.0%	45.1%
Other operating income (expense)	16.2	15.0	108.0%	100.0%
Operating profit	**232.0**	**415.0**	**55.9%**	**44.6%**
(operating margin)	40.0%	38.8%	-	-
Net income	**171.4**	**306.0**	**56.0%**	**45.5%**
EPS (JPY)	**104.19**	**186.00**	**56.0%**	**45.6%**

Domestic sales
Overall progress mostly in line with forecast
(2023 progress excluding Ronapreve: 50.5%
2022 progress excluding Ronapreve: 47.2%)

Overseas sales
Sales of Hemlibra to Roche exceeding forecast

Other revenue
Progress mostly in line with forecast

Cost of sales
Cost to sales ratio mostly in line with forecast

Research and development expenses
Progress mostly in line with forecast

Selling, general and administration expenses
Progress mostly in line with forecast

Other operating income (expense)
Progress mostly in line with forecast

* Jan - Jun progress versus Jan – Dec actual

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This slide shows progress against the full-year forecast.

Looking from the top, the progress rate of revenue is 54.2%, about 11 percentage points better than last year. The rate of progress toward full-year forecasts here is also affected by Ronapreve.

For example, if you look at sales in the domestic market, the figure is 57.9% this year and 41.8% last year, which means that the progress is 16.1 percentage points better than last year. How about if we exclude Ronapreve? Excluding Ronapreve, this year's progress to the full-year forecast is 50.5%, a difference of about 3.3 percentage points from last year.

In overseas sales, progress to the full-year forecast is 55.4% in H1 of this fiscal year, about 9 percentage points above the same period last year. Since overseas sales increase or decrease depending on the timing of shipments, it is difficult to comment on performance based on this progress rate alone. However, it can be said that our exports are doing well, driven by stronger-than-expected sales of Roche outside Japan.

Cost progress was generally in line with our expectations in terms of raw material costs, R&D, and SG&A expenses.

Other operating income was concentrated in H1 and have already achieved the full-year forecast. This is also in line with expectations.

As a result, the timing of the Ronapreve delivery, which was in Q1 of this year, the strong export of Hemlibra, and other operating income that have already exceeded the full year, have resulted in good progress in terms of profit, operating profit and net income. In any case, I think we can say that this was a smooth turnaround toward achieving the full-year forecast.

FY2023 Q2 Consolidated Financial Overview (Core)

Sales Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual 2023 Jan - Jun	Forecast 2023 Jan - Dec	Forecast Progress	2022 Progress *
Sales	**523.0**	**920.0**	56.8%	43.6%
Domestic	**313.6**	**541.7**	57.9%	41.8%
Oncology	**126.5**	**253.3**	49.9%	48.0%
Tecentriq	31.6	67.7	46.7%	46.6%
Avastin	26.2	48.1	54.5%	50.7%
Polivy	15.9	31.6	50.3%	36.1%
Perjeta	16.1	31.0	51.9%	48.3%
Alecensa	14.5	28.2	51.4%	47.4%
Kadcyla	7.7	14.1	54.6%	48.6%
Herceptin	2.5	4.9	51.0%	52.1%
Gazyva	1.7	4.5	37.8%	52.5%
Rituxan	1.9	3.7	51.4%	50.0%
Foundation Medicine	3.7	8.3	44.6%	47.9%
Other	4.6	11.2	41.1%	50.5%

(Billions of JPY)	Actual 2023 Jan - Jun	Forecast 2023 Jan - Dec	Forecast Progress	2022 Progress *
Specialty	**187.1**	**288.4**	64.9%	37.9%
Ronapreve	81.2	81.2	100.0%	29.8%
Hemlibra	26.7	53.7	49.7%	45.0%
Actemra	21.1	44.3	47.6%	48.1%
Enspryng	10.9	21.6	50.5%	42.5%
Vabysmo	6.7	17.4	38.5%	14.1%
Evrysdi	6.6	14.1	46.8%	42.6%
Mircera	4.2	7.6	55.3%	50.0%
CellCept	3.5	6.7	52.2%	48.1%
Edirol	3.8	5.2	73.1%	53.6%
Other	22.4	36.7	61.0%	50.3%
Overseas	**209.4**	**378.3**	55.4%	46.5%
Hemlibra	103.9	185.2	56.1%	47.0%
Actemra	65.1	121.4	53.6%	48.6%
Alecensa	31.4	50.4	62.3%	36.0%
Enspryng	1.1	3.8	28.9%	60.7%
Neutrogin	3.9	7.3	53.4%	52.9%
Edirol	0.0	0.5	0.0%	0.0%
Other	3.9	9.7	40.2%	44.6%

* Jan - Jun progress versus Jan – Dec actual

23

Now we would like to look at the progress of sales of individual products. Page 23.

First of all, progress is being made as expected in each of the areas of oncology, specialty, and overseas.

Evaluating the progress of individual products in the oncology area on the left, Polivy, Perjeta, and Alecensa are progressing well.

In the specialty area, Enspryng and Edirol are doing well. The progress of Vabysmo is a little slow. This is partly because the full-year forecast was somewhat bullish.

Overseas, exports of Hemlibra are strong.

Overall, although progress is less strong for some individual products, we will continue to make steady progress in H2 toward achieving our full-year forecast.

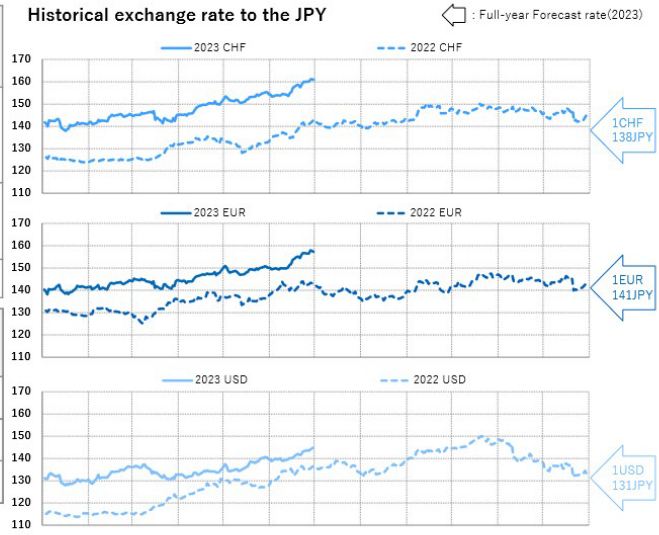
FY2023 Q2 Consolidated Financial Overview (Core)

Impact from Foreign Exchange Jan – Jun

(Billions of JPY)	vs. 2022 Actual rate	vs. 2023 Forecast rate*1
Revenue	+30.8	+2.4
Sales	+25.8	+2.4
Other revenue	+5.0	+0.0
Cost of sales	-23.5	-0.1
Other than above*2	-1.8	-0.4
Operating profit	+5.4	+1.9

Exchange rate (JPY)	2022 Jan - Jun Actual rate*3	2023 Jan - Jun Actual rate*3
1CHF	122.40	138.30
1EUR	134.47	141.96
1USD	112.73	133.45

*1 Foreign Exchange effect from Half-year Forecast rate(2023)
*2 Total of R&D, SG&A and other operating income (expense)
*3 Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit



