SHIONOGI & CO., LTD.

3rd Quarter of Fiscal 2024 Financial Results

January 31, 2025

Presentation

Kyokawa: My name is Kyokawa of SHIONOGI & Co. Thank you for joining us today. We will now hold the SHIONOGI financial results briefing for Q3 of FY2024.

First, let me introduce today's speakers. Dr. Toshinobu Iwasaki, Senior Vice President, Healthcare Business Supervisory Unit.

Iwasaki: Hello. Thank you.

Kyokawa: Next, Koji Hanasaki, Senior Vice President, Supply Supervisory Unit.

Hanasaki: Hello. Thank you.

Kyokawa: Next, Kazuhiro Hatanaka, Senior Vice President, Corporate Supervisory Unit and Corporate Strategy Division.

Hatanaka: Hello. Thank you.

Kyokawa: Next, Dr. Takeki Uehara, Senior Vice President, Drug Development and Regulatory Science. Dr. Uehara is participating online today.

Finally, Masako Kudou, Vice President, Finance and Accounting.

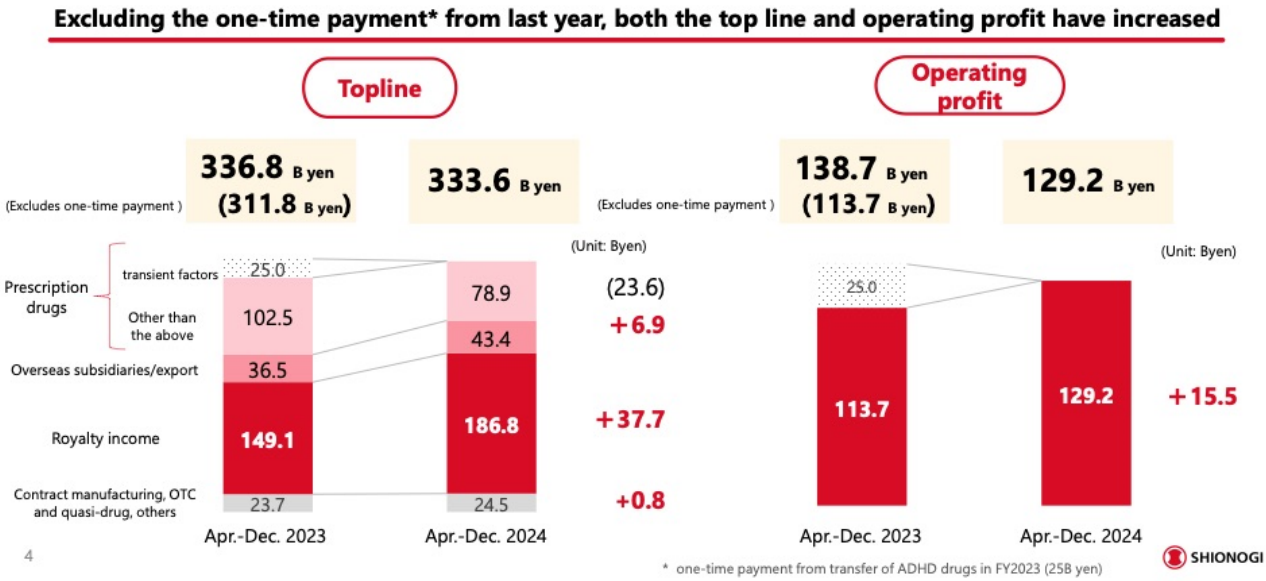
Kudou: Hello. Thank you.

Kyokawa: Now, I will briefly outline today's session. We will begin with an overview of the Q3 results, an explanation of the transformation of our China business and the progress of our pipeline, and finally, we will hold a question-and-answer period. The program is scheduled to end at 18:30.

Please note that simultaneous interpretation capability will be available for today's briefing. To use simultaneous interpretation, please select your preferred language from the globe icon at the bottom of the screen, either Japanese or English.

We will now get started. Ms. Kudou, please go ahead.

Highlight



Kudou: I will now give an overview of the Q3 financial results.

First, on page four, we describe the highlights of the financial results.

Revenue was JPY333.6 billion, JPY3.2 billion less than last year's JPY336.8 billion figure. Excluding the one-time payment of JPY25 billion associated with the transfer of a drug license for ADHD treatment that was recorded in Q1 of last year, royalty income and overseas business grew significantly, and domestic business stabilized.

For the same reason, operating income increased by JPY15.5 billion, excluding one-time payments.

Financial Results

Summary

- **Sales revenue and various profit items landed almost as expected against the full-year forecast**
  - The HIV business and overseas business continue to grow strongly
  - Domestic business is making steady progress due to the stabilization of the infectious disease business.
- **Compared to the same period last year, revenue and profit increased, excluding one-time payments**

(Unit : B yen)

	FY2024			FY2023	Y on Y	
	Forecasts Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	460.0	**333.6**	**72.5**	336.8	**(1.0)**	**(3.2)**
Operating profit	165.0	**129.2**	**78.3**	138.7	**(6.9)**	**(9.5)**
Profit before tax	206.0	**155.9**	**75.7**	164.5	**(5.2)**	**(8.6)**
Profit attributable to owners of parent	171.0	**133.8**	**78.2**	127.2	**5.2**	**6.6**
EBITDA*	-	**146.4**	-	160.2	**(8.6)**	**(13.8)**

Exchange Rate (Average)

	FY2024 Forecast	FY2024 Apr.-Dec. Results
USD($) – JPY(¥)	148	152.64
GBP(£) – JPY(¥)	190	195.50
EUR(€) – JPY(¥)	161	164.89

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*Earnings Before Interest, Taxes, Depreciation, and Amortization : Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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Next, I will discuss consolidated operating results.

The results for Q3 of FY2024 were revenue of JPY333.6 billion, operating profit of JPY129.2 billion, income before tax of JPY155.9 billion, and quarterly income of JPY133.8 billion.

Sales revenue and each profit item were almost in line with the forecast and are progressing steadily against the full-year forecast. This is due to strong growth of the HIV and overseas businesses, as well as the stabilization of the domestic infectious disease business.

With the impact of the one-time sum recorded in the previous fiscal year, revenue was down JPY3.2 billion YoY, and operating profit was down JPY9.5 billion YoY. This is less of a drop than in the Q2 YoY figures. For the full fiscal year, we are aiming for increased sales and revenue, and we are making solid progress. Quarterly profit increased by JPY6.6 billion YoY.

Foreign exchange gains were recorded in each currency due to the weaker-than-expected yen.

Statement of Profit or Loss

(Unit : B yen)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	460.0	333.6	72.5	336.8	(1.0)	(3.2)
Cost of Sales	14.6 67.0	13.8 46.0	68.7	12.6 42.4	8.6	3.6
Gross profit	393.0	287.6	73.2	294.4	(2.3)	(6.9)
Selling, general & administrative expenses, R&D expenses total	48.9 225.0	46.7 155.9	69.3	43.6 146.9	6.1	9.0
Selling, general & administrative expenses	23.7 109.0	22.9 76.4	70.1	22.1 74.3	2.9	2.2
R&D expenses	25.2 116.0	23.8 79.4	68.5	21.6 72.6	9.4	6.8
Other income & expenses	(3.0)	(2.5)	81.7	(8.8)	(72.0)	6.3
Operating profit	35.9 165.0	38.7 129.2	78.3	41.2 138.7	(6.9)	(9.5)
Finance income & costs	41.0	26.7	65.0	25.7	3.5	0.9
Profit before tax	44.8 206.0	46.7 155.9	75.7	48.8 164.5	(5.2)	(8.6)
Profit attributable to owners of parent	171.0	133.8	78.2	127.2	5.2	6.6

Main Variation Factors (Y on Y)

Revenue

Increase
- Overseas subsidiaries /export
- Royalty income

Decrease
- Prescription drugs

Cost of Sales

Increase in expense
- Changes in product mix

R&D expenses

Increase in expense
- Active investment in high-priority development products

Other income & expenses

Decrease in expense
- Costs related to implementation of early retirement program ※

※ Factors that occurred last fiscal year

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Next is page six, the consolidated statement of income.

As I mentioned earlier, sales revenue started from minus JPY25 billion due to a one-time factor that occurred last fiscal year. However, the result improved more than expected due to strong growth in the HIV and overseas businesses.

The cost of goods sold increased 8.6% YoY. This was due to a change in the product mix resulting from growth in overseas business and other factors, and is in line with our full-year forecast.

R&D expenses increased by 9.4% YoY due to a combination of continued aggressive investment in high-priority development pipelines and the impact of foreign exchange rates as a result of the expansion of global clinical trials.

Although the overall progress of expenses, including SG&A and R&D expenses, appears to be somewhat slow, we are implementing cost management measures to achieve the full-year forecast for operating income. If sales revenue continues to be strong, we expect to use the level of expenses in Q4 that we forecast for the full year.

Other revenue expenses increased significantly YoY. This trend in the direction of higher profits YoY is due in part to the implementation of a special early retirement program in Q2 of last fiscal year.

Throughout all of the above, I am sure you will agree that our business is doing very well.

