SHIONOGI & CO., LTD.

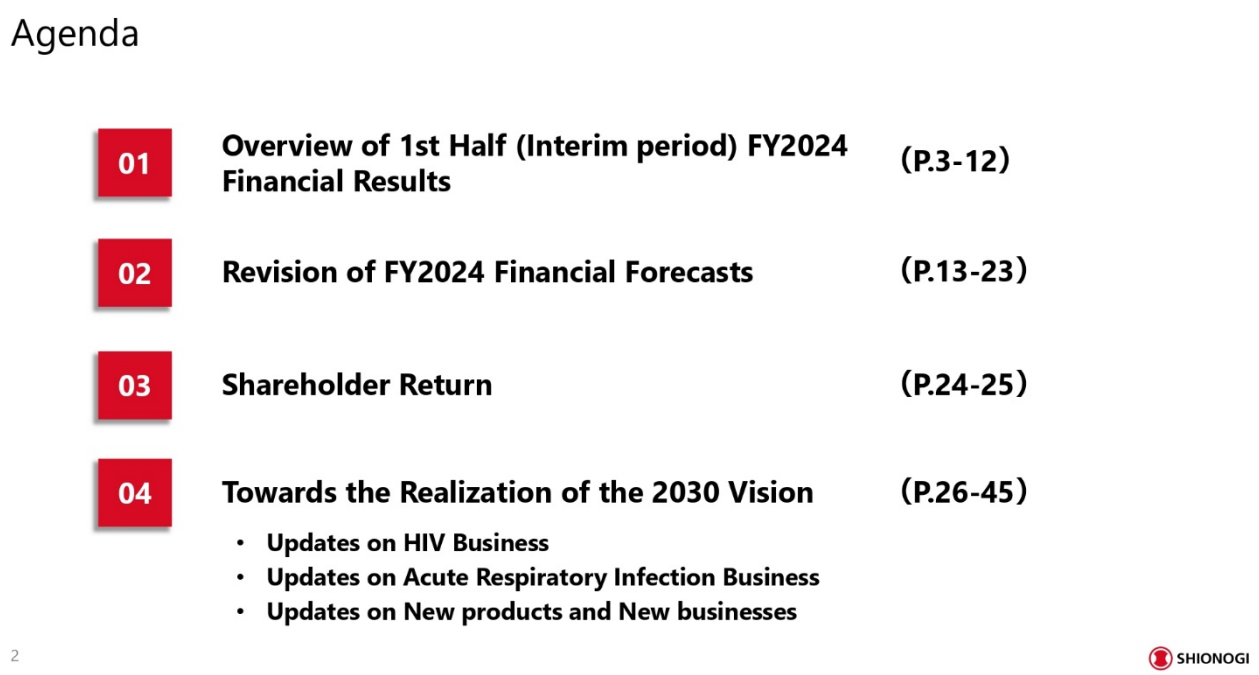
2nd Quarter of Fiscal 2024 Financial Results

October 29, 2024

Presentation

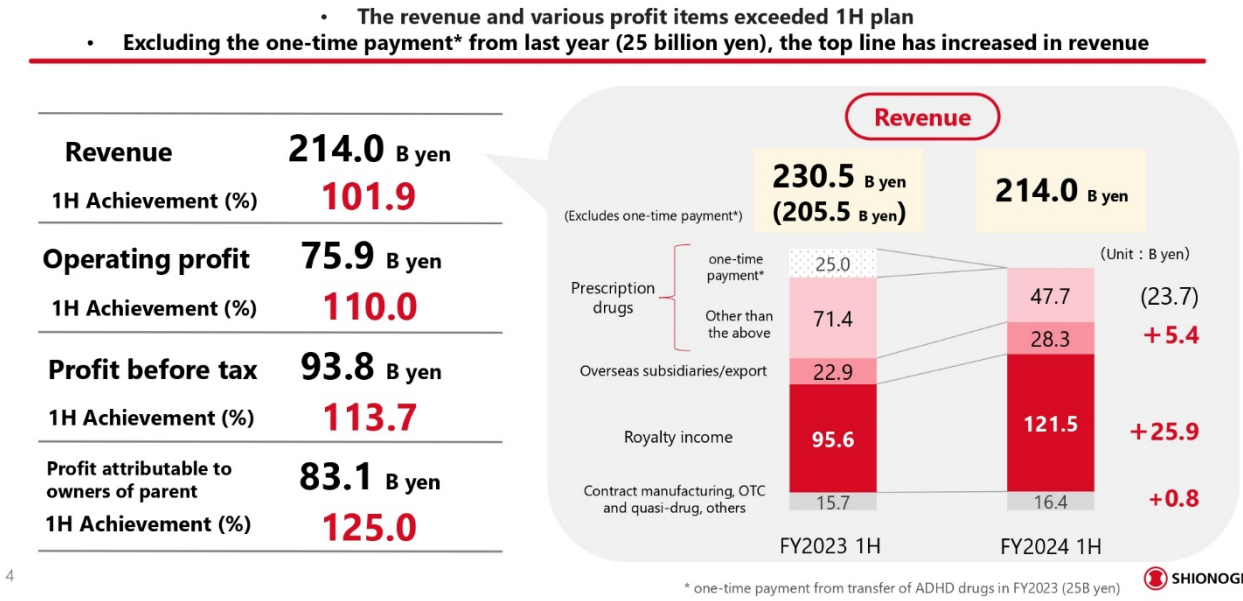
Kyokawa: I'm Kyokawa, at SHIONOGI & Co., Ltd.

Thank you very much for joining us today despite your busy schedule. We start SHIONOGI & Co., Ltd.'s financial results briefing for Q2 of FY2024.



Kyokawa: Today, we would like to start with an overview of our financial results, followed by an explanation of our efforts to realize the 2030 Vision by Teshirogi, John Keller, Uehara, and Iwasaki, in that order. We will also take time for questions and answers after the presentation.

Let me start right away. Dr. Teshirogi, please go ahead.



Teshirogi: Well then, we would like to start the meeting. I am sure you are well aware of the financial figures, so I will make this a little shorter.

First, please see page four.

The point of our company is that there were some special factors, such as the purchase of Xocova with JPY100 billion by the Government the year before last and JPY25 billion of ADHD-related lump sum last year, so in terms of how we measure ourselves, the Company is growing at least without this lump sum. We are working on the basis of growing sales and growing profits.

Of course, we have been conscious of how to control costs in order to achieve what we want to achieve and to land on the right foot by taking into account which sales are likely to be achieved in the middle of the term and how they are likely to be achieved. This is our company's specialty, and we have been working with this in mind.

On the left side of page four, from sales revenue to interim profit, we have managed to achieve our forecast figures. As you can see on the right, excluding the JPY25 billion one-time payment, revenue increased by slightly less than JPY9 billion, and profit increased by about JPY3 billion, which I will explain later. I think we can say that we achieved a reasonable result.

Financial Results

Summary

- **The sales revenue and various profit items exceeded the first half plan**
  - **The HIV and overseas businesses strongly drove the growth**
  - **Costs were as expected, and the development products progressed steadily**
- **In the same period of the previous year, the one-time payment from last year affected the results, leading to a decrease in revenue and profit. However, excluding the one-time payment, there was an increase in both revenue and profit**
  - **In FY2023, a one-time payment of 25 billion yen was recorded due to the transfer of the license for ADHD treatment drug**

(Unit : B yen)

	FY2024 Forecasts Full year	FY2024 Forecasts 1H	FY2024 1H results	FY2024 Achievement (%)	FY2023 1H results	Y on Y Change (%)	Y on Y Change
Revenue	455.0	210.0	**214.0**	**101.9%**	230.5	**(7.2)**	**(16.6)**
Operating profit	160.0	69.0	**75.9**	**110.0%**	98.1	**(22.7)**	**(22.2)**
Profit before tax	200.0	82.5	**93.8**	**113.7%**	115.6	**(18.8)**	**(21.8)**
Profit attributable to owners of parent	163.0	66.5	**83.1**	**125.0%**	90.6	**(8.2)**	**(7.5)**
EBITDA*	-	-	**86.7**	**-**	114.2	**(24.1)**	**(27.5)**

Exchange Rate (Average)

	FY2024 Forecast	FY2024 1H Results
USD($) – JPY(¥)	145	152.78
GBP(£) – JPY(¥)	178	195.57
EUR(€) – JPY(¥)	155	166.06

* 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.)

