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CHUGAI PHARMACEUTICAL CO., LTD.

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CHUGAI PHARMACEUTICAL CO., LTD.

Q2 Results (Jan – June 2021) Conference Call

July 26, 2021

Event Summary

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[Participants]	

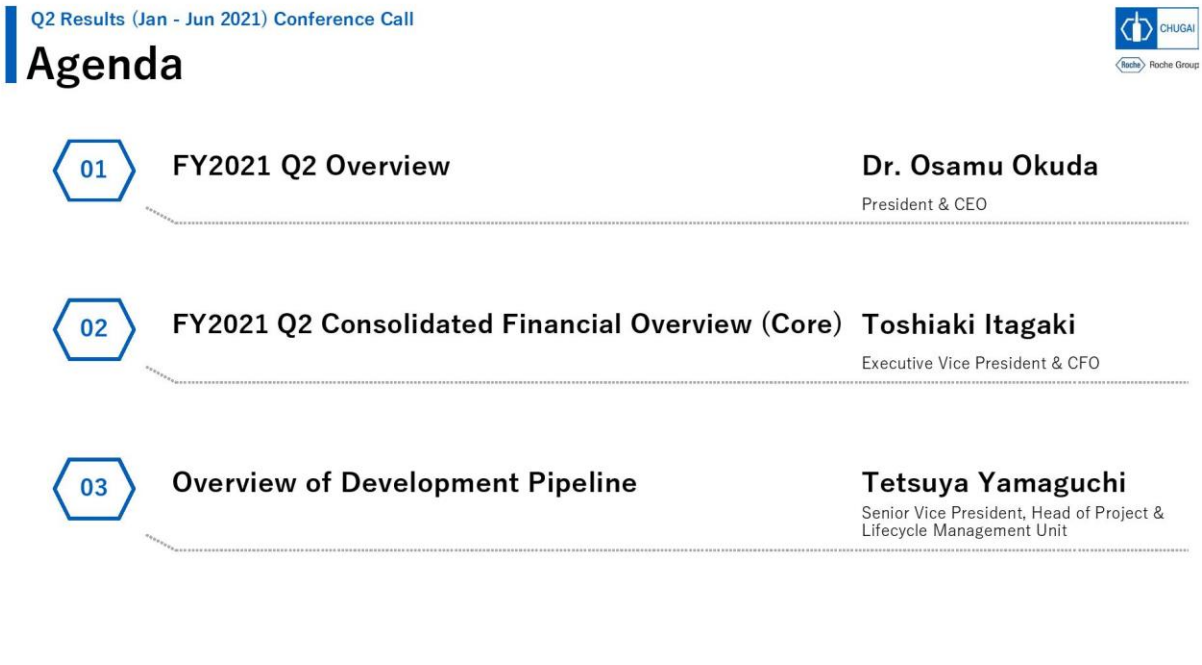
[Number of Speakers]	5	
	Osamu Okuda	President & CEO
	Toshiaki Itagaki	Executive Vice President & CFO
	Tetsuya Yamaguchi	Senior Vice President, Head of Project & Lifecycle Management Unit
	Shinji Hidaka	Vice President, Head of Marketing & Sales Div.
	Toshiya Sasai	Head of Corporate Communications Dept.
[Analyst Names]*	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.
	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Kazuaki Hashiguchi	Daiwa Securities Co. Ltd.
	Motoya Kohtani	Nomura Securities Co., Ltd.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

Presentation

Sasai: Thank you very much for taking time out of your busy schedule to join us today for the briefing on the financial results for the second quarter of fiscal year 2021. I'm Sasai, from the Corporate Communications Department. I'll be your host for today. Thank you for your cooperation.

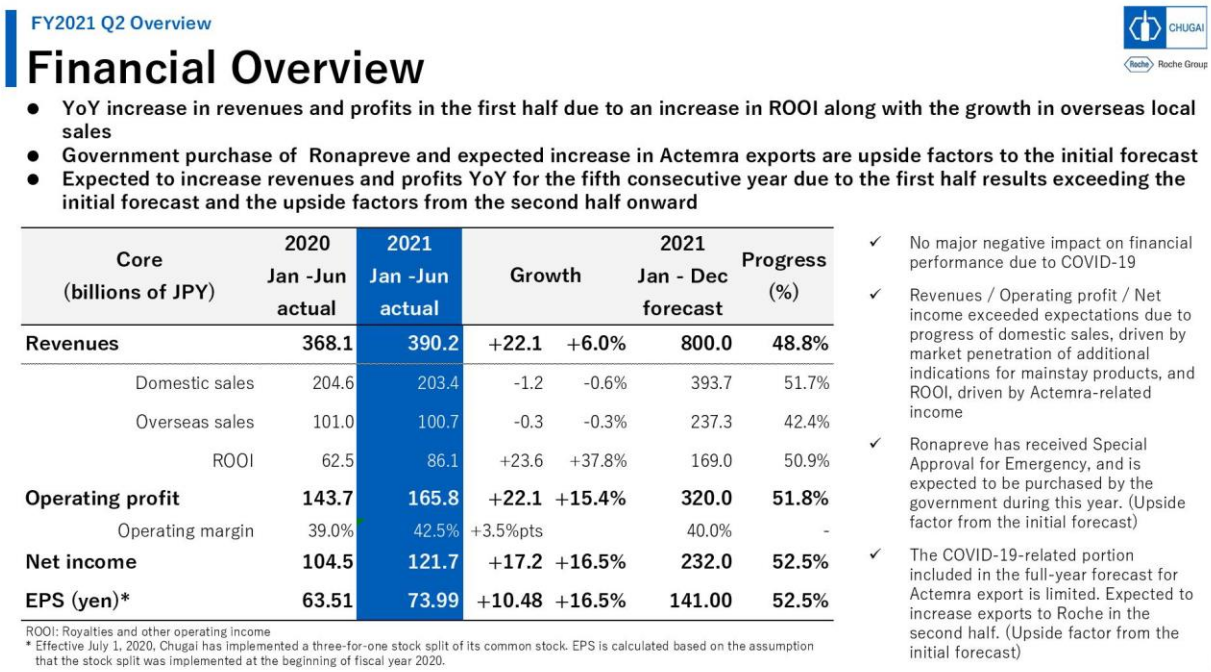
In order to prevent the spread of the coronavirus infection, today's session will be conducted in the form of a conference call.



The agenda for today's meeting can be found on page 3 of the presentation materials.

Questions will be taken after all presentations have been completed.

Dr. Okuda will now provide a summary of the second quarter. Thank you.



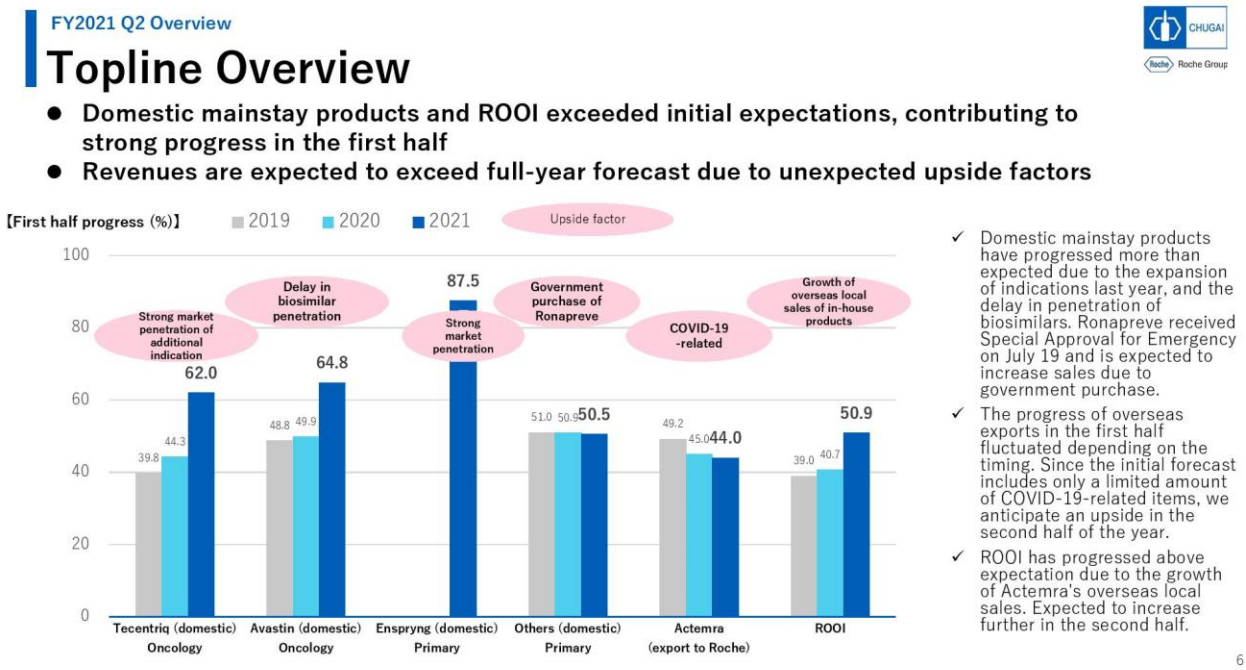
Okuda: Hello. I'm Osamu Okuda, the President and CEO of Chugai Pharmaceutical Co., Ltd.

I will now give a summary of the second quarter results. Please refer to page 5 of the slides.

Sales revenue for the period from January to June was JPY390.2 billion, an increase of 6% from the same period last fiscal year. Operating profit and net income also increased by more than 15% compared to the same period last year. In the first quarter, from January to March, we started the year with a decrease in profit and a decrease in revenues. In the first half overall, however, there has been an increase in revenues and an increase in profit.

Looking at the rate of progress toward the full-year forecast, domestic product sales, ROOI, and royalties exceeded the initial forecast. In particular, royalties are directly related to profits from the growth in overseas local sales of in-house products. As a result, operating profit and net income were also stronger than expected.

In addition to these factors, there are upsides such as Ronapreve and exports of Actemra in the second half and beyond. I will discuss these in the next slide. Together, these factors are expected to result in a fifth consecutive year of increased full-year sales and profits.



Next, let's discuss the upside factors of the top line.

Please see page 6. In this section, we have picked out and shown the upside factors from the initial forecast in the top line.

In terms of domestic product sales, hepatocellular carcinoma, for which the indication for use for Tecentriq was expanded in September last year, is showing strong market penetration. In addition, although not shown in this graph, Kadcyla is also seeing strong penetration of its adjuvant for HER2-positive breast cancer, for which the indication was expanded last August.

As for Avastin, the penetration of biosimilars has been slower than expected. In addition, Enspryng, which was launched last year, has seen a progress rate of 87.5%, showing penetration beyond our expectations.

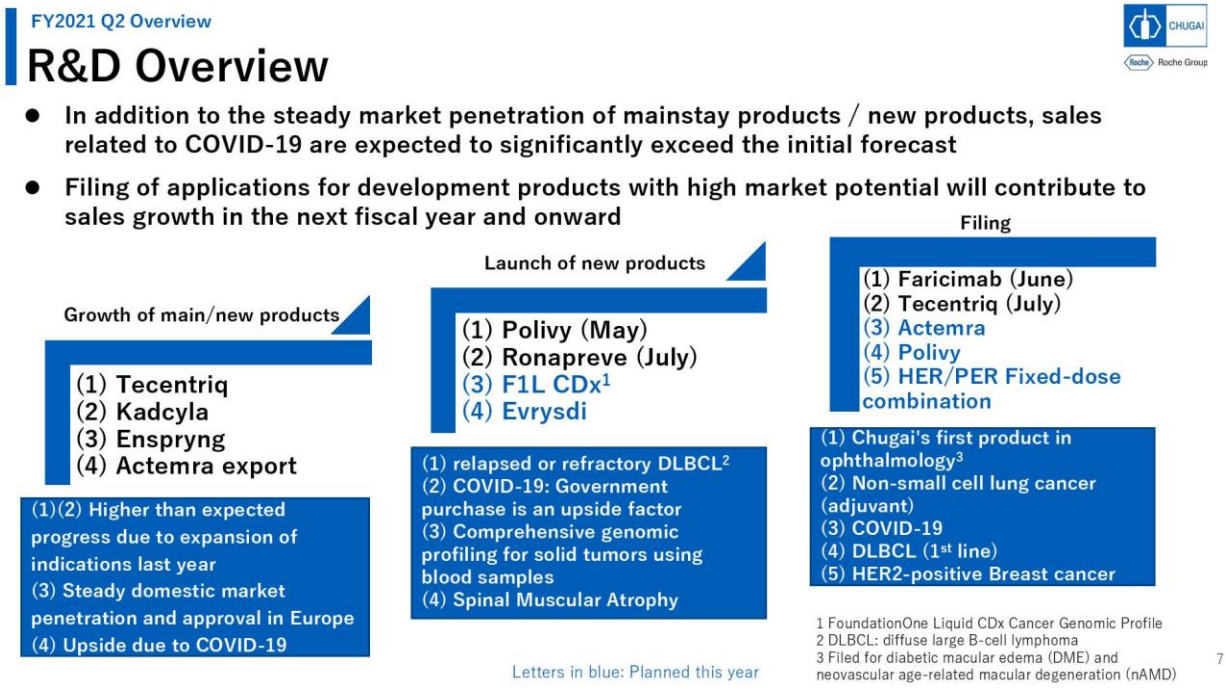
As announced in the press release, Ronapreve, an antibody cocktail therapy for COVID-19, received special approval for emergency on July 19. Based on an agreement with the Japanese government, the government will purchase the treatment in the current fiscal year. Unfortunately, we are not able to disclose the total purchase quantity or price.

Sales of Ronapreve are an upside factor that was not included in the full-year forecast at the beginning of the fiscal year. Once the results are posted, we plan to disclose them as "Other" in the primary area.

The full-year forecast for Actemra exports included only a limited amount of COVID-19-related information. As shown here, the progress of exports of Actemra for Roche in the first half of the fiscal year has been low, but this is due to the timing of exports and is in line with our expectations at the beginning of the fiscal year. In the second half of the fiscal year, exports of Actemra are expected to exceed the full-year forecast.

ROOI and royalties progressed better than expected in the first half of the fiscal year due to growth in local sales of Actemra overseas related to COVID-19. In the second half of the fiscal year, we expect the increase to exceed our full-year forecast.

As a result of these upside factors that were not anticipated at the beginning of the fiscal year, sales revenue is expected to exceed the full-year forecast.



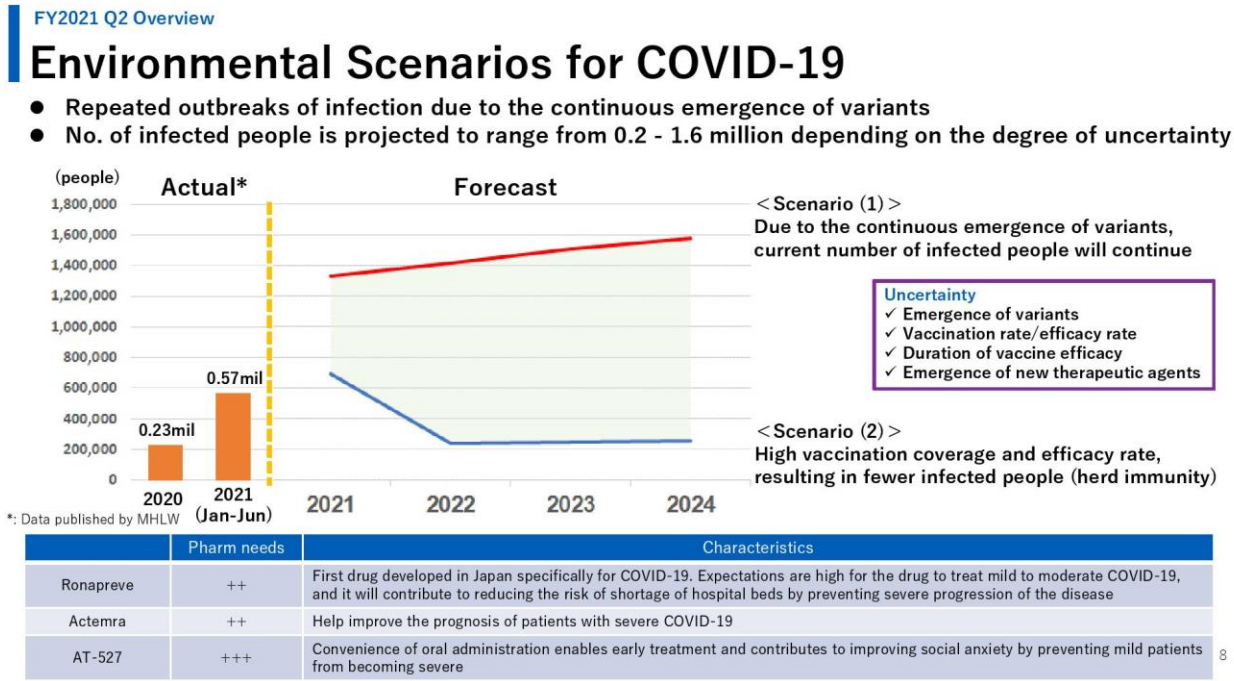
Next, let's talk about R&D. Please see page 7.

