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CHUGAI PHARMACEUTICAL CO., LTD.

3Q Results (Jan - Sep 2021) Conference Call

October 22, 2021

Event Summary

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[Participants]		
[Number of Speakers]	6	
[Analyst Names]*	Dr. 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 Division
	Dr. Junichi Nezu	Vice President, Head of R&D Portfolio Management Department of Projects & Lifecycle Management Unit
	Toshiya Sasai	Head of Corporate Communications Department
	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.
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*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

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Presentation

Sasai: Good evening, everyone. CHUGAI PHARMACEUTICAL CO., LTD. will now hold a conference call to present results for the third quarter of FY2021. Thank you very much for taking time out of your busy schedule to join us today.

My name is Sasai, and I am the moderator of this session.

After the presentation, there will be a 30-minute question-and-answer session, during which any questions you may have will be answered.

Today's speakers are as follows. Dr. Okuda, the President and CEO. Mr. Itagaki, Executive Vice President and CFO. Mr. Yamaguchi, Senior Vice President and Head of the Project and Lifecycle Management Unit. Please have your presentation and disclosure materials ready.

The presentation will now begin. First of all, Dr. Okuda will give a summary of the third quarter.

FY2021 Q3 Overview

Financial Overview

- ✓ YoY increase in revenues and profits in Q3 due to an increase in sales and ROOI
- ✓ Full-year forecast revised upward as outlook for domestic/overseas sales and ROOI exceeded the original forecast
- ✓ Aiming for record highs in the next fiscal year due to growth in mainstay/new products, and an increase in COVID-19-related revenues

Core (billions of JPY)	2020 Jan - Sep actual	2021 Jan - Sep actual	Growth (year on year)		Original Forecast		Revised Forecast	
					Jan - Dec	Progress	Jan - Dec	Vs. 2020 actual
Revenues	576.5	677.5	+101.0	+17.5%	800.0	84.7%	970.0	+23.3%
Domestic sales	303.2	362.6	59.4	+19.6%	393.7	92.1%	513.0	+25.4%
Overseas sales	161.6	176.0	14.4	+8.9%	237.3	74.2%	268.5	+19.8%
ROOI	111.7	138.8	27.1	+24.3%	169.0	82.1%	188.5	+22.7%
Operating profit	231.9	290.7	+58.8	+25.4%	320.0	90.8%	400.0	+29.9%
Operating margin	40.2%	42.9%	+2.7pts	-	40.0%	-	41.2%	+2.1pts
Net income	165.6	209.7	+44.1	+26.6%	232.0	90.4%	293.0	+33.5%
EPS (yen)*	100.68	127.45	+26.77	+26.6%	141.00	90.4%	178.00	+33.4%

ROOI : Royalties and other operating income

* Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. The dividends are calculated based on the assumption that the stock split was implemented at the beginning of the fiscal year 2020.

- Domestic sales were affected by drug price revisions and generics, but mainstay products and new products were steadily penetrating the market, including the supply of Ronapreve to the government and an additional indication for Tecentriq
- In overseas sales, Actemra's exports to Roche decreased YoY, which was in line with original forecasts. Hemlibra sales increased as expected, while Alecensa sales increased more than expected
- ROOI increased mainly due to an increase in royalty and profit-sharing income based on growth in overseas local sales of Hemlibra
- Revised upward to 170.0 billion yen (+21%) in revenues and 80.0 billion yen (+25%) in operating profit



Okuda: My name is Okuda, and I am the Company President & CEO.

I will now give a summary of the third quarter results. Please refer to slide 5.

Sales revenue for the January to September period totaled JPY677.5 billion, up 17.5% from the same period last year. Operating income and quarterly income each increased by more than 25% from the same period last year, resulting in a significant increase in sales and income for the third quarter.

Sales in the domestic market were affected by the NHI drug price revision and the market penetration of generic products. However, sales of several products grew steadily. These include mainstay products such as Tecentriq, which received an indication for the treatment of hepatocellular carcinoma in September last year,

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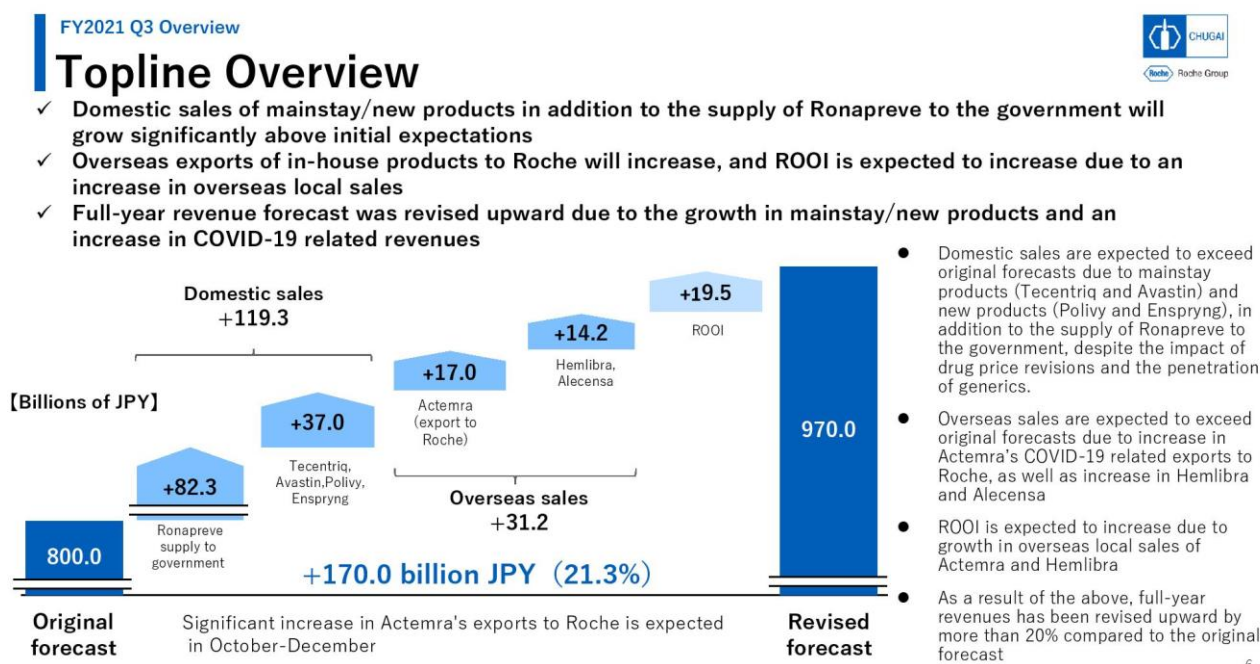


and new products such as Ronapreve, a COVID-19 treatment that received special approval for emergency in July. Deliveries of Ronapreve to the government have begun.

Overseas sales growth was driven by growth of Hemlibra, which was as expected, and higher-than-expected growth in Alecensa. The decrease in exports of Actemra to Roche from the previous year is in line with our expectations.

ROOI increased by nearly 25%, mainly due to increased royalties and profit sharing from the growth in overseas local sales of Hemlibra.

As a result of this progress, which was much stronger than we had initially forecast, we have significantly upwardly revised our original business forecast. After the revision, the forecasts are as follows: revenue is JPY970 billion, operating profit is JPY400 billion, quarterly income is JPY293 billion, and EPS is JPY178. As a result, we expect to achieve record results for this fiscal year. For the next fiscal year, although there are many uncertainties, we will continue to aim for our highest ever financial results.



Let's look at page 6. Here, we can see a breakdown of the difference between the original and revised forecasts for sales revenue.

In terms of sales in the domestic market, delivery of Ronapreve to the government has begun. We expect to record JPY82.3 billion from this for this fiscal year. Furthermore, in addition to mainstay products such as Tecentriq and Avastin, Polivy, and Enspryng are expected to exceed the original forecast, resulting in a total increase of JPY119.3 billion.

As for overseas sales, Actemra exports to Roche are expected to rise by JPY17 billion. This is due to increased demand related to COVID-19. In addition, sales of Hemlibra and Alecensa are both expected to exceed original forecasts.

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ROOI is expected to rise by a total of JPY19.5 billion, mainly due to growth in overseas sales of Actemra and Hemlibra. In total, we have added JPY170 billion to our top line. This constitutes an upward revision of 21.3% from our original forecast.

FY2021 Q3 Overview

R&D Overview



■ Launch and value enhancement of multiple new products that contribute to business performance

- **Polivy** : Launched in May for relapsed or refractory diffuse large B-cell lymphoma(DLBCL). Polivy/R-CHP combination therapy showed significant improvement as a first-line therapy over standard treatment for untreated DLBCL (P3 POLARIX trial); Scheduled to file this year
- **Evrysdi** : Launched as the first oral drug that can be administered from 2 months of age for SMA (August)
- **FoundationOne Liquid CDx** : Launched a liquid biopsy-based comprehensive genomic profiling (CGP) test for solid tumor (August)

■ Progress of development products covering from prophylaxis to severe treatment of COVID-19

Prophylaxis and asymptomatic infection	Ronapreve	Filed for additional indications for prophylaxis and treatment of asymptomatic COVID-19, as well as additional subcutaneous administration (October)
Mild to Moderate	Ronapreve	Approved for the first time in the world (July)
	AT-527	P3 study in progress
Moderate to Severe	Actemra	Scheduled to file this year in Japan

■ Progress of in-house early development products that support medium- to long-term growth

- In-house created mid-size molecule development product LUNA18 entered P1 study as a new modality (October)
- Wide range of early-developed products with our unique antibody engineering technology such as switch antibody STA551

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Next, slide 7. Here's an overview of R&D.

On the R&D front, progress was made in new products, COVID-19 treatment, and early-stage products discovered in-house. Polivy, which was launched in May this year for the indication of relapsed or refractory DLBCL, has seen greater market penetration than expected. Roche has successfully demonstrated a significant improvement in progression-free survival (PFS) in a trial comparing the drug with standard treatment in untreated DLBCL patients. This is the first such improvement seen in about 20 years. We plan to file an application for approval for this first-line indication by the end of this year.

Evrysdi, which was launched in August this year, is the first oral drug for spinal muscular atrophy (SMA). It is suitable for use in both children and adults. Levels of use are higher than expected, especially in patients who have not been treated with SMA drugs before, or who have not had the opportunity to be treated with other drugs due to age or scoliosis.

FoundationOne Liquid CDx, the first liquid biopsy test for solid tumors to provide comprehensive cancer genome profiling in Japan, was also launched in August this year. This enables the provision of CGP testing for patients where tissue specimen testing was not practical. This helps specialists to determine a treatment plan that is appropriate for the patient's situation and stage of treatment.

Next, I would like to introduce the progress of COVID-19-related development products.

Since its special approval for emergency in July, Ronapreve, an antibody cocktail therapy, has been used mainly for preventing progressing to severe in patients with mild to moderate COVID-19. Last week, we filed an application to expand the indications of Ronapreve for the prophylaxis of COVID-19 and for the treatment of asymptomatic infected patients. An application was also submitted to allow subcutaneous administration.

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The RNA polymerase inhibitor AT-527 is currently undergoing global Phase III clinical trials. We are preparing to submit an application for approval of Actemra by the end of this year.

We aim to make further contributions to management of the COVID-19 pandemic. This covers the spectrum from the prevention of disease, all the way to treatment of severe disease.

Lastly, I would like to talk about our early-stage in-house development products.

This month, Chugai started clinical trials for LUNA18, an orally administered cyclic peptide molecule created using Chugai's unique mid-size molecule technology. Mr. Yamaguchi will explain the details later.

In addition, 10 other early-stage products developed using Chugai's unique antibody engineering technologies are undergoing Phase I clinical trials. This includes STA551, a treatment for solid tumors developed using Switch antibody technology.

In order to further accelerate the development of these antibody projects, we have decided to build a new biopharmaceutical API manufacturing facility, named UK4. This was announced today. The UK4 facility will be used for dedicated production of antibody project investigational drugs for initial human clinical trials. Expectations are high for the continued evolution of antibody drugs. Through UK4, we will continue to accelerate development in this area, striving to deliver the results of this innovation to patients around the world.

FY2021 Q3 Overview

Application for Selection of New Market Segment "Prime Market"



■ Results of initial assessment

Chugai received the results of its initial assessment from the Tokyo Stock Exchange on July 9, 2021, and confirmed that the Company complies with the listing criteria for the "Prime Market" in the new market segment.