However, we are still responsible for how the previous year's results were. On the right side here, you can see that revenue was down 7.2%, operating profit was down 22%, profit before tax was down 18.8%, and profit attributable to owners of parent was down 8.2%. Although both revenue and profits were down, we had originally stated that we would aim to increase revenue and profits for the full year, and to achieve the highest revenue and profit for three consecutive years, and we believe that we have finished well toward that goal.

Statement of Profit or Loss

(Unit：B yen)

	FY2024 Forecast Full year	FY2024 Forecast 1H	FY2024 1H Results	FY2024 Achievement (%)	FY2023 1H Results	Y on Y Change (%)	Y on Y Change
Revenue	455.0	210.0	**214.0**	**101.9**	230.5	**(7.2)**	**(16.6)**
Cost of Sales	66.0	28.5	**30.1**	**105.7**	27.9	**8.1**	**2.3**
	14.5	13.6	**14.1**		12.1		
Gross profit	389.0	181.5	**183.8**	**101.3**	202.7	**(9.3)**	**(18.8)**
Selling, general & administrative expenses, R&D expenses total	226.5	111.0	**106.7**	**96.2**	96.5	**10.7**	**10.3**
	49.8	52.9	**49.9**		41.8		
Selling, general & administrative expenses	106.5	52.0	**49.9**	**96.0**	49.2	**1.3**	**0.7**
	23.4	24.8	**23.3**		21.4		
R&D expenses	120.0	59.0	**56.8**	**96.3**	47.2	**20.4**	**9.6**
	26.4	28.1	**26.6**		20.5		
Other income & expenses	(2.5)	(1.5)	**(1.2)**	**82.4**	(8.1)	**-**	**6.9**
Operating profit	160.0	69.0	**75.9**	**110.0**	98.1	**(22.7)**	**(22.2)**
	35.2	32.9	**35.5**		42.6		
Finance income & costs	40.0	13.5	**18.0**	**133.1**	17.5	**2.7**	**0.5**
Profit before tax	200.0	82.5	**93.8**	**113.7**	115.6	**(18.8)**	**(21.8)**
	44.0	39.3	**43.9**		50.1		
Profit attributable to owners of parent	163.0	66.5	**83.1**	**125.0**	90.6	**(8.2)**	**(7.5)**

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, page six.

There is product mix, etc., so the cost of sales appears to be a little higher, as the cost of prescription drug is very low in Japan. Including this and a JPY10 billion increase in R&D expenses, we managed to keep operating profit within the negative JPY25 billion range.

JPY6.9 billion in other income and expenses is the result of our early retirement program that we implemented last year, which had amounted to about JPY6.6 billion, and we don't have it this year anymore.

Revenue by Segment

(Unit : B yen)

	Forecast Full year	Forecast 1H	FY2024 1H Results	FY2024 Achievement (%)	FY2023 1H Results	Y on Y Change(%)	Y on Y Change
Prescription drugs	134.9	58.0	**47.7**	**82.3**	96.4	**(50.5)**	**(48.6)**
Excluding temporary income	-	-	**47.7**	-	71.4	**(33.1)**	**(23.6)**
Overseas subsidiaries/export	53.7	24.7	**28.3**	**114.7**	22.9	**23.5**	**5.4**
Shionogi Inc. (US)	20.6	10.0	**11.2**	**112.1**	8.1	**37.9**	**3.1**
Fetroja	-	-	**9.4**	-	6.5	**44.3**	**2.9**
Shionogi B.V. (EU)	14.4	6.8	**8.3**	**122.1**	6.1	**35.7**	**2.2**
Fetcroja	-	-	**6.4**	-	4.6	**38.7**	**1.8**
Ping An Shionogi/C&O	11.2	4.7	**4.2**	**89.3**	5.2	**(20.0)**	**(1.0)**
Others	7.5	3.2	**4.6**	**144.2**	3.4	**34.3**	**1.2**
Contract manufacturing	15.5	6.5	**7.8**	**119.4**	7.9	**(2.1)**	**(0.2)**
OTC and quasi-drug	16.6	8.0	**8.2**	**101.9**	7.1	**15.1**	**1.1**
Royalty income	232.5	112.2	**121.5**	**108.3**	95.6	**27.1**	**25.9**
HIV franchise	224.6	111.2	**119.6**	**107.6**	94.5	**26.6**	**25.1**
Others	7.9	1.0	**1.9**	**189.9**	1.1	**70.1**	**0.8**
Others	1.8	0.6	**0.5**	**86.3**	0.6	**(19.8)**	**(0.1)**
Total	455.0	210.0	**214.0**	**101.9**	230.5	**(7.2)**	**(16.6)**

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)
- Sales of Taiwan Shionogi

Royalty income

Increase
- Strong sales of ViiV's HIV franchise

※ Factors that occurred last fiscal year

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The next page, page seven.

There is a part of it this year and next year as well, and originally, we said that we would focus on three pillars of growth: the royalty for HIV drug, overseas growth, and domestic sales focusing on infectious diseases drugs, and we will continue to focus on these three pillars.

In Japan, especially for Xocova and Xofluza, in the period from July to September, sales of Xofluza was almost zero, with no cases of influenza. Other than that, including how Xocova did, I think it did not reach a little.

Overseas, revenue increased by more than 30%, especially in the United States and Europe, where revenue grew by more than 30% each.

In addition, OTC sales show a 15% increase compared to the previous year. Five years ago, when the OTC drug business was transferred to SHIONOGI Healthcare, it was a company with sales of less than JPY7 billion, but it has continued to increase revenue and profits and have achieved the highest sales and profits in the history and are on track to do so again this fiscal year.

As for royalty income, the HIV franchise increased by 26.6%, or JPY25.1 billion, which is roughly rounded off to JPY120 billion per half year. I have heard that the yen is particularly weak, but as John will explain later, the base business is still very strong. We are confident that this growth will continue in the future.

Prescription Drugs in Japan

(Unit : B yen)

	FY2024				FY2023	Y on Y	
	Full year	1H	1H Results	Achievement (%)	1H Results	Change(%)	Change
Infectious disease drugs	91.2	37.6	**29.2**	**77.7**	49.0	**(40.4)**	**(19.8)**
COVID-19 related products + Influenza franchise	80.1	32.7	**24.9**	**76.0**	44.4	**(44.0)**	**(19.6)**
Symproic	6.5	2.9	**2.4**	**81.5**	2.1	**12.9**	**0.3**
OxyContin franchise	5.0	2.3	**2.1**	**88.5**	2.2	**(5.6)**	**(0.1)**
Actair	1.4	0.5	**0.4**	**75.1**	0.3	**33.4**	**0.1**
Cymbalta	3.3	1.8	**1.5**	**80.5**	2.1	**(29.7)**	**(0.6)**
Others	27.5	12.8	**12.2**	**95.4**	40.6*	**(70.0)**	**(28.5)**
Prescription drugs	134.9	58.0	**47.7**	**82.3**	96.4	**(50.5)**	**(48.6)**

COVID-19 related products
- Xocova
- COVID-19 vaccines

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja

* Including temporary income from transfer of ADHD drugs

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Please move on to page eight, the domestic business.