As I mentioned, the growth of Tecentriq, Kadcyla, and Enspryng has exceeded our expectations. In addition to these, new products and expanded indications will continue to be launched this year and next. The initial penetration of Polivy, which was launched in May and is indicated for the treatment of relapsed or refractory DLBCL, is going well. In July, we launched Ronapreve for COVID-19.

In addition, we are planning to launch two new products by the end of this year. The first is FoundationOne Liquid CDx, which is used for genomic profiling of solid tumors using blood samples. The second is Evrysdi, which can be administered orally for spinal muscular atrophy, and is very convenient for patients.

There are several products and expanded indications that have been filed this year and are expected to be launched next year. We have already filed for approval in June for faricimab, our first entry into the ophthalmology field, and in July for Tecentriq for adjuvant treatment of non-small cell lung cancer. In addition to this, we have 3 other regulatory filings in the pipeline by the end of this year, including an expansion of the first-line indications for Polivy.

By continuing to file applications for development products with high market potential, we expect to contribute to sales growth in the next fiscal year and beyond. Later, Mr. Yamaguchi will discuss the market potential of late-stage development products.



Please see page 8.

We have 3 drugs in development for COVID-19. This slide will give you an overview of how we are projecting the trend of COVID-19 infection in Japan.

In our analysis, considering various factors of uncertainty, we assumed 2 scenarios for the number of coronavirus infections in Japan. These factors include the emergence of variants, vaccination rates, and vaccine efficacy.

Scenario 1 considers the emergence of new variants, and results in a high number of cases. Scenario 2 is the base case, which assumes that the number of infected people is controlled due to high vaccination and vaccine efficacy rates. The number of infected people varies considerably between the base and high cases, but we estimate that the number of infected people will range from about 200,000 to 1.6 million.

This is the context in which the cocktail therapy Ronapreve has received special approval for emergency. As the first drug for the treatment of mild to moderate disease, we hope that it will contribute to reducing the severity of the disease and thereby reduce the risk of hospital bed shortage.

Although Actemra and AT-527 are not yet approved in Japan, Actemra is expected to improve the prognosis of patients with severe COVID-19. AT-527 is expected to prevent severe disease in mild cases due to the convenience of oral administration and early treatment.

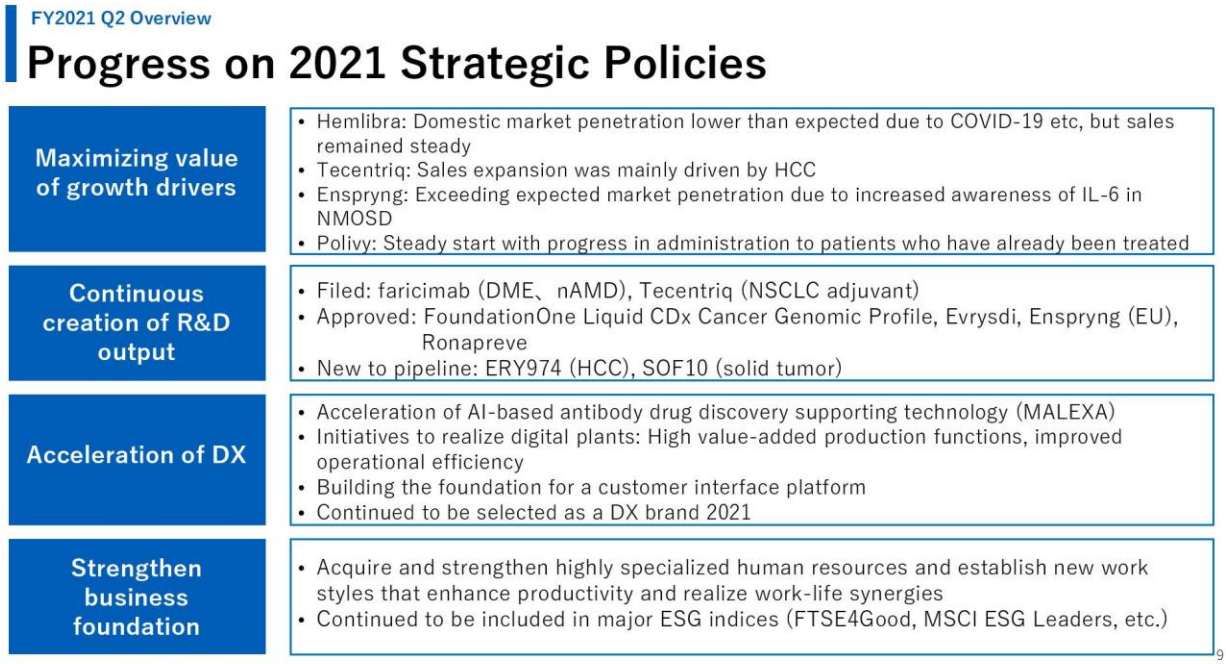
To explain a little bit about Ronapreve, we have agreed with the government to secure the purchase of this product for FY2021. This is as I explained earlier. The government purchases Ronapreve in bulk and provides it to hospitals free of charge in the sales scheme. Therefore, sales of Ronapreve for this fiscal year will be the result of government procurement.

According to our forecast, the number of infected people in Japan in the second half of 2021 is expected to be between 400,000 and 700,000. Furthermore, we assume that 20% to 40% of these patients are at risk for severe progression of the disease. Patients eligible to receive Among those, excluded from cases eligible for

Ronapreve will be those that are asymptomatic which is about 10 to 20%, and moderate II or severe diseases requiring oxygen supply. You also need to be hospitalized to be eligible..

However, according to the financial results for the second quarter released by Roche, sales from government purchases in Germany, Italy, and France in Europe were CHF166 million in the first quarter and CHF317 million in the second quarter, for a total of CHF483 million in the first half of the fiscal year. While vaccination levels and conditions are different in each country, this may be useful as a reference.

The infection situation after 2022 is very difficult to predict because there are so many uncertainties, but we assume that the number of infected people in Japan as a whole will be in the range of 200,000 to 1.6 million. In any case, we are planning to discuss with the government about the supply of Ronapreve from 2022 onward so that we can respond to fluctuations in demand.



Please see page 9. Next, I would like to explain the progress of our priority policies for this fiscal year, which were set at the beginning of the fiscal year.

As for the growth drivers of value maximization and R&D, as I have already explained, revenues are exceeding our expectations and R&D is progressing steadily.

In the area of DX and digital transformation, we are promoting the acceleration of DX across all value chain through the full use of AI, digital, and robotics. We are accelerating DX at a fairly rapid pace, including the use of AI technology for antibody molecular design, building digital plants, and creating AI-based customer interface platforms. We have just been selected as a DX brand for the second year in a row. We are the only company in the pharmaceutical industry to receive this.

We have made steady progress in strengthening our business foundation, including the establishment of a new personnel system and our continued selection for inclusion in major ESG indices.

Please see page 10.

In our growth strategy, TOP I 2030, set forth at the beginning of this year, we aim double our R&D output, and in this way, launch global in-house products every year by 2030. In particular, we are positioning mid-size molecule drugs as a new modality that will drive our mid- to long-term growth.

This press release was issued today to announce the construction of a new synthetic API manufacturing facility for small and mid-size molecule drugs in the Fujieda Plant. We call it FJ3 because it is the third API manufacturing building at the Fujieda plant, which is being built with the latest facilities and concepts. FJ3 is a plant designed for the production of small and mid-size molecule drugs with high potency, APIs for late-stage clinical trials and early production after launch.

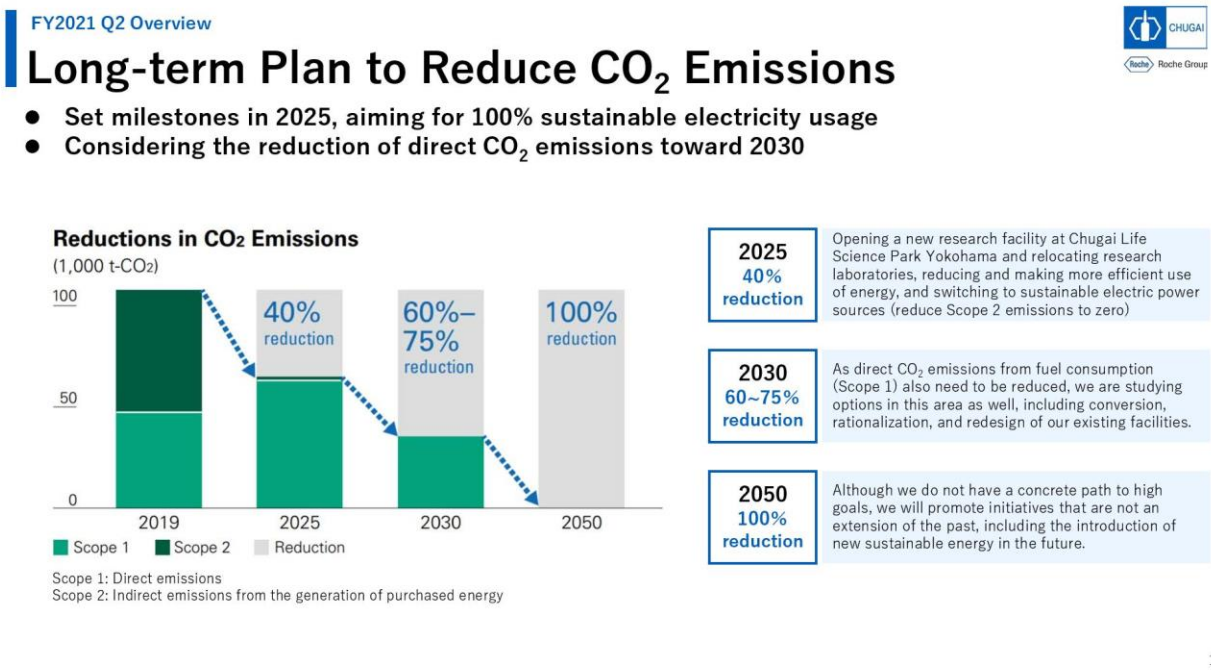
The addition of FJ3 to the existing FJ1 and FJ2 facilities at the Fujieda Plant will enable the Company to provide a consistent supply of APIs from early clinical development to early commercial production, greatly strengthening the foundation for the rapid development and launch of innovative new drug candidates.

The investment of JPY55.5 billion is the largest investment we have ever made in a manufacturing facility. Construction is scheduled to be completed in 2024, and the plant will be operational in March 2025. The structure is designed with thorough consideration of environmental and safety aspects.

Next, I would like to talk a little bit about the Chugai Life Science Park in Yokohama.

As you have already heard, we are planning to consolidate our current laboratories, which are located in Gotemba and Kamakura, and make them our core research bases.

With the temporary suspension of construction due to COVID-19 and other factors, as well as the careful examination of the moving date, the official start of operations is expected to be pushed back about 3 months from the original plan. According to the new plan, construction will be completed in October 2022, and the plant will be officially operational in April 2023.

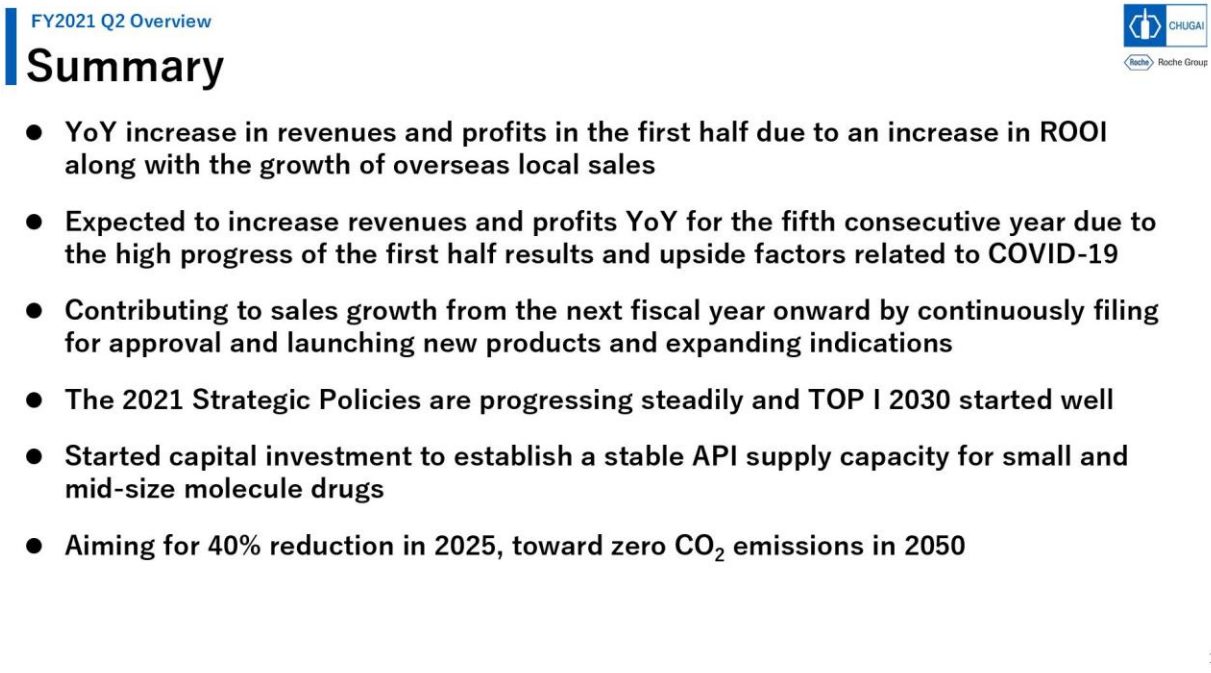


Please see page 11.

In February 2021 and again in February of this year, we analyzed the results of the previous mid-term environmental goals and formulated our Mid-Term Environmental Goals 2030, a comprehensive set of goals related to climate change countermeasures, recycling-oriented resource use, and biodiversity conservation. This is in response to the expectations and demands of society.

As shown here, we will reduce carbon dioxide emissions in stages, aiming for zero CO2 emissions by 2050. By 2025, we aim to achieve a 100% sustainable electricity usage rate. In other words, we will reduce the CO2 emission when we produce electricity to zero. This is Scope 2. In order to achieve a 60% to 75% reduction in emissions by 2030, direct CO2 emission from fuel use will also need to be reduced. This is Scope 1. Therefore, we will also consider the conversion of existing facilities and the consolidation and redesign of facilities.

Reducing CO2 emissions to zero by 2050 is a very challenging goal. Although we do not yet have a concrete path forward, we will continue to monitor trends in the development of new technologies that are effective in reducing CO2 emissions, and in the future, we will work to introduce new sustainable energy sources and other initiatives.



Please see page 12. This is a summary.

Royalties and ROOI increased in line with the growth in overseas and local sales. Both revenues and profits increased in the first half of the fiscal year under review.

Due to the high level of progress in the first half of the fiscal year and upward factors related to COVID-19, we expect revenues and profits to increase for the fifth consecutive year.

We believe that the continued filings for approval and launch of new products and expanded indications will contribute to sales growth in the next fiscal year and beyond.

We are making good progress on our priority policies for 2021. TOP I 2030 has started well.

We have started capital investment to establish a stable supply system for APIs of small and mid-size molecular drugs.

And on the environmental front, we are aiming for a 40% reduction in CO2 emissions by 2025 as the first milestone toward zero CO2 emissions by 2050.

That's all from me.

Sasai: Mr. Itagaki will now provide an overview of the consolidated financial results.

FY2021 Q2 Consolidated Financial Overview (Core)

P/L Jan - Jun (Year on Year)

(Billions of JPY)	2020	2021	Growth	
Revenues	**368.1**	**390.2**	**+ 22.1**	**+ 6.0%**
Sales	305.7	304.1	- 1.6	- 0.5%
Domestic	204.6	203.4	- 1.2	- 0.6%
Overseas	101.0	100.7	- 0.3	- 0.3%
Royalties and other operating income	62.5	86.1	+ 23.6	+ 37.8%
Royalty and profit-sharing income	53.5	83.3	+ 29.8	+ 55.7%
Other operating income	9.0	2.8	- 6.2	- 68.9%
Cost of sales	**-131.2**	**-121.9**	**+ 9.3**	**- 7.1%**
(cost to sales ratio)	42.9%	40.1%	-2.8%pts	-
Operating expenses	**-93.2**	**-102.5**	**- 9.3**	**+ 10.0%**
M&D and G&A *1	-40.2	-42.7	- 2.5	+ 6.2%
Research and development	-52.9	-59.9	- 7.0	+ 13.2%
Operating profit	**143.7**	**165.8**	**+ 22.1**	**+ 15.4%**
(operating margin)	39.0%	42.5%	+3.5%pts	-
Financial account balance	-1.1	0.6	+ 1.7	-
Income taxes	-38.2	-44.7	- 6.5	+ 17.0%
Net income	**104.5**	**121.7**	**+ 17.2**	**+ 16.5%**
EPS (JPY) *2	63.51	73.99	+10.48	+ 16.5%

Domestic sales
Same level as previous year as the negative impact of NHI drug price revision and generic drugs launch was offset by growth in sales volume

Overseas sales
Same level as previous year due to offsetting increases / decreases in export products

Royalty and profit-sharing income
Significant increase in income for Hemlibra

Other operating income
Decrease in one-time income

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

Operating expenses
Increase of M&D and G&A expenses due to recovery in various activities
Increase of research and development expenses due to progress of projects, etc.