■ Future action

Based on the results, after the resolution by the Board of Directors of the Company, we will proceed with the prescribed procedures related to the application for the selection of the new market segment in accordance with the schedule set by the Tokyo Stock Exchange.

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Please see page 8. Finally, we would like to inform you of the status of our company in the market reclassification of the Tokyo Stock Exchange in April 2022.

On July 9, 2021, the Company received an initial determination from the Tokyo Stock Exchange that it complies with the listing maintenance standards for the Prime Market in the new market category. We will proceed with the prescribed procedures for applying for the selection of the new market segment after the resolution of the Board of Directors of the Company.

That is all from me.

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

FY2021 Q3 Consolidated Financial Overview (Core)

P/L Jan - Sep (Year on Year)



(Billions of JPY)	2020	2021	Growth	
Revenues	576.5	677.5	+ 101.0	+ 17.5%
Sales	464.8	538.7	+ 73.9	+ 15.9%
Domestic	303.2	362.6	+ 59.4	+ 19.6%
Overseas	161.6	176.0	+ 14.4	+ 8.9%
Royalties and other operating income	111.7	138.8	+ 27.1	+ 24.3%
Royalty and profit-sharing income	89.1	135.4	+ 46.3	+ 52.0%
Other operating income	22.6	3.4	- 19.2	- 85.0%
Cost of sales	-200.3	-225.7	- 25.4	+ 12.7%
(cost to sales ratio)	43.1%	41.9%	-1.2%pts	-
Operating expenses	-144.3	-161.1	- 16.8	+ 11.6%
M&D and G&A * ¹	-62.2	-66.9	- 4.7	+ 7.6%
Research and development	-82.2	-94.1	- 11.9	+ 14.5%
Operating profit	231.9	290.7	+ 58.8	+ 25.4%
(operating margin)	40.2%	42.9%	+2.7%pts	-
Financial account balance	-2.2	-1.9	+ 0.3	- 13.6%
Income taxes	-64.1	-79.2	- 15.1	+ 23.6%
Net income	165.6	209.7	+ 44.1	+ 26.6%
EPS (JPY) * ²	100.68	127.45	+26.77	+ 26.6%

Domestic sales

Significant increase due to sales growth of new products as well as mainstay products

Overseas sales

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

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

Increased due to higher royalty and profit-sharing income as well as increase in sales

*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: Thank you. I would like to present the financial results in detail.

Please see page 10. First, a YoY comparison of results to date.

Revenues were JPY677.5 billion, an increase of JPY101 billion constituting 17.5% growth. As a breakdown, sales in the domestic market grew by 19.6%. This double-digit growth was due to volume growth of Ronapreve, as well as and core products. This offset the negative impact of NHI drug price revisions and generics.

Overseas sales grew by 8.9% in total, with increases in Hemlibra and Alecensa compensating for the decline in sales of Actemra.

Royalty and profit-sharing revenues related to Hemlibra were JPY135.4 billion, an increase of 52%. On the other hand, other operating income was just JPY3.4 billion. This was due to a decrease in one-time income.

The product cost ratio improved by 1.2% to 41.9%. This was due to an increase in the ratio of sales of in-house products, despite pressure from NHI drug price revisions.

Marketing, general, and administrative expenses increased by 7.6% due to the recovery trend in various activities. R&D expenses increased by 14.5% due to progress in development projects.

As a result, operating profit was JPY290.7 billion, up JPY58.8 billion, or 25.4%. The operating profit margin was 42.9%.

After subtracting financial income and expenses and corporate income tax from this figure, quarterly profit increased by 26.6% to JPY209.7 billion.

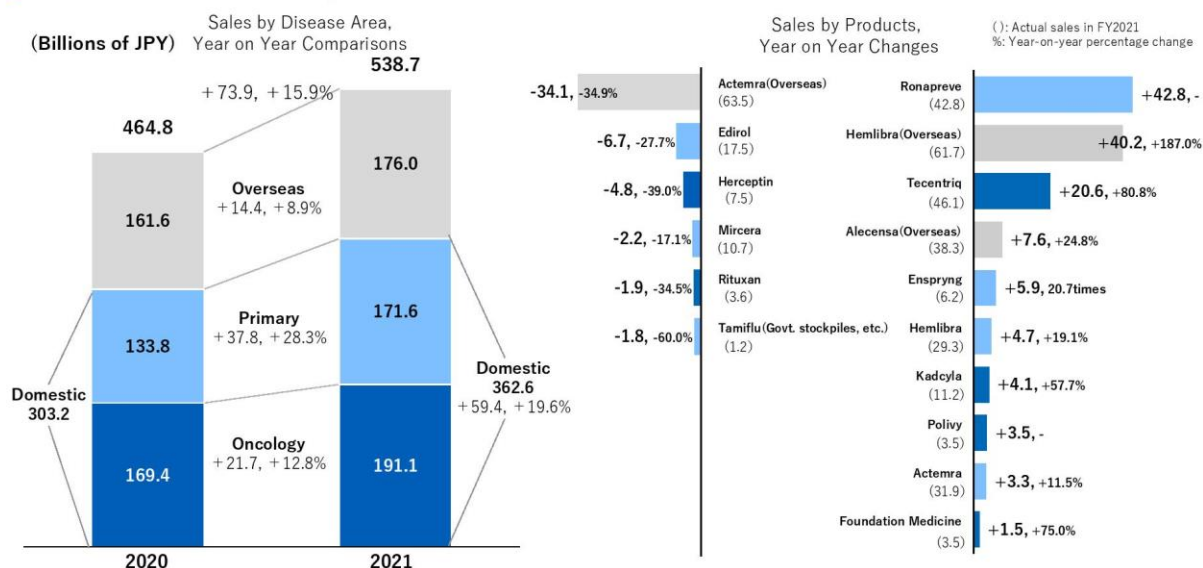
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Sales Jan - Sep (Year on Year)



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Slide 11 shows a breakdown of changes in product sales.

On the left, by area from the bottom, the domestic oncology area grew by 12.8%. Looking at the individual products on the right, we have seen growth based on the addition of indications for Tecentriq and Kadcylla. In addition, sales of Polivy, which was launched in May, totaled JPY3.5 billion. In addition, Foundation Medicine achieved an increase in sales of JPY1.5 billion with the addition of F1 Liquid.

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

Next, in the domestic primary area, we see an increase of 28.3%. Looking at individual products, Ronapreve, which received special approval for emergency in July, recorded sales of JPY42.8 billion. Sales of the in-house products Enspryng, Hemlibra, and Actemra also increased steadily. Enspryng, which was launched in August last year, has been steadily penetrating the market and achieved sales of JPY6.2 billion. Sales of Hemlibra were up 19.1%. This followed a 15% price reduction in January last year due to market expansion recalculation. In terms of volume, this represents growth of about 26%.

On the other hand, sales of Edirol, for which a generic version is available, declined by JPY6.7 billion. Sales of Mircera and Tamiflu for government stockpile also declined.

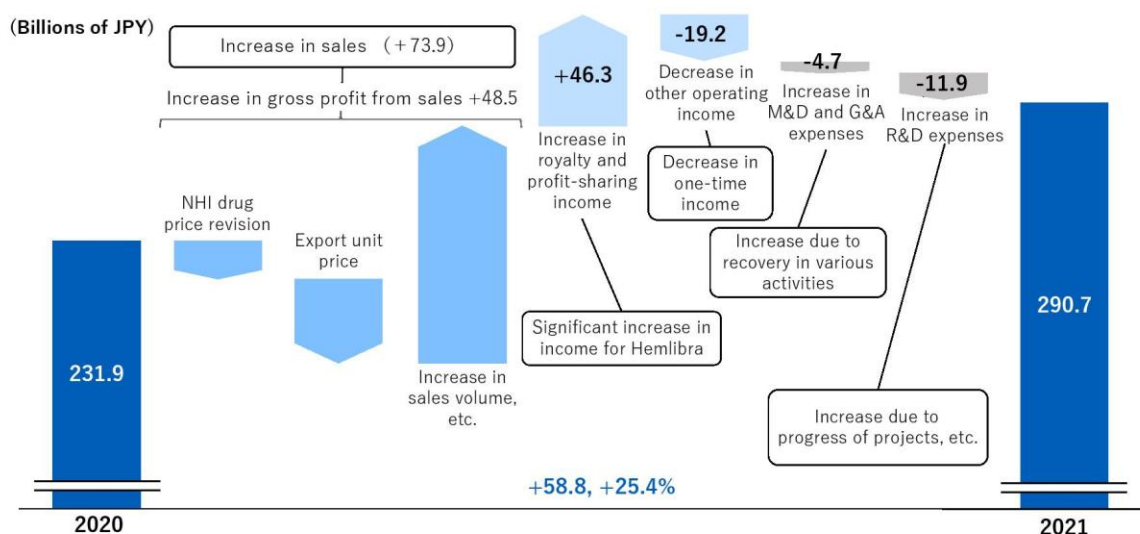
Lastly, overseas profit increased by 8.9%. Sales of Hemlibra overseas grew 187%. Looking at the impact of lower unit prices for exports, the growth rate in volume terms is about 240%. Overseas sales growth for Alecensa was 24.8%, a volume growth of over 70%. Overseas sales of Actemra decreased by 34.9%. This was due to a reaction to the large number of shipments made last year in response to COVID-19 demand. We will look at the details of this later.

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Operating Profit Jan - Sep (Year on Year)



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Page 12 shows the breakdown of the increase in operating profit.

The second, third, and fourth bar graphs from the left show the increase in gross profit, and they are differentiated by element. The negative impact of NHI drug price revisions and export unit prices was absorbed by volume growth, resulting in a net profit increase of JPY48.5 billion.

Next, royalty and profit sharing income increased by JPY46.3 billion, contributing to the increase in operating profit.

On the other hand, other operating income was down JPY19.2 billion due to the absence of the huge one time income posted last year. This difference pushed down the profit figure.

As I have already explained, marketing, general, and administrative expenses increased by JPY4.7 billion. R&D expenses increased by JPY11.9 billion.

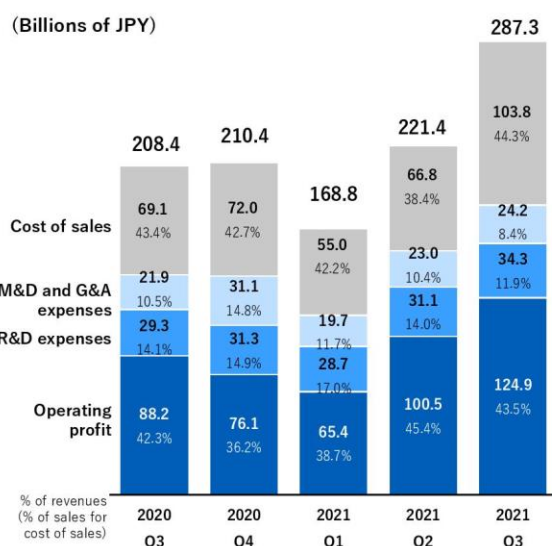
In short, gross profit from volume growth and royalty income contributed JPY58.8 billion to the increase in profit.

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Structure of Costs and Profit by Quarter



vs. Year on Year (2020 Q3)

Cost of sales ratio: rise 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 +36.7 (+41.6%)

vs. Previous Quarter (2021 Q2)

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

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

Operating profit: increase of +24.4 (+24.3%)

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From page 13 onwards, we have 3 more slides looking at quarterly trends.

Slide 13 looks at cost structure. Comments on how it compares to last year's third quarter and to the preceding second quarter are listed above and below on the right, respectively.