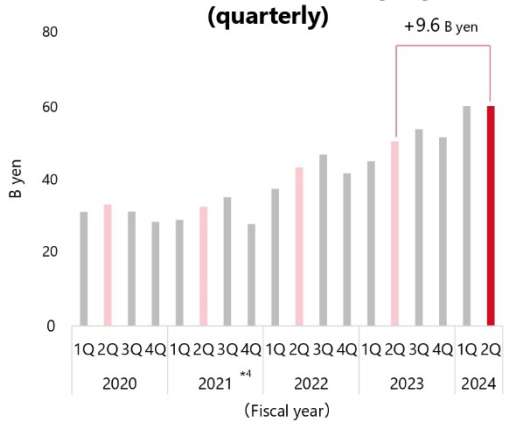
The result of COVID-19 plus influenza franchise was JPY24.9 billion for H1 against the forecast of JPY32.7 billion. We were a little short of the target, which analysts probably thought would be around JPY30 billion to JPY50 billion.

Especially in H1, we had almost no influenza cases, so if we consider only Xocova, the result was 85% or slightly more against the forecast. As I will say later, I think it is fair to say that for an epidemic that has converged quickly, it is steady as far as Xocova is concerned.

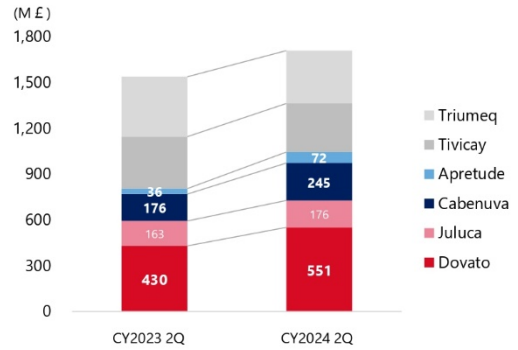
Expansion of the HIV Business

Continued stable growth each quarter, centered on the growth of oral two drug regimens* and LA formulations*2

Transition of SHIONOGI's HIV royalty income (quarterly)



Sales of ViiV's dolutegravir and cabotegravir products*3



LA formulations: Continued strong growth (YoY +49.5%)

* Oral two drug regimens: Dovato, Juluca *2 Long Acting: Cabenuva, Apretude *3 Source: Prepared by SHIONOGI based on GSK financial statements
*4 The additional royalties from the settlement between ViiV Healthcare, GSK, Shionogi and Gilead in Q4 2021 are not included

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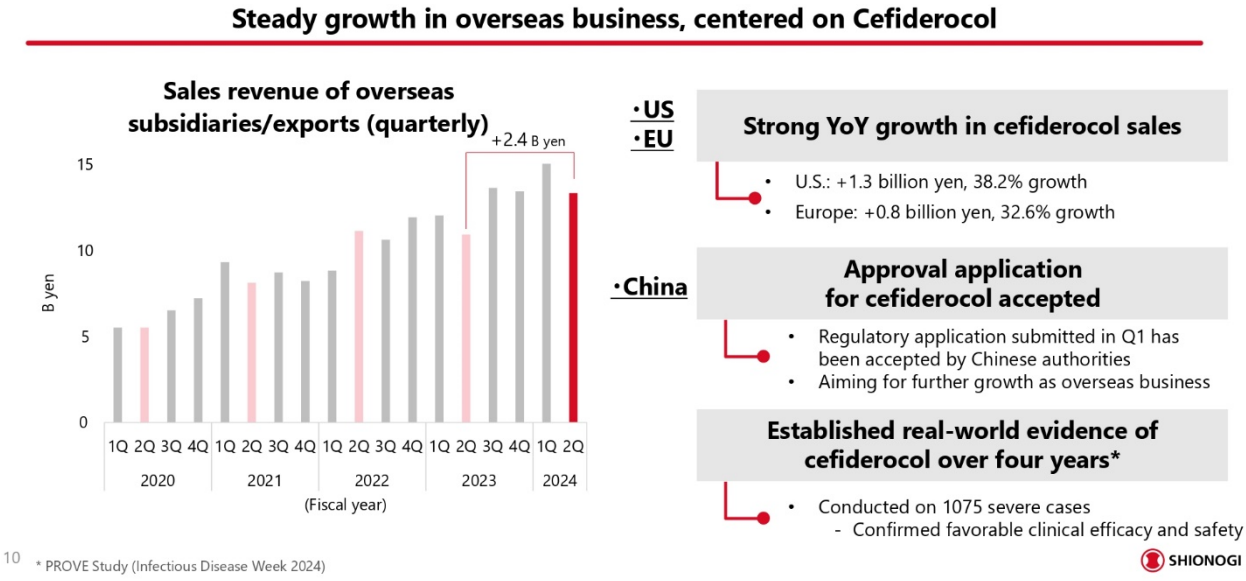
The next page, page nine.

The left-hand side shows our quarterly royalty figures, and the right-hand side shows the growth of our long-acting formulations, Apretude and Cabenuva in blue and light blue, and in particular, sales of Apretude have doubled.

Dovato and Juluca also grew; this is because ViiV has taken the risk of using a two-drug regimen, which has been built up from oral drugs, and it is naturally safer for patients to use two ingredients than three ingredients. In Europe in particular, the two-drug regimen is more affordable than the three-drug regimen, especially in terms of price. The fact is that various strategies, including this one, are really starting to respond, and I believe this trend will continue.

Expansion of Overseas Business

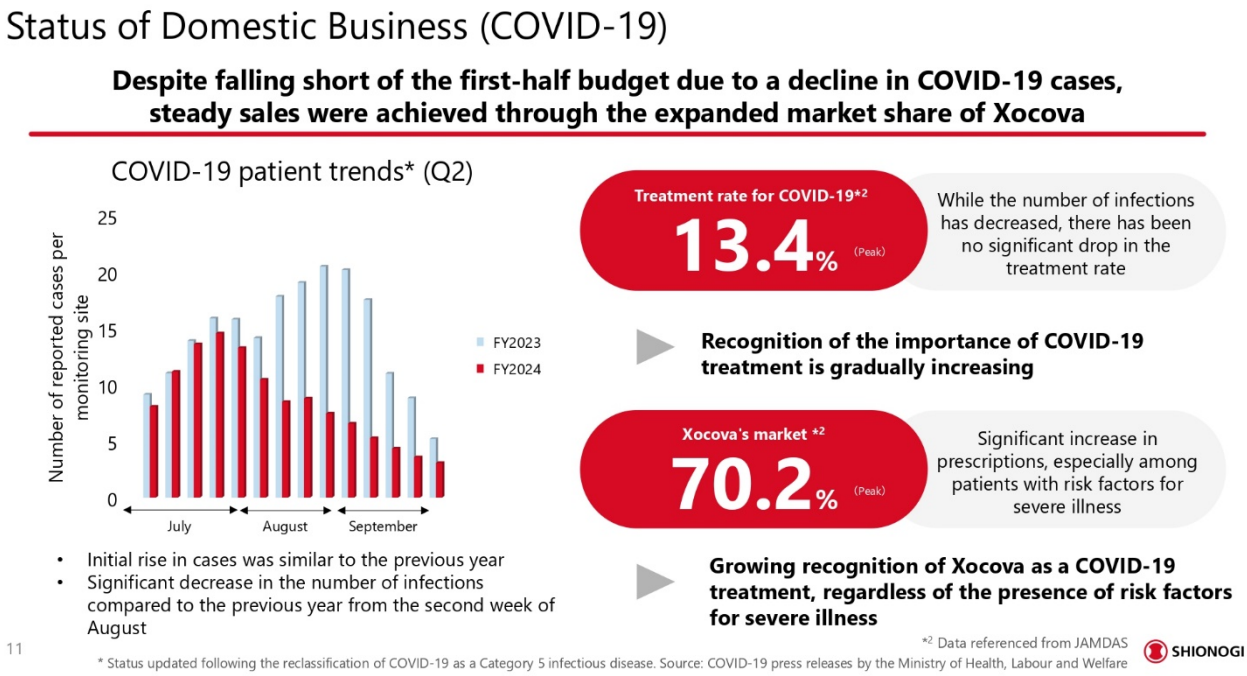


Please see page 10.