Operating profit
Increase due to higher royalty and profit-sharing income

*1 M&D: Marketing and distribution, G&A: General and administration
*2 Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

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Itagaki: I would like to explain the details of our financial results.

Now, please look at page 14. This slide shows the profit and loss results for the first half compared to the same period last year.

Revenues were JPY390.2 billion, up 6% or JPY22.1 billion on the same period last year.

In terms of the breakdown, first of all, for sales in the domestic market, volume growth pushed back the negative impact of NHI price revisions and generics to a near flat level. Changes in overseas sales varied by product, but in total, the results were almost the same as the previous year.

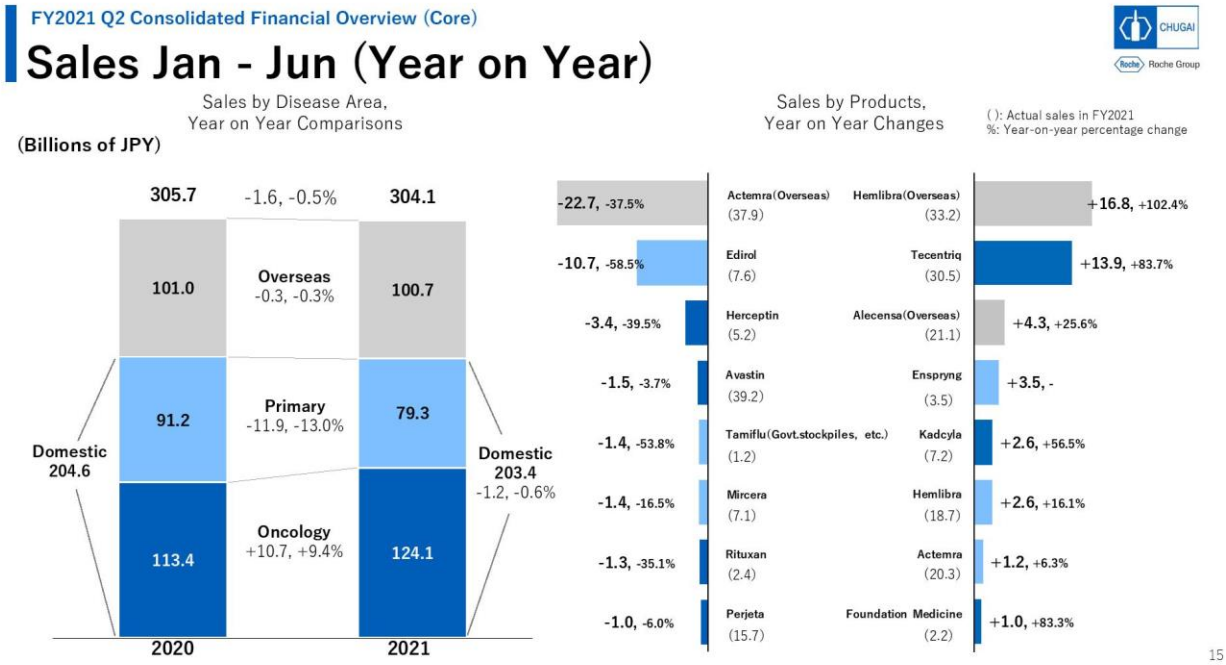
Royalties and profit-sharing income increased by JPY29.8 billion due to a large increase in royalties related to Hemlibra. Other operating income fell to JPY2.8 billion due to the absence of previous one-time income.

As for cost of sales, although there was upward pressure on the cost ratio due to the NHI price revisions in April last year and April this year, the product cost ratio improved by 2.8 percentage points to 40.1% due to an increase in the sales composition of in-house products.

As for expenses, marketing and distribution, general and administrative expenses increased by 6.2% due to the recovery trend in various activities. R&D expenses increased by 13.2%, or JPY7 billion, due to progress in development projects. For your information, we plan to increase R&D expenses by JPY18 billion for the full year.

Compared to the same period last year, operating profit increased by JPY22.1 billion, or 15.4%, which happens to be the same as the increase in revenues. The operating profit margin was 42.5%, the first time it has ever been in the 40% range in the first half of a fiscal year.

Subtracting the financial account balance and corporate income tax from this figure, net income for the first half of the fiscal year was JPY121.7 billion, an increase of 16.5%.



The slide on page 15 shows the breakdown of changes in sales of products.

By therapeutic area, the domestic oncology area grew by 9.4%, and if you look at the individual products on the right, we saw growth in Tecentriq and Kadcyla due to the expansion of indications.

On the other hand, sales of Herceptin, Avastin, Rituxan, and Perjeta decreased due to the impact of generics and NHI price revisions.

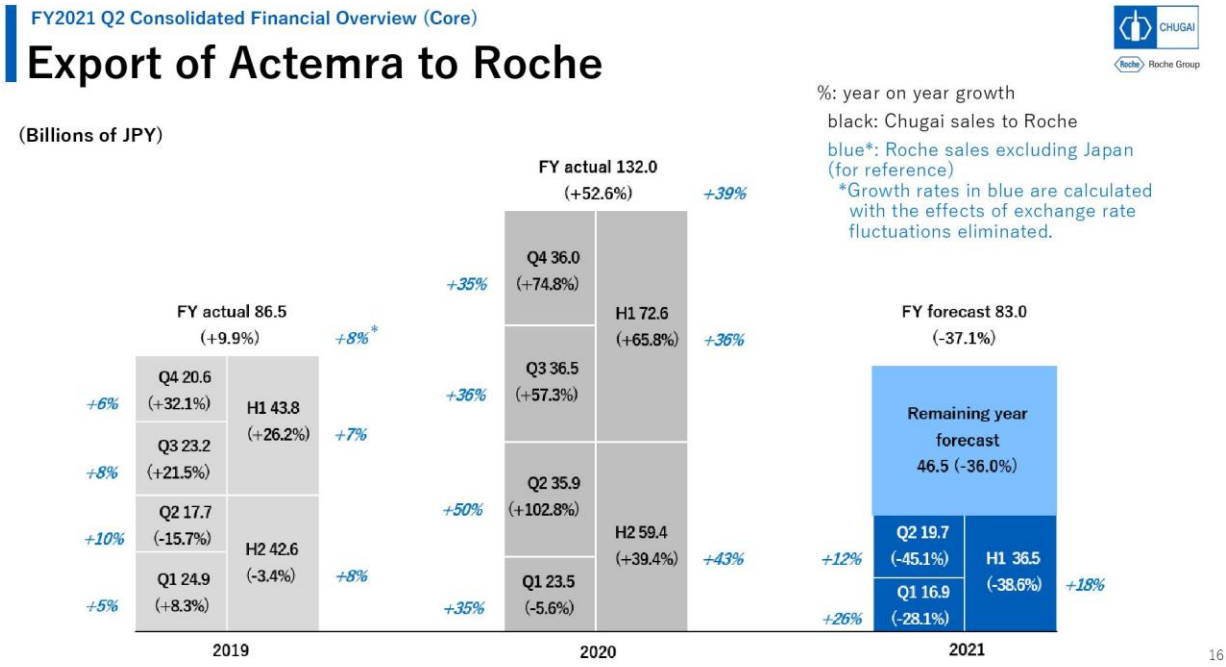
Next, sales in the domestic primary area declined by 13%, with Edirol, for which a generic version is now available, decreasing by JPY10.7 billion. Tamiflu (Govt. Stockpile) and Mircera decreased by JPY1.4 billion each.

On the other hand, sales of in-house products, Enspryng, Hemlibra, and Actemra, grew steadily. Enspryng, which was launched in August last year, has been steadily penetrating the market and has achieved JPY3.5 billion in sales. In terms of volume, this represents a growth of more than 26%. Hemlibra is a 16.1% increase after the 15% NHI price reduction in April last year due to market expansion recalculation. In terms of volume, this represents a growth of more than 26%.

Overseas, the total is almost flat, but the change in sales varies by product.

Products whose sales decreased, Actemra's overseas sales declined by JPY22.7 billion. We will look at the details on the next page.

As for products with increased sales, Hemlibra sales overseas have doubled. Excluding the effect of export unit prices, the growth in volume terms was 2.4 times. Sales of Alecensa overseas grew by 25.6%. Excluding the impact of unit prices of exports, the increase in volume terms was over 70%.



Now, please look at page 16.

The dark blue area at the bottom on the right-hand side shows results for the first half of 2021. The figure of JPY46.5 billion for the second half is the balance after subtracting the actual results of the first half from the full-year forecast.

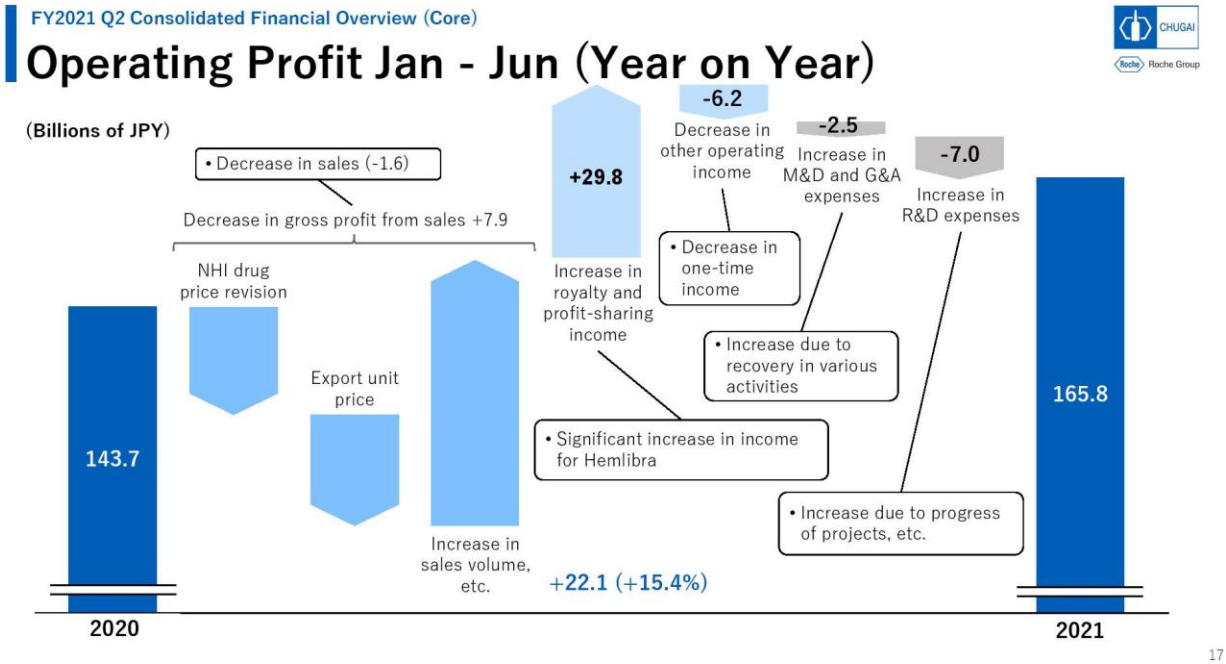
First of all, starting with 2019 on the left, the full-year results were JPY86.5 billion. This represents growth of 9.9%. Since the demand for rheumatoid arthritis is considered to be generally stable, we can assume that more than 40 percentage points of last year's increase is due to the demand for COVID-19, which is the result of increased exports.

The blue figure is the percentage increase in global sales of Actemra by Roche. As you can see here, the growth rate in 2019 was 8%, and 39% in 2020. This means that there has been a significant demand relating to COVID-19 in Roche territory.

Compared to the market growth rate of 39% in Roche territory last year, the rate of increase in our exports to Roche was high at 52.6%, which shows that we have been exporting ahead of schedule.

As you can see on the lower right, exports in the first half of this year were suppressed, and as a result, exports totaled JPY36.5 billion. Exports in the first half of the fiscal year, when we announced the forecast at the beginning of the fiscal year, were generally within the period covered by firm orders, so the actual results of JPY36.5 billion, or a 28.1% YoY decrease, are almost in line with the plan.

However, growth in Roche territory in the first half of the year was 18%, which is still high, and we expect additional export requests to come in towards the end of the period. The full-year forecast of JPY83 billion incorporates only a limited increase in exports due to COVID demand, so we expect the forecast balance to be higher in the second half.



The next page, page 17, is a waterfall graph showing the breakdown of changes in operating profit.

The second, third, and fourth bar graphs from the left are elemental decompositions of the change in gross profit from sales.

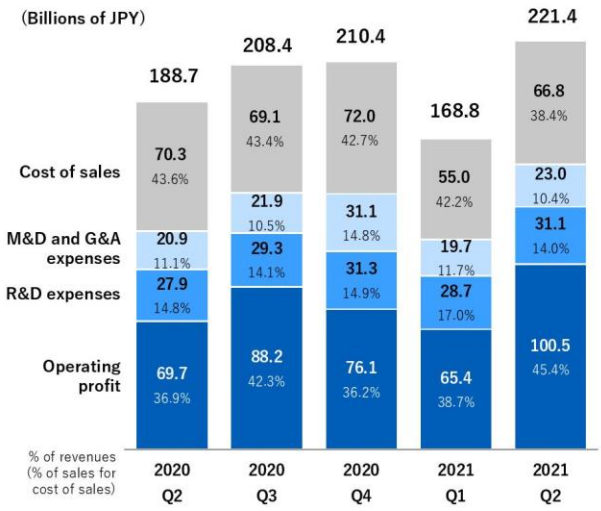
The negative impact of NHI price revisions and export unit prices was absorbed by increase in sales volume , resulting in an increase of JPY7.9 billion.

Next, the JPY29.8 billion increase in royalty and profit-sharing income directly contribute to the increase in profits.

Other operating income decreased as a reaction to a large one time income last year, resulted in a decrease of JPY6.2 billion. M&D, and G&A expenses increased JPY2.5 billion. This is due to the fact that remote and real sales activities are on a recovery trend and our sales activities in China are becoming more active. As already explained, R&D expenses increased by JPY7 billion.

FY2021 Q2 Consolidated Financial Overview (Core)

Structure of Costs and Profit by Quarter



vs. Year on Year (2020 Q2)

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

M&D and G&A expenses: increase due to recovery in various activities

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

Operating profit: increase of +30.8 (+44.2%)

vs. Previous Quarter (2021 Q1)

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

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

Operating profit: increase of +35.1 (+53.7%)

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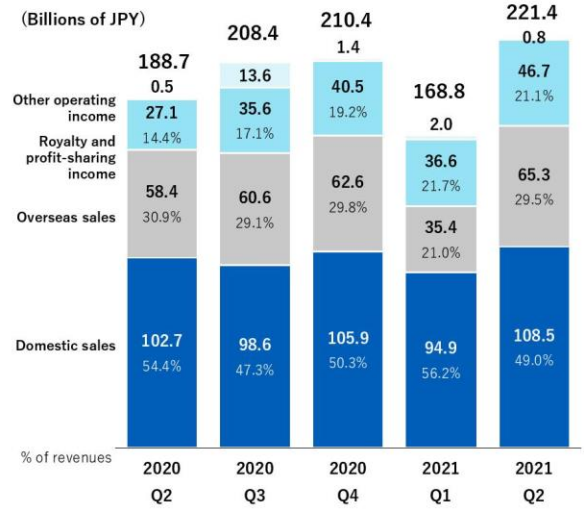
Starting on page 18, there are 3 more slides that show the quarterly trends.

The first slide shows the cost structure. Year on year comparison and quarter on quarter comparison is described on the right side.Common to both of them is the improvement in the cost of sales ratio, the increase in R&D expenses, and the significant increase in operating profit.

M&D and G&A expenses increased compared to the same period of the previous year due to the recovery trend in various activities. No specific comments on quarter on quarter changes, as spending tends to increase from the first quarter to the second quarter.

FY2021 Q2 Consolidated Financial Overview (Core)

Structure of Revenues by Quarter



vs. Year on Year (2020 Q2)

Domestic sales: increase due to sales growth of new products and mainstay products despite impact of generic drugs

Overseas sales: decrease in sales of Actemra, but increase in sales of Hemlibra and Alecensa

Royalty and profit-sharing income: increase in income for Hemlibra

vs. Previous Quarter (2021 Q1)

Domestic sales: increase mainly due to sales growth of new products and mainstay products, in addition to the trend of previous years

Overseas sales: increase in sales of Hemlibra

Royalty and profit-sharing income: increase in income for Hemlibra

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The next page, page 19, looks at the composition of revenue.