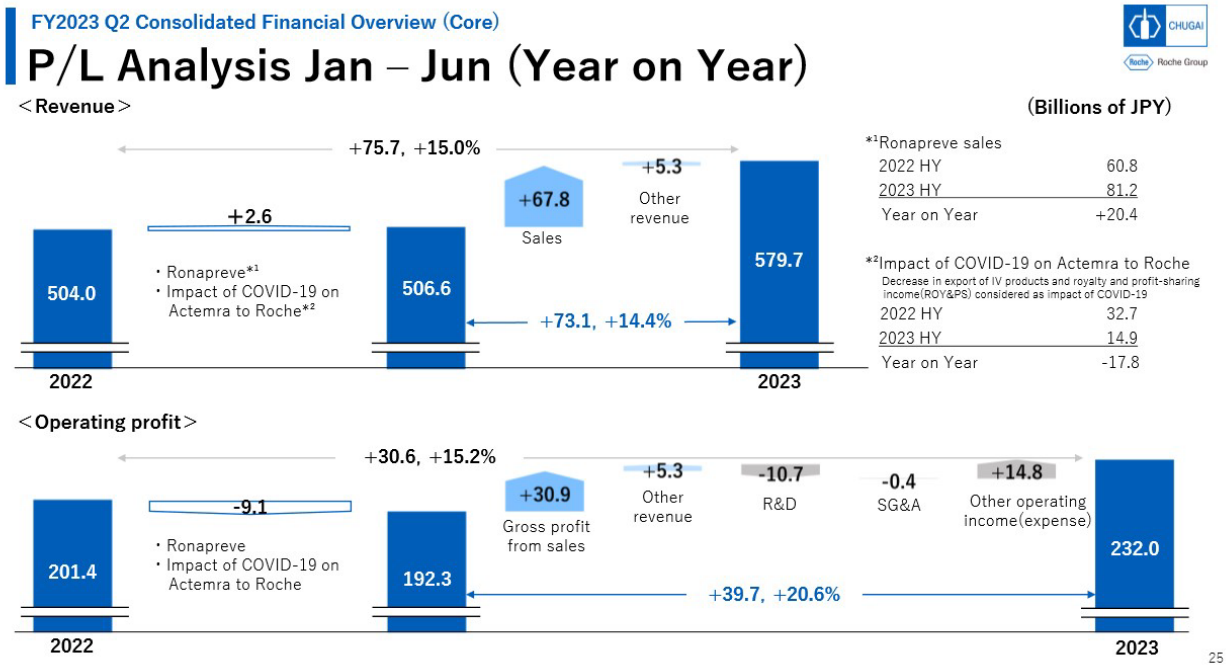
24

Page 24 shows foreign exchange impact.

The bar graph on the right shows the trend of the market exchange rate. The yen has been trending downward since the beginning of last year. Having said that, the Company hedged 80% of its foreign currency transactions in the prior year. That hedge is being used this year.

As you can see in the table on the lower left, the yen has weakened considerably compared to the same period last year, for example, by about 18% against the dollar.

Therefore, as shown in the table above, compared to last year, the depreciation of the yen was favorable for earnings and unfavorable for costs. Of the two, the earnings element is larger, resulting in a net positive contribution in operating profit of JPY5.4 billion. In addition, we were able to successfully use the hedging against the planned exchange rate for H1 to cover the yen's depreciation, resulting in a positive effect of JPY1.9 billion in operating profit for H1.



Next, page 25. This is an analysis of profit and loss, but first I would like you to look at asterisks one and two in the upper right-hand column.

This fiscal year, we delivered Ronapreve to the government JPY81.2 billion. This had the effect of increasing revenues by JPY20.4 billion YoY.

Next, the second asterisk is the impact of the export of Actemra IV formulation due changing COVID-19 demand. This figure was negative JPY17.8 billion.

Netting the above, the effect on revenue of COVID-19 therapies is positive JPY2.6 billion. Excluding this figure, we observe an increase of revenue of 14.4%.

Here is the upper graph, and the lower one is in the same form. If we analyze it in terms of operating profit, the profit from COVID-19 therapeutics was pushed down by JPY9.1 billion in H1. In terms of revenue, it was positive JPY2.6 billion, but in terms of profit, there was a negative effect of JPY9.1 billion. The cost ratio of the portion of Ronapreve's purchases delivered to the government this year was considerably higher than last year due to the yen's depreciation, resulting in a rather negative gross profit margin.

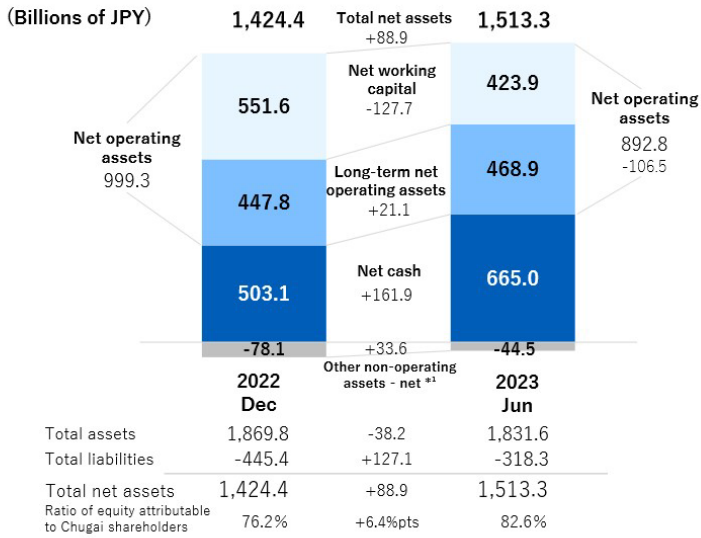
In any case, excluding the negative JPY9.1 billion, operating profit in the core business increased by 20.6% as shown in the graph below.

We are pleased to confirm here that sales and profits from the foundation business remain strong.

This concludes my presentation of P&L and sales.

FY2023 Q2 Consolidated Financial Overview (Core)

Financial Position (vs. 2022 Year End)



	2022 Dec		2023 Jun
Total assets	1,869.8	-38.2	1,831.6
Total liabilities	-445.4	+127.1	-318.3
Total net assets	1,424.4	+88.9	1,513.3
Ratio of equity attributable to Chugai shareholders	76.2%	+6.4%pts	82.6%

Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

Increase in long-term net operating assets

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

Increase in net cash

(See next slide)

Increase in other non-operating assets – net

Increase mainly due to a decrease in accrued corporate tax

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

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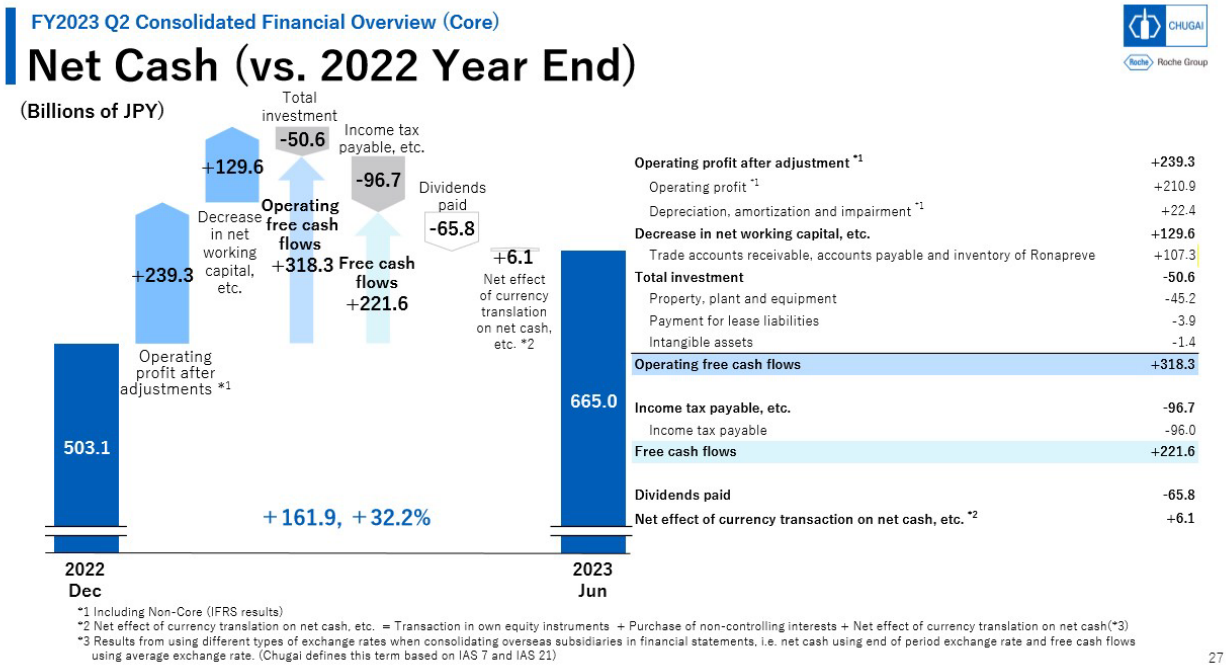
There are three pages left. Page 26 shows the balance sheet situation.