As I mentioned earlier, for cefidelocor, the growth is over 30% in both the US and Europe. We are continuing to maintain strong sales.

I did not mention earlier about the business in China; we still have some work to do including with Ping An, but the NDA for cefidelocor, which we consider to be the next core growth driver, has been accepted based on the tests conducted in China.

We are very excited about this as a value driver for the future, and after all, Real-world evidence has been very well received in the US and Europe. Perhaps not many people, including ourselves, thought that the annual sales of this item would reach JPY30 billion or JPY40 billion, but we believe that this is the direction in which we are moving.

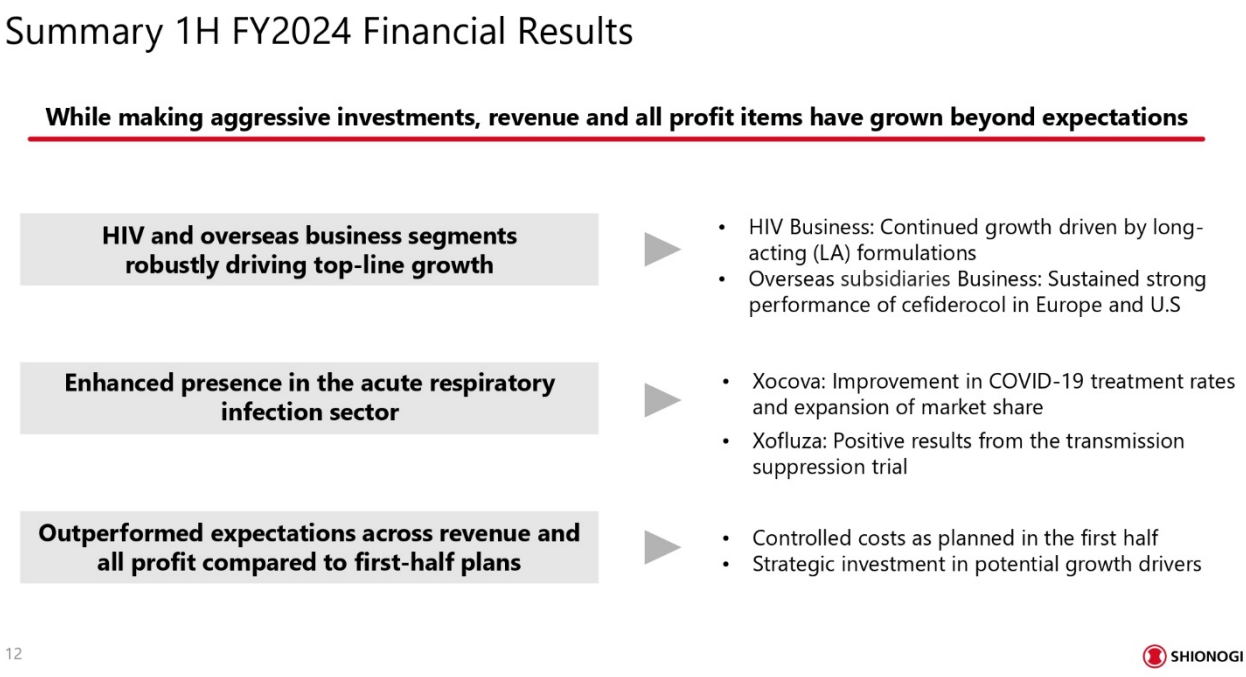


As for domestic influenza and COVID-19, I would like to talk about COVID-19 in particular here.

I'm sure Iwasaki will tell you later about the sales reaction. As you can see, the convergence in August and September, there are the differences between blue and red, which indicates considerably early convergence. We believe that this amount will be equivalent that we did not reach, which I mentioned earlier.

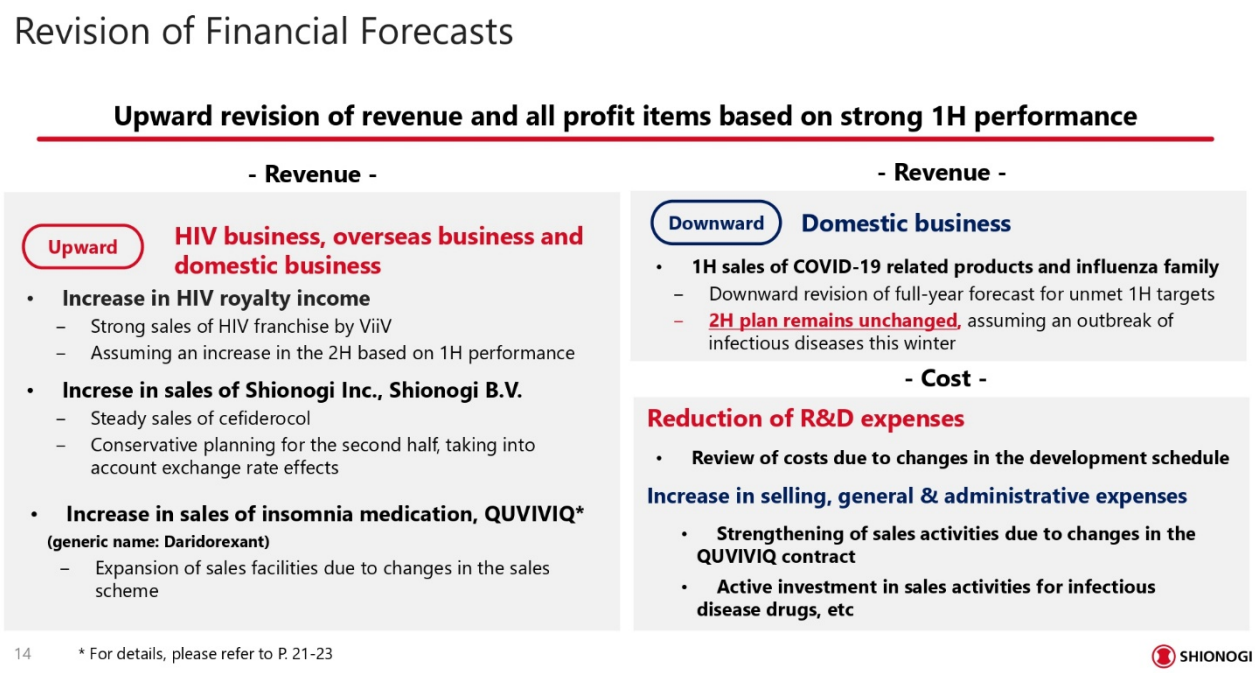
However, as of April, when the 30% copayment was applied across the board, we had a very difficult time including the other two oral drugs, and the treatment rate dropped to below 10% at one point. In the last six months, we have increased our growth rate to the mid-13% range, and the driver of this growth is clearly Xocova, as far as our country is concerned. The market share is over 70%.

We cannot make sales where there is no market, but what we can do is to increase the treatment rate and market share. We believe we are taking good steps in this regard.