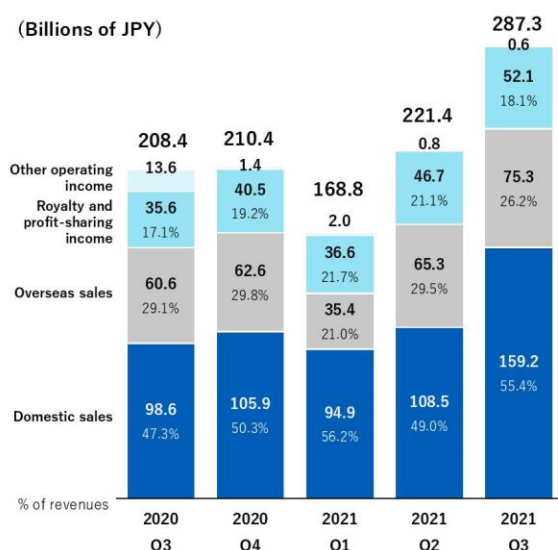
The common denominator in both cases is the increase in the cost ratio. This is due to sales of Ronapreve in the third quarter. Ronapreve is a procured product, so its cost ratio is higher than that of our own products. As for expenses, both marketing, general, and administrative expenses and R&D expenses have increased, but the ratio itself has decreased due to the increase in revenue. Operating profit grew significantly, and the profit margin remained at a high level of 43.5%.

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Structure of Revenues by Quarter



vs. Year on Year (2020 Q3)

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

Other operating income: decrease in one-time income

vs. Previous Quarter (2021 Q2)

Domestic sales: increase mainly due to sales growth of new products

Overseas sales: increase in sales of Actemra and Hemlibra

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

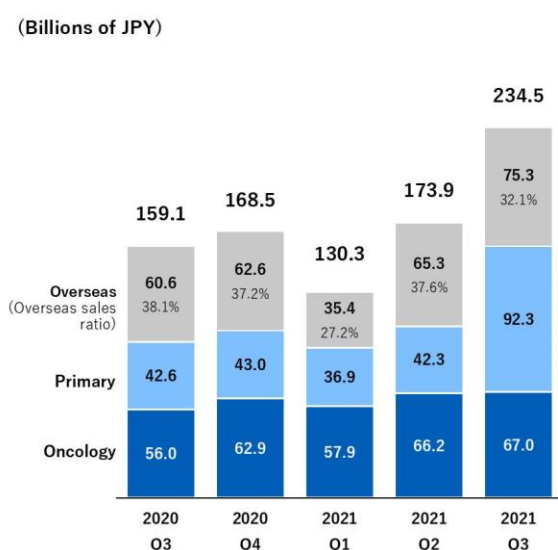
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Page 14 shows the structure of revenues.

Domestic sales, overseas sales, and royalty income have all grown in this third quarter from the same period last year and the previous second quarter.

As a percentage of total sales, both domestic and overseas sales are strong. However, due to Ronapreve sales recognized in the third quarter, the percentage of sales in the domestic market increased to 55.4%.

Structure of Sales by Quarter



vs. Year on Year (2020 Q3)

Overseas	Actemra:	-11.4	Hemlibra:	+23.4
	Alecensa:	+3.3		

Oncology	Tecentriq:	+6.6	Polivy:	+2.6
	Kadcyla:	+1.5	Herceptin:	-1.4

Primary	Ronapreve:	+42.8	Ediol:	+4.0
	Enspryng:	+2.3	Hemlibra:	+2.2
	Actemra:	+2.2		

vs. Previous Quarter (2021 Q2)

Overseas	Actemra:	+5.1	Hemlibra:	+3.8
	Alecensa:	+2.2		

Oncology	Polivy:	+1.7	Tecentriq:	-0.9
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Primary	Ronapreve:	+42.8	Ediol:	+5.2
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The last page of quarterly sales structure is on page 15. This shows sales by product area.

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Across oncology, primary, and overseas areas, this third quarter has seen very strong results. A breakdown of products is shown on the right.

Normally, the next step is to show progress against the forecast. However, performance has been much stronger than the original forecast, and this has led us to revise the forecast upward.

FY2021 Q3 Consolidated Financial Overview (Core)



P/L Jan - Dec (Revision of forecast)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year	
Revenues	800.0	970.0	+170.0	+21.3%	+183.1	+23.3%
Sales	631.0	781.5	+150.5	+23.9%	+148.2	+23.4%
Domestic	393.7	513.0	+119.3	+30.3%	+103.9	+25.4%
Overseas	237.3	268.5	+31.2	+13.1%	+44.3	+19.8%
Royalties and other operating income	169.0	188.5	+19.5	+11.5%	+34.9	+22.7%
Royalty and profit-sharing income	163.0	179.5	+16.5	+10.1%	+49.9	+38.5%
Other operating income	6.0	9.0	+3.0	+50.0%	- 15.1	-62.7%
Cost of sales	- 252.5	- 339.0	- 86.5	+34.3%	- 66.7	+24.5%
(cost to sales ratio)	40.0%	43.4%	+3.4%pts	-	+0.4%pts	-
Operating expenses	- 227.5	- 231.0	- 3.5	+1.5%	- 24.3	+11.8%
M&D and G&A	- 96.0	- 99.5	- 3.5	+3.6%	- 6.3	+6.8%
Research and development	- 131.5	- 131.5	0.0	0.0%	- 18.0	+15.9%
Operating profit	320.0	400.0	+80.0	+25.0%	+92.1	+29.9%
(operating margin)	40.0%	41.2%	+1.2%pts	-	+2.1%pts	-
Net income	232.0	293.0	+61.0	+26.3%	+73.6	+33.5%
EPS (JPY) *	141.00	178.00	+37.00	+26.2%	+44.61	+33.4%
Annual Dividend (JPY)	60.00	Undecided	-	-	-	-

* 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.

Main reason for revision:

Domestic Sales

Reflects the progress and revised assumptions for each product, including the supply of Ronapreve to the government

Overseas sales

Exports of Actemra and Hemlibra to Roche will exceed the original forecast

Royalty and profit-sharing income

Income for Actemra and Hemlibra will exceed the original forecast

Other operating income

One-time income not included in the original forecast

Cost of Sales

Cost to sales ratio higher due to a change in product mix from the original forecast, etc.

Operating expenses

Increase in some expenses including those attributable to foreign exchange effects and increased sales and profits

vs. Year on Year:

Revenues+23.3%, Operating profit+29.9%

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I would like you to take a look at page 16.

We'll start from the top. We have changed our forecast for revenues from JPY800 billion to JPY970 billion. We have decided to upwardly revise and announce the new forecast in line with timely disclosure standards due to the size of the increase: 21.3%.

The main reasons for the revision are government deliveries of Ronapreve affecting sales in the domestic market, Actemra exports due to COVID-19 demand affecting overseas sales, and ROOI increase due to higher royalty income from Actemra and Hemlibra. Finally, we have seen new one-time income.

The cost of sales ratio was revised upward by 3.4% due to a change in product mix from the original forecast. As for expenses, we increased M&D, general and administrative expenses by JPY3.5 billion. This reflects the impact of the weaker yen and an increase in business taxes due to higher profits. As a result, forecast operating profit is just over JPY400 billion, a 25% increase from the original forecast.

Compared to the previous year, sales are expected to increase by 23.3%, operating profit by 29.9%, and net income by 33.5%. We are expecting to achieve a record high for the fifth consecutive year.

Year-end dividend forecast has been revised to undecided in light of the significant changes in the business environment. An interim dividend of JPY30 has already been paid. We will decide on the year-end dividend after the fiscal year end.

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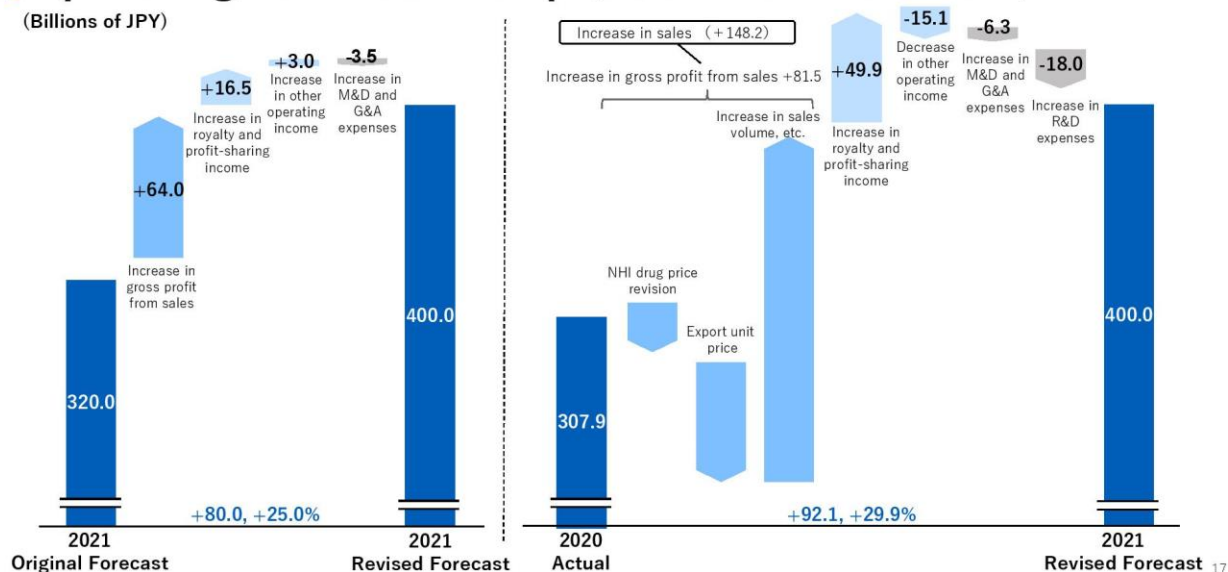
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Operating Profit Jan - Sep (Revision of forecast)

(Billions of JPY)



Page 17 shows a waterfall chart from the original forecast on the left, and another from the previous year's results on the right. These lead up to the new operating profit forecast of JPY400 billion.

In both cases, the contribution of gross profit is very large, indicating that sales are very strong.

On the next page, we will look at the sales forecast by product.

Sales Jan - Dec (Revision of forecast, 1/2)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year	
Sales	631.0	781.5	+150.5	+23.9%	+148.2	+23.4%
Domestic	393.7	513.0	+119.3	+30.3%	+103.9	+25.4%
Oncology	226.7	256.0	+29.3	+12.9%	+23.7	+10.2%
Avastin	60.5	80.1	+19.6	+32.4%	-1.4	-1.7%
Tecentriq	49.2	59.8	+10.6	+21.5%	+22.3	+59.5%
Perjeta	31.8	32.0	+0.2	+0.6%	-1.5	-4.5%
Alecensa	27.0	27.1	+0.1	+0.4%	+1.1	+4.2%
Kadcyla	13.3	14.9	+1.6	+12.0%	+4.7	+46.1%
Herceptin	10.9	9.7	-1.2	-11.0%	-6.2	-39.0%
Polivy	3.5	6.1	+2.6	+74.3%	+6.1	-
Rituxan	5.2	4.8	-0.4	-7.7%	-2.4	-33.3%
Gazyva	5.7	4.4	-1.3	-22.8%	-0.2	-4.3%
Xeloda	2.7	2.6	-0.1	-3.7%	-1.0	-27.8%
Rozlytrek	0.9	0.9	0.0	0.0%	+0.5	+125.0%
Foundation Medicine	7.2	5.6	-1.6	-22.2%	+2.8	+100.0%
Other	8.7	8.1	-0.6	-6.9%	-1.0	-11.0%

Main reason for revision:

Avastin

Market penetration of hepatocellular carcinoma will exceed the original forecast

Original assumptions updated considering market penetration of biosimilar pharmaceuticals

Tecentriq

Market penetration of hepatocellular carcinoma will exceed the original forecast

Polivy

Exceeds the original forecast due to progress in early market penetration

On page 18, we will begin with the sales forecast for oncology products in the domestic market.

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Forecast sales for Avastin and Tecentriq have been raised by JPY19.6 billion and JPY10.6 billion, respectively. The reasons are listed on the right, and the common factor is the strong market penetration in hepatocellular carcinoma. Our new product, Polivy, has been penetrating the market at a faster pace than expected. We have raised the initial forecast from JPY3.5 billion to JPY6.1 billion.

The figures for the domestic primary area and exports are on the next page.