Revenue by Segment

(Unit : B yen)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Prescription drugs	124.7	78.9	63.3	127.5	(38.1)	(48.6)
Excluding temporary income	-	78.9	-	102.5	(23.0)	(23.6)
Overseas subsidiaries/export	57.6	43.4	75.3	36.5	18.8	6.9
Shionogi Inc. (US)	22.6	17.5	77.4	13.1	33.6	4.4
Fetroja	-	14.7	-	10.6	39.6	4.2
Shionogi B.V. (EU)	16.7	12.9	77.5	10.1	28.5	2.9
Fetcroja	-	9.9	-	7.9	25.6	2.0
Ping An Shionogi/C&O	9.1	6.3	68.9	8.3	(24.4)	(2.0)
Others	9.2	6.7	72.5	5.1	32.1	1.6
Contract manufacturing	16.5	10.7	64.8	11.7	(8.9)	(1.0)
OTC and quasi-drug	16.6	12.7	76.5	10.6	20.0	2.1
Royalty income	242.8	186.8	76.9	149.1	25.3	37.7
HIV franchise	234.9	183.5	78.1	146.1	25.6	37.4
Others	7.9	3.3	41.2	3.0	7.7	0.2
Others	1.8	1.1	62.1	1.4	(18.2)	(0.2)
Total	460.0	333.6	72.5	336.8	(1.0)	(3.2)

Main variation Factors (Y on Y)

Prescription drugs

Decrease
- Sales of Infectious disease drugs
- A one-time payment for the transfer of the ADHD treatment drug license※

Overseas subsidiaries/export

Increase
- Sales of cefiderocol (Fetroja, Fetcroja)

OTC and quasi-drug

Increase
- Strong sales of Rinderon and Mucodyne

Royalty income

Increase
- Strong sales of ViiV's HIV franchise

※ Factors that occurred last fiscal year

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Next, on page seven, we discuss revenue by business segment.

Domestic sales of prescription drugs decreased by 38.1% YoY. Excluding a one-time factor of JPY25 billion, the YoY decrease was 23%. As of the Q2 results, these figures were down 50.5% and 33.1% from the previous year, respectively, so you can see that the YoY decline has been improving.

Regarding overseas subsidiaries/exports, revenue for cefiderocol increased YoY by 39.6% in the US and 25.6% in Europe. Although some of the factors are due to foreign exchange rate fluctuations, the volume base is also growing steadily due to an expansion of the number of countries of sale and sales increases in countries where the product has already been launched.

Sales of OTC drugs increased by 20% due to the expansion of Mucodyne and other products in line with the expansion of various infectious diseases as well as Rinderon, our mainstay product.

With regard to royalty income, the HIV franchise grew strongly in Q3, both in terms of volume and foreign exchange, and is progressing steadily in relation to the full-year forecast.

Prescription Drugs in Japan

(Unit : B yen)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Infectious disease drugs	83.4	**50.0**	**60.0**	69.0	**(27.5)**	**(19.0)**
COVID-19 related products + Influenza franchise	72.3	**43.3**	**59.9**	62.0	**(30.2)**	**(18.7)**
Symproic	5.9	**3.8**	**65.0**	3.3	**15.5**	**0.5**
OxyContin franchise	5.0	**3.3**	**66.2**	3.3	**(0.4)**	**(0.0)**
Actair	1.3	**0.7**	**51.1**	0.5	**27.6**	**0.1**
Cymbalta	3.3	**1.9**	**56.4**	3.1	**(40.3)**	**(1.3)**
Others	25.8	**19.2**	**74.4**	48.2*	**(60.1)**	**(29.0)**
Quviviq	3.0	**0.5**	**16.5**	-	**-**	**0.5**
Prescription drugs	124.7	**78.9**	**63.3**	127.5	**(38.1)**	**(48.6)**

Infectious disease drugs

- FINIBAX
- Shiomarin
- ISODINE
- Flumarin
- Baktar
- Fetroja
- Flomox
- Flagyl

COVID-19 related products

- Xocova

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu
- Neo*2

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* Including temporary income from transfer of ADHD drugs *2 This product's sales are only recorded in the 2023 fiscal year results

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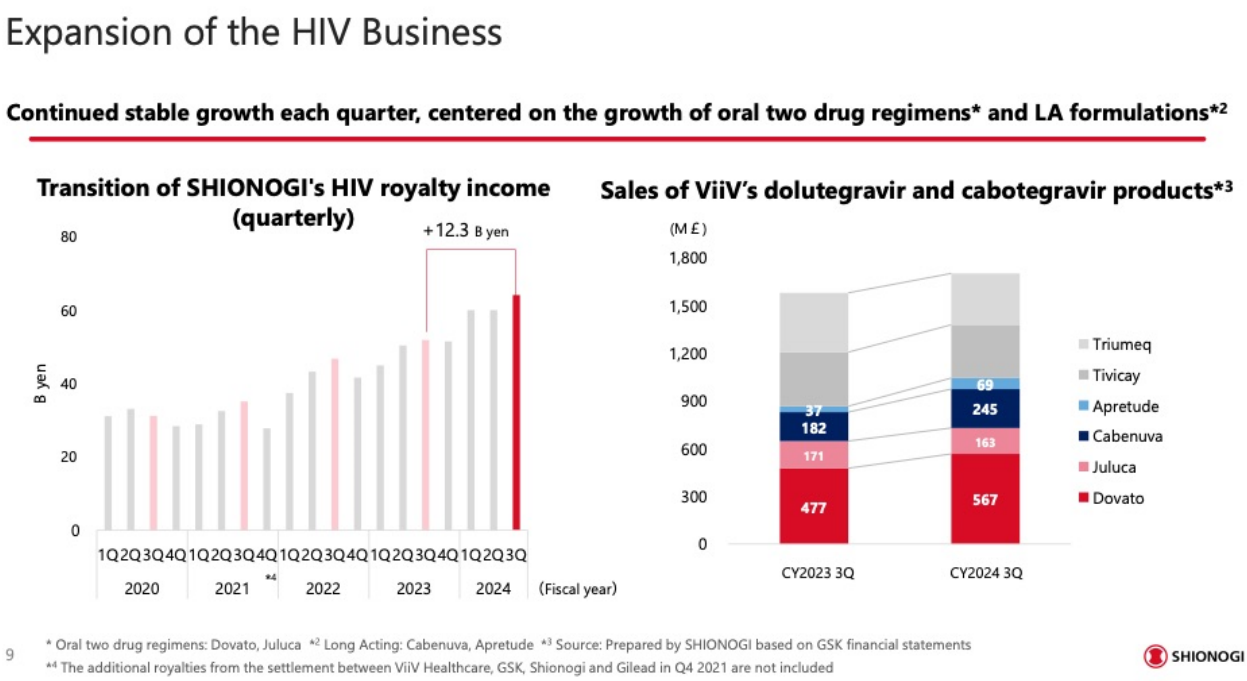
With respect to COVID-19-related products and drugs for the influenza family of infectious diseases, sales of Xofluza and Rapiacta expanded due to the influenza epidemic in December.

When viewed on a YoY basis, the decrease is 30.2%, due in part to the end of public funding for COVID-19 treatment. Looking from Q1 through to Q3, you will see that sales of COVID-19 and influenza family products have been stable.

In Q3, QUVIVIQ, a drug for insomnia, was launched on December 19, and new sales were recorded.

This concludes my presentation.



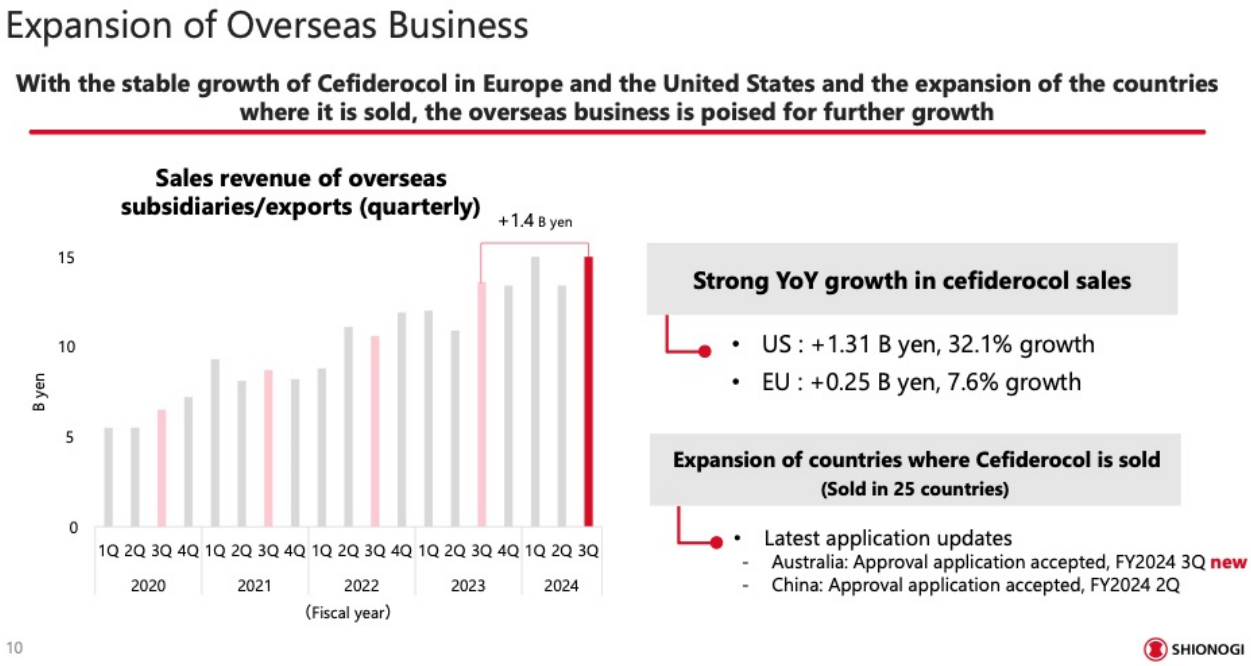
Hatanaka: I would like to continue by presenting the Q3 results. First is page nine, the HIV franchise.

The graph on the left side of the slide shows SHIONOGI's HIV royalty income by quarter. With regard to the HIV franchise, as you understand, it has been increasing very steadily over the medium to long term, but if you look only at 2024, you will see that it is growing significantly. Compared to Q3 of last fiscal year, there was a significant increase, of JPY12.3 billion.

This steady growth in the HIV franchise has been attributed to the growing market share of new product lines, including LA formulations. The graph on the right side of the slide shows ViiV's sales of six products, including dolutegravir and cabotegravir, for July through September compared to last year.