On page 12, it described what I have just said.

One point I didn't mention was this Xofluza transmission suppression trial. I think it was a very good results. In Japan, the tests are actually covered by insurance, so most patients who have influenza go to the hospital for testing and receive antiviral drugs. So probably the positioning of the transmission suppression trial may not be that significant compared to other countries, but this is a very valuable test for the US and Europe, and of course we will work with Roche to expand the indications to the US and Europe as well. We believe it was a very big test against that.



This is the total forecast for FY2024 including the above.

As I mentioned earlier, at least in 2024, some or our three pillars, HIV royalties and sales in the US and Europe, are doing well, and we believe they will continue to do well in H2.

For domestic, we have QUVIVIQ, generic name daridorexant, at the bottom, and then influenza family and COVID. As I mentioned earlier, we are naturally not satisfied with the 13.4% treatment rate.

As statistics from the Ministry of Health, labor and welfare show, the number of deaths in the past year was a shocking 15 times that of influenza. Some may think that COVID is a thing of the past, but you are seeing an increase in the number of hospitalized patients and a large number of deaths.

Having this background, the treatment rate of 13% is still insufficient for our efforts. By raising this treatment rate to 15% or 17% and increasing our market share from 70% to 75% or 80%, there are some questions about how much we will do in H2, but we think we will be able to achieve our H2 plans as scheduled.

As for the cost, of course, some people think it is better to use it if it is available, but we are reviewing the development schedule and our priorities, and even so, the cost has increased by more than JPY10 billion over the previous year, we would like to make good use of this and other factors. On the other hand, we still want to promote Xocova, Xofluza, and QUVIVIQ, mainly in the domestic market, so we think it's okay to include a little more in these selling, general and administrative expenses.

Financial Results

Summary

- **Revenue and operating profit are expected to surpass previous record forecasts**
  - **We are expected to achieve record highs for three consecutive terms**
- **All profit items have also been revised upwards**
  - **Steady increase in sales revenue and review of various expenses**

(Unit：B yen)

	FY2024			FY2023		
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount
Revenue	4,550	4,600	**50**	435.1	**5.7%**	**24.9**
Operating profit	1,600	1,650	**50**	153.3	**7.6%**	**11.7**
Profit before tax	2,000	2,060	**60**	198.3	**3.9%**	**7.7**
Profit attributable to owners of parent	1,630	1,710	**80**	162.0	**5.5%**	**9.0**

FY2024 Exchange Rate (Average)

	Forecast	1H Results	Forecast Change
USD($) – JPY(¥)	145	152.78	**148**
GBP(£) – JPY(¥)	178	195.57	**190**
EUR(€) – JPY(¥)	155	166.06	**161**

15

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Seeing this in total, the next page, page 15.

H1, we overachieved, and H2 will be as originally planned, with a few bumps in the path, but we are confident that we will be able to achieve our goals. We have made a slight upward revision to sales and profits, and while we plan to renew record profits for three consecutive fiscal years, we are planning to increase the range of the revision a little. Revenue will be JPY460 billion, operating profit will be JPY165 billion and profit attributable to owners of parent will be JPY171 billion.

Statement of Profit and Loss

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023	Y on Y	
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Revenue	455.0	**460.0**	**5.0**	245.0	**246.0**	**1.0**	435.1	5.7	24.9
Cost of Sales	14.5 66.0	14.6 **67.0**	**1.0**	37.5	**36.9**	**(0.6)**	13.2 57.6	16.3	9.4
Gross profit	389.0	**393.0**	**4.0**	207.5	**209.2**	**1.7**	377.5	4.1	15.5
Selling, general & administrative expenses, R&D expenses total	49.8 226.5	48.9 **225.0**	**(1.5)**	115.5	**118.3**	**2.8**	47.4 206.0	9.2	19.0
Selling, general & administrative expenses	23.4 106.5	23.7 **109.0**	**2.5**	54.5	**59.1**	**4.6**	23.8 103.4	5.4	5.6
R&D expenses	26.4 120.0	25.2 **116.0**	**(4.0)**	61.0	**59.2**	**(1.8)**	23.6 102.6	13.0	13.4
Other income & expenses	(2.5)	**(3.0)**	**(0.5)**	(1.0)	**(1.8)**	**(0.8)**	(18.1)	-	15.1
Operating profit	35.2 160.0	35.9 **165.0**	**5.0**	91.0	**89.1**	**(1.9)**	35.2 153.3	7.6	11.7
Finance income & costs	40.0	**41.0**	**1.0**	26.5	**23.0**	**(3.5)**	45.0	(8.8)	(4.0)
Profit before tax	44.0 200.0	44.8 **206.0**	**6.0**	117.5	**112.2**	**(5.3)**	45.6 198.3	3.9	7.7
Profit attributable to owners of parent	163.0	**171.0**	**8.0**	96.5	**87.9**	**(8.6)**	162.0	5.5	9.0

16

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Page 16 explains what I have just mentioned with P&L.

When we think about how things have changed; looking at H2 forecast on the right, sales have increased slightly, but if anything, considering some recombination of R&D expenses and selling, general and administrative expenses, expenses will increase by JPY2.8 billion in total, but somehow including the carry-over from H1, we believe that we will be able to land on this figure.

Revenue by Segment

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023	Y on Y	
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Prescription drugs	134.9	**124.7**	**(10.2)**	76.9	**77.0**	**0.1**	151.1	(17.5)	(26.4)
Overseas subsidiaries/export	53.7	**57.6**	**3.9**	29.0	**29.3**	**0.3**	49.9	15.4	7.7
Shionogi Inc. (US)	20.6	**22.6**	**2.0**	10.6	**11.4**	**0.8**	17.9	26.3	4.7
Shionogi B.V. (EU)	14.4	**16.7**	**2.3**	7.6	**8.4**	**0.8**	13.6	23.1	3.1
Ping An Shionogi/C&O	11.2	**9.1**	**(2.1)**	6.5	**4.9**	**(1.6)**	10.6	(14.3)	(1.5)
Others	7.5	**9.2**	**1.7**	4.3	**4.6**	**0.3**	7.8	17.5	1.4
Contract manufacturing	15.5	**16.5**	**1.0**	9.0	**8.7**	**(0.3)**	17.6	(6.3)	(1.1)
OTC and quasi-drug	16.6	**16.6**	**-**	8.6	**8.4**	**(0.2)**	14.6	13.3	2.0
Royalty income	232.5	**242.8**	**10.3**	120.3	**121.3**	**1.0**	200.4	21.2	42.4
HIV franchise	224.6	**234.9**	**10.3**	113.4	**115.3**	**1.9**	195.8	20.0	39.1
Others	7.9	**7.9**	**-**	6.9	**6.0**	**(0.9)**	4.6	72.6	3.3
Others	1.8	**1.8**	**-**	1.2	**1.3**	**0.1**	1.4	25.3	0.4
Total	455.0	**460.0**	**5.0**	245.0	**246.0**	**1.0**	435.1	5.7	24.9

17

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Please see page 17.

In terms of sales and profit, we hope to keep the negative figure to this level for the domestic business, since we have the positive effect of QUVIVIQ, including Xocova and Xofluza in H2. Although the negative margin is much smaller than the negative margin in H1, we believe we will be able to reach this level.

With regard to SHIONOGI Inc. in the United States and SHIONOGI B.V. in Europe, business is continuing to be strong, so we have included this information here, and we are thinking that royalty income will be around JPY240 billion for the whole year.