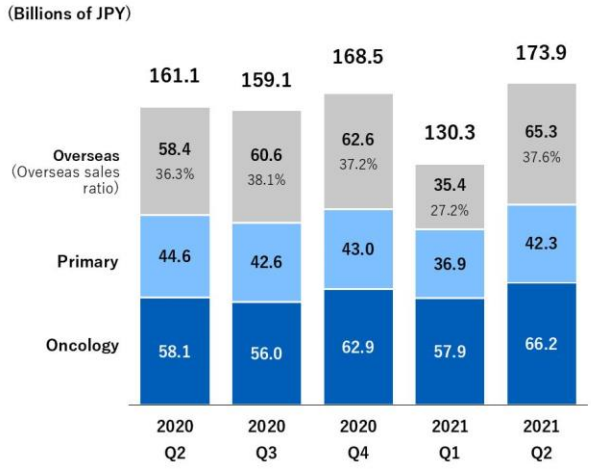
In Japan, despite the NHI price revision in April, performance in the second quarter was strong compared to the same period of the previous year or the previous quarter, thanks to mainstay and new products.

In this second quarter overseas, exports of Actemra declined YoY due to inventory adjustments from the beginning of the period, but exports of Hemlibra continued to grow.

Hemlibra is also growing in Roche territory, so our royalty income is continuing to increase.

FY2021 Q2 Consolidated Financial Overview (Core)

Structure of Sales by Quarter



vs. Year on Year (2020 Q2)

Overseas	Actemra: -16.0	Hemlibra: +16.8
	Alecensa: +4.3	
Oncology	Tecentriq: +7.6	Kadcyla: +1.5
	Herceptin: -1.5	
Primary	Edirol: -4.8	Enspryng: +2.2
	Hemlibra: +1.7	Actemra: +1.3

vs. Previous Quarter (2021 Q1)

Overseas	Hemlibra: +16.2	Alecensa: +9.0
	Actemra: +3.1	
Oncology	Tecentriq: +2.3	Avastin: +1.6
	Alecensa: +1.1	
Primary	Actemra: +1.8	Edirol: +1.8
	Hemlibra: +1.1	Enspryng: +0.8
	Tamiflu (Govt. stockpiles, etc.): -1.2	

20

This is the last page of the Quarterly Trends section, which shows sales by product area. See page 20. I will mainly explain where the increase and decrease are reversed between the year-on-year change and the quarter-on-quarter change.

First of all, by therapeutic area, the primary area showed a decrease year on year, and an increase in sales compared to the first quarter.

The main reason for this is that the generic version of Edirol was launched in the third quarter of last year, which caused a significant decrease in sales compared to the previous year. However, the demand for Edirol is gradually returning due to production issues at the other end, and sales are increasing compared to the first quarter.

By product, as I have already explained, Actemra exports related to provisional COVID demand were suppressed in the first half due to inventory adjustments, resulting in a year-on-year sales decrease of 16 billion yen. But quarter-on-quarter, sales were up by JPY3.1 billion. Although COVID exports did not start at the beginning of the fiscal year, it is growing due to the already acquired indications such as rheumatoid disease.

FY2021 Q2 Consolidated Financial Overview (Core)

P/L Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual 2021 Jan - Jun	Forecast 2021 Jan - Dec	Progress	2020 Progress *1
Revenues	**390.2**	**800.0**	**48.8%**	**46.8%**
Sales	304.1	631.0	48.2%	48.3%
Domestic	203.4	393.7	51.7%	50.0%
Overseas	100.7	237.3	42.4%	45.0%
Royalties and other operating income	86.1	169.0	50.9%	40.7%
Royalty and profit-sharing income	83.3	163.0	51.1%	41.3%
Other operating income	2.8	6.0	46.7%	37.3%
Cost of sales	**- 121.9**	**- 252.5**	**48.3%**	**48.2%**
(cost to sales ratio)	40.1%	40.0%	-	-
Operating expenses	**- 102.5**	**- 227.5**	**45.1%**	**45.1%**
M&D and G&A	- 42.7	- 96.0	44.5%	43.1%
Research and development	- 59.9	- 131.5	45.6%	46.6%
Operating profit	**165.8**	**320.0**	**51.8%**	**46.7%**
(operating margin)	42.5%	40.0%	-	-
Net income	**121.7**	**232.0**	**52.5%**	**47.6%**
EPS (JPY) *2	73.99	141.00	52.5%	47.6%

Domestic Sales
Progress steady in view of overall forecast

Overseas sales
Progress nearly in line with forecast

Royalty and profit-sharing income
Progress steady in view of forecast due mainly to income for Actemra

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 steady in view of forecast

*1 Jan – Jun progress versus Jan – Dec
*2 Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the fiscal year.

21

Now, I would like to take a look at the progress toward the full-year forecast announced at the beginning of the fiscal year. Please see page 21.

We have explained that the first quarter results were in line with our expectations, but this time, both revenues and profits are progressing well.

First of all, sales were strong in Japan, while overseas sales were in line with expectations. We will look at the details later.

As for royalties and other operating income, Actemra in Roche's territory, is growing by 18%, and royalty income grew accordingly. In the full-year forecast, we have not factored in COVID demand not only for exports but also for royalty income, so the rate of progress is high.

Other operating income are in line with forecast.

The rate of progress in cost of sales is almost in sync with the rate of progress in product sales, which is generally in line with forecast.

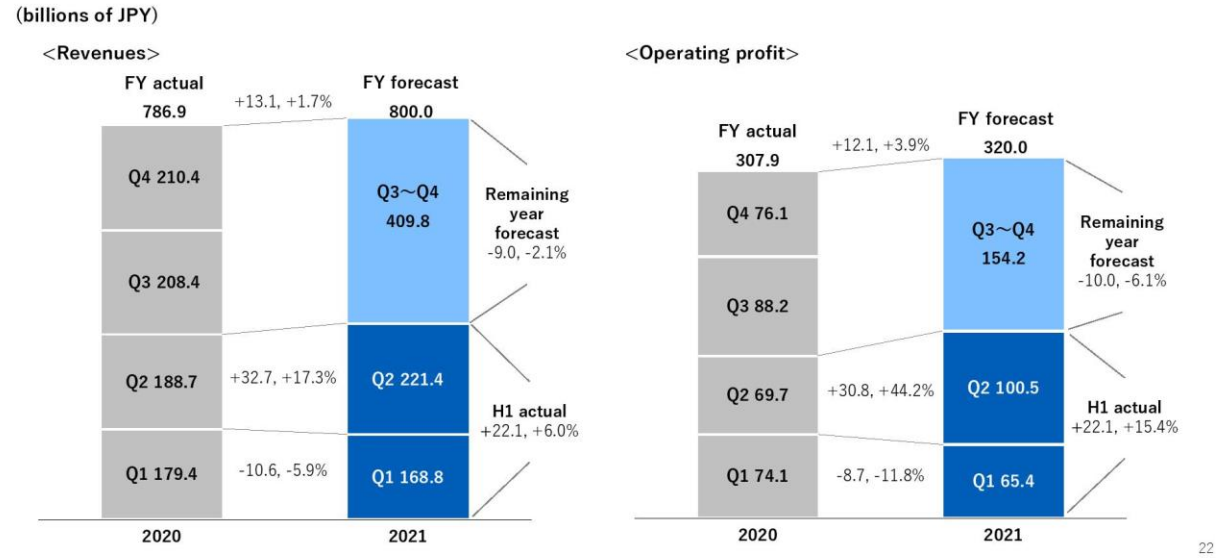
Expenses were almost as expected, with 45.1% progress, the same as last year.

As a result, operating profit was 51.8%, driven by sales in the domestic market and royalty income.

Now, I would like to explain the next slide to show progress toward the full-year forecast.

FY2021 Q2 Consolidated Financial Overview (Core)

H1 Actual and Remaining Year Forecast (Year on Year)



22

I think this slide will be my focus slide in this presentation, and I would like to start with the revenues on the left.

Growth was 6% in the first half. Subtracting the actual results for the first half from the full-year forecast, we are left with JPY409.8 billion, or a 2.1% decrease in sales for the second half. Progress in the second quarter is 17.3%, and we do not see any reason for a sudden slowdown in the second half. We do not expect any decrease in revenues.

Next, please take a look at the operating profit on the right, which also increased by 15.4% in the first half. Progress to the forecast is 44.2%. Based on these results, it is difficult to imagine a 6.1% decline in profit in the second half of the fiscal year. We expect the growth momentum of the first half to continue in the second half.

In addition, we expect to see a resumption of Ronapreve and exports of Actemra in the second half of this fiscal year due to COVID demand.

However, as far as we can estimate with confidence at this point in time, neither sales nor profits have yet reached the level that would require a revision, so we have decided to leave our earnings forecast unchanged.

FY2021 Q2 Consolidated Financial Overview (Core)

Sales Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual 2021 Jan - Jun	Forecast 2021 Jan - Dec	Forecast Progress	2020 Progress *
Sales	**304.1**	**631.0**	**48.2%**	**48.3%**
Domestic	**203.4**	**393.7**	**51.7%**	**50.0%**
Oncology	**124.1**	**226.7**	**54.7%**	**48.8%**
Avastin	39.2	60.5	64.8%	49.9%
Tecentriq	30.5	49.2	62.0%	44.3%
Perjeta	15.7	31.8	49.4%	49.9%
Alecensa	13.1	27.0	48.5%	47.3%
Kadcyla	7.2	13.3	54.1%	45.1%
Herceptin	5.2	10.9	47.7%	54.1%
Gazyva	2.1	5.7	36.8%	45.7%
Rituxan	2.4	5.2	46.2%	51.4%
Polivy	0.9	3.5	25.7%	-
Xeloda	1.3	2.7	48.1%	55.6%
Rozlytrek	0.4	0.9	44.4%	25.0%
Foundation Medicine	2.2	7.2	30.6%	42.9%
Other	4.1	8.7	47.1%	53.8%

(Billions of JPY)	Actual 2021 Jan - Jun	Forecast 2021 Jan - Dec	Forecast Progress	2020 Progress *
Primary	**79.3**	**167.0**	**47.5%**	**51.6%**
Hemlibra	18.7	51.7	36.2%	47.2%
Actemra	20.3	38.5	52.7%	48.6%
Edirol	7.6	17.3	43.9%	65.8%
Mircera	7.1	11.7	60.7%	48.6%
Bonviva	4.1	8.5	48.2%	47.2%
CellCept	4.1	8.3	49.4%	49.5%
Oxarol	3.0	5.5	54.5%	48.4%
Enspryng	3.5	4.0	87.5%	0.0%
Tamiflu(Ordinary use)	-0.1	0.8	-12.5%	87.5%
Tamiflu(Govt. stockpiles, etc.)	1.2	1.2	100.0%	70.3%
Other	9.9	19.6	50.5%	50.9%
Overseas	**100.7**	**237.3**	**42.4%**	**45.0%**
Hemlibra	33.2	89.7	37.0%	62.8%
Actemra	37.9	85.3	44.4%	45.1%
Alecensa	21.1	44.2	47.7%	37.9%
Enspryng	0.9	3.9	23.1%	7.1%
Neutrogin	4.8	8.7	55.2%	50.0%
Other	3.0	5.4	55.6%	45.8%

* Jan – Jun progress versus Jan – Dec

23

Next, on page 23, the progress of sales of products. I mentioned that domestic sales were strong and overseas sales were in line with our expectations.

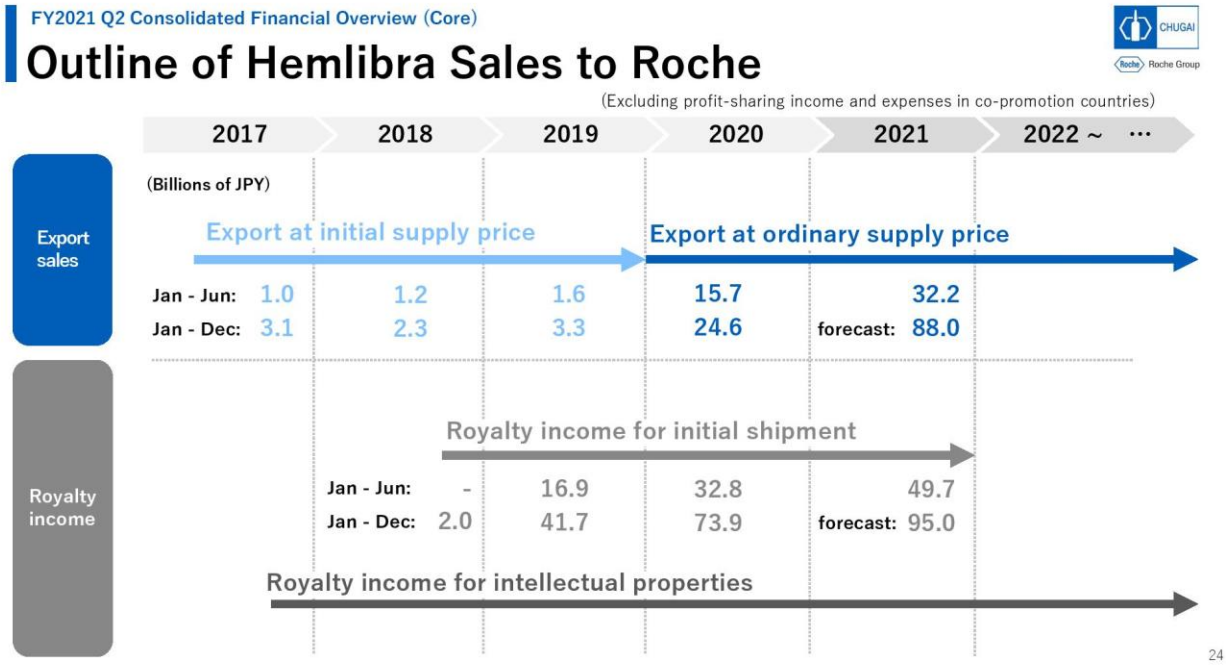
However, individual products may vary. In the oncology field, Herceptin, Gazyva, and Rituxan, which are shown in the middle row on the left, are slightly below the current forecast.

Foundation Medicine is progressing at 30.6%, but since we received approval for FoundationOne Liquid in March, we plan to grow in the second half of the fiscal year.

Next, in the primary area, the Hemlibra is slightly behind the forecast.

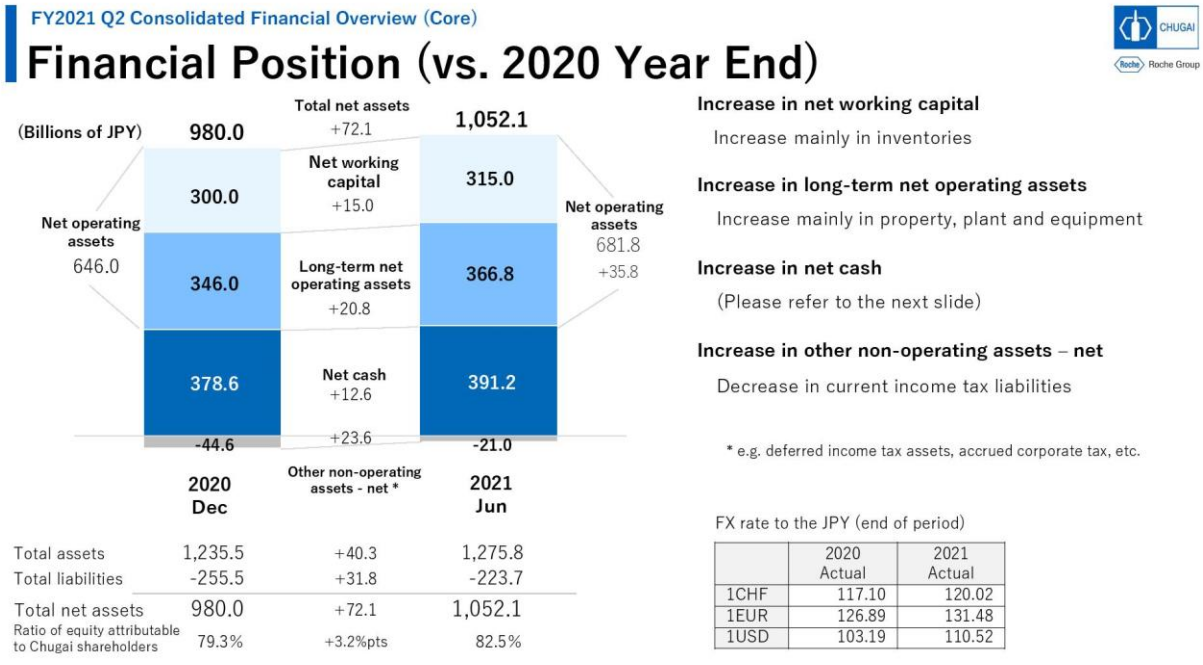
On the other hand, products that progressed ahead of forecast were the mainstay products in oncology, Avastin and Tecentriq, the top two on the left, and two lines below, Kadcyla, as well as Actemra and Enspryng in the primary area. Especially for Enspryng, the number of patients has been higher than expected, and the progress has been much higher than expected.