Total assets, the second line from the bottom on the left, increased by JPY88.9 billion from the end of last year to JPY1.5133 trillion. The shareholder equity ratio under this total is 82.6%, which shows a more robust financial position.

Net cash, shown in the middle of the figure, increased by JPY161.9 billion to a balance of JPY665 billion at the end of June.

The next page provides a breakdown of the change in that net cash.



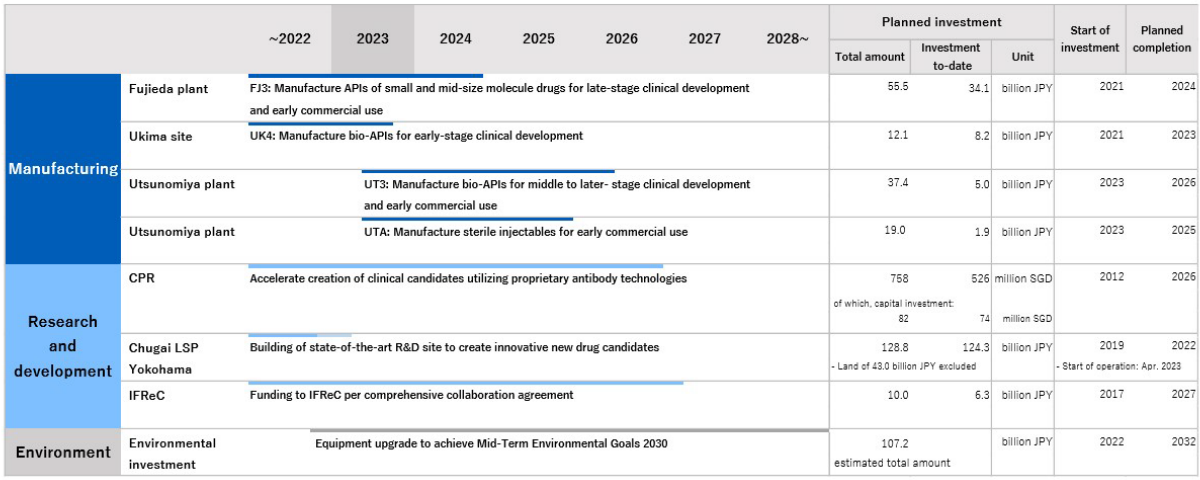
In the second figure on the left, cash flow from operating activities, the first and largest component is adjusted operating income, which is a plus of JPY239.3 billion if we add back operating profit without cash outflows such as depreciation and amortization. A decrease in net working capital of JPY129.6 billion resulted from collection this year of Ronapreve accounts receivable delivered at the end of last year and Q1 of this year, which were cashed in during H1. This means that net working capital has reduced significantly.

After subtracting JPY50.6 billion in capital investment payments, operating free cash flow was positive at JPY318.3 billion.

In addition, we have also cashed out last year's income taxes payable (JPY96.7 billion) and year-end dividends (JPY65.8 billion), resulting in a net cash increase of JPY161.9 billion in H1 and a net cash balance of JPY665 billion at the end of June.

FY2023 Q2 Consolidated Financial Overview (Core)

Current Status / Plan for Major Investments



		~2022	2023	2024	2025	2026	2027	2028~	Planned investment: Total amount	Planned investment: Investment to-date	Planned investment: Unit	Start of investment	Planned completion
Manufacturing	Fujieda plant	FJ3: Manufacture APIs of small and mid-size molecule drugs for late-stage clinical development and early commercial use							55.5	34.1	billion JPY	2021	2024
	Ukima site	UK4: Manufacture bio-APIs for early-stage clinical development							12.1	8.2	billion JPY	2021	2023
	Utsunomiya plant		UT3: Manufacture bio-APIs for middle to later- stage clinical development and early commercial use						37.4	5.0	billion JPY	2023	2026
	Utsunomiya plant		UTA: Manufacture sterile injectables for early commercial use						19.0	1.9	billion JPY	2023	2025
Research and development	CPR	Accelerate creation of clinical candidates utilizing proprietary antibody technologies							758 of which, capital investment: 82	526 74	million SGD million SGD	2012	2026
	Chugai LSP Yokohama	Building of state-of-the-art R&D site to create innovative new drug candidates							128.8 - Land of 43.0 billion JPY excluded	124.3	billion JPY	2019 - Start of operation: Apr. 2023	2022
	IFReC	Funding to IFReC per comprehensive collaboration agreement							10.0	6.3	billion JPY	2017	2027
Environment	Environmental investment		Equipment upgrade to achieve Mid-Term Environmental Goals 2030						107.2 estimated total amount		billion JPY	2022	2032

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Page 28 shows the status of major investments.

As well as updating the actual amount of investment, we have now added UT3 and UTA at the Utsunomiya Plant. We have already announced this to the press. These two investments will exceed JPY55 billion. The details are as described in the press release, so I will omit an explanation of these here.

That is all from me. Thank you very much.

Miyata: Next, Mr. Yamaguchi will explain the status of our development pipeline. Thank you.

Overview of Development Pipeline

Q2 Topics

As of July 27, 2023

Launched	Hemlibra	Hemophilia A without inhibitors (Taiwan)	July 2023
Approved	FoundationOne Liquid CDx	Capmatinib hydrochloride hydrate: *MET* exon 14 skipping mutation-positive advanced and/or recurrent unresectable NSCLC	May 2023
Filed	crovalimab/RG6107	PNH (Japan, EU, U.S.)	June 2023
	Mitchga®	Prurigo nodularis, pruritus associated with atopic dermatitis (pediatric) (Japan)	Q2 2023*
Pipeline entry	ROSE12	Solid tumors	P1 study (June 2023)
	RG6179 (anti-IL-6 antibody)	UME	P3 study (June 2023)
Medical conference	crovalimab/RG6107	COMMODORE 1/2 studies (PNH): EHA	June 2023
	orforglipron /LY3502970**	Phase 2 study in adults with obesity or overweight: ADA Phase 2 study in adults with type 2 diabetes: ADA	June 2023
	NXT007/RG6512	NXTAGE study (healthy adults, hemophilia A): ISTH	June 2023
Development discontinued	Tecentriq	Early breast cancer (adjuvant) / P3 study (IMpassion030 study)	
Other	Chugai Venture Fund, LLC	Investment activities for drug discovery targets, drug discovery technologies, and digital technologies that lead to the creation of innovative new drugs (location: Boston area)	To be established by the end of 2023

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan) Letters in black : others 30

* Out-licensed to Maruho in Japan ** Out-licensed to Eli Lilly and Company

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

Please see page 30. First, these are the main themes in Q2.

In terms of applications, in Japan Chugai filed for regulatory application for the in-house product crovalimab on June 14, for PNH. Roche subsequently completed its applications in Europe and the U.S. as well.

As mentioned earlier, Maruho, out-licensed in Japan, has submitted an application to expand the indications of nemolizumab to include the treatment of prurigo nodularis and pruritus associated with atopic dermatitis in children.

We have two pipeline entries.

As mentioned earlier, the new in-house project ROSE12 has started Phase I trial for solid tumors. Detailed information on the mode of action will not be disclosed at this time. This is a new Switch Antibody project following STA551. I will explain in more detail a little later.