Prescription Drugs in Japan

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023	Y on Y	
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Infectious disease drugs	91.2	**83.4**	**(7.8)**	**53.5**	**54.1**	**0.6**	82.9	**0.5**	**0.4**
COVID-19 related products + Influenza franchise	80.1	**72.3**	**(7.8)**	**47.4**	**47.4**	**0.1**	73.4	**(1.5)**	**(1.1)**
Symproic	6.5	**5.9**	**(0.6)**	**3.6**	**3.5**	**(0.1)**	4.5	**30.7**	**1.4**
OxyContin franchise	5.0	**5.0**	**-**	**2.7**	**2.9**	**0.3**	4.2	**20.4**	**0.8**
Actair	1.4	**1.3**	**(0.1)**	**0.9**	**0.9**	**0.0**	0.7	**86.1**	**0.6**
Cymbalta	3.3	**3.3**	**-**	**1.5**	**1.8**	**0.4**	3.8	**(13.7)**	**(0.5)**
Others	27.5	**25.8**	**(1.7)**	**14.8**	**13.7**	**(1.1)**	55.0*	**(53.0)**	**(29.1)**
QUVIVIQ	1.6	**3.0**	**1.4**	1.6	**3.0**	**1.4**	-	-	-
Prescription drugs	134.9	**124.7**	**(10.2)**	**76.9**	**77.0**	**0.1**	151.1	**(17.5)**	**(26.4)**

COVID-19 related products
- Xocova
- COVID-19 vaccines

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja

* Including temporary income from transfer of ADHD drugs

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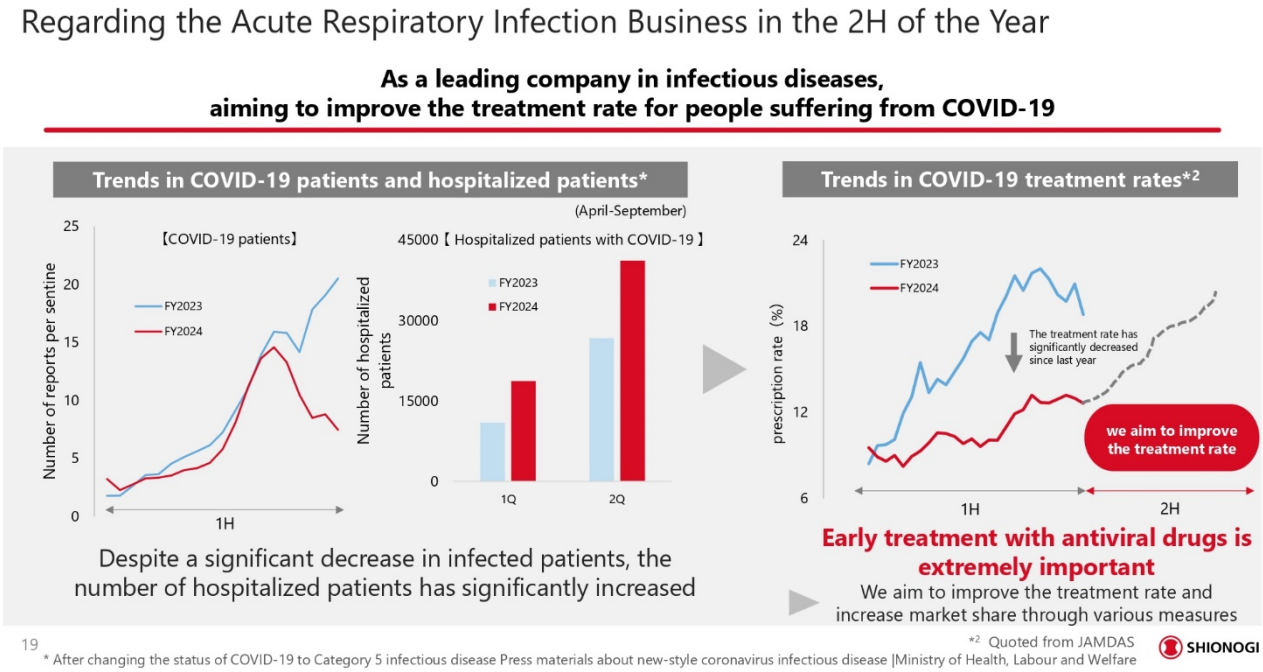
Prescription drugs in Japan.

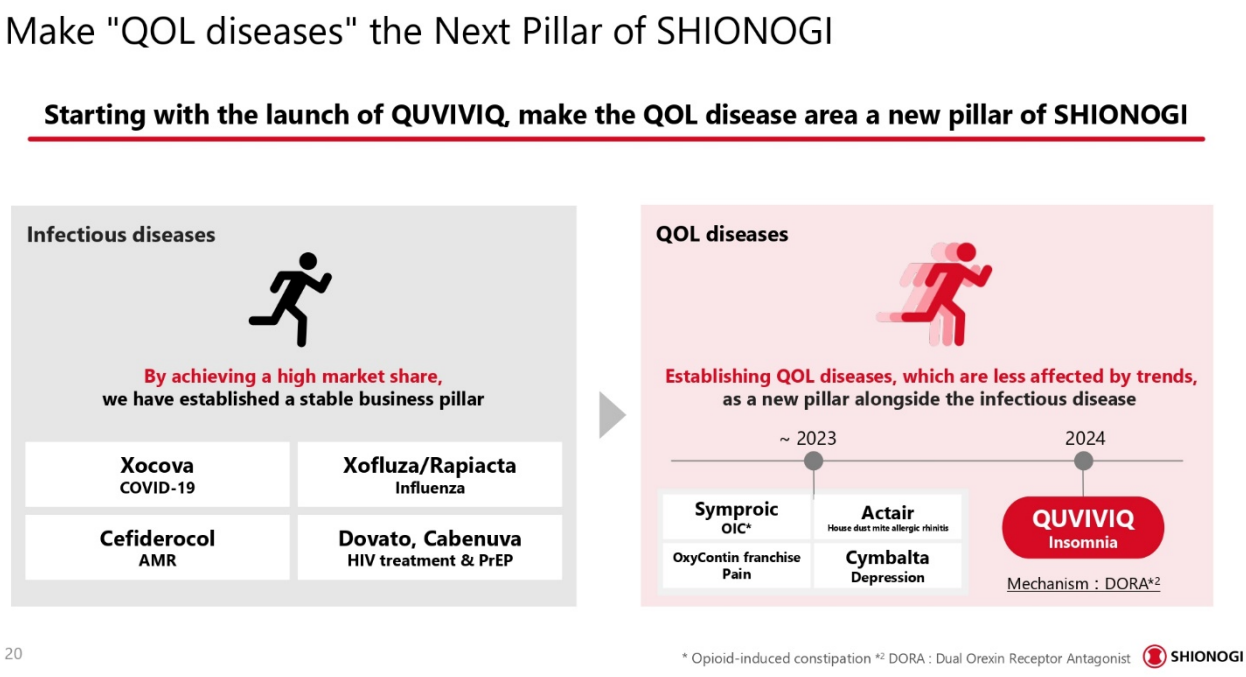
As I mentioned earlier, we will revise downward for the full year as well for the portion that did not reach us in H1, but for H2, we think it will be on-track, and after giving some thought to QUVIVIQ, we think we can go as far as this level, maybe a little bit stiffer, but we will start from here.



I would like to talk a little bit about what I mentioned earlier on page 19.

The COVID-19 patients, looking at only H1, are blue and red, and the red is still considerably lower. Despite this, the number of hospitalized patients has increased considerably in the red. As I mentioned earlier, the number of deaths has not decreased at all in 2024.

We think one major reason is this difference in treatment rates, the red is much lower than the treatment rates when we still had government assistance in the blue. We believe that by raising the number in the red to the blue or higher level, we will be able to reduce the number of deaths and hospitalizations, and we would like to promote our business including our investment in this.