Shown in red is the oral two-drug regimen including dolutegravir, which saw sales increase 12.7% YoY. The LA products shown in blue are CABENUVA, a therapeutic agent, and APRETUDE, a prophylactic agent, which together increased 43.4% YoY.

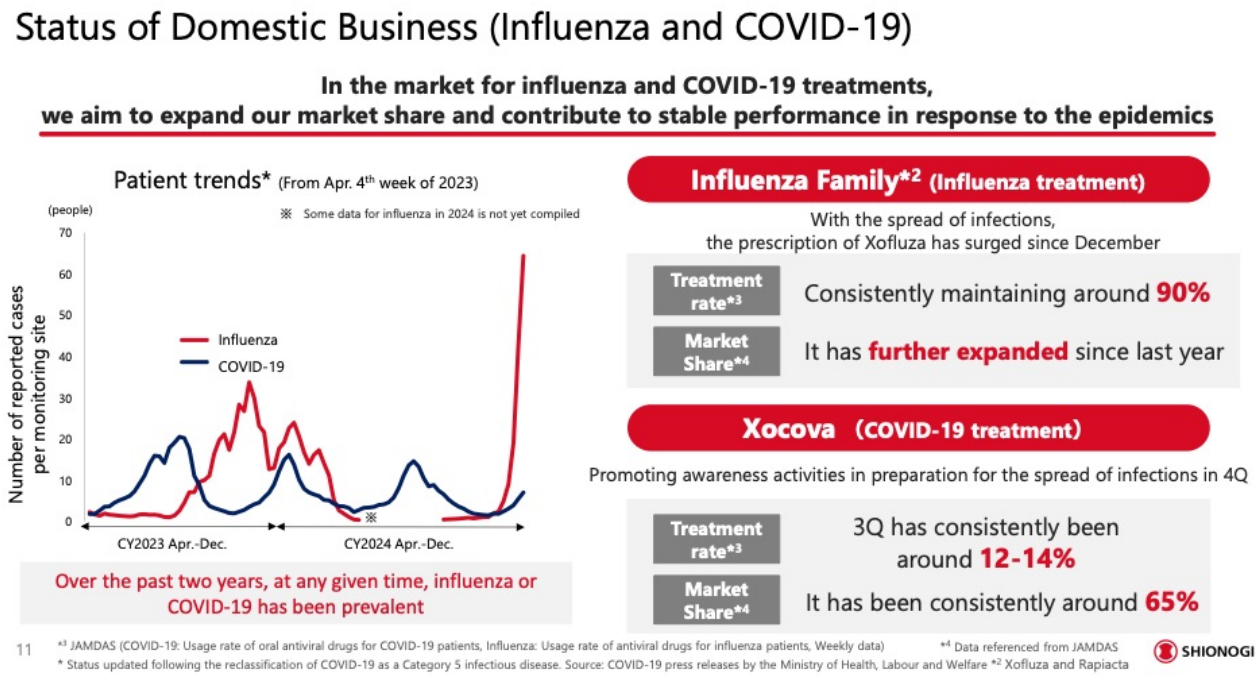
HIV royalties are showing very strong growth. We anticipate further growth in the future, as we expect to launch a new treatment or prophylaxis every four to six months.



Next, page 10. Overseas business has achieved steady growth, especially in cefiderocol.

The graph on the left shows the quarterly sales trend of our overseas business, and you can see that it has been growing steadily since the launch of cefiderocol. Compared to Q3 of last fiscal year, there was a significant increase, of JPY1.4 billion.

The product is currently sold in 25 countries, and to further expand the market, applications for approval have been submitted and accepted in Australia and China. Based on the continued growth of cefiderocol, we will accelerate the global expansion of other development pipelines to achieve further growth of our overseas business.

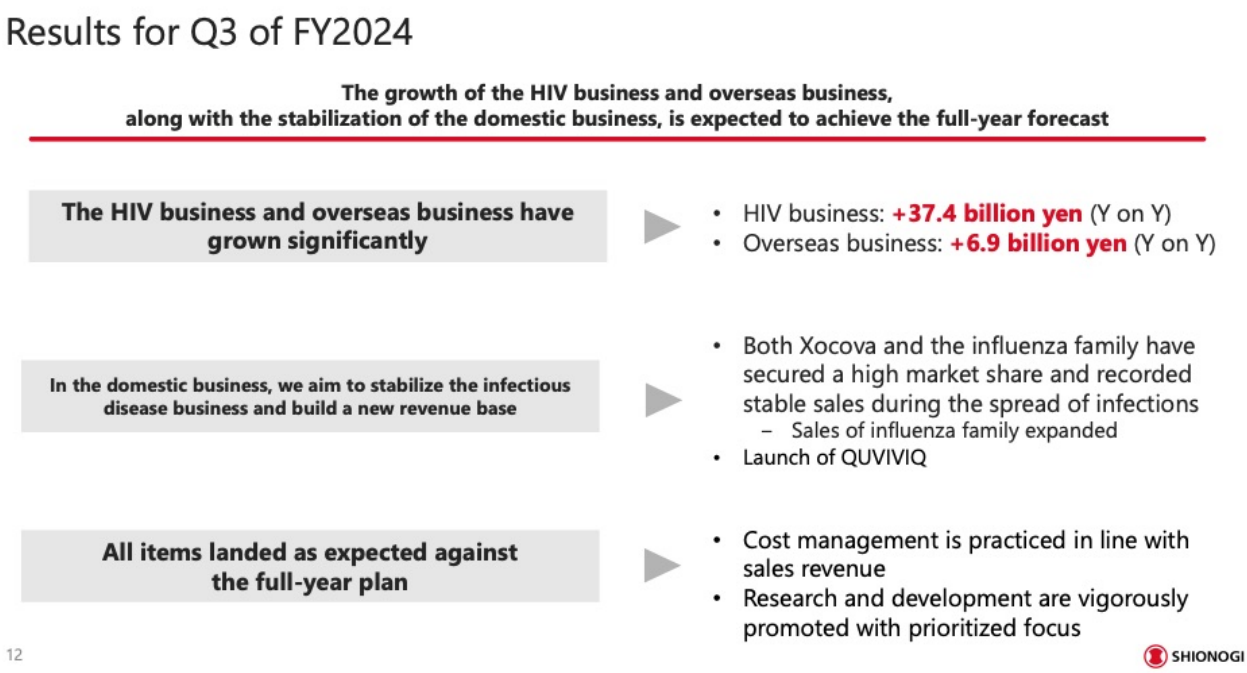


Page 11 shows the status of the Acute Respiratory Infections project in Japan.

The graph on the left side of the slide shows the evolution of COVID-19 and influenza infections since April 2023. I think you can see a situation where either COVID-19 or influenza has been a constant epidemic for the past two years. By having drugs for each of these two infectious diseases and by gaining a large share of the market for each of these drugs, the infectious disease business, which was previously considered unstable, has become a very stable business model that can generate earnings on a quarterly basis.

In Q3, sales of influenza family products, including Xofluza, expanded in December as a result of the spread of influenza. As for COVID-19, the cure rate has been consistently maintained at 12% to 14%, but there is still a large gap between this figure and that of influenza.

The hospitalization rate is known to be higher than that of influenza, so in preparation for the spread of infection in Q4, we are actively developing educational activities. We are also supporting coronavirus insurance, which supports the reduction of co-payment for antiviral drug treatment. In this way, we aim to deliver appropriate treatment to patients who need it.



Continuing on page 12, here is a summary of the Q3 results.

To reiterate, the top line, especially in our profit drivers the HIV and overseas businesses, is growing steadily, achieving YoY revenue growth, excluding transitory factors.

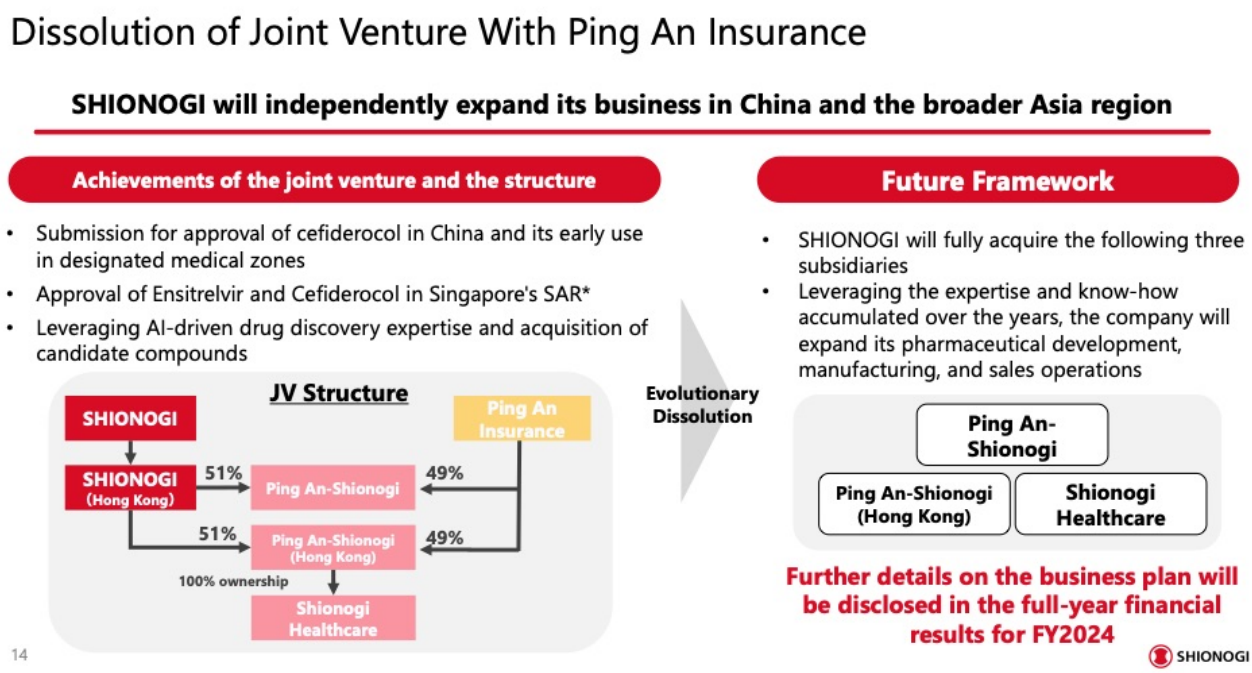
As for the domestic business, the COVID-19 and influenza treatments Xocova and Xofluza have both gained a high market share and made a stable contribution to earnings. We were able to launch QUVIVIQ, which is a mainstay for quality of life diseases.