For overseas sales, the progress rate depends on the timing of exports, so it is difficult to say how the results compare to the previous year, but in the first half of this fiscal year, there were many firm orders, so the results were almost in line with the forecast. Exports are expected to increase toward the end of the fiscal year. We can also expect exports of Actemra due to COVID demand, which is not included in the forecast.



On page 24 is the usual slide of the Hemlibra sales to Roche. Exports at ordinary supply prices started last year, and shipments have been gaining momentum in terms of volume since the second quarter, so progress is in line with the forecast.

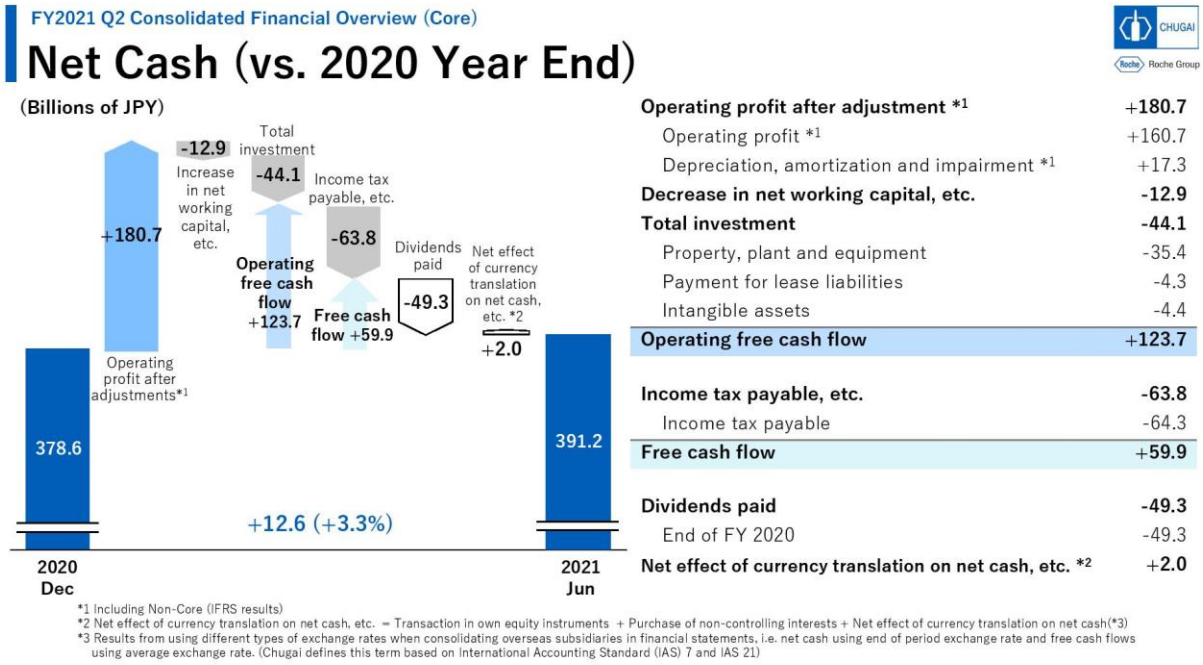
In addition, royalty income for initial shipment or royalty 2 was in line with the forecast, and we can say that the income of JPY95 billion for the full year is solid. This concludes the explanation of profit and loss.



On page 25 is the balance sheet, and if you look at the figure on the left from the top, net assets at the end of June were JPY1.0521 trillion, exceeding JPY1 trillion for the first time. Due to the increase in inventories and fixed assets, net operating assets increased by JPY35.8 billion from the end of last year, to JPY681.8 billion at the end of June. Net cash also increased by JPY12.6 billion to JPY391.2 billion. Net cash accounts for approximately 37% of net assets.

As you can see in the figure below, while total assets have increased, liabilities have decreased since the end of the fiscal year, so the reverse leverage has been effective and the ratio of equity attributable to Chugai shareholders has increased to 82.5%.

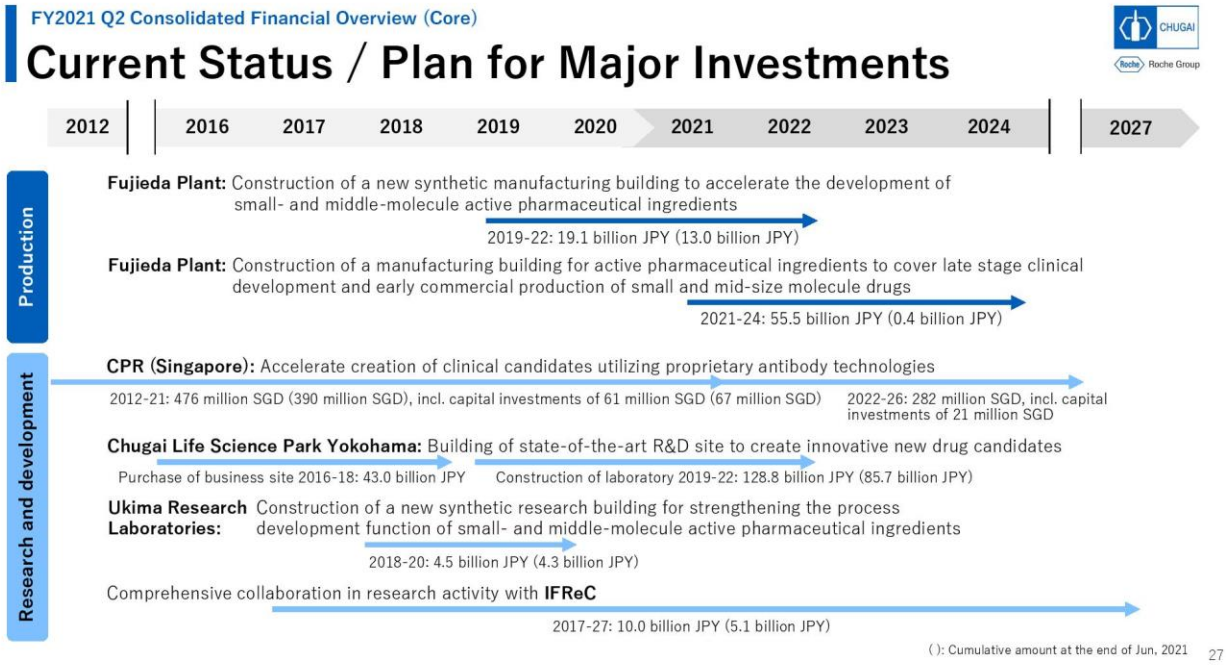
Let's take a look at the breakdown of the increase in net cash on the next page.



First of all, there was a cash inflow of JPY180.7 billion from operating activities. After subtracting the increase in net working capital and investments in the construction of new laboratories and manufacturing facilities, operating free cash flow was positive JPY123.7 billion.

As a result, net cash increased by JPY12.6 billion from the end of last year to JPY391.2 billion at the end of June.

We plan to use these cash reserves for future investments, and today we announced a new capital investment in a press release.



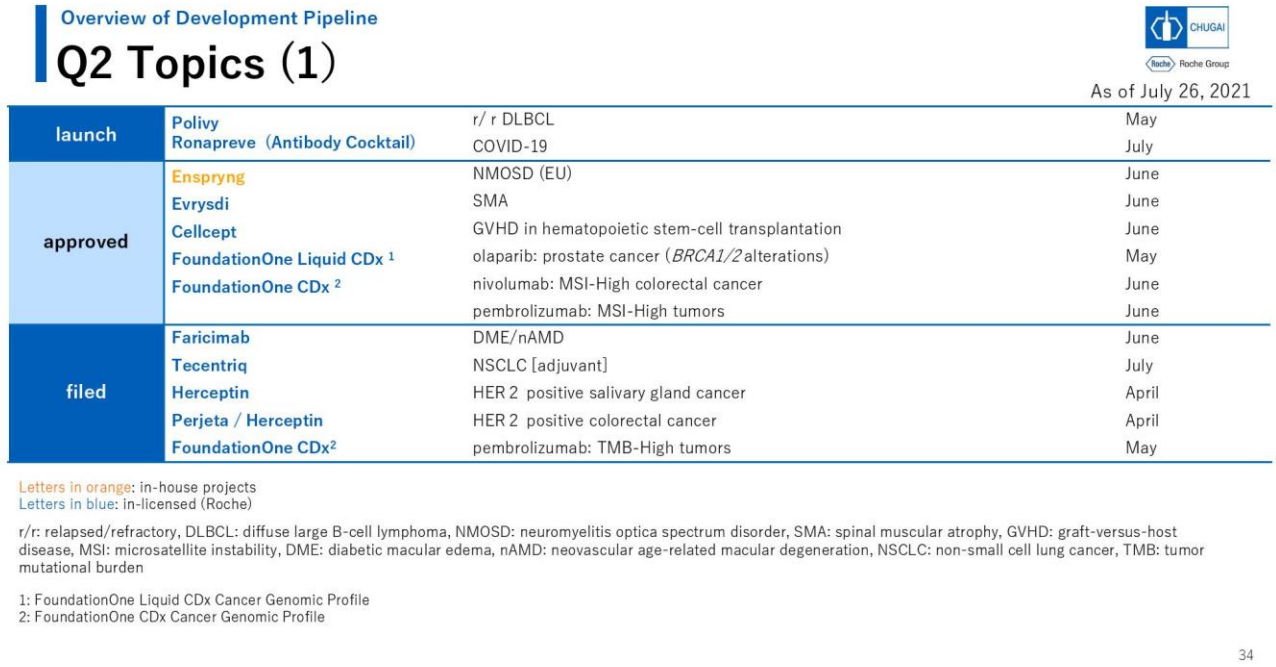
This is the status of our major investments, and there are four changes from the previous list.

First, we are updating our actual investments. Second, in production area, "facilities for pre-filled syringe form products at Utsunomiya Plant," and "Manufacturing building for antibody API at Ukima Plant" referred to as UK3 have been removed.Also, as Dr. Okuda explained earlier, we have invested JPY128.8 billion in the new research institute, which is about JPY300 million more than the previous investment for the environmental features.

Lastly, we have added a synthetic API manufacturing building for small and mid-size molecule drugs, which is being announced today. The project will be completed in 2024 with a total investment of JPY55.5 billion.

That concludes my presentation. Thank you very much.

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



Tetsuya Yamaguchi: Now, let's look at the development pipeline.

Please see page 34. First, I would like to summarize the topics for the second quarter.

In May, we launched Polivy for relapsed or refractory diffuse large B-cell lymphoma. The readout of the first-line results of the study is scheduled in the second half of the fiscal year. Based on the results, we will aim to submit an application by the end of this year.

As for Ronapreve, as mentioned earlier, it received special approval for emergency on July 19 as a treatment for mild to moderate COVID-19. This is the world's first pharmaceutical approval for this product. By working closely with the government and related businesses, we have been able to quickly start domestic supply.

We will then move on to approval.

First of all, Enspryng was successfully approved in Europe in June for the treatment of neuromyelitis optica spectrum disorders. This means that the approval has been completed in Japan, the US, and Europe.

This is the first oral drug that can be used for home treatment of spinal muscular atrophy (SMA), and we have just introduced its approval in June.

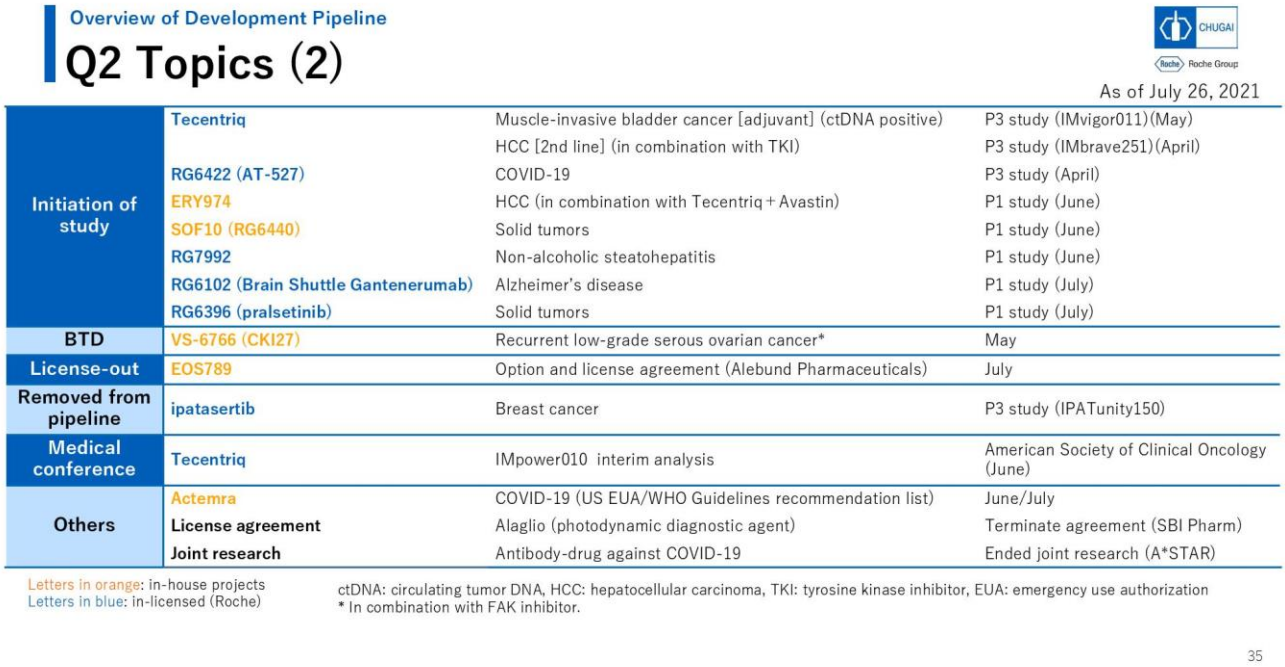
In addition, CellCept has been approved through a public knowledge-based application.

The FoundationOne Liquid CDx, which uses blood, and the FoundationOne CDx, which uses tumor tissue, have additional companion diagnostic functions as described for each.

As you know, in June, we completed the simultaneous filing of applications for faricimab for 2 indications: diabetic macular edema and age-related macular degeneration.

In addition, we have already submitted an application for Tecentriq as an adjuvant for non-small cell lung cancer in July, based on the results of the interim study analysis of IMpower010 at the beginning of this year.

In addition, Herceptin for HER2-positive salivary adenocarcinoma, and Perjeta/Herceptin for HER2-positive colorectal cancer, have been filed based on favorable results of investigator-initiated studies.



Overview of Development Pipeline

Q2 Topics (2)

As of July 26, 2021

Initiation of study	Tecentriq	Muscle-invasive bladder cancer [adjuvant] (ctDNA positive)	P3 study (IMvigor011)(May)
		HCC [2nd line] (in combination with TKI)	P3 study (IMbrave251)(April)
	RG6422 (AT-527)	COVID-19	P3 study (April)
	ERY974	HCC (in combination with Tecentriq + Avastin)	P1 study (June)
	SOF10 (RG6440)	Solid tumors	P1 study (June)
	RG7992	Non-alcoholic steatohepatitis	P1 study (June)
	RG6102 (Brain Shuttle Gantenerumab)	Alzheimer's disease	P1 study (July)
	RG6396 (pralsetinib)	Solid tumors	P1 study (July)
BTD	VS-6766 (CKI27)	Recurrent low-grade serous ovarian cancer*	May
License-out	EOS789	Option and license agreement (Alebund Pharmaceuticals)	July
Removed from pipeline	ipatasertib	Breast cancer	P3 study (IPATunity150)
Medical conference	Tecentriq	IMpower010 interim analysis	American Society of Clinical Oncology (June)
Others	Actemra	COVID-19 (US EUA/WHO Guidelines recommendation list)	June/July
	License agreement	Alaglio (photodynamic diagnostic agent)	Terminate agreement (SBI Pharm)
	Joint research	Antibody-drug against COVID-19	Ended joint research (A*STAR)

Letters in orange: in-house projects
Letters in blue: in-licensed (Roche)

ctDNA: circulating tumor DNA, HCC: hepatocellular carcinoma, TKI: tyrosine kinase inhibitor, EUA: emergency use authorization
* In combination with FAK inhibitor.

35

This is page 35.

As shown on page 35, we have started a global Phase 3 study of Tecentriq in postoperative patients with muscle-invasive bladder cancer and positive circulating tumor DNA with high risk of recurrence.

In addition, we have started a global Phase 3 study of Tecentriq in combination with lenvatinib or sorafenib as second-line treatment for hepatocellular carcinoma.

Next is AT-527, an oral RNA polymerase inhibitor, which is being used in a global Phase III study for COVID-19.