FY2021 Q3 Consolidated Financial Overview (Core)



Sales Jan - Dec (Revision of forecast, 2/2)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year		Main reason for revision:
Primary	167.0	257.0	+90.0	+53.9%	+80.2	+45.4%	
Ronapreve	-	82.3	+82.3	-	+82.3	-	Ronapreve Obtained approval in July 2021, supplied under the agreement with the Japanese government
Actemra	38.5	42.5	+4.0	+10.4%	+3.2	+8.1%	Hemlibra Downward revision against ambitious original forecast
Hemlibra	51.7	40.3	-11.4	-22.1%	+6.2	+18.2%	Edirol Temporary increase in demand due to insufficient supply and shipping adjustments by competitors
Edirol	17.3	21.2	+3.9	+22.5%	-6.6	-23.7%	Enspryng Exceeds original forecast due to successful acquisition of new patients
Mircera	11.7	13.4	+1.7	+14.5%	-4.1	-23.4%	Actemra (Overseas) Exceeds original forecast due to the impact of increased demand of COVID-19, etc.
Enspryng	4.0	9.3	+5.3	+132.5%	+8.0	+615.4%	Hemlibra (Overseas) / Alecensa (Overseas) Exceeds original forecast
CellCept	8.3	8.3	0.0	0.0%	-0.8	-8.8%	Enspryng (Overseas) Downward revision due to difference in Roche's assumptions of global market penetration, etc.
Bonviva	8.5	8.1	-0.4	-4.7%	-0.8	-9.0%	
Oxarol	5.5	6.1	+0.6	+10.9%	-0.3	-4.7%	
Evrysdi	1.0	1.0	0.0	0.0%	+1.0	-	
Tamiflu(Ordinary use)	0.8	-0.1	-0.9	-112.5%	-0.9	-	
Tamiflu(Govt. stockpiles, etc.)	1.2	3.4	+2.2	+183.3%	-0.3	-8.1%	
Other	18.5	21.1	+2.6	+14.1%	-6.8	-24.4%	
Overseas	237.3	268.5	+31.2	+13.1%	+44.3	+19.8%	
Actemra	85.3	102.7	+17.4	+20.4%	-31.7	-23.6%	
Hemlibra	89.7	99.0	+9.3	+10.4%	+72.9	+279.3%	
Alecensa	44.2	50.4	+6.2	+14.0%	+6.1	+13.8%	
Enspryng	3.9	1.2	-2.7	-69.2%	-4.4	-78.6%	
Neutrogin	8.7	9.2	+0.5	+5.7%	+0.2	+2.2%	
Other	5.4	6.1	+0.7	+13.0%	+1.3	+27.1%	

19

For the primary area in the domestic market, we have newly added the forecast for Ronapreve as JPY82.3 billion. Sales here are not recorded when the contract is signed with the government, but rather, when Ronapreve is purchased and delivered to the government. In Q4, we expect to deliver JPY39.5 billion in addition, bringing the total to JPY82.3 billion for the full year.

The forecast for Hemlibra has been revised downward by about 20%, as our initial plan was somewhat ambitious.

Forecast sales of Edirol are up due to a temporary increase in demand resulting from shipment adjustments by generic manufacturers. Also, sales of Enspryng are steadily increasing, so we have made an upward revision in the forecast here.

Overseas, although we lowered our forecast for Enspryng, other products such as Actemra, Hemlibra and Alecensa have performed well. We have increased our export forecast by JPY33 billion over these 3 products.

I will say more about Actemra and Hemlibra in the next slide.

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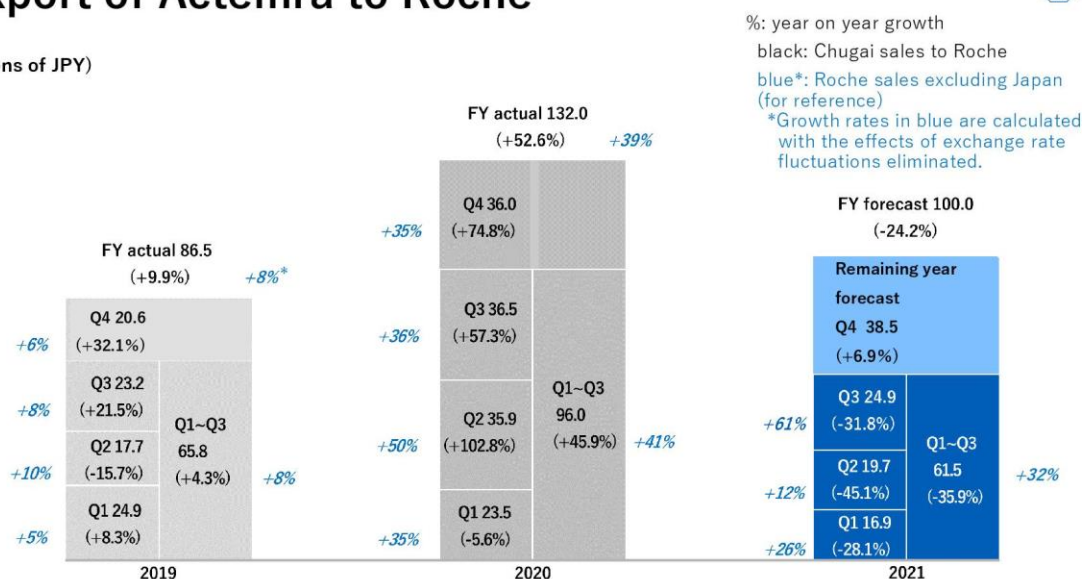
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Export of Actemra to Roche

(Billions of JPY)



20

Next, page 20.

In this slide, exports of Actemra to Roche are shown in chronological order from left to right and quarterly order from the bottom. The blue figures on both sides are the percentage increase in Actemra sales by Roche.

First of all, looking at the full-year results shown in the upper part of the chart, the growth rate for 2019 was 9.9%, but last year it jumped 43 points to 52.6%. We expect that most of the increase in exports will be due to demand relating to COVID-19.

On the other hand, the incremental increase in Roche territory in blue is from 8% in 2019 to 39% in 2020, an increase of 31 percentage points.

This means that our exports to Roche exceeded demand last year. In addition to the reaction to this, vaccinations have started worldwide since the beginning of this year, and Roche has been making inventory adjustments since the beginning of this year. As a result, our exports have fallen considerably.

As you can see on the far right, our export sales have decreased by 35.9% cumulatively through the third quarter.

However, overseas demand has been rising again in August and September. The spread of the delta strain has led to concerns about a temporary tightening of supply in the United States and other countries and regions.

Therefore, the planned export in Q4 is JPY38.5 billion. This is the largest quarterly result of this fiscal year and FY2020. We expect export sales of JPY100 billion for the full year.

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Outline of Hemlibra Sales to Roche

(Excluding profit-sharing income and expenses in co-promotion countries)



21

The next page, page 21, summarizes Hemlibra sales to Roche.

Export sales in the upper part of the table, on a cumulative basis to the third quarter, were JPY60 billion. This is about 3 times the level of the same period last year. Since progress has been better than we had expected at the beginning of the fiscal year, we have raised our full-year forecast by 10% from JPY88 billion to JPY96.9 billion.

Next, in the royalty income section shown at the bottom, we have raised our forecast for royalty income and royalty 2 income related to the initial shipment. Due to an increase in the unit price of inventory subject to royalty 2, we have made an upward revision of our forecast for the current fiscal year from JPY95 billion to JPY96.5 billion. In addition, we have determined that the amount to be carried over next year will be in the range of JPY5 billion to JPY10 billion. This is because some of the target inventory dosing vials will remain until next year.

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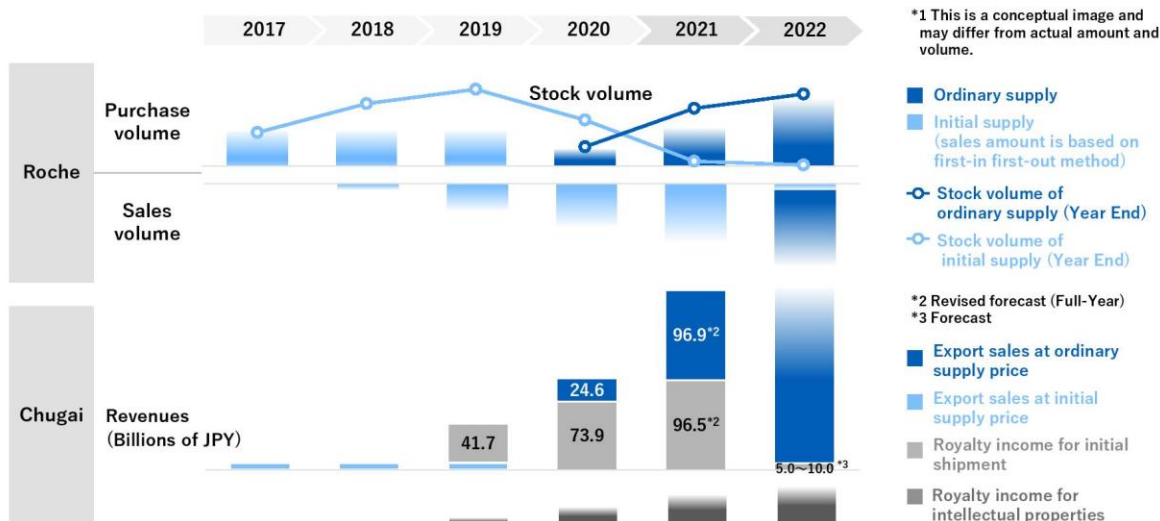
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Outline of Hemlibra Sales to Roche

Image for Timing of Export Sales and Royalty Income*1



22

These are illustrated in the image on page 22.

Please refer to sales revenue at the bottom. This year's royalty 2, the gray bar, has been revised from JPY95 billion to JPY96.5 billion. The next part, export sales, which is represented by the blue bar, has been revised from JPY88 to JPY96.9 billion.

In 2022, we will see a further increase in export sales, with royalty 2 levels of JPY5 billion to JPY10 billion. If you add up both of these factors, the figure for next year will be the same as the figure this year, and I think it will be possible to avoid the so-called "royalty 2 cliff" next year.

In addition to Hemlibra, Tecentriq is doing well, and it is anticipated that new products such as Polivy, Enspryng, and Evrysdi will further penetrate the market. In addition, the approval and launch of faricimab is scheduled, and although we cannot say definitively, there may be an upside to Actemra and Ronapreve due to COVID-19.

For these reasons, I believe that we can aim for another record high next year, and that the potential for this is very great.

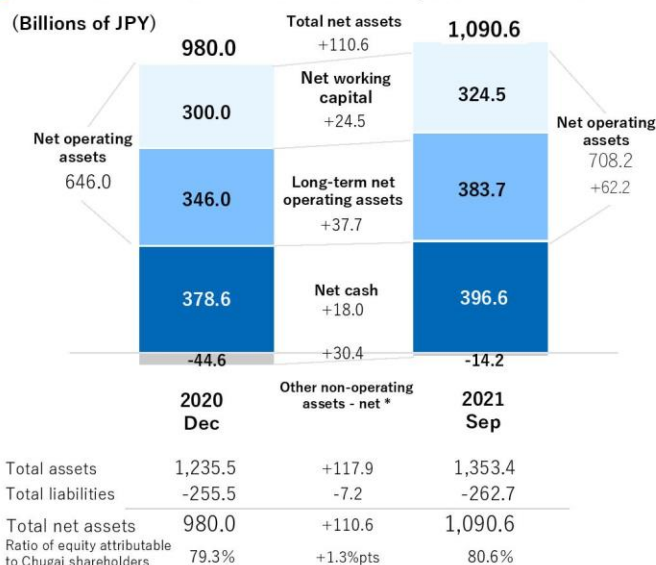
This concludes the section on profit and loss.

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Financial Position (vs. 2020 Year End)



Increase in net working capital

Increase mainly in trade accounts receivable

Increase in long-term net operating assets

Increase mainly in property, plant and equipment

Increase in net cash

(Please refer to the next slide)

Increase in other non-operating assets - net

Decrease in current income tax liabilities

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

FX rate to the JPY (end of period)

	2020 Actual	2021 Actual
1CHF	117.10	119.76
1EUR	126.89	129.85
1USD	103.19	111.97

23

Page 23 concerns the balance sheet.

As you can see from the top of the figure on the left, total net assets at the end of September were JPY1.0906 trillion. Of this, inventories and property, plant and equipment assets increased, and as noted here, net operating assets increased by JPY62.2 billion to JPY708.2 billion. Net cash increased by JPY18 billion to JPY396.6 billion.