In the future, we will make the infectious disease business a stable business pillar by acquiring a high market share in the domestic business, and promote activities to focus on QOL diseases, which are less susceptible to epidemic effects.

In terms of costs, while continuing to conduct precise cost management in line with sales revenues, we prioritize and aggressively promote research and development.

In general, we believe that the Q3 results were in line with our expectations, and we expect to achieve our full-year forecast.

That concludes my presentation.



Iwasaki: Next, I would like to present our business transformation in China. Page 14.

First, let me explain the dissolution of the joint venture with Ping An Insurance. The partnership with Ping An Group in China started in November 2020 with the establishment of a joint venture in China. The aim of this venture was to generate synergies by combining Ping An Group's cutting-edge AI and other digital technologies with SHIONOGI's drug discovery know-how.

After sincere discussions between the two companies, both have come to the conclusion that the joint venture in China will be dissolved and SHIONOGI will become a wholly owned subsidiary. We agreed to maintain a good relationship between the two companies.

During the joint venture period, Phase 3 trials of two new drugs, cefiderocol and naldemedine, were completed in China, and the application for cefiderocol was accepted for approval. We also achieved prior approval in the special medical zone on Hainan Island. In Southeast Asia, we have also obtained approval under the Special Access Route for and started providing ensitrelvir and cefiderocol.

In the area of AI drug discovery, as described in the next page, we have progressed to the point of verifying the results of several candidates in non-clinical trials targeting respiratory and CNS diseases.

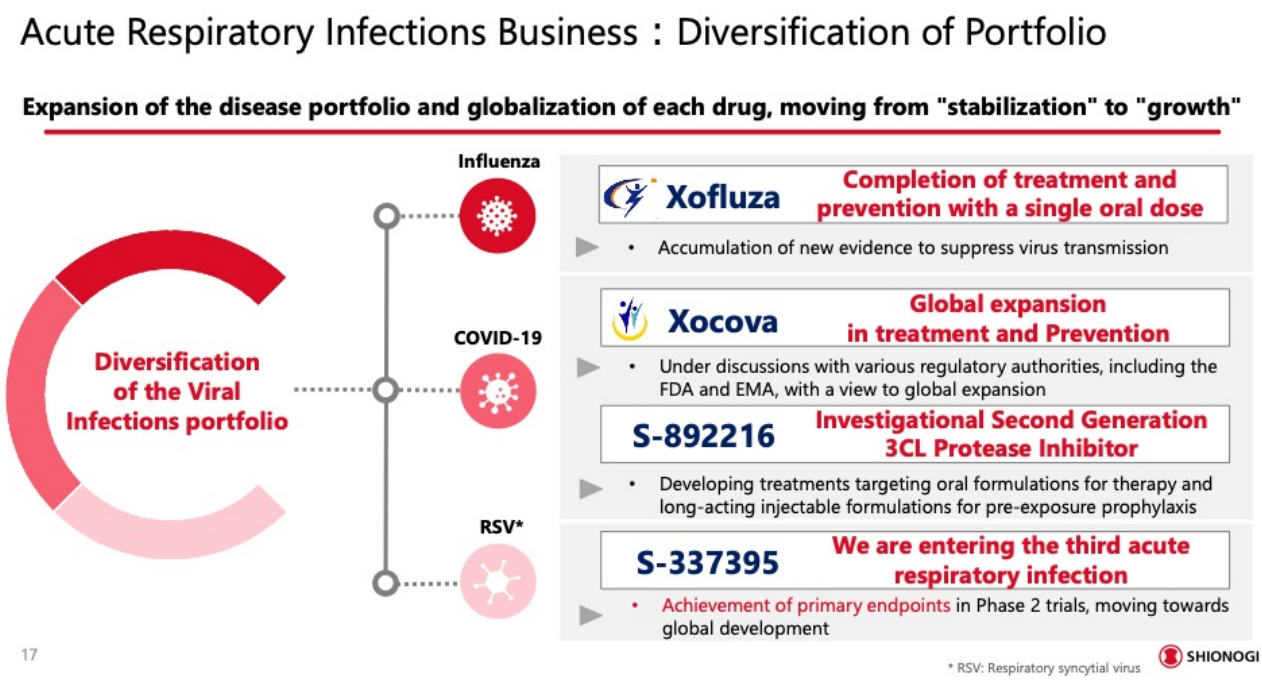
Going forward, the Ping An SHIONOGI companies in Shanghai and Hong Kong, as well as SHIONOGI Healthcare, will become wholly owned subsidiaries of SHIONOGI. This is in line with our aim to establish a business structure in Asia, centering on China. The details will be explained again at the fiscal year-end presentation later this year.

Next, page 15. This page provides an overview of the future outlook for business in China.

Due to changes in the demand environment and other factors, we have been promoting our activities with a shift to the new drug business. Going forward, we will further focus on the new drug business and accelerate the launch of SHIONOGI new drugs and the creation of new drugs in the Chinese market.

As for the launch of SHIONOGI new drugs, we will further accelerate the development and preparation for the launch of two new drugs for which Phase 3 trials have been completed. We aim to obtain approval for cefiderocol by the end of 2025. For naldemedine, for which Phase 3 trials have been completed, we aim to file for approval in April of this year.

We have already started PoC validation of the IPF drug candidate in an investigator-initiated trial, and are aiming to progress to clinical trials for the other candidates as well.



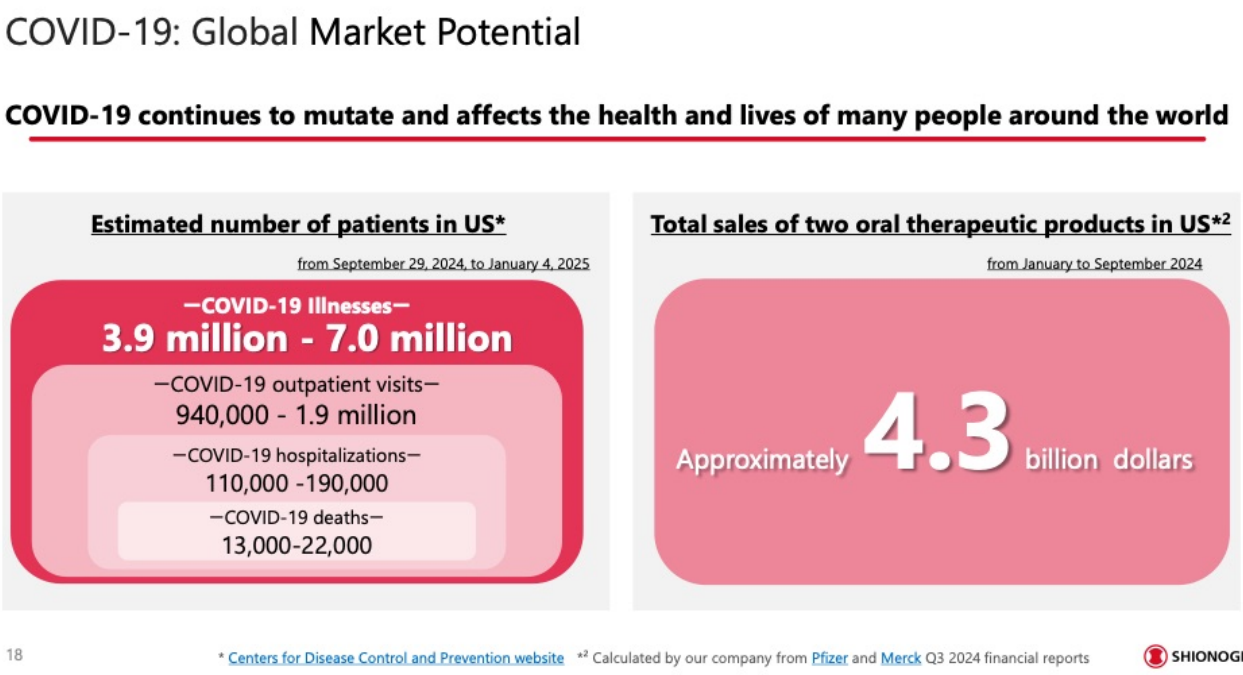
Uehara: Next, I will report on progress in the development pipeline.

Slide 17 shows a summary of the diversification of the portfolio of the acute respiratory infection business. As Mr. Hatanaka mentioned at the beginning of this presentation, we are in a situation where we have been able to obtain stable sales in Japan because of influenza and COVID-19.

As for Xofluza, we have accumulated new evidence that a single oral dose of Xofluza is sufficient to complete treatment and prevention and, as I mentioned the other day, that taking the medication inhibits the spread of the disease among family members.

We continue to maximize the value of the influenza family, including Rapiacta. We are in discussions with various regulatory authorities regarding COVID-19 to promote global development of Xocova in therapeutic prophylaxis.

In addition, a new next-generation inhibitor of 3CL protease, a compound called S-892216, which I will talk about later, has emerged that is very interesting. In addition to this pipeline, we are entering the field of RSV infection, the third area of acute respiratory tract infection. As we announced in a press release, we have obtained favorable Phase 2 trials results.