We have started a Phase Ib study of ERY974, a bispecific antibody against glypican-3 and CD3, in combination with Tecentriq and Avastin in patients with hepatocellular carcinoma (HCC) that expresses high levels of glypican-3, and will evaluate its safety and efficacy.

In addition, we have started clinical trials of SOF10, an antibody against latent TGF-β1, which was developed in-house for the treatment of solid tumors. This project has already been out-licensed to Roche, and I will explain the details later.

Chugai has introduced three projects from Roche, and has started Phase I.

RG7992 is a bispecific antibody that acts as an agonist against FGFR1 and KLB. In Phase Ib overseas, a decrease in hepatic fat content has been confirmed, and we expect improvement in liver pathology in the future.

Brain Shuttle Gantenerumab will be explained in detail later.

A Phase I study of pralsetinib, a RET inhibitor, for solid tumors has been initiated.

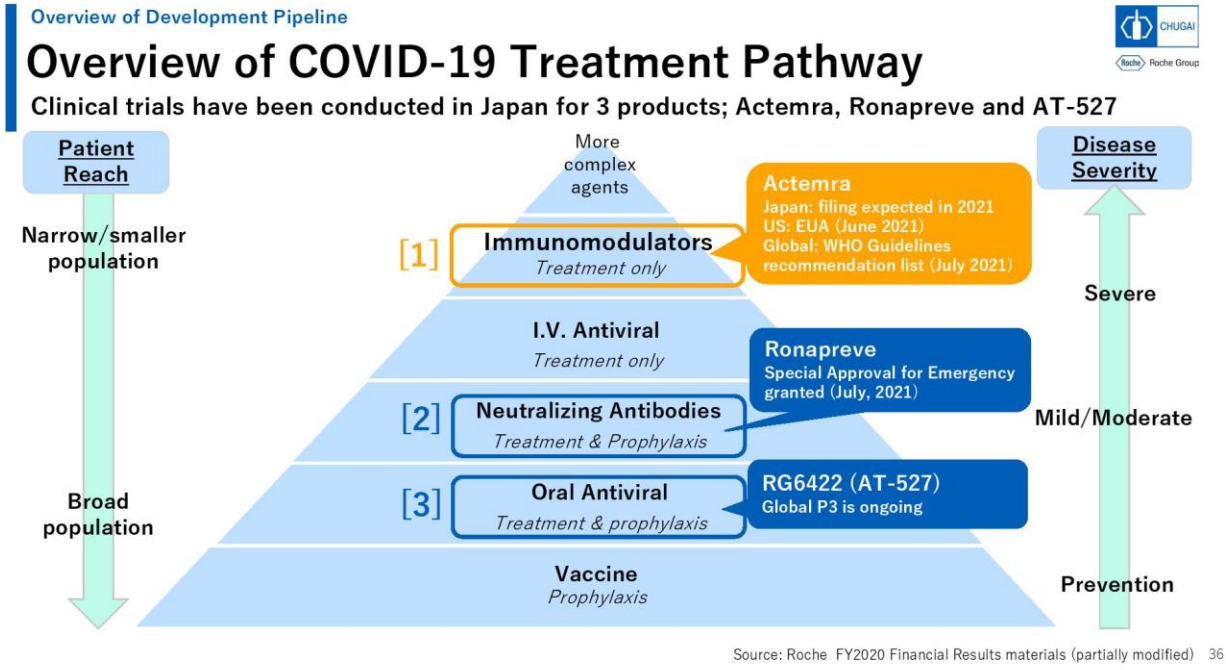
In addition, CKI27, an RAF/MEK inhibitor discovered in-house and licensed to Verastem Oncology, has recently been granted Breakthrough Therapy Designation (BTD) by the FDA.

The BTD designation was granted based on the results of an investigator-initiated trial of FAK inhibitor combination therapy for low-grade serous ovarian cancer.

In addition, we have concluded an option license agreement with Alebund of China for the exclusive worldwide rights to develop, manufacture and sell EOS789, a drug candidate for hyperphosphatemia discovered in-house.

Unfortunately, we have decided to discontinue the development of the AKT inhibitor ipatasertib for breast cancer.

The ASCO presentation on the Tecentriq, non-small cell lung cancer, adjuvant IMpower010 study will be presented later.



Next, let's go to page 36.

We are developing Actemra, Ronapreve and AT-527, 3 drugs with different positions.

We have just received FDA approval for emergency use and WHO guideline recommendation for Actemra.

The following is an overview of the Ronapreve project that has received special approval.

Overview of Development Pipeline

RONAPREVE: Antibody Cocktail

- The world's first regulatory approved treatment granted under Special Approval for Emergency as the first treatment for mild to moderate COVID-19 in Japan
- P3 study in mild to moderate I COVID-19 showed Ronapreve decreased hospitalization or death, and symptom duration
- Retain activity against emerging variants identified so far

severity	oxygen saturation	clinical condition
mild	96% or above	no pneumonia
moderate I	below 96% 93% or above	pneumonia dyspnea
moderate II	below 93%	oxygen therapy
severe		ECMO at the ICU setting

Medical guidance for COVID-19 Version 5.1 (MHLW)

Key results from REGN-COV 2067 study (P3)

	1,200 mg IV	placebo
	n=736	n=748
Patients with ≥1 COVID-19-related hospitalization or death through day 29		
Risk reduction	70% (p=0.0024)	
Number of patients with events	7 (1.0%)	24 (3.2%)
Time to COVID-19 symptom resolution		
Median (days)	10	14
Median reduction (days)	4 (p<0.0001)	

variant	activity
(α) detected in UK	no change
(β) detected in South Africa	no change
(γ) detected in Brazil	no change
(ε) detected in California	no change
(ι) detected in New York	no change
(δ / κ) detected in India	no change

Data from pre-clinical study conducted by Regeneron

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Ronapreve is a cocktail of 2 recombinant monoclonal antibodies, casirivimab and imdevimab, against the COVID-19 spike protein. It was created by Regeneron in the US and introduced by our company through Roche at the end of last year.

In the Phase III study in mild to moderate 1 patients with aggravation risk factors, as shown in the middle of the slide, the risk of hospitalization and death was reduced by 70%, and the time to symptom resolution was shortened by 4 days.

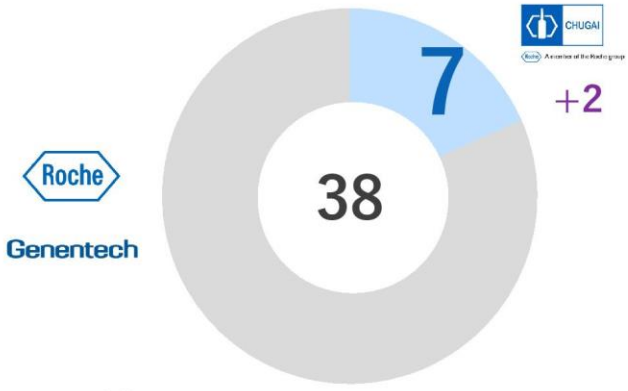
In addition, preclinical studies have confirmed that Ronapreve is effective against multiple mutant strains, including the Delta strain.

Overview of Development Pipeline

Creation of Innovative Drugs

9 indications / 6 projects in in-house projects have been granted US BTD

Chugai originated products account for about 20 percent of Roche group's BTD products



year	product	indication
2021	VS-6766 (CKI27)*	recurrent LGSOCI under development at Verastem Oncology
2019	nemolizumab	Prurigo nodularis under development at Galderma
2018	Enspryng	NMOSD
	Hemlibra	Hemophilia A (non-inhibitor)
2016	Actemra	giant cell arteritis
	Alecensa	ALK positive NSCLC [1st line]
2015	Actemra	Systemic sclerosis
	Hemlibra	Hemophilia A (inhibitor)
2013	Alecensa	ALK positive NSCLC [2nd line]

*in combination with FAK inhibitor (defactinib)

As of July 2021

BTD: Breakthrough Therapy Designation LGSOC: low-grade serous ovarian cancer

38

The status of the FDA's Breakthrough Therapy designation is summarized on page 38.

The Roche Group has acquired a total of 38 BTDs, which is one of the highest in the industry, and 7 of them were discovered by Chugai.

In addition, with CKI27 and nemolizumab out-licensed from Galderma, we have acquired 9 BTDs for Chugai products. We believe that this is proof of Chugai's high level of drug discovery capabilities.

Overview of Development Pipeline

Major Licensed-out Projects

CKI27 and OWL833 made good progress

As of July 26, 2021

Development code Chugai/generic name (Partner code)	Licensee	Indication	Stage	Mode of Action	Progress
CKI27 (VS-6766)	Verastem Oncology	LGSOC	Global: P2	RAF/MEK inhibitor	• US FDA BTD★ (recurrent GSOC, in combination with defactinib)
		NSCLC			-
CIM331/ nemolizumab	Global (Galderma) Japan (Maruho)	Atopic dermatitis	Global: P3	Anti-IL-31 receptor A humanized monoclonal antibody	-
			Japan: filed		• Filed in Q3 2020 (Japan)
		Prurigo Nodularis	Global: P3		• US FDA BTD
			Japan:P2/3		-
OWL833 (LY3502970)	Eli Lilly and Company	Type 2 diabetes	Global: P1	Oral non-peptidic GLP-1 receptor agonist	• Results of P1a were presented at ADA2021★ - Clinical data support **once-daily dosing** with **no food or water restrictions**. • 12-week **proof-of-concept study** in patients with type 2 diabetes **is ongoing**★ • Potential for **Phase 2** initiation in **late 2021/early 2022**★

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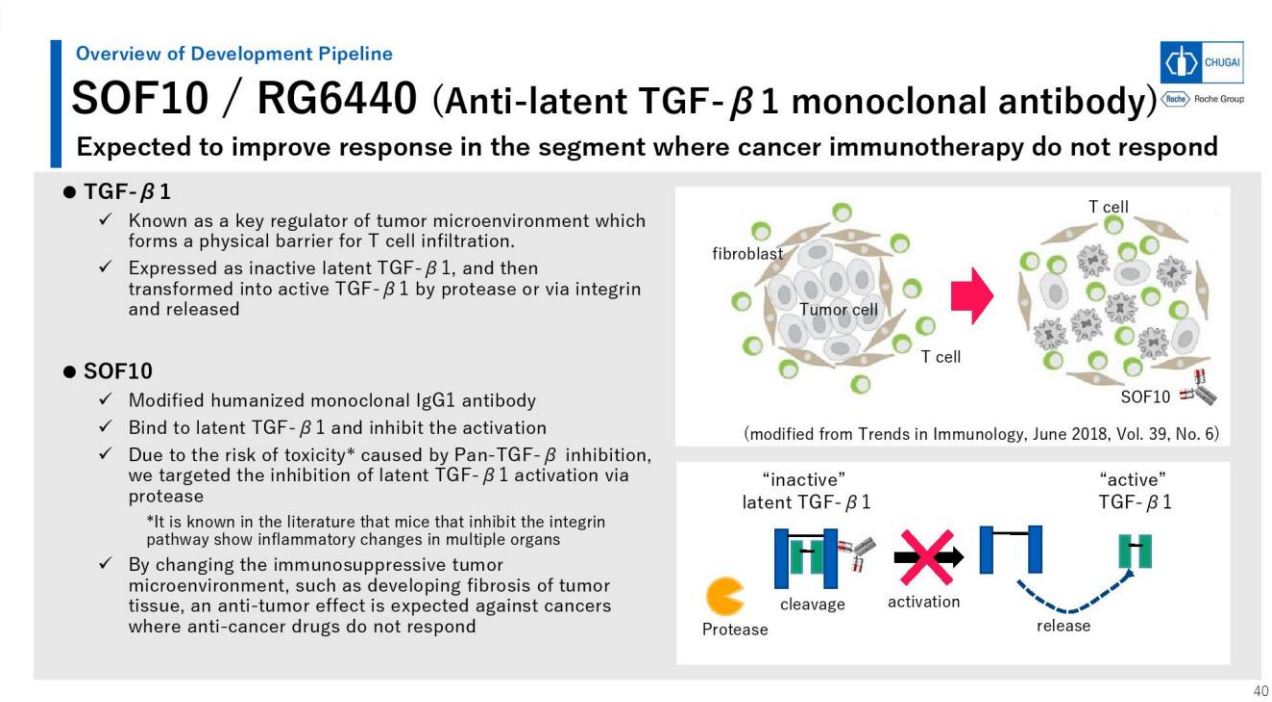
LGSOC: low-grade serous ovarian cancer NSCLC: non-small cell lung cancer ADA: American Diabetes Association

★: changes since April 22, 2021

Moving on to page 39, this slide shows the major projects for third-party licensing.

There has also been significant progress on OWL833, which is on the bottom row. OWL833 is a non-peptide oral GLP-1 receptor agonist. We have already out-licensed the drug to Eli Lilly and Company of the US, which has one of the world's top diabetes franchises.

In the Phase Ia study in healthy subjects, data supporting the target of once-daily oral administration and no food or drink restriction after taking the drug have been obtained. We are currently conducting a 12-week PoC study in type 2 diabetic patients. If the results are positive this fall, Eli Lilly has announced plans to initiate a Phase II trial later this year or early next year.



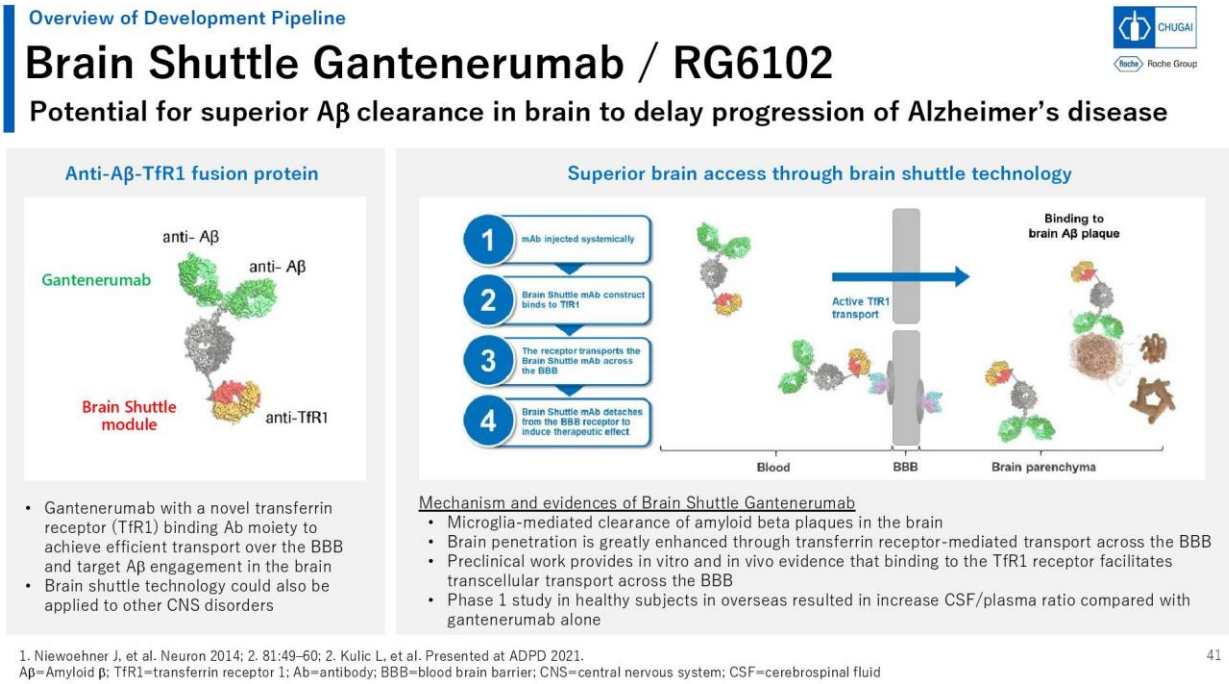
Next, starting on page 40, I would like to introduce 2 new projects that have entered clinical trials.

The first one is SOF10, which was created in-house.

SOF10 is expected to induce anti-tumor effects in the so-called immune excluded segment, where immune checkpoint inhibitors fail to work.

First of all, TGF-β is a factor that promotes barrier formation by fibroblasts, and as a result, it is thought to prevent T cells from infiltrating tumor cells. A latent form of TGF-β1 is activated by the protease or integrin pathway. In fact, non-clinical studies have shown that TGF-β inhibition can lead to toxicity, and the inhibition of the integrin pathway is strongly suggested in this mouse toxicity.

This drug was developed in the hope that by inhibiting protease-mediated TGF-β1 activation, toxicity caused by the inhibition of the integrin pathway could be avoided. Phase I trials have been underway since June, and we are also planning to proceed with development in collaboration with Roche where we out-licensed the compound.