If you look at the bottom of the page, you will see that while our assets have increased by 10% since the end of last year, we have kept our liabilities almost flat, so the ratio of equity attributable to Chugai shareholder has improved to 80.6%.

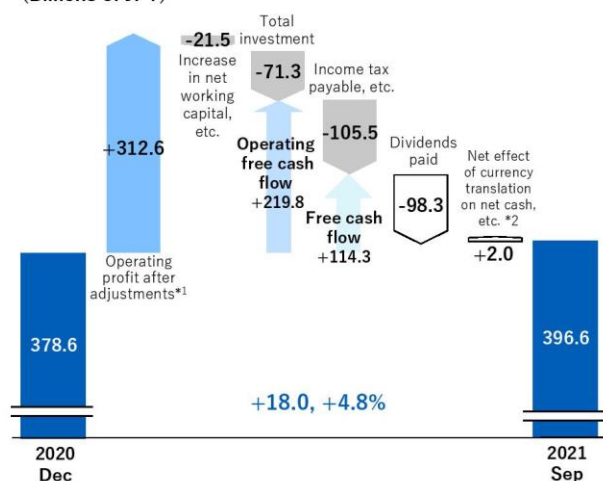
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Net Cash (vs. 2020 Year End)

(Billions of JPY)



Operating profit after adjustment * ¹	+312.6
Operating profit * ¹	+282.8
Depreciation, amortization and impairment * ¹	+26.0
Increase in net working capital, etc.	-21.5
Total investment	-71.3
Property, plant and equipment	-58.1
Payment for lease liabilities	-6.3
Intangible assets	-6.9
Operating free cash flow	+219.8
Income tax payable, etc.	-105.5
Income tax payable	-103.6
Free cash flow	+114.3
Dividends paid	-98.3
Net effect of currency transaction on net cash, etc. * ²	+2.0

*¹ Including Non-Core (IFRS results)*² Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(*³)*³ Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

24

Now let's take a look at the breakdown of the increase in net cash on page 24.

First of all, there was a net cash inflow of JPY312.6 billion from operating activities. After subtracting the increase in net working capital and payments for new laboratories and manufacturing facilities, operating free cash flow was a positive JPY219.8 billion.

Cash outflows of JPY105.5 billion and JPY98.3 billion, respectively, were due to the payment of corporate taxes, and last year's year-end dividend and this year's interim dividend.

As a result, net cash increased by JPY18 billion from the end of last year to JPY396.6 billion at the end of this September.

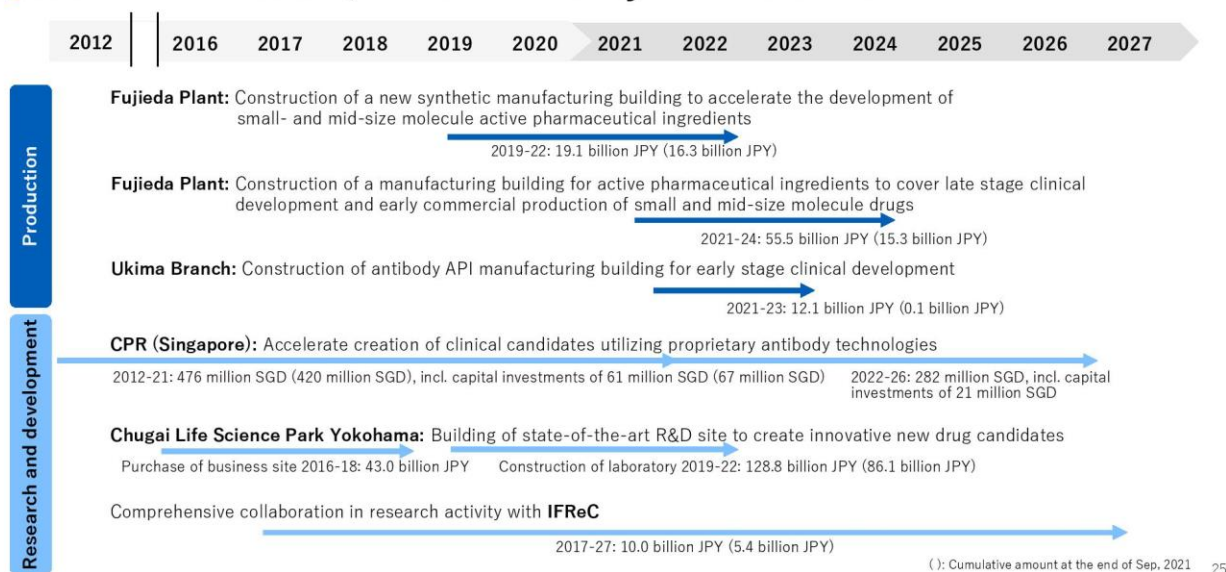
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Current Status / Plan for Major Investments



We plan to use these cash reserves for future investments, and the status of major investments is shown on page 25.

The Ukima plant, or UK4, which was announced today, has been added to this slide. The fourth biopharmaceutical API manufacturing building was announced today. It is shown in the third line from the top.

Construction is scheduled to be completed in September 2023, with a planned investment of JPY12.1 billion. On top of that, the construction of the third synthetic API manufacturing building at the Fujieda plant, or FJ3, which was announced in July, will also begin.

In addition, construction of the Chugai Life Science Park Yokohama, which you can see in the second line from the bottom, is progressing smoothly toward completion in October next year.

This concludes my presentation.

Sasai: Next, Mr. Yamaguchi, Head of Project & Lifecycle Management Unit, will provide an update on the status of the development pipeline.

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Q3 Topics

As of October 22, 2021

Launch	FoundationOne Liquid CDx	Blood-based CGP test for solid tumors, CDx	August
	Evrysdi	Spinal muscular atrophy (SMA)	August
Approved	Rituxan	Systemic sclerosis	September
Filed	Actemra	COVID-19 pneumonia (EU)	September
	Ronapreve	Prophylaxis and treatment of asymptomatic COVID-19	October
	Ronapreve	Subcutaneous administration	October
Pipeline entry	RG6171 / giredestrant	Breast cancer (adjuvant)	P3 (August)
	Enspryng	Generalized myasthenia gravis (gMG)	P3 (October)
	LUNA18	Solid tumors (RAS inhibitor)	P1 (October)
Topline results	Polivy	Previously untreated diffuse large B-cell lymphoma : Primary endpoint met	P3 (POLARIX)
Medical conference	Enspryng	SAkuraStar/SAkuraSky studies: four-year data	ECTRIMS** (October)
Others	Hemlibra	Acquired Hemophilia A	Orphan drug designation (October)
	nemolizumab	Pruritus for dialysis patients	Out-license of domestic development and marketing rights to Maruho (September)
	OBP-301*	Oncolytic virus therapy	Agreement on termination of exclusive license agreement
	Evrysdi	SMA: FIREFISH study Part 2	Published in NEJM
	Ronapreve	COVID-19: REGN-COV 2067 study	Published in NEJM

*In-licensed (Oncolys BioPharma Inc.) **Congress of the European Committee for Treatment and Research in Multiple Sclerosis Letters in orange : in-house projects, Letters in blue : In-licensed(Roche)

34

Tetsuya Yamaguchi: I would like to discuss the status of the development pipeline.

Page 34 shows the topics for the third quarter.

First of all, we are launching 2 new products in August. The first is FoundationOne Liquid CDx Cancer Genomic Profile, which is the first cancer gene panel test in Japan that combines complete genomic profiling of solid tumors using blood samples and companion diagnostic functions for multiple cancer drugs. The second is Evrysdi, the first oral drug that can be used to treat spinal muscular atrophy in a home setting.

In terms of approvals, Rituxan received approval in September for systemic sclerosis.

Regarding applications, an application for Actemra for COVID-19 pneumonia has been filed in Europe. We will also discuss the expansion of indications for Ronapreve, use of Enspryng for the generalized myasthenia gravis, and the mid-size molecule project LUMA18.

We have also started Phase III trials of RG6171, or giredestrant, a breast cancer adjuvant.

As for the top-line presentation of late-stage development products, Polivy, which was introduced earlier, has achieved its primary endpoint in the POLARIX trial. This is a Phase III trial for untreated DLBCL.

In the POLARIX trial, the combination of Polivy and R-CHP was compared with the standard of care, R-CHOP.

In the primary endpoint of progression-free survival, the Polivy group showed a statistically significant and clinically meaningful improvement. Based on the results of this trial, we will submit an application for expansion of the first-line indication within this year.

In the pivotal SAkuraStar and SAkuraSky studies, patients with neuromyelitis optica spectrum disorders and anti-aquaporin-4 antibody-positive patients showed sustained relapse reduction after 4 years of continuous treatment with Enspryng. This was announced at the ECTRIMS Congress.

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In addition, Hemlibra received Orphan Drug Designation for acquired hemophilia A. Maruho was granted the rights to develop and market nemolizumab in Japan for pruritus in dialysis patients. Regarding OBP-301 (telomelysin), we have agreed to terminate the exclusive license agreement with Oncolys BioPharma, which was signed in April 2019.

Overview of Development Pipeline



Chugai's Unique Platform for Mid-Size Molecule

APOLLO (Artificial, Peptidic, Orally available, Limitlessly Localizable Omicron*) molecules

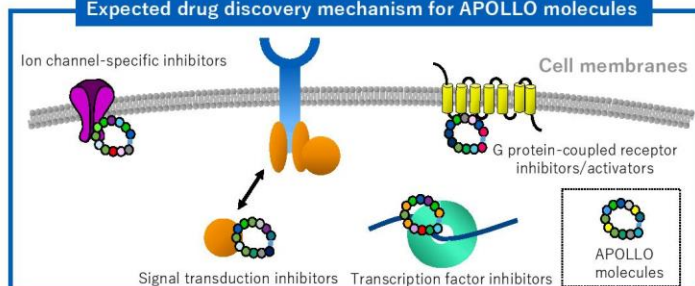
- By modifying compounds from a uniquely constructed unnatural amino acid-containing peptide library, APOLLO platform is possible to create orally administrable drug candidate molecules with high target specificity that have both membrane permeability and metabolic stability.
- ⇒ Able to target intracellular tough targets that have been difficult to approach with small molecules and antibodies
(Extracellular targets can also be bound)

Comparison of modalities

	Small molecules	APOLLO molecules	Antibody
Molecular weight	-500	500-2000	-150,000-
Administration route	Oral/ Injection	Oral/ Injection	Injection
PPI** inhibition	△	◎	◎
Intracellular targeting	◎	○	△
Target selectivity	△	◎	◎

*Omicron: Image of Greek letter "O," cyclic peptide
**PPI: Protein-Protein interaction

Expected drug discovery mechanism for APOLLO molecules



35

LUNA18 has entered the first clinical trial as a new drug discovery modality, a mid-size molecule drug. In this slide, I will begin by explaining Chugai's unique mid-size molecule technology.

In our growth strategy, TOP I 2030, we have set up a multi-modality strategy, and mid-size molecule drug discovery is the most important target.

The name of Chugai's original mid-size molecule platform is APOLLO, which is derived from its characteristics: Artificial, Peptidic, Orally Available, Limitlessly Localizable Omicron.

Our unique peptide library containing constructed amino acids makes it possible to create drug candidate molecules with high target specificity that combine membrane permeability and metabolic stability for oral administration. It is possible to target intracellular and extracellular targets that have been difficult to target with conventional technologies such as small molecules and antibodies.

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LUNA18 (RAS Inhibitor)

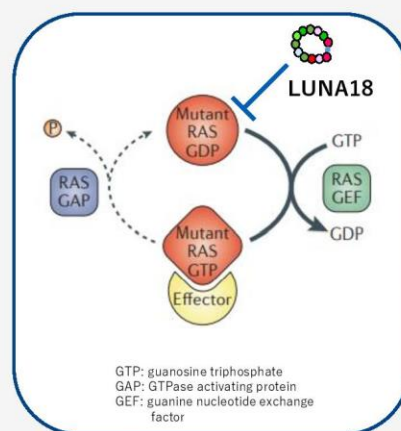
Expected to show anti-tumor effects on segments with a wide range of *RAS* alterations

• RAS

- A small molecule GTPase that activates upon binding to GTPs and transduces signals through networks such as RAF/MEK/ERK and PI3K/AKT.
- Plays an important role in cell differentiation, proliferation and survival.
- *Ras* alterations are the most commonly detected oncogenic genetic abnormalities in cancer cells.