Now, first of all, COVID-19.

On the topic of global marketability, the virus is still mutating repeatedly. The figure on the left is a tally from the US CDC.

As I indicated, the estimated number of COVID patients in the three months from September 2024 to January is 3.9 million to 7 million. From among them, a large number of people, approximately 1 million to 1.9 million, are still being seen and hospitalized, and serious illness remains a major issue.

In this context, there are currently two trend treatment drugs available in the US. The total for the period from January to September is approximately USD4.3 billion, which is a very large share of the market, and new threats are repeatedly appearing.

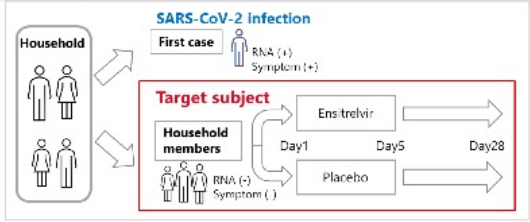
In this context, we are also interested in the ensitrelvir and Xocova products. Also, we are currently developing the next generation of 3CL proteases. I will give you a little update on that.

Ensitrelvir: Positive Results From the SCORPIO-PEP* Trial

Demonstrated the world's first preventive effect against the onset of COVID-19 with an oral antiviral drug*2

Trial design*3

Country	US, South America, Africa, Asia including Japan
Trial Design	Multicenter, randomized, placebo-controlled, double-blind trial
Subjects	Family members or cohabitants of COVID-19 patients (approximately 2,400 cases)
Dosing Regimen Sample Size	• Once daily for 5 days (Same as treatment indication) • Ensitrelvir: 1,200 cases, placebo: 1,200 cases
Main purpose	Verification of the effect of suppressing the onset of COVID-19 symptoms for10 days after starting ensitrelvir administration



Preliminary trial results

Results Summary	**—Achieved primary endpoints—** **<Primary endpoint>** • Significantly reduced the proportion of subjects who became infected with SARS-CoV-2 and developed COVID-19 symptoms within 10 days of administration **<Secondary endpoint>** • The proportion of subjects infected with SARS-CoV-2 also decreased • No new safety concerns • Pharmacokinetics similar to those in therapeutic trials
Detailed Report	Details will be announced at CROI*4 in March 2025 (Late-breaker)

* PEP: Post-Exposure prophylactic
*2 Press release dated October 29, 2024 *3 jRCT: 2031230124
*4 The Conference on Retroviruses and Opportunistic Infections

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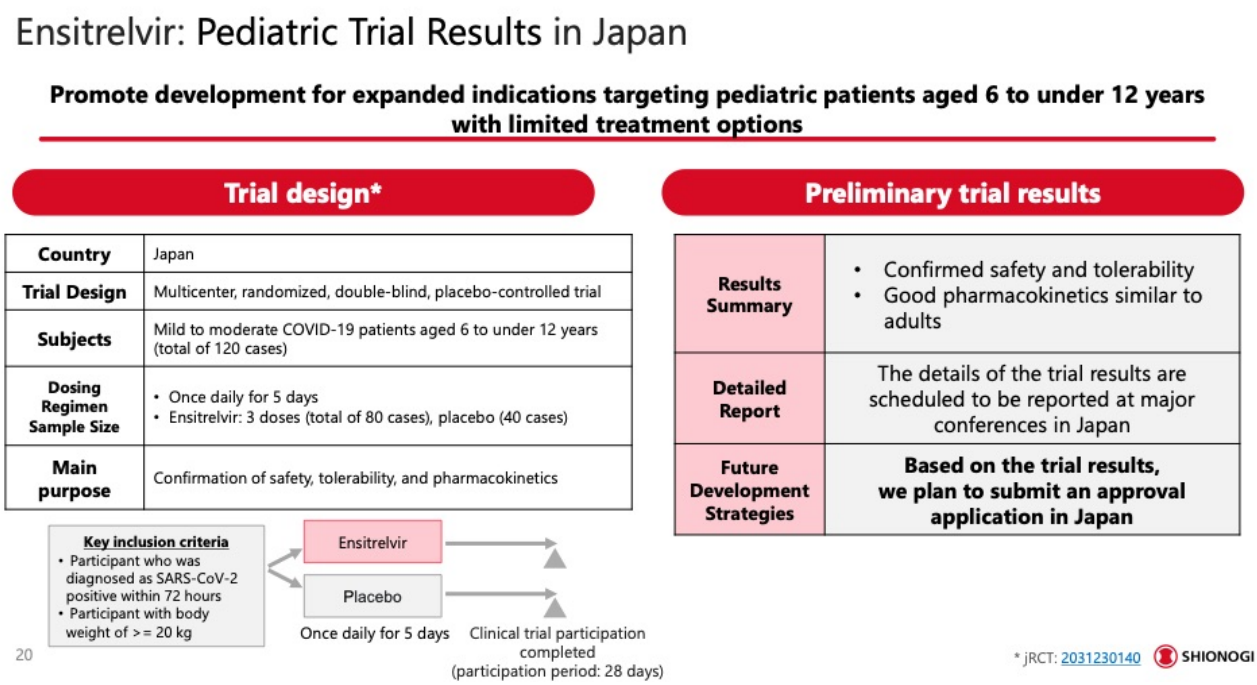
This is page 19.

This is the ensitrelvir PEP trial. Specifically, this trial investigated if taking the medication would prevent infection. This is a trial in which family members who have been in close contact with an infected person are asked to take the medication.

As I mentioned, we achieved the main evaluation items. We have verified that there is a statistically significant decrease in the number of patients who develop COVID-19 infection over a 10-day period.

In addition to the onset of disease, we evaluated various secondary endpoints, such as the decrease in patients with viral infections, and found significant differences for almost all items. We have submitted an abstract for a late-breaker presentation at CROI, which will be held in the US in March, and will report the details in an oral presentation.



We have also conducted a Phase III trial of ensitrelvir in pediatric patients in Japan.

Specifically, we have prepared tablets that are slightly smaller in size than those currently taken by adults and adolescents, and have set doses for each weight group that provide the same exposure as those for adults. We have conducted a study to confirm the safety, PK, and blood concentration of the tablets.

As expected, we have confirmed that the drug is well tolerated and that the exposure level is the same as that of adults at the dosage and administration levels we have set this time.

Ensitrelvir: Status of Global Development

Promoting various initiatives to maximize the value of ensitrelvir, including expanding indications and global deployment

Development status

Clinical trial	Status
SCORPIO-SR (Asia: Phase 3)	Achieved primary endpoints
SCORPIO-HR (Global: Phase 3)	Primary endpoint not achieved
Pediatric trial (Japan: Phase 3)	Confirmed preliminary trial results (safety and pharmacokinetics)
SCORPIO-PEP (Global: Phase 3)	Achieved primary endpoints
STRIVE trial (Global: Phase 3)	Ongoing
Long COVID (Investigator-initiated trials)	Collaborative research in progress with Osaka University

Status of applications to various countries/regions

Countries/region	Status
US	Pre-application consultation in progress
Europe	Pre-application consultation in progress
Japan	Normal approval obtained Application in preparation for expansion of indications pediatric and PEP
China	In discussion with regulators
Singapore	SAR approved Under review (Normal approval application completed)
Taiwan	Application for approval was submitted / Government stockpiling contract was signed
Korea	Plans to add data from the SCORPIO-PEP trial and resubmit application

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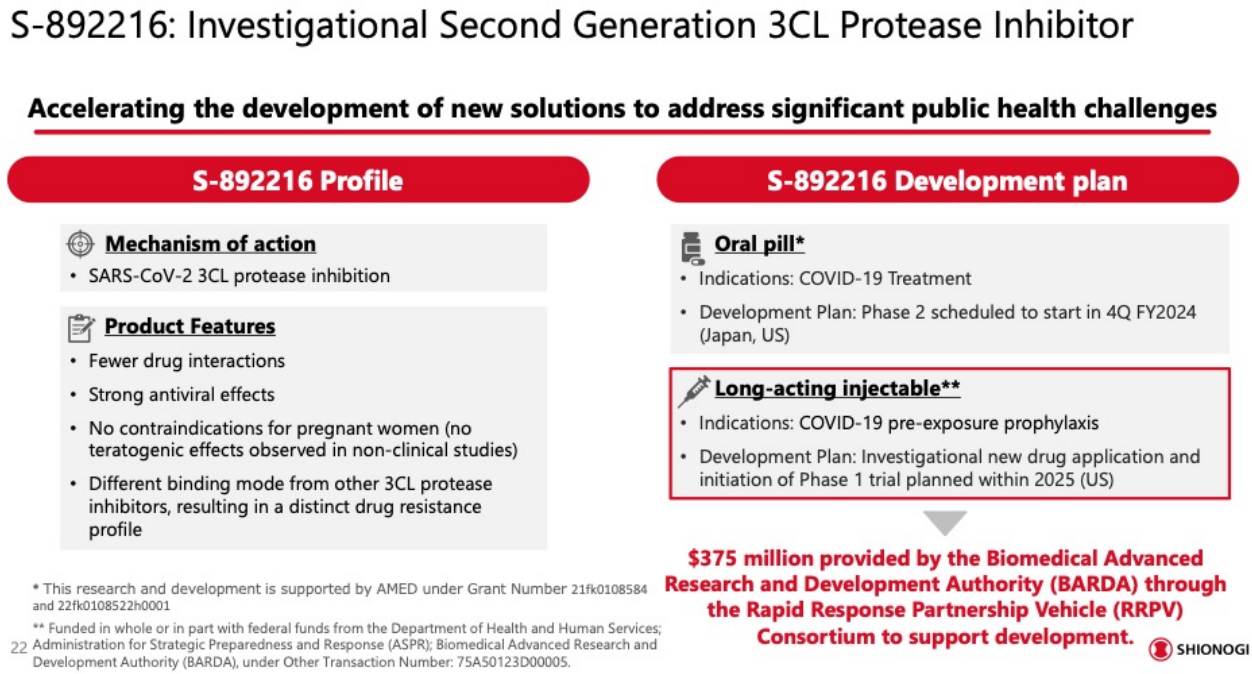
Now, in addition to these trials, the overall status of the trials is listed here.