As for Roche's products, Chugai has joined to a global Phase III trial for RG6179 for the treatment of non-infectious uveitic macular edema. This is a disease with high unmet medical need. We hope that this product will further contribute in the field of ophthalmology that we have made with Vabysmo.

Three in-house projects have been presented at medical conferences.

Crovalimab was presented at the European Hematology Association for the global Phase III trials COMMODORE 1 and COMMODORE 2, on which the application was based.

As for orforglipron, as Dr. Okuda mentioned earlier, Eli Lilly and Company will present the results of Phase II trials for obesity and type 2 diabetes at the American Diabetes Association meeting.

As for NXT007, the healthy adult part of the Phase I trial was presented at ISTH. Patient-part trial is currently ongoing, and development is taking place with the aim of achieving healthy human-level blood coagulation performance in hemophilia.

In terms of development discontinuation, the decision has been made to discontinue investigation of Tecentriq as an early-stage breast cancer adjuvant.

As for other topics, as mentioned earlier, we are currently in the process of preparing for the establishment of a corporate venture capital firm in the Boston area. In particular, we want to accelerate the creation of innovative new drugs. By targeting our investment activities toward drug discovery targets or drug discovery technologies, as well as digital technologies that support drug discovery, we hope to increase access to this information, enter into that community, and then, as a group, we hope to accelerate innovation.

Overview of Development Pipeline

2023: Key R&D Milestones

Underlined and bolded are new progress since April 27, 2023

	Product	Indication/Study name	Progress
Projects to be approved	Actemra	Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)	
	Hemlibra	Moderate hemophilia A (EU)	✓
	crovalimab	PNH (China)	
	RG6264 (PER/HER FDC)	HER 2 positive Breast cancer/Colorectal cancer	
P3/Pivotal readouts	Alecensa	ALINA Study: NSCLC [adjuvant]	
	crovalimab	COMMODORE 1/2 study: PNH	✓
	nemolizumab	ARCADIA 1/2 study: Atopic dermatitis*	✓
	Tecentriq + Avastin	IMbrave050 study: HCC [adjuvant]	✓
	Tecentriq	IMpassion030: eBC [adjuvant]	×
	Tecentriq	IMvoke010 study: HNC [adjuvant]	
	Tecentriq+ tiragolumab	**SKYSCRAPER-01 study: NSCLC [1st line]**	**2023-2024**
	mosunetuzumab+Polivy	SUNMO study**: r/r aNHL	
	delandistrogene moxeparvovec	EMBARK study: Duchenne muscular dystrophy (DMD)	

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

* Out-licensed to Galderma overseas ** Readout expected 2023-2024

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I will move on to the next slide. This is the progress of major R&D items in 2023.

The SKYSCRAPER-01 study, which was being conducted for the first-line treatment of non-small cell lung cancer in combination with Tecentriq and tiragolumab, has been delayed due to a lack of progress in the number of events. The new readout is expected in Q4 of this year or Q1 of next year. The filing schedule has been changed to 2024, one year later than the original schedule.

Overview of Development Pipeline

ROSE12: Solid Tumors

ROSE12 is a Switch Antibody™ project following STA551. P1 study in solid tumors was started.

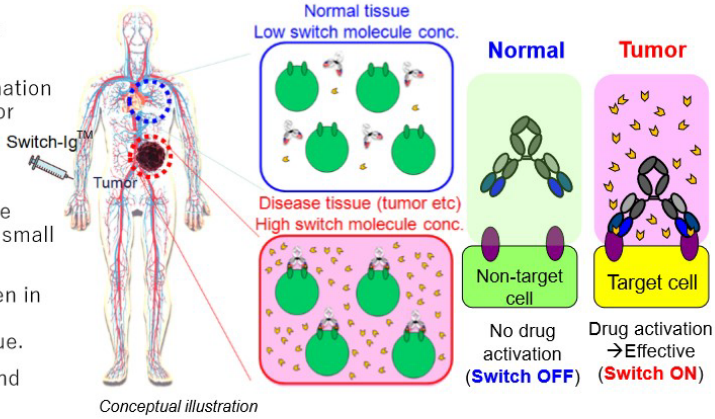
About ROSE12

- ROSE12, like STA551, binds to targets other than tumor antigens and exerts anti-tumor effects.
- P1 study of ROSE 12 monotherapy and in combination with Tecentriq in pateints with locally advanced or metastatic solid tumors was started in June

General characteristic of Switch-Ig™

- Switch Antibody™ binds to the antigen only in the presence of high concentration of tumor specific small molecule metabolite (switch molecule).
- Switch-Ig™ specifically binds to the target antigen in the tumor microenvironment without detectable binding to the antigen in plasma and normal tissue.
- Switch-Ig™ technology enables more effective and safer antibody therapeutics in oncology field.

General image of Switch-Ig™



Conceptual illustration

Source: Slides partly modified from Chugai Information Meeting on Antibody Engineering Technologies(Dec, 2019)

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In the next slide, I will describe our new in-house project, ROSE12.

ROSE12 applied our proprietary Switch-Ig technology. The target is not disclosed, but as with STA551, our first Switch Antibody project, this binds to targets other than tumor antigens.

ROSE12 is activated by a switch molecule, in this case ATP, which is present at high concentrations in tumor tissues. In short, ROSE12 is designed to exhibit antigen binding ability through ATP.

The concentration of ATP is very low in plasma and normal tissues, which means that binding to the antigen is almost nonexistent. This is expected to reduce side effects while permitting an increased dosage. This is expected to allow a strong anti-tumor effect.

Currently, ROSE12 is in Phase I trial for solid tumors in combination with Tecentriq.

Overview of Development Pipeline

Crovalimab, an Expected New Global In-House Product

The results of Global P3 studies were presented at EHA. Crovalimab was filed for the treatment of PNH in Japan, the U.S. and Europe.

■ **Efficacy**

- COMMODORE 2 in complement inhibitor–naïve PNH patients met its co-primary endpoints, demonstrating non-inferiority of crovalimab to eculizumab for hemolysis control and transfusion avoidance

		crovalimab (N=134)	eculizumab (N=69)
Hemolysis Control from Week 5 to Week 25 (central LDH ≤1.5×ULN), mean % [95% CI]		79.3 [72.9, 84.5]	79.0 [69.7, 86.0]
Odds Ratio [95% CI]	Non-inferiority margin at the lower limit of 95% CI: 0.2	1.02 [0.57, 1.82]	
Transfusion Avoidance from baseline to Week 25, n (mean %) [95% CI]		88 (65.7) [56.9, 73.5]	47 (68.1) [55.7, 78.5]
Difference in proportions, % [95% CI]	Non-inferiority margin at the lower limit of 95% CI: 20%	-2.8 [-15.7, 11.1]	

- Crovalimab is non-inferior to eculizumab for the efficacious secondary endpoint of breakthrough hemolysis and hemoglobin stabilization.
- Clinically meaningful improvement in FACIT-Fatigue scores* occurred in both arms, with an improvement to healthy adult level with crovalimab.

*an increase of ≥5 points from baseline

■ **Safety**

- COMMODORE 1 and 2 showed that crovalimab is well tolerated in both C5 inhibitor-experienced and –naïve patients with PNH.

■ **In addition to efficacy and safety, crovalimab is expected to decrease the treatment burden and improve the QOL of patients with PNH, by administering sc injection every four weeks during maintenance dosing and reducing dosing time.**

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We expect that crovalimab will grow significantly as a new in-house global product.