Please see page 20.

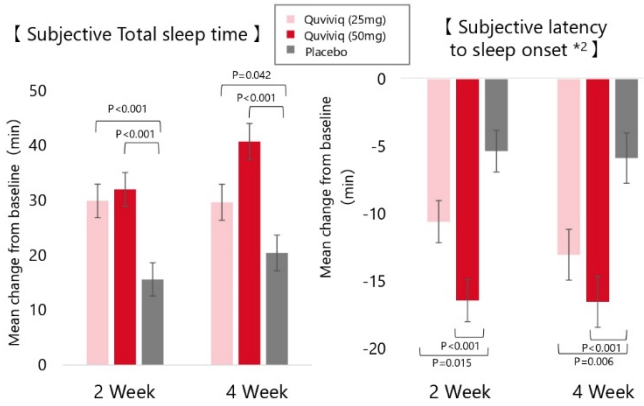
Nevertheless, I have always wanted to somehow make quality of life diseases a pillar of my practice at John and Uehara's place, but we have been told by many people that we are not making a sale by saying such a thing.

Sleep apnea and hearing loss are both interesting fields, but from the point of view of when they will really become real business, QUVIVIQ will be introduced for the first time as a new quality of life-related disease in addition to the existing ones, and as I will explain later, zuranolone, our antidepressant drug, is also very promising. We would like to make this a second pillar.

QUVIVIQ*: Nxera Pharma Japan has Obtained Manufacturing and Marketing Approval

All primary and secondary endpoints were achieved in Phase 3 trial in Japan

Positive results from Phase 3 trial in Japan*



Primary Endpoint: Comparison of changes from baseline to 4 weeks in subjective total sleep time and subjective sleep latency between the QUVIVIQ 50mg group and the placebo group.

Secondary Endpoint: Comparison of changes from baseline to 4 weeks in subjective total sleep time and subjective sleep latency between the QUVIVIQ 25mg group and the placebo group.

- QUVIVIQ significantly improved subjective Total Sleep Time, a primary endpoint defined as the change from baseline compared to placebo at 2 week ($p<0.001$ for 50mg)
- QUVIVIQ also significantly improved sleep onset as measured by a decrease in subjective Latency for Sleep Onset, a primary endpoint defined as the change from baseline compared to placebo at 2 week ($p<0.001$ for 50mg)
- No serious side effects have been reported due to the administration of QUVIVIQ

21

* Discovered by Idorsia *3 Time from lights out or bedtime to sleep onset

*2 Conducted by Nxera Pharma Japan and Mochida pharmaceutical: Data cited from the Articles (Sleep Medicine 122 (2024) 27-34) and created by SHIONOGI

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QUVIVIQ: Unmet Needs in Insomnia Treatment and Features of QUVIVIQ

Potential to Become the Best-in-Class Treatment in the Expanding Insomnia Field by Meeting Unmet Needs

Important Unmet Needs in Insomnia Treatment

- **Nocturnal awakenings**
- **Rapid sleep onset**
- **Carry-over effects to the next day after medication**

Features of the New Insomnia Treatment, QUVIVIQ

Dual Orexin Receptor Antagonist

- Alleviates excessive wakefulness through strong inhibition of orexin receptors
- **Recommended in the 2023 European Insomnia Guidelines**
  - In the pharmacological treatment of short-term and long-term insomnia, it is recommended as the only orexin receptor antagonist that can be used*

Outstanding pharmacokinetic profile

Tmax ▶ **about 0.5-1.4 hour**

T 1/2 ▶ **about 6-9 hour**

- Significant improvement in next-day sleepiness and daytime functioning confirmed in global trials*2

22

* ESRS Home | European Sleep Research Society *2 Lancet Neurol 2022; 21: 125–39.

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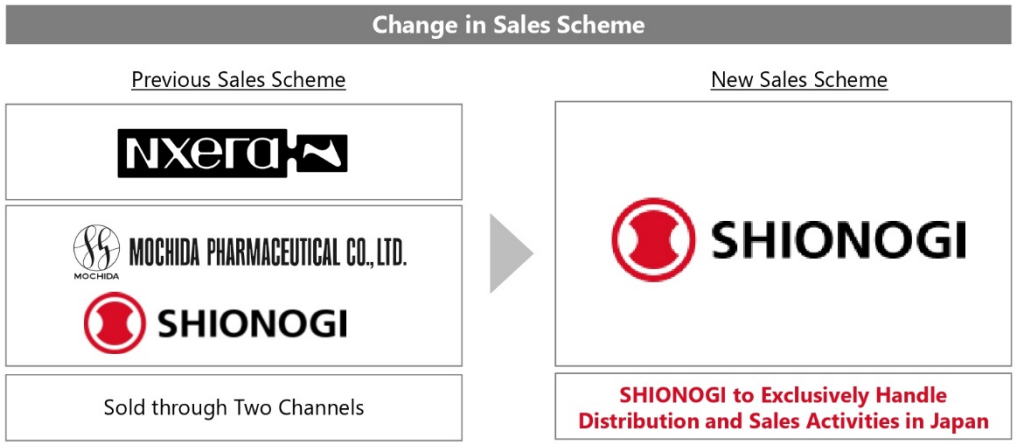
As for page 21 and 22, the data we received from Nxera shows that they work very nicely.

In particular, on page 22, the European insomnia guideline 2023 recommends it as the only orexin receptor antagonist that can be used. There is also very strong evidence overseas, and although this is a market that is very crowded, we would like to enter this market, including zuranolone, which is scheduled to arrive in the next fiscal year, and make it a franchise.

QUVIVIQ: Change in Sales Scheme

QUVIVIQ, which has excellent efficacy and plays a central role in the QOL disease area, will be sold exclusively in Japan



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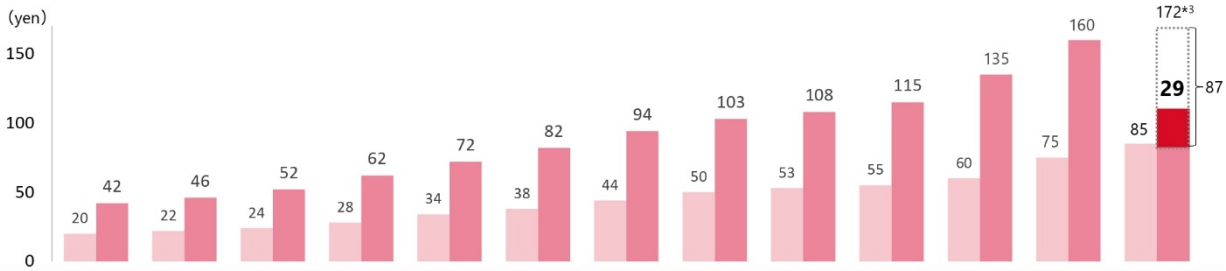
I cannot go into detail on each of the items on page 23, but the sales situation was quite complicated involving Nxera, Mochida, and our company, but we have now consolidated sales into one company.

We will take responsibility for this in a clear manner, and as I mentioned earlier, with zuranolone coming on board, we would like to take a step forward to make the CNS area, QOL diseases and pillar of our business.