On the left, SCORPIO-SR, HR, as well as the pediatric subject trial I mentioned, and the prevention trial. Based on these trials, we aim to roll out ensitrelvir globally. We are currently conducting pre-application consultations with regulatory authorities in the US and Europe. After these pre-application consultations, we will apply for approval at the appropriate time, and we will update you with more details.

In Japan, the drug is already being used for treatment, and we are in detailed discussions with the PMDA to expand the indications.

As for Asia, we have recently withdrawn the South Korean application. We are preparing for this by adding a PEP trial and submitting another application for approval.

In addition to Japan and Singapore, we have also concluded a separate contract for government stockpiling in Taiwan as part of the application for approval. We are now in a position to use the product in a third country internationally.



In addition to ensitrelvir and Xocova, we are developing S-892216, a next-generation inhibitor of 3CL protease.

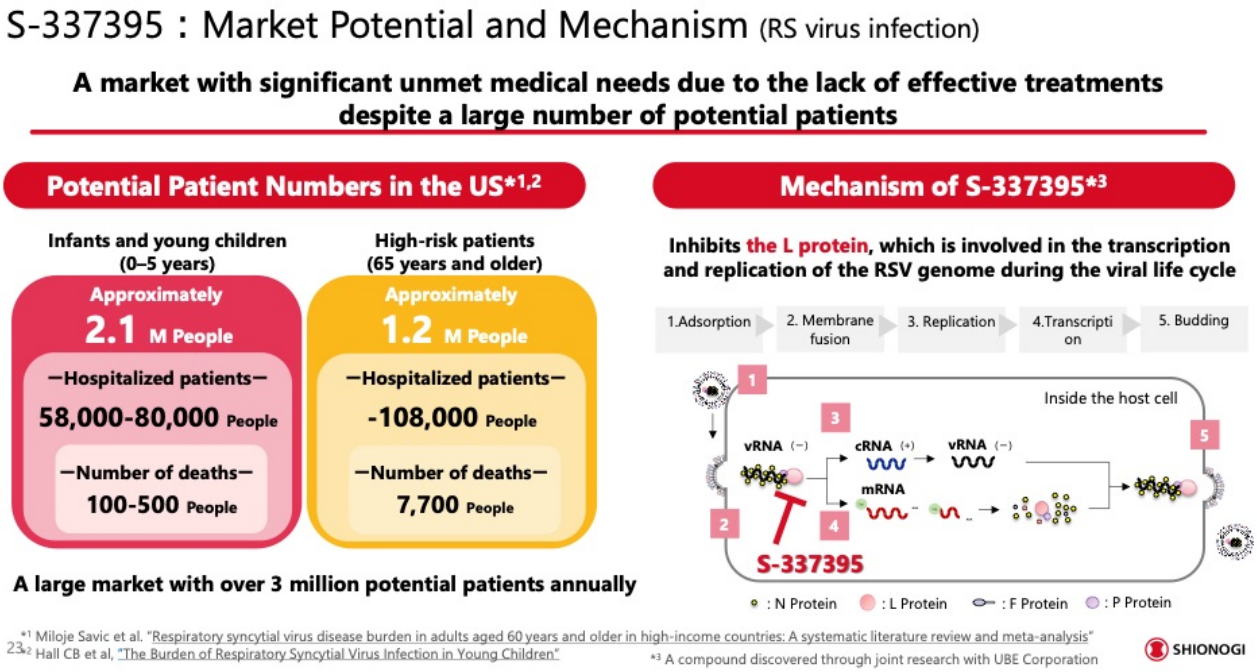
As an inhibitor of 3CL protease, it is similar to ensitrelvir, but there are medical needs that have not yet been met by existing oral agents.

Specifically, we are aiming for fewer drug interactions. Also, it has a stronger antiviral effect and no contraindication for pregnant women. Creating such drugs is part of our goal to create new and better products. We are now at the stage of advancing global Phase II trials for the oral formulation.

Furthermore, the threat of COVID-19 continues, as we have also set out in this press release. Pre-Exposure Prophylaxis is an important theme. This is a little different from the use of a vaccine for the prevention of HIV in the case of those who are in close contact with HIV patients. This is not a substitute for the vaccine, but it is well known that the vaccine does not work in immunosuppressed patients and those with low immunity levels even if they are vaccinated.

In this context, we have prepared a formulation that, once administered, maintains blood levels for an extended period of time for such patients as a pre-exposure prophylaxis to prevent infection by administering the drug in advance.

We have received funding from the US government agency BARDA, and have concluded an agreement to receive a grant of USD375 million, or approximately JPY58.5 billion, for the development of this product. We are now going to IND in the US and will proceed with Phase I trial.



The third area is RS virus.

As you are all aware, there are currently no oral antiviral drugs that can be used, so the unmet need is very large, and the market is also large.

There are more than 3 million potential patients per year, including infants, children, and high-risk patients over 60 years of age and the elderly.

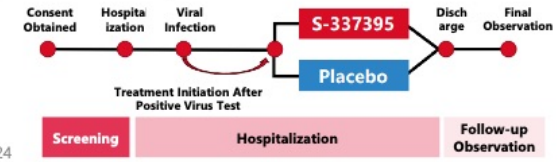
S-337395, which we are currently developing, inhibits polymerase, specifically the L-protein, which is the main protein that increases in cells. You can see how that affects the life cycle here. We are currently in the process of developing compounds created through joint research with UBE Corporation.

S-337395：Top-Line Result in Phase 2 Trial*

In the Phase 2 trial, a statistically significant reduction in viral load was confirmed

Trial Design

Country	United Kingdom
Trial Design	Randomized, placebo-controlled, double-blind comparative, Challenge Trial
Subjects	Healthy adults (Total: 114 participants)
Dosing Regimen Sample Size	• Once-daily oral administration for 5 days • S-337395： 4 dosage, Placebo: Minimum dose group 10 participants, Other groups: 26 participants
Primary Endpoint	AUC of RSV viral load measured by qRT-PCR



Preliminary Trial Results

Results Summary	**-Achieved primary endpoints-** • In the highest dose group, there was an 88.94% reduction in viral load (P<0.0001) • Dose-dependent reduction in viral load confirmed • Statistically significant improvement in clinical symptom scores • No concerns regarding tolerability and safety
Detailed Report	Detailed results of the trial will be reported at major international conferences
Future Development Strategies	Based on these trial results, we are considering development strategies to conduct late-stage global trials

*3 Joint devlopment with UBE Corporation

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We have also issued a press release on the Phase II trial, which confirmed a very strong antiviral effect. We conducted a challenge study in the UK to see the dose-dependent effect of viral suppression and to set the doses for the Phase II and III trials.

Since we have obtained the expected results and further confirmation that the symptoms improve, we are in the process of preparing for late-stage development.

Progress of Major Development Products - Infection diseases -

※ The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2024 / FY2025	Note
COVID-19 treatments	Ensitrelvir	COVID-19	Preparation for global submission		
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	Complete enrollment (FY24 2Q)	**Confirmed preliminary trial results: January 2025**
	Ensitrelvir	COVID-19 PEP	Phase 3	Complete enrollment (FY24 2Q)	**Primary endpoint achieved : October 2024**
	S-892216	COVID-19	Phase 1	Phase 2 start (FY24 4Q) — Topline results (FY25 3Q)	
		COVID-19 PrEP	Preclinical		
COVID-19 vaccines	COVGOZE (S-268019)	COVID-19 (Wuhan, Vaccine)	Approval		
	S-268024	COVID-19 (JN.1, Vaccine)	Preclinical	Phase 2 start (FY24 4Q) — Topline results (FY25 2Q)	**Preparing for Phase 3 trial**
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	Phase 1 start (FY24 4Q) — Topline results (FY25 2Q)	
Infection diseases	Olorofim	Invasive aspergillosis	Phase 3		
	S-337395	RSV infections	Phase 2	Topline results (FY24 3Q) — Adult Verification trial start (FY25)	**Primary endpoint achieved : January 2025**
	S-743229	AMR (Complex urinary tract infection)	Phase 1	Phase1 (combined use) topline (FY24 3Q)	
	S-649228	AMR (Gram-negative bacteria infection)	Phase 1	Phase1 (combined use) start (FY24 2Q) — Topline results (FY24 3Q)	