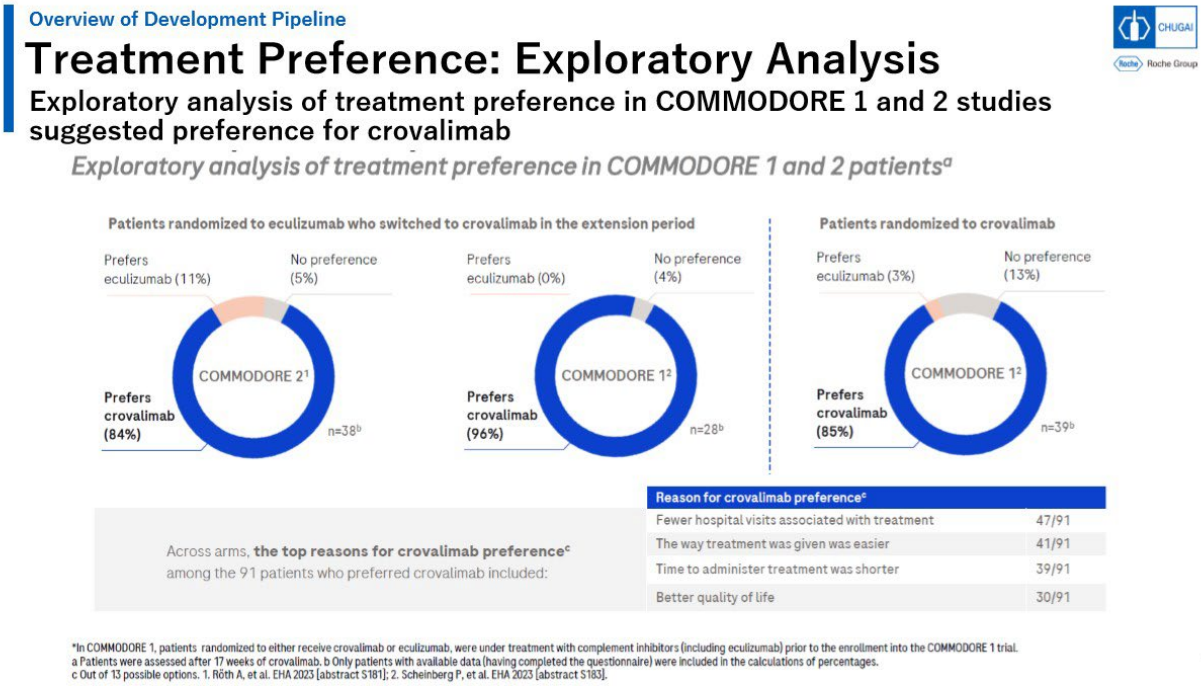
At the European Hematology Association in June, we presented the results of the global Phase III COMMODORE 1/2 studies. In particular, this slide shows the results of COMMODORE 2 study, comparing eculizumab with complement inhibitor untreated PNH patients. Non-inferiority was confirmed in the primary endpoints of hemolysis control and transfusion avoidance.

In addition, non-inferiority to eculizumab was verified in the secondary endpoints of breakthrough hemolysis and hemoglobin stabilization.

The FACIT-Fatigue score, a measure of fatigue, also showed clinically meaningful improvement in both arms, particularly in the crovalimab arm, which improved to the level of healthy adults.

The COMMODORE 1/2 studies have confirmed that the drug is well tolerated.

Last year, Roche filed an application in China based on the COMMODORE 3 trial. Following this, in June, we filed an regulatory application for PNH in Japan, the U.S., and Europe.

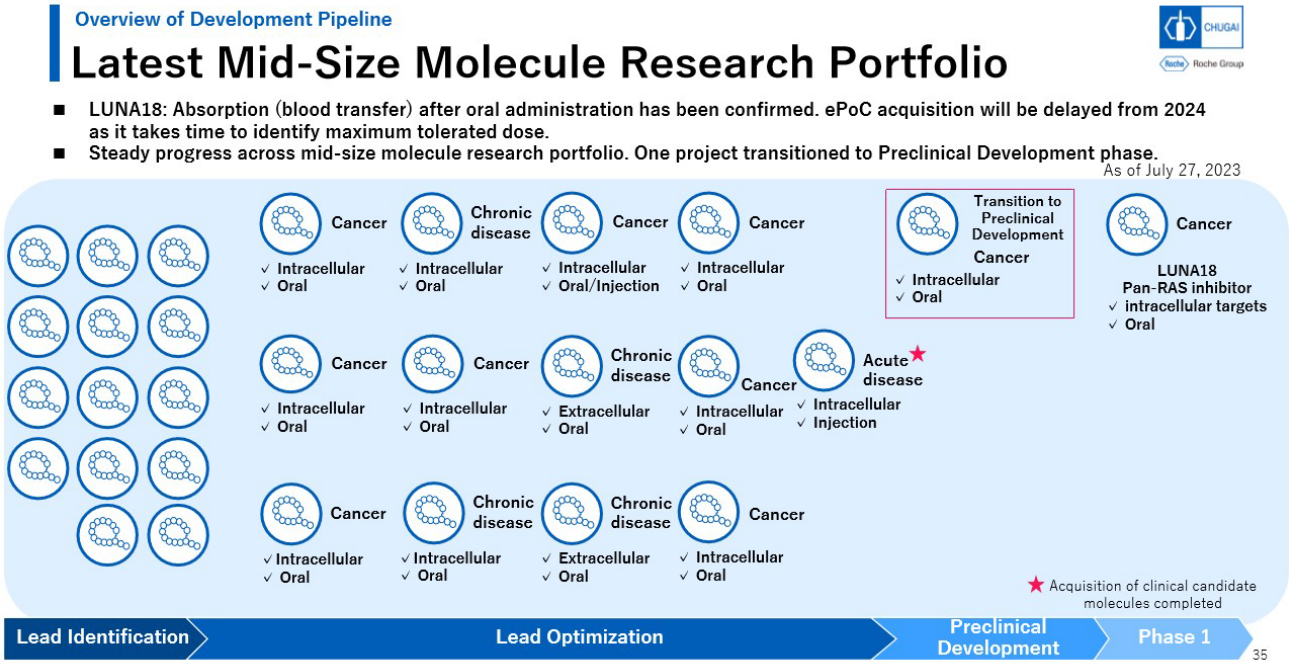


The next slide shows the results of exploratory analysis of treatment preference for crovalimab in the COMMODORE 1/2 studies.

The crovalimab arm, which includes patients who also received eculizumab, were surveyed at 17 weeks of crovalimab administration. As shown in blue, over 80% of the patients indicated that they would prefer crovalimab treatment.

The main reasons for this are listed in the table below. The main reasons are that subcutaneous administration reduces the frequency of hospital visits, and the administration time is significantly shortened to less than one minute.

In addition to efficacy and safety, we are confident that we can provide new value by reducing the burden of treatment on patients and improving their quality of life through subcutaneous administration every four weeks for maintenance administration, shortening the administration time, and reducing the time required for hospital visits.



The next slide summarizes our current mid-size molecule research portfolio.