• LUNA18

- An orally administrable cyclic peptide molecule created by APOLLO platform.
- Inhibits protein-protein interaction between RAS and GEF to retain RAS in an inactive state.
- Exhibits growth inhibitory activity against tumor cells with various *RAS* alterations (mutations or amplifications) and can be expected to have anti-tumor effects against cancers with *RAS* alterations where there are no therapeutic drugs yet.



Nat Rev Drug Discov. 2014; 13: 828-51

36

In this slide, I would like to explain LUNA18, which is the first project in mid-size molecule drug project.

LUNA18 is a RAS inhibitor, and a Phase I study for solid tumors started this month. It is expected to have anti-tumor effects on a wide range of cancers with RAS alterations.

RAS is a low-molecular-weight GTPase that binds to and activates GTP, and plays an important role in cell differentiation, proliferation, and survival by signaling through the RAF/MEK/ERK and PI3K/AKT pathways. Genetic alterations in the *RAS* gene are the most common oncogenic genetic abnormality detected in cancer cells.

LUNA18 is an orally administered cyclic peptide molecule created with APOLLO technology. It inhibits the protein-protein interaction between RAS and GEF and keeps RAS in an inactive state. It has shown growth inhibition activity against tumor cells with various *RAS* gene alterations. It is expected to have anti-tumor effects on cancers with *RAS* gene alterations for which there is no treatment at present.

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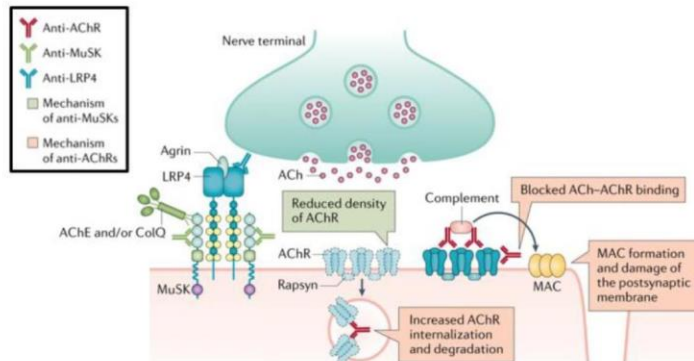
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Generalized Myasthenia Gravis (gMG)

Enspryng: IL-6 blockade may reduce pathogenic autoantibody production



Source: Roche Pharma Day materials (September 14, 2021)

- 1) Myasthenia gravis clinical practice guideline 2014 (supervisor: Japanese Society of Neurology); Nankodo
- 2) Kerty E, Elsaïs A, Argov Z, et al. EFNS/ENS Guidelines for the treatment of ocular myasthenia. European Journal of Neurology 2014;21:687-93.
- 3) Gilhus N, Tzartos S, Evoli A, et al. Myasthenia gravis. Nat Rev Dis Primers 2019;5(30). Available from the Internet: <https://www.nature.com/articles/s41572-019-0079-y>
- 4) Health and Labor Sciences Research Grants Policy Research Project for Intractable Diseases (Policy Research Project for Intractable Diseases) Verification of Diagnostic Criteria, Severity Classification, Guidelines and Patient QOL Based on Evidence of Neuroimmune Diseases Summary / Sharing Research report (2018)

- gMG is an organ-specific autoimmune disease against molecules on the postsynaptic membrane of the neuromuscular junction and is characterized by painless muscle loss with easy fatigability of skeletal muscle.¹⁾
- Transition from initial symptoms such as ptosis and diplopia to systemic type is observed. gMG with cervical limb weakness, dysarthria, dysphagia, breathing disability, etc. accounts for 85% of the total.^{1) 2)}
- Although the autoantibody positive rate varies slightly depending on the report, it is reported that 80% of the total are acetylcholine receptor (AChR) antibody positive and about 7% are muscle specific kinase (MuSK) antibody positive.³⁾
- In Japan, the 2018 National Epidemiological Survey estimates that there are 29,210 MG patients, or 23.1 per 100,000.⁴⁾

37

In this slide, I would like to explain the expected additional indication of Enspryng for generalized myasthenia gravis (gMG).

A Phase III trial for Enspryng in gMG started this month. We expect that blockade of IL-6 by Enspryng will inhibit pathogenic autoantibody production.

Generalized MG is an organ-specific autoimmune disease in the postsynaptic membrane of the neuromuscular junction, characterized by muscle weakness with painless skeletal muscle paresis. It is said that 85% of all cases are of the generalized type, which begins with initial symptoms such as droopy eyelids and diplopia and presents with weakness in the neck and limb muscles, dysphagia, and respiratory problems. It has been reported that 80% of MG patients are positive for acetylcholine receptor antibodies, and about 7% are positive for muscle-specific kinase antibodies. In Japan, an epidemiological survey in 2018 estimated that there are 29,210 patients with MG.

Although there are no data directly evaluating the efficacy of Enspryng for gMG, it has been reported that serum IL-6 levels are higher in gMG patients than in healthy subjects, and that the severity of the disease correlates to some extent with peripheral blood IL-6 levels in acetylcholine receptor antibody-positive patients.

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Clinical Status of Therapeutic Drugs in COVID-19 Treatment

Three drugs under development for patients with mild to moderate and severe infections

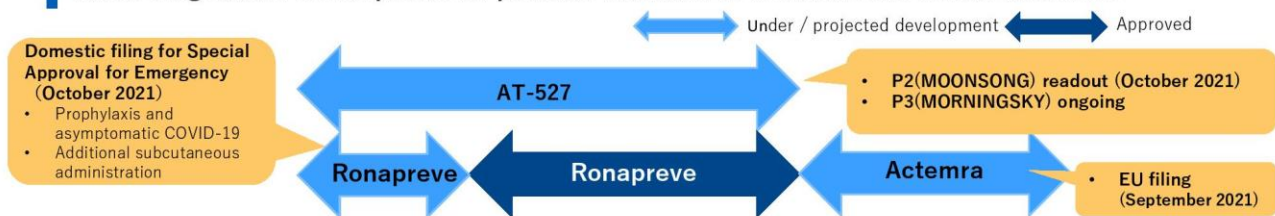
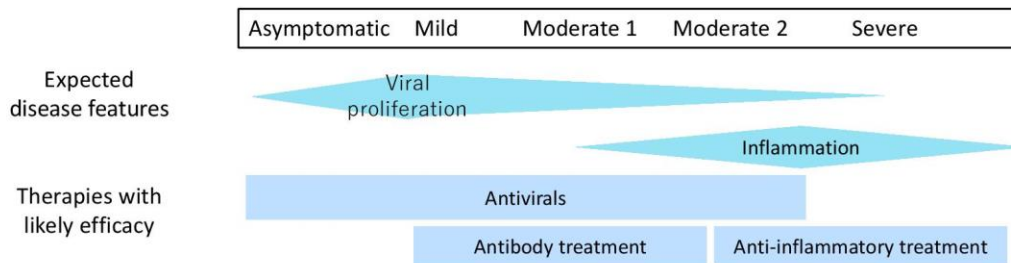


Figure conceptualizing COVID-19 severity and treatment



Source: Japanese Association for Infectious Diseases: Approaches to Pharmacotherapies for COVID-19, 8th ed. (July 31, 2021)

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Next, I would like to explain the 3 therapeutic agents that are being developed for COVID-19.

First of all, the figure at the bottom of the slide shows the concepts in drug treatment for COVID-19 according to severity. This is modified from a document by the Japanese Association of Infectious Diseases. After infection, COVID-19 can develop from an asymptomatic phase and progress from mild to severe disease as the virus multiplies. Treatments are proposed according to progression of the infection and severity.

In the upper part of the slide, we show 3 drugs, Ronapreve, Actemra, and AT-527. We believe that they can contribute to the treatment of COVID-19 across this spectrum, covering a wide range of patients from asymptomatic to severe disease. With regard to Ronapreve, we have already obtained special approval for the treatment of mild to moderate disease I stage, where symptoms have already developed and oxygen administration is not required. Through filing applications for prophylaxis indications, such as prevention in close contacts and at the asymptomatic phase, we hope to make further contributions to the field.

In addition to the intravenous administration that was already approved, an application for additional subcutaneous administration was also submitted in conjunction with this indication expansion.

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Application for Additional Indication of Ronapreve (Antibody Cocktail)

Prophylaxis / Early Treatment and Subcutaneous Administration in Japan

- Submitted a domestic application for Special Approval for Emergency based on the results of the REGN-COV 2069, REGN-COV 20145, and the Japanese P1 study (JV43180) aimed at evaluating safety, tolerability, and pharmacokinetics.
- Submitted a simultaneous application for additional subcutaneous administration

< REGN-COV 2069 study > : Global P3 study for prophylaxis and asymptomatic COVID-19

- Primary endpoint met
 - ✓ One dose of antibody cocktail (1,200 mg subcutaneous administration) to prevent infections reduced the symptomatic COVID-19 infections by 81% ($p < 0.0001$)
- All major secondary points met
 - ✓ When individuals treated with antibody cocktail who still experienced a symptomatic infection, # of weeks with symptoms (mean) in symptomatic individuals was shortened to 1.2 weeks compared to 3.2 weeks with placebo ($p < 0.0001$)
 - ✓ In a cohort of recently-infected asymptomatic patients, antibody cocktail reduced the overall risk of progressing to symptomatic COVID-19 by 31% ($p = 0.0380$)
- No new safety signals were observed

< REGN-COV 20145 study > : Global P2 study for dosage and administration determination

- P2 study for low-risk* outpatient showed significant and comparable viral load reductions across doses ranging from 300 to 2,400 mg.

* Symptomatic patients with COVID-19 having low-risk in progressing to severe, or asymptomatic patients with COVID-19

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The next slide shows the schedule for the application for the additional indication of Ronapreve.

First, the REGN-COV 2069 study was conducted for COVID-19 prophylaxis and asymptomatic infection.

In prophylaxis of infection, risk of symptomatic infection was reduced by 81%, achieving the primary endpoint. Even in the case of symptomatic infections, the average duration of symptoms has been reduced from 3.2 weeks to 1.2 weeks. In another cohort of asymptomatic patients, there was a 31% reduction in the risk of conversion to symptomatic status. No new safety signals were observed.

In addition to this, the REGN-COV20145 is a Phase II study that investigated the dosage and administration. In patients without risk of progressing to severe disease, significant and similar reduction in viral load was observed in all doses between 300 and 2400 mg.

In addition to these 2 studies, we have submitted an application together with the results of domestic Phase I clinical trials to evaluate safety, tolerability, and pharmacokinetics in Japanese patients.

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P1 Development Status of Chugai Originated Products (Oncology 1)

As of October 22, 2021

Project	GC33	ERY974	AMY109 (CIT)
MoA (Modality)	Anti-Glypican-3 humanized monoclonal antibody	Anti-Glypican-3/CD3 bispecific antibody	Recycling antibody
Target indication	Hepatocellular carcinoma	<ul style="list-style-type: none"> Solid tumors Hepatocellular carcinoma 	Solid tumors
Study start	October 2010	August 2016	March 2020
Status	<ul style="list-style-type: none"> Scheduled to start a P1 study (Investigator Initiated Trial) with GC33 alone in pediatric cancer patients expressing GPC3 	<ul style="list-style-type: none"> A domestic P1 study (single agent) is ongoing with a study design where Actemra is premedicated as a preventive measure against cytokine release syndrome (CRS). A P1b study in patients with hepatocellular carcinoma in combination with Tecentriq and Avastin (premedication with Actemra) is underway in Japan and Taiwan. 	<ul style="list-style-type: none"> A P1 study (combined with Tecentriq) in patients with solid tumors is ongoing. Expected to strengthen tumor immunity and enhance the anti-tumor effect of Tecentriq

MoA: mode of action

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P1 Development Status of Chugai Originated Products (Oncology 2)

As of October 22, 2021

Project	STA551	SPYK04	SOF10/RG6440
MoA (Modality)	Anti-CD137 agonistic Switch antibody	Small molecule	Anti-latent TGF- β 1 monoclonal antibody
Target indication	Solid tumors	Solid tumors	Solid tumors
Study start	March 2020	September 2020	June 2021 (Out-licensed to Roche)
Status	<ul style="list-style-type: none"> A P1 study is ongoing with STA551 alone and in combination with Tecentriq. 	<ul style="list-style-type: none"> A P1 study is ongoing in Japan and the United States for solid tumors. Recruiting patients from EU and Asian countries are considered going forward. In the expanded cohort part, the anti-tumor effect is preliminarily examined. The targets include non-small cell lung cancer and ovarian cancer. 	<ul style="list-style-type: none"> A P1 study in combination with Tecentriq for solid tumors is ongoing. Lung cancer, stomach cancer, pancreatic cancer, etc. are considered as planned indications. Expected to show anti-tumor effect in the segment where cancer immunotherapy is difficult to respond.