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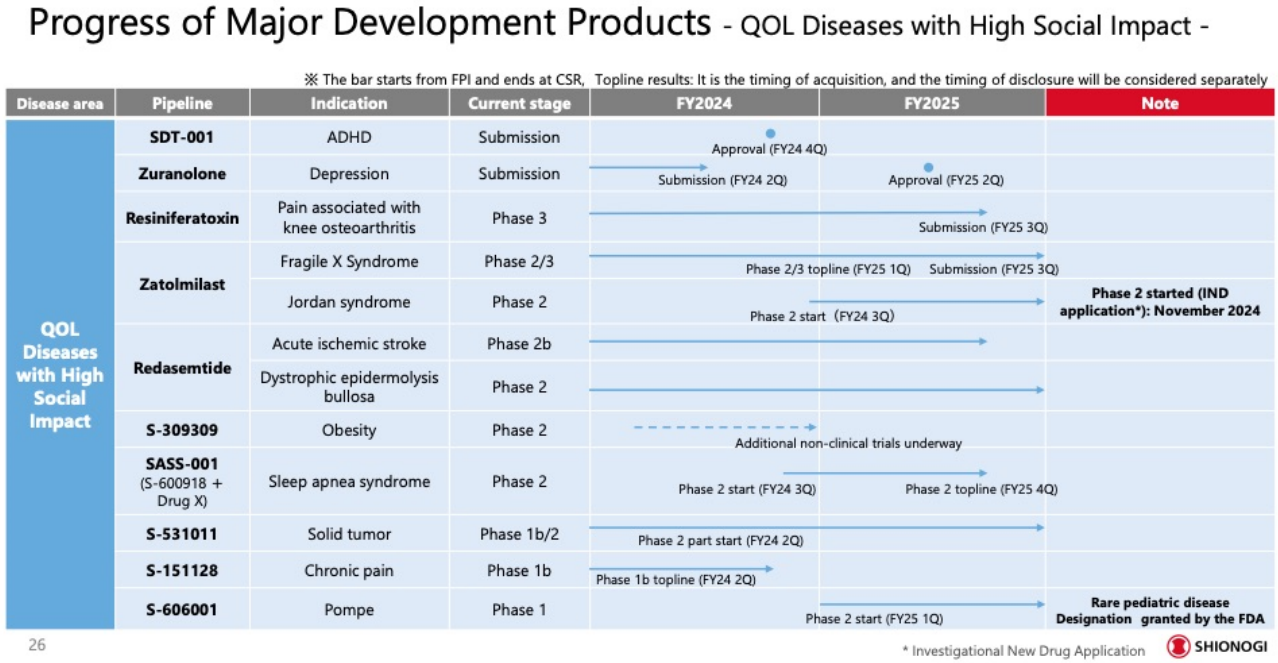
Now, I would like to talk a little bit about the rest of the pipeline.

This is the infectious disease pipeline. I have already given the major updates. As I mentioned earlier, we are currently preparing for the Phase III clinical trial of the vaccine S-268024, which is a vaccine for JN.1. We are now in the process of advancing the Phase III trial as soon as possible and filing an application for approval in Japan.

Other updates are as indicated here.



Other diseases that have a high impact on quality of life are listed here.

As a major update, we are conducting a Phase II/III trial of Zatolmilast for Fragile X syndrome in the United States.

Because of this mechanism of action, and the fact that these effects are very promising even in a non-clinical setting, patient groups and doctors specializing in the treatment of patients with Jordan syndrome, a rare genetic disorder known to cause cognitive decline, have decided to conduct clinical trials to verify the efficacy of the drug and to create an environment in which it can be used in the United States. We have started Phase II trial in the US and are now in the process of registration.

In addition, we are preparing to conduct Phase II trial for S-606001 for Pompe disease. We have received orphan drug designation from the FDA, so we are now in the process of developing this drug as well.

This concludes my presentation.

Question & Answer

Kyokawa : Mr. Yamaguchi of Citi, please go ahead.

Yamaguchi : Thank you. I am Yamaguchi from Citigroup Global Markets. As you mentioned, we have seen a lot of cases of influenza since December, while COVID-19 has not been so active. In terms of COVID-19, we're probably at about 60% progress to the full-year forecast for Infectious disease drugs in prescription drugs in Japan.

January has seen a lot of influenza cases. What is the current status of this? Simply looking at it, it seems that the rate of progress is low, but I am not sure about Q4 yet. Considering that it is up to Q4, I wonder if the numbers are achievable or not. Could you comment on that?

Iwasaki : I will answer. It is very difficult to predict, but as we see it, type A influenza will be over in January, type B in February, and COVID-19 is likely to spread after the influenza season is over, as we have seen in the past.

It is not that there is a rapid increase yet, but from the middle of February, after the Chinese New Year, and following that, there is still a very large number, so from that point of view, the revenue will now go up in the Xocova. We also think that roughly JPY20 billion in total can be covered in these two months.

Yamaguchi : Okay, thank you. Also, I know that applications for several indications have been filed for Xocova in the US, but do you have a timeline for when the applications, including PEP, will be ready?

Uehara : I will answer. We are still in the process of consulting with the US, so in general, we are preparing for six to seven months from the time we obtain the top line results, but we are still discussing the overall package of development applications, so I would like to refrain from giving specific timing.

Yamaguchi : I understand. Lastly, investors often ask about share buybacks, but of course since there has been no M&A announcement, I assume they understand that there will be no share buybacks. Is this situation still the same, and in light of such a situation continuing, if M&A occurs, it will occur, and if not, the Company's performance is strong, so are share buybacks anticipated? Please let me know if there are any updates on the current situation.

Kudou : I will answer. We will continue to examine business investments and share buybacks, and we will closely examine how we should invest funds from both perspectives.

Yamaguchi : So you are saying that the situation will not change.

Kudou : It hasn't changed. This is under ongoing consideration.

Yamaguchi : So it is under consideration. Understood. Thank you very much. That is all.

Kyokawa : Thank you very much. Next, Mr. Ueda from Goldman Sachs.

Ueda : Ueda, Goldman Sachs Securities. I would first like to ask about trends in the HIV franchise. The progress of royalties up to Q3 looks good with a high progress rate, despite the usual trend of a slight decline in the Q4. How does actual progress compare with the Company's plan? If there is a discrepancy, could you please explain what points are different from your expectation?

Kudou : Okay, I will answer this. We are assuming an upward swing in Q4, so we believe results will exceed our full-year forecast.

Ueda : Thank you very much. By the way, can you tell me which part in particular will deliver the upswing? For example, is it the long-acting injectable? Any hints would be helpful.

Kudou : The new products like the one you mentioned are indeed making significant progress.

Ueda : Thank you very much. The second point I would like to ask is about the acute respiratory infections business. In your explanation today, I think you mentioned that you are moving from stability to growth, but at present, from the outside, it seems that volatility is still high. From your company's perspective, what is seen as a base revenue and profit level for stability?

In other words, when we look at this area from the next fiscal year onward, what level of sales can we expect, and what kind of time frame will we be able to confirm in terms of growth?

Iwasaki : I will answer. In Japan, one of our goals is JPY100 billion for products on influenza and COVID-19.

The treatment rate for influenza has increased considerably, and the market share has also increased. We are now planning to apply for pediatric Indication to expand our business in the pediatric field.

As for COVID-19, disease awareness, recognition, and treatment rates are still low. We would like to get this treatment rate from 20% to 25%, and when we get stably our share to 70%, we think we can clear the minimum line of JPY100 billion.

Ueda : Thank you very much. Do we then need to wait for the RS virus or the next generation S-892216 to come out or something like that to see this growth?

Iwasaki : In Japan, yes, but in the future, we expect that the overseas development of ensitrelvir will come first, followed by S-892216, and then S-337395.

Ueda : Understood. Thank you very much. That is all from me.

Kyokawa : Thank you very much. Next, Mr. Sakai from UBS Securities. Please go ahead.

Sakai : Sakai, UBS. Two things I would like to ask briefly, one is the royalty from ViiV, which I know is a royalty, but I understand it is like the commonly seen special dividend. Especially since their fiscal year ends in December, GSK has not announced their financial results yet, but I wonder if there is any possibility left for them to do so.

Naturally, I don't think it is included in your company's plan for this fiscal year, but what is the current situation in that area? This is my first question.

Kudou : I will answer. Achievement for projection of finance income and costs shows 65%, and it appears that progress has been somewhat slow. The ViiV dividend has increased compared to the previous fiscal year. There is some change based on the cash position.

As for Q4, as you mentioned, a special preferred dividend is expected to be paid, so we believe that we will be in line with our initial forecast.

Sakai : So this is not recorded in the royalty line, but in the other revenue and expense line?

Kudou : Dividends are recorded in the financial income and costs section.

Sakai : You mean the line under operating income.

Kudou : Yes.

Sakai : How much is the full-year forecast for this now?

Kudou : We now believe that the full-year forecast will land as projected for the full year.

Sakai : Unchanged at JPY41 billion.

Kudou : Yes.

Sakai : It looks like a little more in Q4, presumably because of that. Is that correct?

Kudou : Yes. You are correct.

Sakai : Okay, thank you. Next, I think that the China business is a daunting challenge for your company.

Regarding the dissolution of the joint venture with Ping An, you said that the joint venture was dissolved due to the circumstances of the other party. I was wondering if the Chinese government had any influence in that decision.

Dr. Iwasaki mentioned that the details will be announced in May when the financial results are announced, but you talked about specifics in the table on page 15, is there anything else you would like to add? That is my second question.

Iwasaki : With regard to China, I would like to talk about what kind of framework cefiderocol and naldemedine will be developing in the future, and also about Ping An SHIONOGI's governance review in Korea, ASEAN, and Taiwan, where the company has had jurisdiction. I would like to talk about that at the next financial results presentation.

Also, there are some things within Ping An that are difficult to understand. We assume that Ping An wanted to focus on their core business.

Sakai : I think that at one time there was a plan to use Good Doctor to develop the business, but that plan was dropped and the OTC business was transferred to the China business, I believe. Is that correct?

Iwasaki : Yes, that's right. As for Good Doctor, I can honestly say that the original plan did not produce results. Also, regarding OTC, we were under Ping An SHIONOGI, but now Shionogi Healthcare is developing its own business in China, so we will continue OTC in the future, although the form will change.

Sakai : I understand. Thank you very much.

Kyokawa : Thank you very much. Next, Mr. Hashiguchi from Daiwa, please go ahead.

Hashiguchi : Daiwa Securities, this is Hashiguchi. Thank you. The first is about the concept of developing a long-lasting injectable formulation of S-892216. How many times would this be administered, and if more than once, what administration schedule are you aiming for? Also, please tell us how this will be used compared with a vaccine.

Uehara : Thank you very much. I will answer your question. This is a proposal from BARDA in the US, and the stipulated formulation is generally one injection and is expected to last for three months.