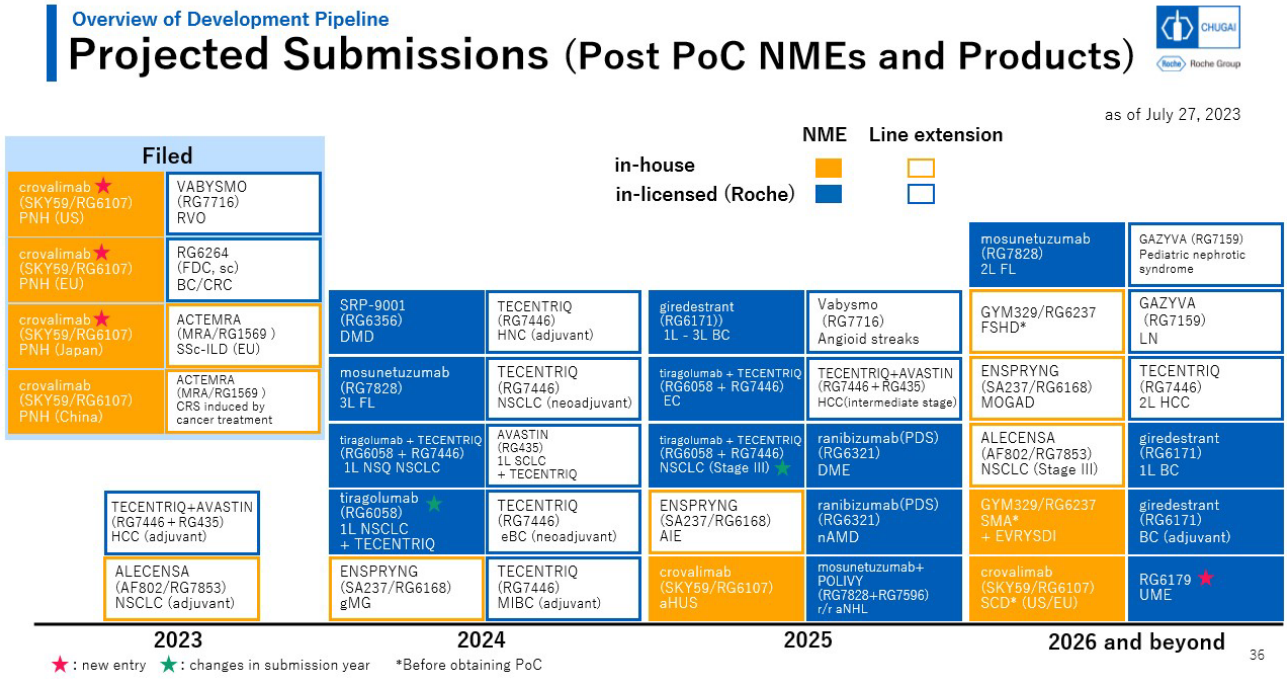
LUNA18, which is at the forefront of our mid-size molecule project, has been confirmed to be absorbed and transferred into the bloodstream through oral administration in the Phase I study currently underway.

The dose-escalation part also confirms that the drug concentration in the blood increases in a dose-dependent manner. In addition, events suggestive of inhibition of the RAS/MAPK signaling pathway have been observed in several cases.

On the other hand, it takes the longer time than planned to identify the human maximum tolerated dose. For this reason, we have previously explained that the early PoC acquisition date would be 2024, but it is now expected to be slightly delayed from this timeline.

On the other hand, overall mid-size molecule research is progressing well. One new project has now moved into the preclinical development stage. In addition, we have completed the acquisition of a clinical candidate molecule in another one project.

The recent finding that LUNA18 is fully absorbed by oral administration in humans and that it can achieve exposure that shows inhibitory activity in vivo has given us even greater confidence in our mid-size molecule drug discovery efforts. In the area of mid-size molecules, as in the case of antibodies, we will aim for continuous drug discovery.



This will be the schedule for future applications. Red stars indicate new additions and green stars indicate projects whose year of application has changed.

I have already explained everything, but I would like to add one point: the expected filing year for stage III non-small-cell lung cancer with tiragolumab and Tecentriq has been changed from 2024 to 2025, based on the progress of the trial.

Please refer to the following slides and references as appropriate.

That is all from me.

Miyata: Thank you very much.

Question & Answer

Miyata [M]: Now we will move on to the Q&A session.

Please be advised that Mr. Hidaka, Executive Vice President, Head of Marketing and Sales Division, is also present for the Q&A session.

We would like to limit each person to two questions. Thank you.

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

We will first take questions from those attending at the event, followed by those attending via Zoom. If anyone in the audience has questions, please raise your hand. We will give you a microphone. Please state your name and company name, followed by your question.

We will start with you.

Hidemaru Yamaguchi [Q]: Yamaguchi, Citigroup. Thank you.

I would like to ask about the performance of Hemlibra. I understand that the overseas sales were solid, and on a Roche basis, there is about 8% YoY growth. I think there was also inventory reduction in Roche. With those two factors involved, do you think the full-year performance is likely to go up or down if things continue as they are? From what I heard today, I have the impression that the tone is a little upward, but I am not sure if that is correct. Could you comment on Hemlibra exports?

Itagaki [A]: Itagaki. Thank you.

Regarding Hemlibra exports for Roche, the full-year forecast is JPY181.5 billion. Progress in H1 is 56.4%. While there is some variability in results depending on the timing of shipments, Roche's side is doing well. Globally, the Roche figure grew by 20% YoY.

Even if we exclude Japan, the Roche figure is growing at 15%, which means that global growth is higher than we originally expected. We have initially given the export forecast for this year with consideration of the rolling forecast from Roche.

We have talked about the impact of optimizing Roche's safety stock levels in this year's plan, which will have an impact of about one month or about JPY20 billion on our exports. Because of the overall demand, it is natural that there are areas where volume is being pulled upward.

We are quite confident of achieving this goal for the full year. Although we suggested in our forecast at the beginning of the fiscal year that it would be about JPY9.6 billion below the previous year's level, we are now reading that it may be on par with last year's level.

Hidemaru Yamaguchi [Q]: Thank you very much.

My second question is about LUNA18, which you mentioned in the last section. You said that it was taking time to determine the maximum tolerated dose, but is this because it is taking a long time to escalate the dose level? I would be grateful if you could tell me why it is taking longer than expected. Is it because relatively high doses are tolerated?

Tetsuya Yamaguchi [A]: I will answer.

We are not able to disclose the details, but as you are aware, we are gradually escalating the dose level in each cohort with 3 patients . As is often the case in clinical trials, there have been cases where the treatment was withheld because some patients with extremely progressed tumor were enrolled in the trial. we have to change the plan from the shortest forecast

In addition, as I mentioned earlier, it is taking time to determine the MTD due to a combination of factors such as dosage adjustment when RAS inhibition is actually observed in the cohort.

Hidemaru Yamaguchi [Q]: I think there was a conference where you can present early-stage data, maybe AACR or ASCO. Will you soon be in a position to present early-stage data at one of these conferences? Or is it still a little way away?

Tetsuya Yamaguchi [A]: Yes, we believe this will be a little further along. I think we need some data at higher dose levels.

Hidemaru Yamaguchi [M]: Thank you very much.

Miyata [M]: Thank you very much.

Next question.

Hashiguchi [Q]: Hashiguchi, Daiwa Securities.

I would also like to ask one thing about the export of Hemlibra, including a little confirmation. Is my understanding correct that the optimization of safety stock levels has already been completed, in H1?

In other words, in H2, will Roche's end sales be in a kind of parallel format with Chugai export, or will it be a little while before this optimization takes place, going over several quarters, influencing H1 and H2, before becoming parallel a bit later on?

Itagaki [A]: I think that inventory optimization has been occurring throughout the entire year, including in H1. In our own examination, for example, our exports for H1 have grown by 14% YoY. However, some of this is due to the depreciation of the yen. If we flatten the exchange rate, the growth would be in the low single digits.

On the other hand, Roche's growth excluding Japan with flat exchange rates is 15%. In any case, even with the time lag, our exports are still somewhat weak, and as I said, safety stock adjustments are also included here in H1.

However, looking at the rolling forecast for H2, it looks as though there is a certain amount of inventory. I am sure that adjustments are being made, but the adjustment level is probably about several months or so. If demand increases, the amount of inventory will also increase, and of course the demand for our company's shipments will also increase. In this case, I am sure that we would see an increase over the full-year forecast.

Hashiguchi [Q]: So far, the safety stock adjustment will be completed in H2, is that right?

Itagaki [A]: We currently believe that adjustments will mostly be completed by the end of the year.

Hashiguchi [Q]: Thank you very much.

The second point is about the subcutaneous injection of Tecentriq. It seems that development is going on at Roche in the US and Europe, but will it be developed in Japan? Could you please comment on the significance, advantages and disadvantages of developing in Japan, taking into account the differences between the medical environment in Europe, the US and Japan?