MoA: mode of action

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On the next page, you will see 3 slides showing the progress of Phase I trials for our in-house developed products.

Due to our development strategy, the level of detail in our disclosures may vary, and we would appreciate it if you could refer to them as appropriate.

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P1 Development Status of Chugai Originated Products (Others)

As of October 22, 2021

Project	PCO371	AMY109	GYM329/RG6237	NXT007
MoA (Modality)	PTH1 receptor agonist	Recycling antibody	Anti-latent myostatin sweeping antibody	Anti-coagulation factor IXa/X bispecific antibody
Target indication	Hypoparathyroidism	Endometriosis	Neuromuscular disease	Hemophilia A
Study start	June 2015	February 2018	October 2018 (Out-licensed to Roche)	August 2019
Status	<ul style="list-style-type: none"> A P1b study for hypoparathyroidism was discontinued early due to grade 3 adverse events and the uncertain benefit-risk balance in the target patients at this time. 	<ul style="list-style-type: none"> An antibody with anti-inflammatory action, aiming to contribute by a MoA different from hormone therapy, which is the standard of care. A P1 study was suspended due to the impact of COVID-19, but the recruitment was completed. 	<ul style="list-style-type: none"> A P1 study is ongoing. A study on disuse muscular atrophy is in progress to evaluate the effect of GYM329 in the Netherlands. P2/3 study combination with Evrysdi for patients with spinal muscular atrophy is scheduled to start in Q1 2022. (announced by Roche) 	<ul style="list-style-type: none"> Aiming at achieving healthy adult level hemostatic effect and improvement of PK profile. Although the project was affected by COVID-19, P1 /2 study is ongoing as planned.

MoA: mode of action

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Today, I would like to explain only GYM 329. Please go to page 43.

GYM329 is a sweeping antibody that binds to latent myostatin. We have already licensed it out to Roche. It inhibits upstream myostatin signaling, which suppresses muscle growth and hypertrophy. It is expected to be effective in neuromuscular diseases associated with muscle atrophy and muscle weakness.

As announced by Roche, a phase II/III study in combination with Evrysdi for the treatment of spinal muscular atrophy (SMA) is scheduled to start in the first quarter of next year.

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Projects under Development (1)

As of October 22, 2021

AS of October 22, 2021

	Phase I	Phase II	Phase III	Filed		
Cancer	GC33 / codrituzumab - HCC	RG6026 / glofitamab - hematologic tumors	OBP-301* - esophageal cancer	AF802 (RG7853) / Alecensa - NSCLC (adjuvant)	RG435 / Avastin (Tecentriq combo) - SCLC - HCC (adjuvant) - HCC (intermediate stage)	RG7446 / Tecentriq - NSCLC (adjuvant)
	ERY974 - solid tumors	RG7446 / Tecentriq (Actemra or tiragolumab combo)	RG7596 / Polivy - DLBCL	RG7440 / ipatasertib - prostate cancer	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	
	RG7421 / cobimetinib - solid tumors	RG6194 / HER2-TDB - solid tumors	RG6264 (Herceptin+Perjeta) - breast cancer (Fixed-dose combination, subcutaneous injection)	RG6058 / tiragolumab (Tecentriq combo) - SCLC - NSCLC - NSCLC(stage III) - esophageal cancer		
	RG7802 / cibisatamab - solid tumors	OBP-301* (Tecentriq/Avastin combo) - HCC	RG6171 / giredestrant - breast cancer - breast cancer (adjuvant) ★			
	RG7828 / mosunetuzumab - hematologic tumors	SOF10 (RG6440) - solid tumors				
	AMY109 - solid tumors	RG6396 / pralsetinib - solid tumors				
	STA551 - solid tumors	LUNA18 - solid tumors ★				
	SPYK04 - solid tumors					

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

★: Projects with advances in stages since July 26, 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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Projects under Development (2)

As of October 22, 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 (BS-Gante) - Alzheimer's disease	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease SA237 (RG6168) / Enspryng - generalized myasthenia gravis gMG ★	
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II) RG7992 (anti-FGFR1/KLB) - 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 (AT-527) - COVID-19	RG7716 / faricimab - DME - nAMD RG6413+RG6412 / Ronapreve - COVID-19* ★

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 July 26, 2021

PNH: paroxysmal nocturnal hemoglobinuria

nAMD: neovascular age-related macular degeneration

DME: diabetic macular edema

*prophylaxis of COVID-19 and treatment of asymptomatic COVID-19

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The next 2 slides show the status of the development pipeline.

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FoundationOne CDx Cancer Genomic Profile

Companion diagnostic indications

As of October 22, 2021

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

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

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FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of October 22, 2021

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

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Indications relating to the companion diagnostic function of FoundationOne CDx are on page 46. Those for the companion diagnostic function of FoundationOne Liquid CDx are on page 47.

This concludes my presentation.

Sasai: This concludes the presentation section. I would now like to move on to the Q&A session.

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Question & Answer

Sasai: I'm very sorry, but in order to allow as many people as possible to ask questions, we would like to limit the number of questions to 2 per person. When it is your turn to ask a question, I will call your name. When asking a question, please let us know your name and company name.

Please note that the audio of your questions, along with this presentation, will be posted on our website at a later date. Please note that we are also joined for the question-and-answer session by Mr. Hidaka, Vice President and Head of Marketing and Sales Division. Thank you.

We will now begin the question-and-answer session.

Your first question. Mr. Kohtani of Nomura Securities, please go ahead.

Kohtani: I'm Kohtani from Nomura Securities.

The first question is about the plan for Ronapreve for next year. Former Prime Minister Suga commented in one of the TV shows that he procured 500,000 units of Ronapreve at JPY310,000 per unit. He stated that he increased the number of units from 200,000 to 500,000 because he wanted to buy as many as he could.

If we simply calculate this amount, it would be JPY155 billion, and the sales recorded by your company here is JPY82.3 billion. What is the reason for this discrepancy? I also wonder if there will be any part of that total that cannot be delivered by the end of this year and will be moved to next year.

In addition, looking ahead to next year, at least one coronavirus oral drug will come out. I think the price will be in the region of tens of thousands of yen per dose, so I thought that Actemra and also antibody cocktail therapy might be at a disadvantage next year because of the JPY310,000 unit cost of antibody cocktail therapy.

However, you said that your company can aim for a record high next year, so I think your assumption here is that Actemra and Ronapreve will increase further.

Itagaki: Thank you very much. This is Itagaki.

The quantity and unit price of Ronapreve cannot be disclosed due to contractual confidentiality obligations. Therefore, I do not have any particular comment on the figures quoted. As I explained, sales are not recorded at the time of agreeing a contract, but on a product delivery basis. This full-year forecast is for the portion of sales to be delivered to the government by the end of the year.

As for next year and beyond, we are still in the planning phase, and I don't think we are at a stage where we can make any particular statement about the figures for next year. In addition, we are not yet at the stage where we can say how our products relate to those of other companies.

Kohtani: Am I correct in thinking that at this point, a contract has already been signed for doses to be delivered next year, so there should be no issue of delays?

Itagaki: We don't have anything more to say other than that our forecast is based on the delivery by the end of this year within the scope of the current contract.

Also, I think Dr. Okuda may want to say a few words regarding the forecast for next year.

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Okuda: Indeed, thank you.

Whether or not the government will make additional purchases next year is, of course, very difficult to predict. However, in the overall picture of the government's efforts to ensure peace of mind in the face of ongoing spread of the infection, the government has placed importance on securing therapeutic drugs in preparation for a worst-case scenario in the sixth wave of infection and beyond.

Of course, it is expected that oral drugs will be available, and there are other antibody treatments. Having said that, I think this shows that it is important for the government to have a variety of treatment options available in the event of a widespread infection.

In this sense, there are many uncertain factors, but we certainly feel there is a possibility of additional purchases next year.

Sasai: Is that alright?

Kohtani: Yes, thank you. Understood.

My second question is about LUNA18. The drug inhibits the binding of SOS1 protein to RAS. I am not sure which RAS is involved here, but it also inhibits the binding, as shown in the figure, so it prevents activation by GTP.

What I would like to ask is that this is for patients with RAS alterations, and I wonder if you can tell us whether this is effective for all mutations, such as KRAS G12C, G12D, and G12V.

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

The compound can be thought of as a pan-RAS inhibitor. That is all from me.

Kohtani: Am I correct in understanding that it works on all the various mutations I just mentioned, but does not bind to the wild type?

Tetsuya Yamaguchi: Sorry, my answer wasn't very clear. It has been shown to have inhibitory activity against a very wide range of RAS mutations, as well as the wild type.

Kohtani: Yes, thank you. Understood. Thank you very much.

Sasai: Thank you very much.

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

Wakao: This is Wakao from JPMorgan.

First of all, Mr. Kohtani just asked about the record-high profit results, but based on your explanation, I think that the additional purchase of Ronapreve and Hemlibra are almost flat according to the graph you showed us today. It is my understanding that the biggest contribution to profit increase will be in these two areas. If there are any other factors, I would like to know about them.

Also, in Mr. Itagaki's explanation earlier, it was mentioned that there was an upside related to coronavirus, but what you are trying to say is that you expect some upside depending on the infection situation, in addition to the additional purchase that you are currently anticipating. Could you tell us a little more about this record high profit?

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Also, if the impact of the coronavirus pandemic is significant in the next fiscal year, do you think that there will be a subsequent rebound in the fiscal year after next? Or do you anticipate a steady increase from here to the next fiscal year and the following fiscal year as well?

Okuda: Thank you for your question, Mr. Wakao. I will give you an answer.

We talked about the delivery next year of the government's purchase of Ronapreve, or additional purchases. In addition to this, Actemra is an in-house product, so we can expect export sales of Actemra depending on COVID-19 infections globally.

If you look at the current situation, as announced by Roche, Actemra is being used to such an extent that the supply cannot keep up with the demand. It is a little difficult to predict whether this will end up in the rest of the world, and our view is that exports of Actemra are expected to continue next year.

Hemlibra is as you said. It now seems that we can eliminate the so-called royalty 2 cliff. The basis for this is the growth of Hemlibra in Europe and the United States. Roche has also announced that their market share has gone from 29% to 31%. Sales will also increase accordingly.

Furthermore, in addition to this, more fundamental areas are showing growth. As I explained in the forecast for this fiscal year, our main products in Japan are growing faster than expected, and we expect this to continue in the next fiscal year and beyond.

Tecentriq, Polivy, Enspryng, and Evrysdi are our new products, and from the next fiscal year, adjuvant Tecentriq for lung cancer and faricimab for ophthalmology will also be launched. If we include these products, domestic sales are expected to grow very steadily. With all of these factors, we are in a position to declare that we are aiming for record-high profits in the next fiscal year and beyond.

You asked about the fiscal year after next, and this is even more difficult than reading the next fiscal year, and there are many different scenarios that could play out. I think you can appreciate the fundamentals, so I can't really add much about the fiscal year after next.

Wakao: Understood, thank you very much.

Secondly, sales of Actemra, which was one of the points you just explained, will be lower in 2021 than in the previous fiscal year, and I think it will be a smaller portion of total. Since Roche's sales at the end of the line are very strong, I thought there would be slightly higher exports in Q4.

Considering the scale of exports for next year or so, the export value seems to be a little smaller than the terminal value. However, this is a reflection of the large exports from the previous fiscal year and is also represented to some extent in the Q1 results of this fiscal year.

So, if the current infection situation continues, is it safe to assume that sales will be roughly the same in 2022?

Itagaki: This is Itagaki.