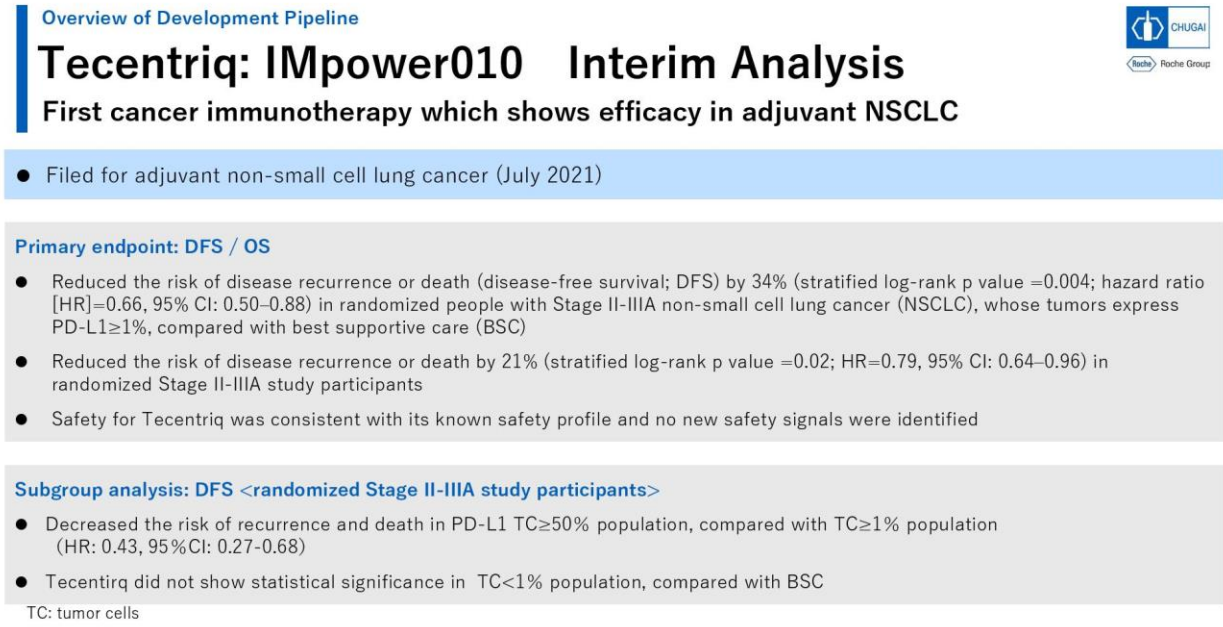


On the next slide, page 41, we introduce Brain Shuttle Gantenerumab/RG6102, which was introduced by Roche for the treatment of Alzheimer's disease.

Aducanumab has already been approved in the US for this disease area on a fast-track basis, and we are currently developing gantenerumab, which is also an antibody that aims to eliminate amyloid-β, in Phase III trials.

RG6102 is the next generation of Gantenerumab with Brain Shuttle technology, which is intended to enhance the migration in the brain. Specifically, by adding a portion of the transferrin receptor antibody to gantenerumab, the molecular design aims to improve brain migration by crossing the blood-brain barrier via the transferrin receptor.

In a Phase I study conducted overseas in healthy adults, RG6102 achieved a drug concentration ratio approximately 8 times higher than that of gantenerumab in the cerebrospinal fluid. We expect that this drug will be more effective than gantenerumab and existing high amyloid-β antibodies due to its improved migration into the brain.

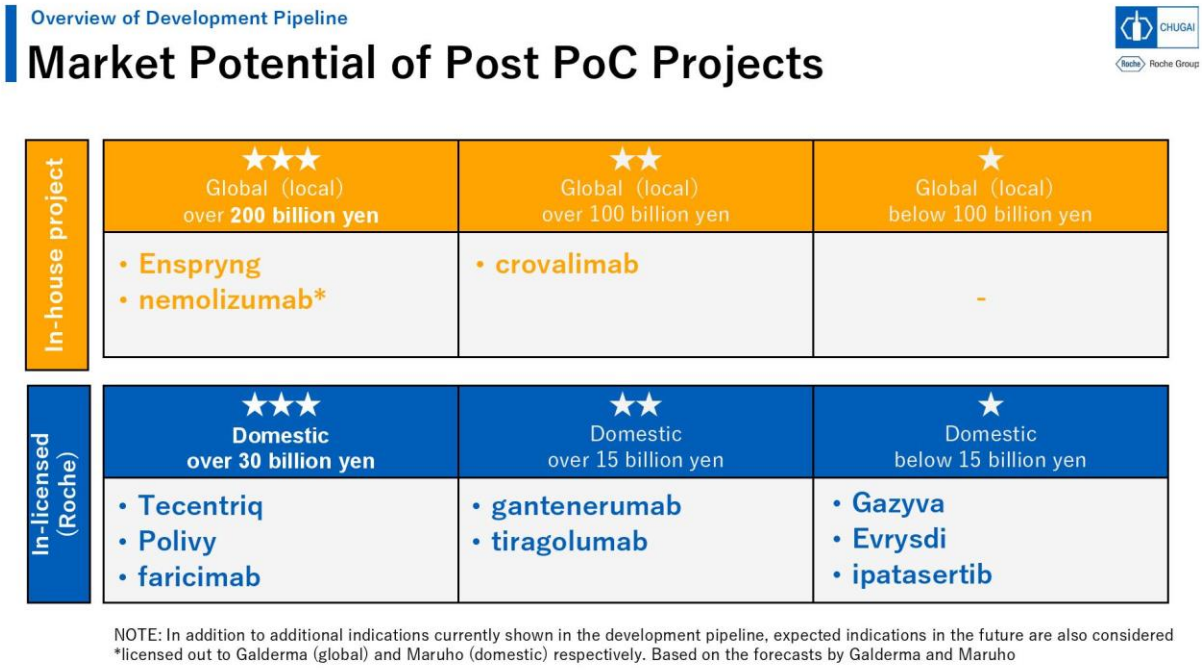


On page 42, we introduce the interim analysis results of the IMpower010 study of Tecentriq, the first cancer immunotherapy to demonstrate efficacy in adjuvant therapy for non-small cell lung cancer.

The IMpower010 study is a phase III multinational trial to compare the efficacy and safety of adjuvant therapy with best supportive care in stage IB to IIIA non-small cell lung cancer.

In a population of patients with stage II to IIIA PD-L1 expression of 1% or greater, Tecentriq reduced the risk of relapse or death by a hazard ratio of 34%. The safety profile of the product is the same as that of the product that has been approved so far, and no new concerns have been identified.

Based on the results of this interim analysis, we have already submitted an application for approval in July.



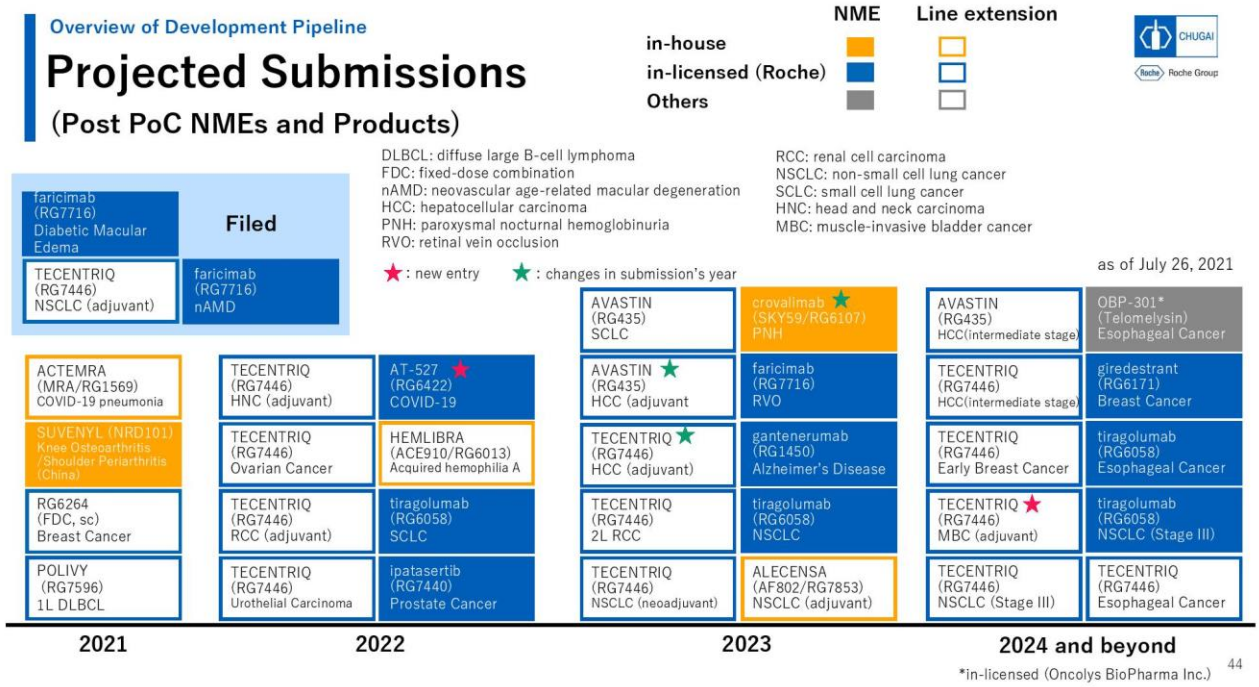
Page 43 shows the expected sales potential of new products and late-stage development products that will be the key to future growth, based on certain assumptions about the competitive situation and expansion of indications. I hope you will bear in mind that there is a high degree of uncertainty in all of these.

In the upper row, products created in-house are categorized according to the scale of local sales in the global market, including Japan.

We expect Enspryng, nemolizumab, and crovalimab to all be blockbusters with peak sales of over JPY100 billion. Nemolizumab has been classified based on the forecasts of Galderma and Maruho, our licensees.

Roche's in-licensed products are shown in the bottom row, which are categorized by the scale of domestic sales.

In addition to Tecentriq, Polivy and faricimab are all expected to be large, with peak sales of more than JP30 billion.



On page 44, you can see the schedule for future applications.

The red asterisk indicates that the application was added this time, and the green asterisk indicates that the application year was changed.

Overview of Development Pipeline

Projects under Development (1)

As of July 26, 2021

	Phase I	Phase II	Phase III	Filed
Cancer	GC33 / codrituzumab - HCC ERY974 - solid tumors RG7421 / cobimetinib - solid tumors RG7802 / cibisatamab - solid tumors RG7828 / mosunetuzumab - hematologic tumors AMY109 - solid tumors STA551 - solid tumors SPYK04 - solid tumors RG6026 / glofitamab - hematologic tumors RG7446 / Tecentriq (Actemra or tiragolumab combo) - pancreatic adenocarcinoma RG6194 / HER2-TDB - solid tumors OBP-301* (Tecentriq/Avastin combo) - HCC SOF10 (RG6440) - solid tumors ★ RG6396 / pralsetinib - solid tumors ★	OBP-301* - esophageal cancer	AF802 (RG7853) / Alecensa - NSCLC (adjuvant) RG7596 / Polivy - DLBCL RG7440 / ipatasertib - prostate cancer RG6264 (Herceptin+Perjeta) - breast cancer (Fixed-dose combination, subcutaneous injection) RG6058 / tiragolumab (Tecentriq combo) - SCLC - NSCLC - NSCLC(stage III) - esophageal cancer RG6171 / giredestrant - breast cancer RG435 / Avastin (Tecentriq combo) - SCLC - HCC (adjuvant) - HCC (intermediate stage) RG7446 / Tecentriq - NSCLC (neoadjuvant) - NSCLC(stage III) - urothelial carcinoma - MIBC (adjuvant) ★ - RCC (adjuvant) - RCC - early breast cancer - ovarian cancer - HCC (adjuvant) - HCC (intermediate stage) - HNC (adjuvant) - esophageal cancer	RG7446 / Tecentriq - NSCLC (adjuvant) ★

In principle, completion of first dose is regarded as the start of clinical studies in each phase.
★: Projects with advances in stages since April 22, 2021
Letters in orange: in-house projects
Letters in blue: in-licensed (Roche)
*in-licensed (Oncolys BioPharma Inc.)

DLBCL: diffuse large B-cell lymphoma
HCC: hepatocellular carcinoma
SCLC: small cell lung cancer
RCC: renal cell carcinoma

NSCLC: non-small cell lung cancer
HNC: head and neck carcinoma
MIBC: muscle-invasive bladder cancer
TDB: T cell-dependent bispecific

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Overview of Development Pipeline

Projects under Development (2)

As of July 26, 2021

	Phase I	Phase II	Phase III	Filed
Bone & Joint			NRD101 / Suvenyl (China) - knee osteoarthritis /shoulder periarthritis	
Autoimmune	RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG6100 / semorinemab - Alzheimer's disease RG6102 - Alzheimer's disease ★	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease	
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II) RG7992 - non-alcoholic steatohepatitis ★		RG7716 / faricimab - retinal vein occlusion MRA (RG1569) / Actemra (JPN) - COVID-19 pneumonia ACE910 (RG6013) / Hemlibra (JPN) - Acquired hemophilia A SKY59 (RG6107) / crovalimab - PNH RG6422 - COVID-19 ★	RG7716 / faricimab - DME ★ - nAMD ★

Letters in orange: in-house projects
Letters in blue: in-licensed (Roche)
In principle, completion of first dose is regarded as the start of clinical studies in each phase.
★: Projects with advances in stages since April 22, 2021

PNH: paroxysmal nocturnal hemoglobinuria
nAMD: neovascular age-related macular degeneration
DME: diabetic macular edema

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The next 2 slides show the development pipeline.

Overview of Development Pipeline

FoundationOne CDx Cancer Genomic Profile

Companion diagnostic indications

As of July 26, 2021

* Underlined are the companion diagnostic features and relevant drugs currently filed for regulatory approval

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
KRAS/NRAS wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite Instability-High		nivolumab (genetical recombination)
Microsatellite Instability-High	Solid tumors	pembrolizumab (genetical recombination)
Tumor Mutational Burden-High		pembrolizumab (genetical recombination)
NTRK1/2/3 fusion gene		entrectinib, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

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Overview of Development Pipeline

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of July 26, 2021

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib

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Also shown is the status of the companion diagnostic function for FONE CDx and FONE Liquid CDx. I hope you can refer to it if necessary.

This is the end of the presentation.

Question & Answer

Sasai: We will now move on to the question-and-answer session.

For the question-and-answer session, Mr. Hidaka, Vice President and Head of Marketing and Sales, will also be present.

We would like to limit the number of questions to 2 per person.

When it is your turn to ask a question, we will call your name. If you have any questions, please let us know your company name and your name.

Now let's move on to the first question. Mr. Kohtani of Nomura Securities, thank you very much.

Kohtani: I'm Kohtani from Nomura Securities.

This may be a bit of a specific question, but I wanted to confirm what is included in the post-PoC project potential on page 43.

I heard that you are factoring in the expansion of indications based on certain assumptions, so with regard to Enspryng, after the PoC, NMOSD is naturally included, as well as generalized myasthenia gravis. Is it correct to assume that nemolizumab has already been disclosed, so it includes prurigo nodularis and atopic dermatitis, and that crovalimab probably includes aHUS and PNH at this point in time? Or is it the same as it has always been, or is it just the indications that are written in your current documents?

Tetsuya Yamaguchi: Thank you very much for your question. I am Yamaguchi.

First of all, the evaluation of the potential includes the indications for which we are planning to conduct trials in the future, so please understand that some of the potential indications that you mentioned earlier are included in this evaluation.

However, for strategic reasons, I would like to refrain from mentioning specific disease names or what is included in the list. That is all.

Kohtani: Nemolizumab has some unusual indications, such as prurigo nodularis, and although it might not seem intuitive, there is data supporting the indication of generalized myasthenia gravis for Enspryng.

Crovalimab is a bit small, I must admit. This may be the case with PNH or aHUS. We have known for a long time that complement is involved in nephropathy, IgA nephropathy, and other rare kidney diseases, however, do I understand correctly that those diseases are not included in the evaluation?

Tetsuya Yamaguchi: It would be difficult to go into details, but we believe that the potential is as you pointed out, and while we have included several factors such as the competitive environment and the appropriateness of development, we have presented the potential at this 2-star level.

In the future, if any specific expansion of the indications becomes a reality, we will of course review it, and I hope you understand that this is just our estimate at the moment.

Kohtani: Understood.

Secondly, and lastly, gantenerumab, I'm sorry, this chart of yours was probably presented in 2018, I think it was IBI 18, and it hasn't been updated since then, that's my understanding. Gantenerumab at that time, I believe it said over JPY20 billion. Normally, when a drug with a similar mechanism is approved in the US, confidence in the drug would increase, but I wonder if they are taking a slightly smaller view of this drug because it has been released first.

Also, one of the biggest mysteries of gantenerumab is that it is administered by subcutaneous injection of 1,200 mg, and the antibody concentration is usually 100 mg to 200 mg per ml. I think that the maximum dose for subcutaneous injection is about 1.5 ml, so this would require injections in 4 to 8 places, and considering the fact that the dose would have to be titrated upwards over 9 months, I wonder if this would make the drug difficult to use. Can you make any comments about this area? This is the last one.