Tetsuya Yamaguchi [A]: I'll talk first on this.

Development for subcutaneous injection of Tecentriq is still under consideration. There is currently no particular timeline for a further decision. We believe that it is necessary to consider the possibility of subcutaneous injection in the context of the current intravenous infusion situation.

Hashiguchi [M]: Thank you very much.

Miyata [M]: Thank you very much.

Please go ahead.

Sakai [Q]: Sakai, Credit Suisse.

I think Roche will also explain this, but regarding the delay of SKYSCRAPER, is this simply because the PFS figure is not very good, and as a result, you're waiting for the OS figure? Is the event occurrence rate lower than expected? Please let me know if you have any updates.

Tetsuya Yamaguchi [A]: Thank you.

Yes, it is as you say. I personally have a very optimistic view that the OS, in short, death events are occurring less frequently than expected, and that we may be experiencing a phenomenon that is characteristic of TIGIT, where the further you go, the less likely you are to have an event. I personally have a very optimistic view, but in reality, we don't know until the analysis and readout are done.

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

I would also like to ask about the corporate venture capital in Boston area. I believe the investment is up to USD200 million. What is your goal with this amount of money? I think the amount itself is a bit low.

Given the level of cash your Company has, I am not saying that you should add a single zero, but I am wondering if the amount could be increased a little more. What are you going to target? You are talking about startups, which is a bit vague. Can you tell us what you are targeting in terms of technology?

Okuda [A]: First of all, as shown in the slide, we have three areas that we are targeting. The first is targets, and specifically, novel therapeutic targets and technology that helps us understand the disease biology to help identify targets, analyze data, and so on. This is the knowledge related to the target molecules, or seeds, as some might call them, and that's one of the scopes of the project.

The idea is that by doing so, new drugs can be created by combining Chugai's drug discovery modalities.

The second scope is technology that could enhance or complement our drug discovery modality platform. It could also be a technology that is new to Chugai or new to the Roche Group.

Third, digital technologies that accelerate drug discovery and translational research and create competitive advantage.

Therefore, the investment targets here are mainly early-stage startups, seed companies, and Series A companies. We will tap or invest a modest amount as an initial investment amount. I think that about USD200 million will be enough to cover the cost of the project.

So, although it may take some time, we are aiming for an evergreen type of CVC by having companies that generate returns and then reinvesting those returns further.

Sakai [Q]: I'm sorry, this may be a bit of an addition, but in the translational research area, do you already have a candidate?

Okuda [A]: We have not established it yet, we are just getting started. Chugai is currently focusing on human prediction technology, which is a major focus of Chugai, or technology that uses the QSP model to increase the probability of success in translational research and human clinical trials. We are currently focusing on translational research and technologies to increase the probability of success in human clinical trials.

Sakai [M]: Thank you very much.

Miyata [M]: Thank you very much.

Please raise your hand if you have a question.

We will then continue with a Zoom webinar to allow participants to ask questions.

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

Muraoka [Q]: Hello. Morgan Stanley, Muraoka.

I think there was an announcement that there was a lawsuit relating to Biogen over an Actemra biosimilar. Even in Biogen's most recent financial statements and other documents, the Actemra biosimilar was being mentioned much less often, so I was wondering if perhaps the impact in the next fiscal year could be minimized considerably. I was wondering if the impact of the lawsuit could be minimized in the next fiscal year.

On the other hand, in Roche's H1 report today, Roche expects Actemra/RoActemra biosimilars will launch in H2 of 2023 in the US and Europe. Any ideas you can give us would be appreciated.

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

As for the Biogen story, as announced by the other party, this biosimilar was created by Chinese company Bio-Thera, with an application for approval filed and received by the EMA on September 30, 2022. This is an IV injection. The application was then filed with and received by the FDA on October 9, 2022. The timing of the market launch is unknown. The normal review period is about 10 to 12 months, so the situation is such that approval could conceivably be in H2 of 2023.

On the other hand, a patent infringement lawsuit has been filed against Biogen by Chugai, Roche, and Genentech, since Biogen has filed an application for approval of a follow-on biologics product. This was on July 13 of this year. This is a lawsuit seeking confirmation of patent infringement under the US Biologics Price Competition and Innovation Act, the BPCIA.

However, although a lawsuit has been filed, we are not aware of any direct impact on the FDA's review of this case since it is a patent infringement lawsuit.

That is the information I am able to provide at this time.

Muraoka [Q]: Understood.

If it is delayed, I think there will probably be two groups of analysts, those for higher profits and those for lower profits, but I am hoping that the risk of lower profits next year will be reduced considerably. Exports of Hemlibra are strong currently, but would that be an important point to watch next year?

Okuda [A]: To that question, as I answered earlier, I think you can understand that it is difficult to tell which is which, if you understand the current situation.

However, I can also say that we are prepared to respond in good faith to any offer by a company of a follow-on product to license our patents. However, please understand that we are not in a position to discuss further details.

Muraoka [Q]: Understood. Thank you very much.

Just one more thing, regarding orforglipron, as you may know, transaminases go up with competing products. As you explained in Yokohama the other day, your company makes full use of IT when you conduct various simulations, and you have a high simulation ability. It has not been observed in clinical trials, but if there is any analysis such as lotiglipron showing the change in the virtual world but orforglipron not showing, please let me know.

Tetsuya Yamaguchi [A]: Yamaguchi here.

As you can see, we licensed out the entire drug to Eli Lilly and Company at the pre-clinical stage, and they have been conducting development of the drug since then. We are not involved in any of this.

Therefore, I think the current situation is that you should contact Eli Lilly and Company regarding the question you have just asked.

That is all we are able to say.

Wakao [Q]: Wakao, JPMorgan. Thank you.

My first question is a continuation of Mr. Muraoka's question about orforglipron just now. You may tell me to ask Lilly, but if possible, I would like to know your Company's opinion on the safety data in the New England Journal.

I thought the safety profile was good overall, but on the other hand, I think there is a cardiac disorder. There was no particular discussion of it in the paper, so I thought that maybe it is not so important. If you have any views on this, please let me know.

I would also like to know more in depth about the economic conditions relating to orforglipron. I think the potential of this drug is growing from this data and the current competitive situation. On the other hand, the product was out-licensed at the pre-clinical stage, I would imagine that the royalty rate would be lower.

Regarding the royalty rate, I think there are many possible scenarios. In some cases, it could be done based on sales level, and so on. If possible, could you comment on why your Company has such high expectations for this drug? Maybe there are some financial circumstances that I am not aware of. Thank you.

Tetsuya Yamaguchi [A]: Thank you. Yamaguchi here.

First of all, we would like to ask for your understanding that we cannot make any reference to the clinical development trials being conducted by Eli Lilly and Company, including side effects.

From my personal point of view, I think one clue is that Eli Lilly is currently conducting very rapid and proactive development for the Phase III trials.

We have received several inquiries about royalty rates in the past, but we are unable to disclose the royalty rates. We can only give you an idea of the royalty rates that those were negotiated with multiple companies in the third-party royalty discussions during the pre-clinical phase.

I'm afraid that's all I can say.

Wakao [Q]: Thank you very much.

Second, I would like to know about LUNA18 and other early-development items. First of all, in your explanation of LUNA18, I think you mentioned that you could see the inhibitory activity, is it my understanding that you can see the response here? Are you saying that you are monitoring biomarkers? I would like to know about this.

I think that early PoC of LUNA18 was an event to prove Chugai's innovation such as has the achievement of in-house compounds. That is [inaudible], but then I would like to know if there is some data or event that will confirm a progress of your innovation next year.

Looking at clinical trials information website and so on, I believe SOF10 and DONQ are scheduled to finish their trials in due course. I think all of these are enrolling patients, so I was wondering if we can see the data, do you have any comments?

That is all.