From animal experiments, we can expect a sufficient level of exposure. We are now in the process of confirming in humans how long blood concentrations can be maintained, including in Phase I.

As I mentioned earlier, but for those who do not respond to the vaccine, this drug can be used to protect them. This product is designed to replace the vaccine, or rather, to protect even those who have already received the vaccine by using this drug.

Hashiguchi : Thank you very much. Secondly, regarding Xofluza, you mentioned in your presentation that its market share is expanding. Would it be possible to receive specific figures?

Also, I am looking at the slides from the November 2022 financial results meeting again, and I believe that at that time you mentioned that you wanted to make sales and prescription volume near equal, and that you wanted to improve the traceability of inventory.

Since the December influenza season was so strong this time around, should we assume that there is indeed a slight discrepancy between prescription volume and sales this time around? I believe that the number of patients has been rapidly decreasing since January, so I would like to know if the situation of the distribution inventory is well controlled as you said in 2022.

Iwasaki : I will answer. There are various databases, so we do not know the share, exactly, but we read that we are getting around 35%.

Also, what is the current selling and prescribing situation? Probably at the end of the year, I can honestly say that we had more orders than patients. Since this is based on vacations, there are areas that have been over-ordered.

We are still not sure how much of this inventory will be available at the time of convergence in the city, and to be honest, we are not sure how much will be backed up by medical institutions to the wholesaler at the time of convergence in February.

Hashiguchi : I'm looking at the transcripts again, but I think you said that you wanted to refuse returns as much as possible, but you haven't quite gotten to that point yet. While there are some areas where you seem to agree, is that situation not unavoidable to a certain degree?

Iwasaki : No, we do not accept returns. It is only that once the product is returned from the medical institution to the wholesaler, if there is another epidemic, that is where it will go out to the medical institution again.

Hashiguchi : Understood. Thank you very much, that is all.

Kyokawa : Thank you very much. Next, Mr. Tsuzuki from Mizuho Securities. Please go ahead.

Tsuzuki : Thank you. My name is Tsuzuki of Mizuho Securities. Thank you.

Firstly, regarding the RSV (Respiratory Syncytial Virus), I believe we have achieved the primary endpoints. I would like to know the schedule going forward, considering that the challenge trial was a Phase 2a trial. What kind of trial will the next one be, and what is the timeline for it?

Additionally, since there are no approved drugs on the market, it might be challenging to estimate the market size. I would appreciate any insights you could provide on this matter.

Thank you.

Uehara : Thank you. As for the future schedule, as you mentioned, this is a Phase IIa trial, so the timeline is to proceed with Phase III after conducting the Phase IIb trial in actual clinical practice.

How about the size of the patient population, Mr. Iwasaki?

Iwasaki : We have not yet reached the PoC stage, and vaccines are being introduced now, so we will be closely examining the situation in the future.

Tsuzuki : Yes, I understand, thank you. Also, I believe that S-151128, for chronic pain, had preliminary data in Q2, and I would be happy to receive some comments on this.

Uehara : We are currently discussing this internally and will report back to you as soon as we are ready to do so.

Tsuzuki : Thank you very much. Next, the mid-term management plan aims for sales revenue of JPY550 billion in FY2025. In working to achieve this goal, could you highlight any areas that are below your forecast?

Kudou : I will answer. First of all, in presenting a sales forecast of JPY460 billion for this fiscal year, we are assuming that the HIV business will grow consistently and that this will be the first year of Xocova's global expansion.

In the domestic business, as I mentioned earlier, the infectious disease business has stabilized and is generating profits, and QUVIVIQ is expected to get back on track, and we are also planning to launch the antidepressant zuranolone in H2 of FY2025.

We believe that we will be able to add several tens of billions of yen in the next fiscal year compared to the current fiscal year, as I mentioned, but to compensate for the gap between the current and JPY550 billion, we are always considering the introduction of new products and M&A. In light of the above, at this point, we would like to proceed with our forecast of JPY550 billion unchanged.

Tsuzuki : I understand very well. Thank you very much.

Kyokawa : Thank you very much. Next, Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka : Muraoka, Morgan Stanley. Thank you very much. Regarding Ping An, the capital alliance is continuing, I believe the figure is 2%, and their holdings have not changed.

Having said that, given that your company will no longer have a business relationship, I wonder if buying that part out is one option for your company, but is that not a high priority for you?

Kudou : At this point, both parties are aware that we should continue to maintain a good relationship, so we are not yet at the stage of considering such specific plans.

Muraoka : So Ping An also wants to keep it?

Kudou : Yes.

Muraoka : Okay, thank you. I would also like to ask about S-337395 for RSV, and I apologize that my way of seeing this may be mistaken. The clinical data shows that the treatment group had 89% lower virus level, but just to be sure, what was the placebo?

I would assume there would be almost no decrease in the placebo group, is that correct?

Uehara : Thank you. This shows the transition for the placebo, when the virus is seeded, the virus is increasing more and more. We are trying to control the increase of the virus by administering the medication right at the time when it increases.

We calculated the change of the virus in the placebo by calculating the change in area, and we found that the treatment group suppressed the area by 89%, so it lowered the virus much, much more than the placebo.

Muraoka : So this 89% suppression is 89% suppression vs. placebo.

Uehara : That's right.

Muraoka : I think you said earlier that the next trial will be a Phase IIb and then a Phase III, but is the next trial not a challenge trial like this but using clinical patients who are actually infected in the field?

Is RSV a seasonal infection? Or are there always lots of patients?

Uehara : As you mentioned, we will be testing on real patients in a real clinical setting. The epidemic is spreading a little earlier than influenza, and although it is seasonal to some extent, the infection continues for a relatively long period of time.

Since there is no cure, we are not in a situation where we have to be so aggressive in testing, but when a cure is available, our current assumption is to provide an environment where diagnostic agents can also be used in conjunction.

Muraoka : I understand. Is this the type of RSV trial where it is possible for an outbreak to settle during the trial period, as happened with the influenza and COVID-19, and we have to wait another year?

Uehara : To some extent, it is plausible that that could happen in this trial.

Muraoka : I understand. Thank you very much. One more thing, about S-892216. This is a long-acting compound. I was wondering, given the potential trend against vaccines in US politics, could this compound be promoted as an alternative to vaccination? Is this something that you are thinking about?

Uehara : It is difficult for me to say that it is possible, but I imagine that there are many possibilities.

However, I still have the impression that while these drugs may be widely used as a substitute for vaccines, including for ordinary people who are not immunosuppressed, the main focus of use will be in higher risk populations.

There will not be any change in the concept of boosting immunity with vaccines. The current basic public health approach is to use these drugs for those who lack the ability to do that.

Muraoka : I understand. Thank you, that's all.

Kyokawa : Thank you very much. Next, Mr. Wakao from JPMorgan Securities. Please go ahead.

Wakao : This is Wakao from JPMorgan, thank you very much. The first is the status of Xocova's application in the US. You didn't tell us much, but what are you doing now, what kind of meetings have you had or are you planning to have? Is it possible for you to be a little more specific and tell us what the situation is now?

I am not sure of the changes from the last time, and I am not sure what will happen in the future, so could you be more specific?

Uehara : Specifically, in the US, there are SR and HR trials, as well as real-world evidence, including when used with PEP, that guide the indications we can gain approval for. We are in the process of discussing what to apply for as a package.

For PEP, we believe we can obtain approval for the indication as the Phase 3 trial has met its primary endpoint, but the issue now is how to proceed with the other indications for treatment.

Wakao : Have you already held some kind of Type C Meeting or Pre AND Meeting?

Uehara : That's right. We are now in the process of continuing the discussion. We have submitted meeting requests and so on.

Wakao : Okay, I understand. HIV royalties are doing very well, and I can tell that also from the prescriptions. I understand that if prescriptions grow further from this point of view, sales will increase and royalties will increase, but I am wondering if another factor, foreign exchange, will be even more positive in the next fiscal year. Is that understanding correct?

I think the yen weakened against the pound this term, and I think your company hedged in the previous term, so the amount hedged in the current term will make a positive contribution next term, so is it correct to assume that this part will be positive next term?

Kudou : I will answer. In terms of the increase from the previous year in Q3, the impact of volume and foreign exchange rates was about half of the increase.

As you mentioned, we will continue to implement forward exchange contracts this year and next year, so we believe that the impact of exchange rates will also make a significant contribution.

Wakao : Okay, thank you very much. Finally, I have a question about the assumptions of the KPIs in the medium-term plan that was mentioned earlier, and there was a mention of introductions or even M&A. Considering the products introduced and the royalty forecast for the next fiscal year, I think we may be short by JPY50 billion to JPY100 billion, although I am not sure. That may be too much, but I think we are missing a reasonably large number.

Then, when it comes to compensating for that in some way, there may be some kind of product acquisition, but it seems more like M&A, so I was wondering if you are considering M&A. I'm still rather certain that we can achieve that KPI. I wonder if it is safe to assume that the level of focus on M&A is increasing.

In terms of contributing to the next fiscal year's performance, is it safe to assume that some action will be taken at an early stage?

Kudou : I'll say a few words first. We are aware that there is a gap as you mentioned, and we are actively planning and considering M&A projects, but we do not have any information to report at this time.

Hatanaka : As Ms. Kudou has just explained, it is sometimes difficult to launch new products quickly or to expand globally, so we are always looking for M&A opportunities.

We would like to avoid introducing any special deals, or rather, we are unable to do so, but we would like to stick to the target of JPY550 billion by somehow finding something that can achieve it, not only through M&A, but certainly without lowering this target of JPY550 billion.

When we report on this next, we would like to be able to properly present some solid information, so we will have to ask you to wait a little longer.

Wakao : Understood. Thank you very much. That is all.

Kyokawa : Thank you very much. Now that we have reached the end of our time, we will finish up there.

Thank you for joining us today. That is all.

[END]