Tetsuya Yamaguchi: Gantenerumab, since the last time we showed you this chart, the competitive environment has changed a lot and the situation has also changed. Although there was a recent development of aducanumab in the US, our stance is that we will continue to confirm its efficacy.

In addition, there is the issue of diagnosis, the issue of NHI prices, and the issue of what cases the drug will be approved and reimbursed for.

Kohtani: Is the idea, or the comment itself, that you just mentioned, that you have to inject in 4 to 8 places under the skin, is that wrong? Do you have any comments?

Tetsuya Yamaguchi: I will refrain from answering that part of the question.

Kohtani: I understand. Thank you. That's all.

Sasai: Thank you very much.

I would like to move on to the next question. Mr. Hashiguchi of Daiwa Securities, please.

Hashiguchi: This is Hashiguchi from Daiwa Securities. Thank you.

The first is the impact on Ronapreve's business performance. On page 5, in both the upper left and lower right-hand side of the table, the upside factors are written before those for Ronapreve rather than Actemra, so is it correct to say that the size of the deviation from the initial forecast is likely to be larger for Ronapreve than for Actemra?

Okuda: Mr. Hashiguchi, this is Okuda. Thank you for your question.

The meaning and positioning of the slides on page 5 are not arranged in any particular order, so you guessed the relationship between Ronapreve and Actemra with a very deep insight. It is not intended or implied to indicate the size of sales or upside potential. Please understand.

Hashiguchi: Yes, I understand.

The second point is about the future of Actemra. In the past, you have mentioned the possibility of adjusting the unit price if approval is obtained, but in response to the recent EUA in the US, what kind of measures are likely to be taken in the future?

Itagaki: I'm Itagaki.

In principle, the export unit price is determined by the weighted average of Roche's foreign sales in the previous year. In the past, off labels were used, and this time, position statements have been issued in the UK

and France, and EUAs have been issued in the US, but in principle, they are based on those statements. In principle, we will consider what will happen in the next fiscal year and beyond based on that contract, so we do not expect any impact in the current fiscal year.

Hashiguchi: In that case, the unit price of your company's products for the next fiscal year will change depending on how Roche sells them. Based on the composition of the region, we can guess that the average unit price will be lower than before. More than that, is there a situation where the unit price of sales in each region is decreasing for Roche?

Itagaki: We are not in a position to talk about the unit price information of Roche's external sales, so I would like to refrain from answering that question.

Hashiguchi: That's all. Thank you very much.

Sasai: Thank you very much.

The next speaker is Muraoka from Morgan Stanley Securities.

Muraoka: Hello. This is Muraoka from Morgan Stanley. Thank you.

The first question is about business performance. Regarding business performance in relation to the next fiscal year, you mentioned that there is a high possibility of an upward revision of the JPY320 billion forecast for the current fiscal year, and I understand the reasoning behind this.

Considering the next fiscal year. Royalties of at least JPY95 billion will disappear entirely, and the biosimilar risk to Actemra will possibly have to be considered. On the other hand, Alecensa and Hemlibra are in a great situation. In addition, I wonder if we can expect to see a government stockpile of AT-527 next year.

I would appreciate it if you could give me some direction as to whether it is possible for your company to increase profits in the next fiscal year. This is the first question.

Itagaki: Thank you very much for your question.

As there are many uncertainties in the forecast for the current fiscal year, it is a little early to talk about how we think about the next fiscal year based on the assumptions we have made.

Obviously, what we know is that in Japan, price revisions are conducted every year, and there is also the impact of generics and biosimilars. On the other hand, Avastin and Tecentriq are doing very well, and Hemlibra is still in the process of growth, so there are positives and negatives, and we will continue to refine our plans for next year depending on how we place the remaining uncertainties.

Muraoka: I understand. I thought that would probably be the answer.

Second, you mentioned stockpiling AT-527, but your company is also participating in global clinical trials for this, and the results will be available by the end of the year or early next year. If all goes well, I think we will naturally be talking about stockpiling, leaving aside whether your company can include stockpiling in the forecast for the next fiscal year, January or February, but I would like to know if that is the correct understanding.

Looking back, when you were stockpiling Tamiflu about 10 years ago, there was talk of manufacturing it in Japan.

Tetsuya Yamaguchi: I would like to explain.

In conclusion, I think the reality is that nothing at all has been decided yet. First of all, it depends on the test results, but whether the government will purchase it or not will depend on the government's future thinking.

In addition, the current situation is still a blank sheet of paper, including the question of how much of the infection is currently infected, whether it will be used for treatment, and whether stockpiling will be necessary. That's all.

Muraoka: I understand what you are saying, but I think the preparations for manufacturing must have been made well ahead of schedule, probably because of the volume, but is that area completely blank?

Tetsuya Yamaguchi: Roche will be manufacturing the product, but we have not yet obtained the results of the Phase III trials. Furthermore, as I mentioned earlier, the results of the trials are expected to be available in the first half of next year, but even if the data are positive, it will take quite some time before the application is submitted and approved.

In such a situation, there is a question as to whether or not the government will take any action, taking into account such factors as the extent to which manufacturing capacity can be prepared on a global basis, but in any case, at this stage, the response is to be confirmed.

As for the manufacturing side, I understand that Roche will examine and prepare the data as it becomes available.

Muraoka: I understand. That's all. Thank you.

Sasai: Thank you very much.

Next, Mr. Wakao from JPMorgan Securities, please go ahead.

Wakao: This is Wakao of JPMorgan. Thank you.

The first is related to Mr. Kohtani's question earlier, but the peak sales of Enspryng are over JPY200 billion, which I think is a very high figure. In the case of NMOSD, the number of patients is very small, so I did not expect the number to be as high as it is now, but can I assume that the contribution of generalized myasthenia gravis (gMG), which has recently started or is about to start, will be significant?

At the same time, you will be competing with Alexion's products, so again, what are Enspryng's strengths in gMG? Are the dosing schedule and the dosing regimen still the strong points here? This is the first question.

Tetsuya Yamaguchi: Thank you very much. This is Yamaguchi.

First of all, as you pointed out, the sales forecast is based on the potential disease groups, including not only NMOSD but also gMG and beyond.

In addition, the differentiation of gMG from Alexion's products will be an issue to be resolved in the future, but we believe that gMG can be positioned quite differently in terms of inhibiting IL-6. That is all.

Wakao: Thank you very much. I understand that you have included several adaptations, but in terms of composition, is it correct to assume that gMG will be the largest?

Tetsuya Yamaguchi: I'm sorry, but I'm not going to disclose that level of detail.

Wakao: I understand. Thank you.

Also, regarding AT-527, in the global MORNINGSKY trial completed in August, I think, but the results are expected in the first half of next year. In addition to this global clinical trial, will you also be applying for other trials in Japan?

Also, regarding the target patients, the clinical trial does not limit the patients to those who are at risk of becoming seriously ill, so I think it is correct to say that a wide range of patients, from mild to moderate, are included without being limited by the risk of becoming seriously ill.

Tetsuya Yamaguchi: Yes. We would like to keep details of CDP undisclosed. Also, regarding the progress of the test, from a global perspective, the results will not be known until the first half of next year. This includes the areas where the situation is necessarily different from the previous announcement.

In addition, the positioning of this oral viral drug is to be developed for mild to moderate disease, which is the first step in our testing and development intentions.

Wakao: Thank you very much. That's all.

Sasai: Next, Mr. Yamaguchi from Citigroup Global Markets Japan, please go ahead.

Hidemaru Yamaguchi: I'm Yamaguchi from Citi. Thank you.

My first question is about the verbal explanation given by the President at the beginning of the presentation about the target patients for Ronapreve. I think he said that the risk of severe disease is 20% to 40%, and 10% to 20% are asymptomatic. I'm sorry, I didn't hear the part about where it was targeted. Could you please check that one more time?

Okuda: Thank you for your question, Mr. Yamaguchi. I am Okuda. To explain one more time, the number of patients so far this year is about 570,000, and we are predicting that the number of people infected with coronavirus in the second half of this year will be between 400,000 and 700,000.

From there, we estimated how many patients had risk factors for severe disease, and it was about 20% to 40%. There are many factors that contribute to the severity of the disease. There are people with pre-existing conditions, the elderly, and so on. That's a rough estimate.

Ronapreve is administered to those who have symptoms. As you may know from clinical trials, we start administering the drug within 7 days of the onset of symptoms. In other words, asymptomatic patients are not eligible. These people are excluded. I'm guessing that this is about 10% to 20%, which is also a rough reading.

Hidemaru Yamaguchi: So that means half.

Okuda: Well, rather 10% to 20% of all people infected with the coronavirus are asymptomatic.

Hidemaru Yamaguchi: I understand. I see.

Okuda: And then there are those who are excluded from treatment, those who are severely ill, or those who are not covered, those who are above moderate 1 as written in the package insert, and those who are more severely ill, those who are designated as moderate 2 or 3. In addition, the Ministry of Health, Labor and Welfare (MHLW) has issued an administrative notice stating that patients with these risk factors for serious illness should be hospitalized. So, if there is an overlap, but the patient is still hospitalized, we can calculate it this way.

It's very difficult to understand, but I don't know what percentage it is, because I haven't done the calculations, but it's about this level.

Hidemaru Yamaguchi: I understand. So, you look at 20% to 40% of all people infected, minus 10% to 20%, and your target is a part of that remaining population.

Okuda: Yes.

Hidemaru Yamaguchi: Thank you very much.

I would also like to ask one more question: I believe that your company has been continuously commenting on the mid-size molecule compounds. It is also a point in the mid-term plan, and the expectations of blockbuster candidates are high. This time, you have decided to make a large-scale investment in a new factory.

Externally speaking, I don't think there has been much discussion about whether or not to include one in the mid-term plan this year. Your company is starting to invest so much and I know that your company is expecting a lot. I think it would be difficult to see the timing of showing this to the outside world, or explaining the technology, because the factory won't be ready for a while yet.

I think it would be great for your company to send out a strong message that there is a new compound in the future, but I wonder if you are gaining more confidence in this direction, including this investment. And will the first clinical trials and explanations of the technology take place this year? How about this area?

Okuda: Thank you for your question, Mr. Yamaguchi.

As for the question about the mid-size molecules, as we have explained from the beginning, the first project is scheduled to enter clinical trials by the end of this year. As for the plan to start within this year, we have been working on non-clinical trials, and there is no change in the plan so far. We will start clinical trials by the end of this year.

I would be happy to provide an explanation to the outside world about the full scope of these molecules when the appropriate time comes. This investment in FJ3 and Fujieda plant is also a concrete investment that shows that we have high expectations for mid-size molecules, so I hope you can understand it that way. That's all.

Hidemaru Yamaguchi: That's all from me.

Sasai: Thank you very much.

The next speaker is Mr. Sakai from Credit Suisse Securities.

Sakai: This is Sakai from Credit Suisse.

The table on page 24 is Hemlibra Royalty 2, and I'm wondering if we won't have to look at it next year. What I would like to ask is whether this JPY95 billion can be cut off in FY2021 or not. I have confirmed this many times, but the time is approaching, and conversely, if it can be extended, you can create a model where the so-called Royalty Cliff will be extended to 2022.

If, for lack of a better word, it becomes zombified and something else keeps coming up, I think it could be seen as a risk in a sense.

Itagaki: Thank you, Mr. Sakai.

As I write here, this year, as announced at the beginning of the fiscal year, royalties are JPY95 billion. As a result, the results for the first half of the fiscal year were in line with our expectations, and at this point, we believe that we will receive JPY95 billion in revenue this year. A deviation could mean that the JPY95 billion figure is not attained. As a result, we don't want to postpone the project to the next year or anything like that. This means that we believe we will attain the JPY95 billion target.

We are now in the process of reconfirming this with Roche for the second half of the fiscal year, so if there are any changes at that point, we will make an announcement at the appropriate time.

Sakai: I understand. Thank you.

Also, regarding gantenerumab, I think about 30% of the questions in the Roche conference call were about this drug or antibody. Roche has said quite definitively that there will be no movement like an application for approval until the second half of 2022, when the GRADUATE 1 and 2 trials are completed. I'm not going to ask you about that, but I would like to ask you about the timing of Roche's global Phase III application in addition to the domestic Phase I application. If the results are favorable, whether the domestic application can be filed at about the same time as Roche's application. And the applicant is via Chugai, is that correct? Please tell me about this point.

Tetsuya Yamaguchi: This is Yamaguchi.

First of all, as for the applicant, Chugai is developing the project in Japan, and Chugai is the applicant. As for the timing of application, as shown in the application schedule on page 44, we are planning to apply in 2023.

However, we believe that the discrepancy in the timing of this application with Roche will not be so large, so we will be able to apply with the same data. That's all from me.

Sakai: I understand. Thank you very much.

Sasai: Next, Mr. Akama from the Nihon Keizai Shimbun, please go ahead.

Akama: Thank you. My name is Akama and I work for the Nihon Keizai Shimbun. Thank you.

With regard to the Fujieda Plant, I would like to ask you about the plant for APIs for small and mid-size molecule drugs that you have announced capital investment in. First of all, what is the planned scale of production? The first question, which can be qualitative, is whether it will be enough to cover the entire range of products that will be focused on in the future.

The second question is about the significance of manufacturing APIs domestically, which I think has implications for strengthening the supply chain. Due to the friction between the US and China and COVID, I think there are more and more cases of international fragmentation.

Okuda: Thank you for your question. This is Okuda.

I think the first question was about the capacity of FJ3 at the Fujieda plant. With FJ3, we have the capacity to take on the late-stage development of small and medium molecules as well as early-stage commercial production. Since we will have multiple lines, we cannot limit the number of items, but we have the capacity to cover initial commercial production for a small number of items.

The second question is about the significance of domestic production and manufacturing. The coronavirus pandemic has certainly reaffirmed the importance of the supply chain.

On the other hand, Chugai has 3 main plants in Japan, and we are considering a plant construction plan that makes use of the skills and experience of the human resources within those plants. In particular, the Fujieda plant specializes in the commercial production of small molecule compounds, and we will use our exponents there to produce high-potency small and mid-size molecule drugs. As part of this strategy, we will produce in Japan.

As a result, the supply chain in Japan will be strengthened, and the risk of supply chain fragmentation in other countries will be mitigated.

Akama: Could you make one more point? In the supply of generic drugs, I think there is some kind of shipment adjustment of Edirol or other drugs. Please let me know if there is a way to solve this problem or if you have any countermeasures. Thank you.

Okuda: Thank you for your question. The question now is whether there are any measures in production or supply to deal with the fact that shipments of Edirol and other products are being adjusted.

Triggered by the production and supply adjustments by the

generic manufacturers, we are adjusting the shipments. We are trying our best to produce and supply as much as possible within our production capacity so as not to cause any inconvenience to patients and medical institutions.

At this point, I would like to refrain from commenting on what kind of response we can take and by when, as there is also the factor of recovery of production by generic manufacturers.

Akama: Thank you very much.

Sasai: I'm sorry, but my next question will be the last.

Mr. Mitsutake, Nihon Keizai Shimbun, please continue.

Mitsutake: This is Mitsutake from the Nikkei Shimbun. Thank you.

Please tell me about the API manufacturing building in Fujieda. At JPY55.5 billion, this is the largest capital investment in the company's history.

Okuda: The main reason the investment is so high is to build a facility that can handle small and mid-size molecules compounds with high pharmacological activity. When we handle compounds with high pharmacological activity, we have to build various facilities to protect the safety of the factory employees who work with them.

In addition, we need to have facilities that do not release such high-potency substances into the environment. Such double safety measures are necessary, and that is the main reason for this high investment.

Of course, as I explained earlier, the FJ3 has a certain size to cover the initial commercial production in terms of capacity. This is one of the reasons why it is so expensive.

Mitsutake: I see. I understand. In that case, does it mean that the price is high because it has high pharmacological activity, and not because it is a mid-size molecule drug?

Okuda: Yes, I hope you understand it that way. Please understand that the containment facility is expensive.

Mitsutake: I understand.

One more point: Could you tell us again about the position of the development of mid-size molecule drugs in your company?

Okuda: I will answer this as well.

At the beginning of this year, we launched a new growth strategy called TOP I 2030. The concept of the drug discovery strategy is multimodality drug discovery, and we have very strong engineering technologies for small molecules and antibody drugs. In short, the technology to design and create compounds is very strong. The idea is to combine this with biological techniques to create new drugs.

Our drug discovery strategy is to create new and innovative drugs by adding a mid-size molecule modality and combining it with biological techniques. Therefore, the success of the mid-size molecule projects will be very important for the future growth of our company.

Mitsutake: Thank you very much.

Sasai: Thank you very much.

This concludes the financial results briefing for the second quarter.

If you have any questions that we were unable to answer due to time constraints, please contact the Corporate Communications Department. Phone numbers and email addresses can be found 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 for your time.

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