Tetsuya Yamaguchi [A]: First of all, LUNA18, as explained earlier, responses have been observed in multiple cases, but what are these responses? What I can say is that LUNA18 is a pan-RAS inhibitor. I hope you understand that we cannot disclose any further at this stage, only to state that events such as those expected with a pan-RAS inhibitor have been observed.

I must confess that I have not yet been able to sort out the extent to which I can disclose at this point today whether there will be any major milestones in our projects in the next fiscal year. As we are able to disclose more information in the future, we would like to be proactive in communicating it to you.

The timing of this presentation on LUNA18 and the status of mid-size molecule research is one of our attempts to explain the progress of R&D as much as possible, but at the same time, the project is still at the stage of Phase I administration where it is administrated to humans in a competitive environment and with a high degree of uncertainty.

Sogi [Q]: Hello. Sogi, Bernstein. I have two questions.

First, I have a question regarding crovalimab. You have shared the results of crovalimab trial, but I would like to know your current assumptions about what kind of patients will be eligible when crovalimab enters the PNH market.

For example, will the patients be those already receiving other complement 5 inhibitors, such as Soliris? Or will they be new patients?

If you start with new patients, it will be a very slow market penetration. As you mentioned at the briefing the other day, there is also the possibility of antibody complexes and side effects during the switch, so that must be taken into consideration. Please tell us how this product will penetrate the PNH market.

Also, I would be happy to hear what the impact of Novartis' oral iptacopan would be, if new patients are main target for crovalimab.

Tetsuya Yamaguchi [A]: I will take this question.

We are in the process of developing the marketing plan.

However, as you just pointed out, both new patients and switches will naturally be considered. The first target will be patients who find value in the four-weekly maintenance dosing of crovalimab. This offers benefits for patients as it can be administered subcutaneously and can eventually be self-administered. That is one of our targets, and we would like to explore this segment more deeply in the future.

With regard to the switch, you mentioned your concern about drug-target-drug conjugates. In fact, there were no instances in the clinical trials where the drug could not be administered due to this concern. We have heard from some doctors that it is manageable, so we do not think it will be a major obstacle.

As you mentioned iptacopan, we believe that for the time being, for very life-threatening diseases, C5 inhibitors, which have already been established, will be the first standard of care, so we believe that this will come first.

I understand that clinical trials are currently underway to obtain data on a wider range of patients, and as such data become available little by little, the oral administration of iptacopan is likely to have its own segment. That is my opinion.

However, I understand that it is administered orally twice a day, so in that sense a little bit, I think that compliance will be a very important factor. I understand that the drug has a short half-life in the blood, so maintaining drug concentration will be a crucial factor in a disease as serious as this. I believe that this will be an important factor.

As I mentioned above, we are still at the stage of fleshing out our marketing measures.

Thank you.

Sogi [Q]: Thank you very much.

I have one more question regarding your company's use of cash. Particularly, the announcement of the establishment of Chugai Venture Capital. Your company is very rich in cash, and looking at other companies, we see that they are moving to break down their cash levels and invest more for future growth. In addition to CVC, do you intend to maintain the cash level as it is, or do you intend to invest in future growth while actively breaking down the cash level?

Okuda [A]: Thank you for your question.

We plan to continue to make aggressive capital investments in production and R&D. At this stage, we are not able to give specific examples. In the area of drug discovery and R&D, for example, we could use cash to introduce early-stage project themes, or to invest in technology introduction, such as the development of a new drug discovery platform by integrating our technology with theirs.

Furthermore, if it is likely to be more effective if it is not only licensed, but also acquired, we will take advantage of such opportunities.

However, we have no intention of making Chugai simply a company that grows in size, and our overall policy is to actively invest in R&D and value-creating production facilities in some form.

Our strategy is to pay dividends to shareholders in accordance with our business performance.

Sogi [M]: Thank you very much.

Miyata [M]:

Next, Nikkei BP, Hashimoto.

Hashimoto [Q]: Thank you.

This is related to the previous question, but I understand that you intend to continue to invest aggressively in production facilities, and that you intend to continue to invest at the current level every year for the foreseeable future.

Okuda [A]: We will make aggressive investments as needed, when it is necessary to increase production and functionality. We also plan to make capital investments related to environmental investments, such as reducing CO_2 emissions and using green materials, as I believe was mentioned in Mr. Itagaki's slide.

As you can see on the slide here, we are estimating that we will invest approximately JPY107.2 billion to 2032. As to whether or not we will continue to invest the same amount of money as before, please understand that at this point, we are not in a position to say that we will.

Hashimoto [Q]: I'm sorry, but this slide seems to indicate that the production facilities will be completed in 2027 to 2028, and then the environmental investment will continue until 2030 or so.

Okuda [A]: This includes items that are currently envisioned or that have already been settled. Please understand that in the future, say next year or the year after, if there is a discussion about the need to invest in new production facilities and settle the matter, there is a possibility that it will be added here.

Hashimoto [Q]: Thank you.

I would like to ask one more question about CVC. Your company has a business development unit and is quite active in open innovation. As you can see in the diagram on the right, you have chosen to use the word "far" in relation to the CVC. I would like to ask you how the open innovation that is done by creating a CVC actually differs from the open innovation that has been done to date.

Also, in terms of fostering biotechnologies, I understood that your company's stance was more focused on fostering various technologies in Japan. I would like you to explain a little more about the reason for being located in Boston.

Okuda [A]: In the picture on the right side of page 11, the x-axis shows the degree of technological development. The left side plots technologies that are close to practical application, the right side plots technologies that are far from practical application, and the y-axis, the vertical axis, plots technologies that are close or far away from the Chugai existing technology area.

The in-house R&D area is where the practical application is close to the existing technology and the technological area that Chugai has.

CVC, as you pointed out, is somewhat far away from those, maybe a long way from practical application, but with potential, and then there are technologies that Chugai is not yet working on internally.

We are thinking about tapping these things from a very early stage so that when the technology develops and evolves, it can be immediately integrated with the technology inside and outside the Company.

When new science or technology discovered through CVC activities reaches the stage of collaboration, this is where partnering comes in.

For example, when it comes to joint research, joint development, or perhaps even acquisition, the relationship is truly a gray area, and as it progresses, it is incorporated into the Company.

I believe the second question is about why we chose the Boston area. As Japan is our base for research, we are well-positioned for collaboration with Japanese academia.

But on the other hand, as you know, the Boston area is home to the number one drug discovery ecosystem in the world. Our intention is to establish a base there and a base for the Chugai Venture Fund, a Chugai venture capital company, so that we can create a network that will enable us to access potential science and technology more quickly and more reliably.

However, although we are locating the CVC in the Boston area, this does not mean that we will focus only on the Boston area. Of course, there are a number of biotech startups in Silicon Valley as well. In the digital field, we understand that there are even more startups in Silicon Valley.

There are other ventures growing in the U.S., and not only in the U.S. but in many European countries as well. Furthermore, as we have said here, Japan is also a target area for investment, so although we are based in Boston, we would like to keep an eye on a wide range of new science technologies from around the world.

Mamegano [Q]: Mamegano, BofA Securities.

Sorry, I know others have already asked this question, but could you please say a little more about the progress of LUNA18? Thank you.

You say that obtaining an early PoC takes time, but am I correct in understanding that the delay in determining the maximum tolerated dose is basically due to the lack of dose-limiting toxicity? Is it correct to say that the dosage has not yet risen high enough to show toxicity?

Tetsuya Yamaguchi [A]: Yamaguchi here.

I am sorry, but at this time, we are unable to disclose the details of why it is taking so long to find the maximum tolerated dose.

Miyata [M]:

In that case, we will now conclude the question-and-answer session. This concludes the presentation of the financial results for Q2 2023.

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If you have any questions that we were unable to answer, please contact corporate communications. Phone numbers and email addresses are listed on the last page 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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