Mr. Wakao, when you talk about new exports for Actemra, if you look at the slide on page 20, you will see that even though the Company expects to export JPY100 billion this year, it appears to be a 24.2% drop compared to last year.

First of all, in 2020, we were quite a bit ahead of the market in terms of sales to Roche, so if we think of it as being 12 to 13 percentage points ahead of the market, that's 12 to 13 percentage points of our 2019 sales, so roughly speaking, we were about JPY10 billion ahead of the market.

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If that is the case, the actual amount of last year's budget was JPY132 billion, of which a little over JPY10 billion was already spent, so if we assume that JPY10 billion was spent, JPY122 billion would be the launch pad for last year's budget. Since we are looking at JPY100 billion this year, there was a rebound in that amount, so when corrected, it is JPY110 billion.

In addition, the unit price of Actemra's exports is constantly reviewed, and the unit price and exchange rate are also reviewed. If you add these 2 factors together, I think about 10% of the total was hit this year, so if you correct for that, it looks almost flat, the same as last year.

As Mr. Okuda said earlier, it is hard to imagine that COVID-19 infections will suddenly stop. Considering that the current demand is very strong, we have high expectations for next year as well. This is the basis for our expectations for product next fiscal year.

Wakao: Understood. Thank you. That's all.

Sasai: Thank you very much.

The next speaker is Mr. Hashiguchi from Daiwa Securities.

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

The first question is about Hemlibra exports to Roche. I understand from your explanation on page 22 that you expect export sales of JPY96.9 billion at the normal shipping price for this fiscal year, but you expect that this could nearly double next year.

I don't think the sales recorded by Roche are growing at such a fast pace at the moment, but do you expect the growth of sales recorded by Roche to accelerate in the next fiscal year? Also, do you expect that Roche's inventory is low at the moment and that there is a possibility that Roche's purchase volume will increase significantly in the next fiscal year? Can you give us some background on this?

Itagaki: Mr. Hashiguchi, this is Itagaki. Thank you.

This year, there is still inventory from the initial shipments, and based on that, Roche is currently making orders. Next year, while that inventory is not at full capacity, Roche will make sure that the inventory is stable in preparation for future demand. As you can see in the blue bar, we are expecting a large volume of shipments.

Hashiguchi: In that case, is it correct to say that you expect sales in 2022 to be in line with the sales at the end of the year without any irregularities, given that 2021 was a particularly low year?

Itagaki: Yes, that's correct. I think it is correct to say that the appropriate amount of exports will be recorded based on the final sales trend and the future demand forecast, since there is a lead time ahead of the final sales.

Hashiguchi: Thank you very much.

My other question is about GYM 329. Since you are suddenly entering phase II/III trials, I would like to know if you have obtained any data showing the efficacy of the drug in patients, and if you have any plans for the publication of such data.

Also, could you tell us why you chose to develop a combination therapy from the beginning instead of a monotherapy?

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Nezu: Thank you very much for your question. My name is Nezu from the R&D Portfolio Management Department. I will take your question.

First of all, GYM329 is undergoing phase I trials, so we are confirming its safety.

In addition, we are currently considering the development of a single agent. In the SMA study, we are starting a trial to confirm the add on effect to Evrysdi, as there is a rational based on effects in non-clinical studies.

Sasai: Is that alright?

Hashiguchi: Yes, understood. Thank you very much.

Sasai: Thank you very much.

The next speaker is Mr. Muraoka from Morgan Stanley Securities.

Muraoka: This is Muraoka from Morgan Stanley.

Regarding CIM331, nemolizumab, I understand that it should be up for discussion by the committee in Japan soon, but it may be a little delayed. I appreciate that it may be hard to comment on this.

Overseas trial results for atopic dermatitis and PN (prurigo nodularis) should be available soon, so am I correct in thinking that that is the case?

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

First of all, I cannot go into the status of the review process in Japan here, but given the timing of the application, it is undeniable that it has been delayed a bit.

As for overseas trials, we are proceeding steadily with the planned timeline for atopic dermatitis and prurigo nodularis, although COVID-19 has had a slight impact. That is the current situation. That is all from me.

Muraoka: In other words, even if the deliberations in Japan are a bit behind schedule, is it correct to understand that there aren't any major problems?

Tetsuya Yamaguchi: Thank you very much.

There aren't any issues relating to safety or effectiveness, and I would say that discussion points could not be described in terms of major problems.

Muraoka: Thank you very much.

Also, regarding the trend in demand for Actemra, I understand that it sold well during the period from July to September, but your assumption is that the demand will not decline in the next fiscal year. Is it correct to say that there is some assumption of an increase in infection in developing countries or other regions, and that there will be a certain degree of growth there? There is a slight gap between my impressions here and the explanation we've heard today in this area, so I would be grateful if you could explain on this a little.

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

We are seeing increases in infections in some countries where significant parts of the population have been vaccinated. Additionally, we see that in some countries, the vaccination rate seems to hit a ceiling at around 50%.

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In the United Kingdom, for example, as economic activity resumes, the number of new infections is increasing. The situation is much the same in the United States. It seems we are now transitioning to allowing a certain number of new infections with increased economic activity.

Therefore, even if the vaccine is completely effective, breakthrough infections can still occur, and if we include such factors as the persistence of infections in developed countries and in less-vaccinated countries, it makes sense to think that there should be a certain level of demand for Actemra. As you pointed out, this is a very difficult area to read. We don't know which way it will swing, but we believe there is a fair chance that demand will continue.

Muraoka: Understood. Thank you. That's all.

Sasai: Thank you very much.

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

Hidemaru Yamaguchi: This is Yamaguchi from Citi.

I'm sorry if I'm asking the same question, but I think this is the first time you mentioned that the royalty 2 cliff would be covered in the Hemlibra deal with Roche.

On the other hand, it seems that you are aiming for record high profit overall, and I think you are talking about adding up the various increases in existing businesses and the increase in Actemra. I was wondering if your company's assumption is that the positive and negative effects of Ronapreve for the current and next fiscal year have been factored in, and that you are aiming for an increase in profits for the next fiscal year. Could you please say a little more on that point?

Itagaki: This is Itagaki. Thank you.

For Ronapreve, considering the current disease trends in Japan and the various factors involved, I think we can be assured of a certain level of demand. Within our assumptions, we don't anticipate a scenario with zero demand. I can't tell you exactly how many doses we will be able to reach, but even if there are uncertainties, I think we are starting to see the range we can aim for.

Hidemaru Yamaguchi: Understood.

Also, perhaps this could be my question 1A or 1B, but could you explain the basis for the JPY5 billion to JPY10 billion royalty 2 figure in 2022 for Hemlibra?

Itagaki: In this year's initial forecast, it may appear that we would receive JPY95 billion for this fiscal year and that would be the end of it, but we receive the difference calculated from the inventory corresponding to the initial shipment against Roche's global sales. So we can definitely expect it.

However, the unit price may change depending on the country where the product is sold. With that in mind, if we make one more precise update on our footing of how much and when the target inventory is sold in which regions, the total increase will be about JPY6.5 billion to JPY11.5 billion. Due to timing issues, some of this will be delayed to next year. This is how we have reached these figures.

Hidemaru Yamaguchi: Understood. Thank you.

Secondly, I would like to briefly mention that mid-size molecule project, LUNA18 is very interesting. As for the mid-size molecule, you explained it briefly this time, but I think there was some talk about holding an information meeting.

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Sasai: Allow me to answer.

It is tentatively scheduled for the end of the year, but details will be announced separately.

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

Sasai: Thank you very much.

Next, Mr. Otsuka from Jiji Press, please go ahead.

Otsuka: I'm Otsuka from Jiji Press.

The first thing I would like to ask you about in the area of drug approvals is AT-527. The other day, I heard that the results of the Atea Pharmaceuticals test were not very straightforward, but this did not stop Atea from reassembling Phase III. As a result, there will be a significant delay in the release of the schedule.

Your company's application schedule for AT-527 is unchanged for 2022, but even if you say 2022, it is still quite far. That's my first question.

The other point is that you mentioned a year-end date for Actemra, but we are already at the end of October, so if there is anything more you can show about the schedule or your thinking in this area, please let me know. That's all.

Tetsuya Yamaguchi: Thank you very much. I will reply to your question.

First of all, the results of the Phase II study of AT-527 announced by Atea have just come out, and the details of the data will be discussed and analyzed in the future. We are told that there is additional data that may be available. In that sense, we are still in the process of discussing with Roche and others how to proceed with the global Phase III trial, which is currently underway, after carefully examining the data. We are still in the process of discussing with Roche about the timing of the application.

As for the application for Actemra, as you know, the application for Actemra has already been completed in Europe. In Japan, although there isn't much of the year left, I can confirm that the application will be submitted within this year. We are already in the process of submitting this application in consultation with PMDA. That is all from me.

Otsuka: Understood. Thank you.

In that case, will you be seeking Special Approval for Emergency?

Tetsuya Yamaguchi: Thank you very much.

Actemra application will be a normal application for an additional indication.

Otsuka: Understood. Thank you.

Sasai: Thank you very much.

Next, Mr. Yamada from the Nihon Keizai Shimbun, please go ahead.

Yamada: Thank you. I'm Yamada from Nihon Keizai Shimbun.

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I'm sorry for the repetition, but I have a question about AT-527. Merck and other companies are also working on the development of an oral therapy, and I think there is some concern that it may take a little longer to commercialize this drug. How do you think delays in development in this area will affect your competitiveness and earnings in the future? If possible, I would like to hear President Okuda's perspective on this.

One more point, thank you very much for your explanation on the mid-size molecule drug. I know it's difficult to talk about it at this stage, but I would be very happy if you could tell us about the future development schedule and when the drug will be available. Thank you.

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

As for the prospects for AT-527, I will answer your question. Of course, various pharmaceutical companies have been working on therapeutic agents for COVID-19. Of course, since this is pharmaceutical development, there are times when things go well and times when things are quite challenging.

The data from the Phase II trial was from Roche, and as Yamaguchi explained earlier, we are now in the process of conducting a detailed analysis. This detailed analysis will allow us to better understand what kind of patients AT-527 is effective in, and what kind of viral reduction is being seen in those patients.

As I explained earlier, this will provide us with knowledge on how to modify the study design of the ongoing global Phase III study to make development more successful.

So, at this stage, as I explained earlier, we are not thinking of changing the timing of the application. I think this is the right time for us to think about how this will affect our earnings, and to give a lot of thought to that at this point.

Tetsuya Yamaguchi: This is Yamaguchi.

Unfortunately, we are not able to disclose the development schedule of the mid-size molecule drug that you asked about, but since it is a RAS inhibitor, it would be helpful to consider the development schedule of such drugs.

Regarding the mid-size molecule projects in general, we would like to move a variety of development candidates to clinical stage. We believe that the development schedule will vary considerably depending on the target indications. That is all from me.

Yamada: Thank you very much.

Sasai: Thank you very much.

Due to time constraints, I will conclude with the next question. Thank you.

The next speaker is Mr. Sakai from Credit Suisse Securities, please go ahead.

Sakai: This is Sakai, Credit Suisse. Thank you.

Regarding the mid-size molecule project, the materials state that compounds are created from a peptide library. There is an image on the slide. I think there's a lot going on. Basically, the idea is that things will come out of the library, and I think there are several candidates for the 4 channels described here, but I got the impression that the targets for cells in particular have been narrowed down quite a bit at this point. Will you explain this in detail at the year-end briefing? Any comments you can make at this point would be appreciated.

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Also, regarding LUNA18, I believe Roche has first refusal right. Normally, your company has had a policy of not proceeding with opt-in or opt-out negotiations with Roche until you have had a PoC. I have the impression that you are starting negotiations at an earlier timing. What is the current status of the negotiations with Roche regarding LUNA18? Please tell me about this point.

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

Regarding your first point about the peptide library, unfortunately, I am not at liberty to provide any more technical detail today.

Regarding the first refusal right of Roche, you have mentioned comments that the timing of the introduction may have been accelerated, but this is not necessarily the case. Decisions are made on a project-by-project basis, which is the way both companies approach discussions.

We are not able to disclose the status of LUNA18 at present, so we hope you will bear with us on this point.

Sakai: Understood. Thank you very much.

Sasai: Thank you very much.

This concludes today's third quarter conference call. If you were unable to ask a question due to time constraints, please contact the Corporate Communications Department.

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

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