Shareholder Return Policy through which Shareholders can Feel Our Growth

- Implemented a stock split to enhance stock liquidity and broaden the investor base (effective date: October 1, 2024)
  - Split each share into three shares and revised the forecasted dividend per share to 29 yen
  - Pre-split equivalent year-end dividend: 87 yen (effectively an increase)
- **Planning for the 13th consecutive year of dividend increases** in FY2024
- Aiming to improve capital efficiency through share buybacks and cancellations, as well as reducing cross-shareholdings



FY		12	13	14	15	16	17	18	19	20	21	22	23	24
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	75 B yen	-
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	10.84 M Shares*2	-
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9	4.0	4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.9	13.0 over (expected)

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020

Values calculated based on IFRS after 2019

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*2 Resolution passed on July 31, 2023, and treasure shares cancelled on April 17, 2024 *3 Providing figures that do not take stock splits into account

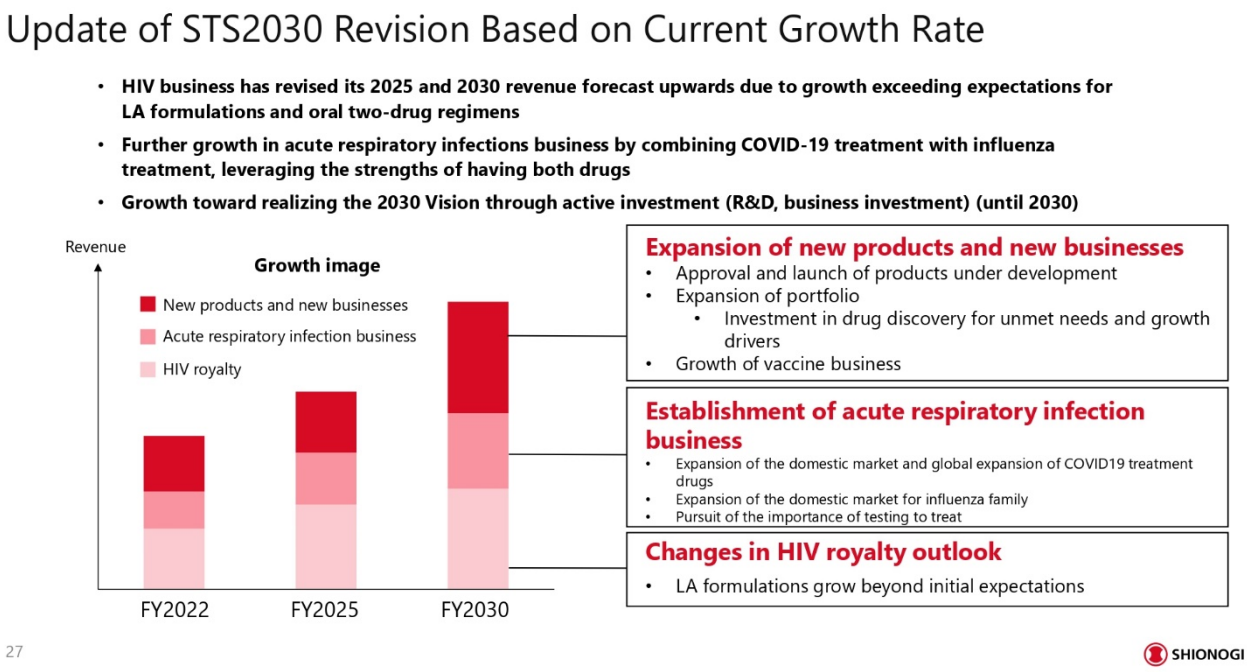
I would like to talk about shareholder returns on page 25.

We always discuss share buybacks at our board meetings, almost every board meeting. Naturally, we are talking about what scale and at what timing.

Naturally, if there is a really good investment for growth, which is our priority, and I believe the Board of Directors supports us in this regard. Our position has not changed: we will continue to consider share buybacks in a flexible manner, taking into account such factors as timing and the prices of items we are planning to purchase or introduce.

Regarding dividends, last year we increased the dividend by JPY25, the largest increase in our history. For the interim period, we started by increasing the dividend by JPY10 from JPY75 to JPY85, and since we split the dividend into three, the original plan was for the dividend to be JPY85, but it is now planned to be JPY87, and the current plan is for the dividend to be JPY172 this year.

As for H2, we have been discussing with the Board of Directors how much we should pay dividends, including the expected value, while considering the landing point, and we will continue to consider whether we can somehow pay more in H2, as we have done in the past.



This is the last of my versions. Moving onto page 27.

We have revised this table after discussing with ViiV, as we have heard from many analysts and others that it was not easy to understand.

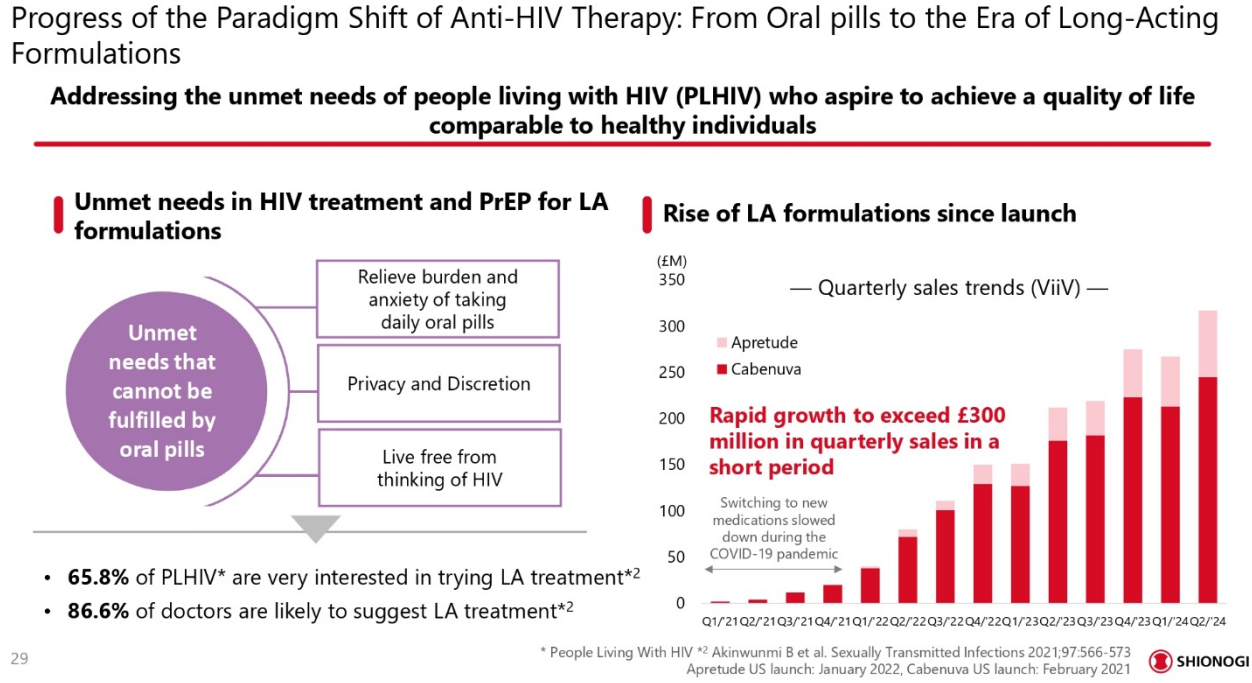
You may think that not much has changed, but for the HIV royalty portion at the bottom, we were able to come up with this picture as we worked with ViiV throughout the year to finalize a picture that will continue to grow, rather than cliff, as an absolute sales amount.

For us, we are still concerned about how much we can think straight about what will happen to HIV royalties, a major source of revenue, or even most of the revenue. This is not unrelated to what kind of investments we will make, what kind of future pipeline we will build, and what kind of sales we will make. We are confident

that HIV royalties will continue to be strong, and we think that ViiV's comment that they are very comfortable about it is a significant theme for us.

We will continue to grow by including acute respiratory infections, vaccines, and quality of life-related diseases, and we would like to continue growing in the future as well.

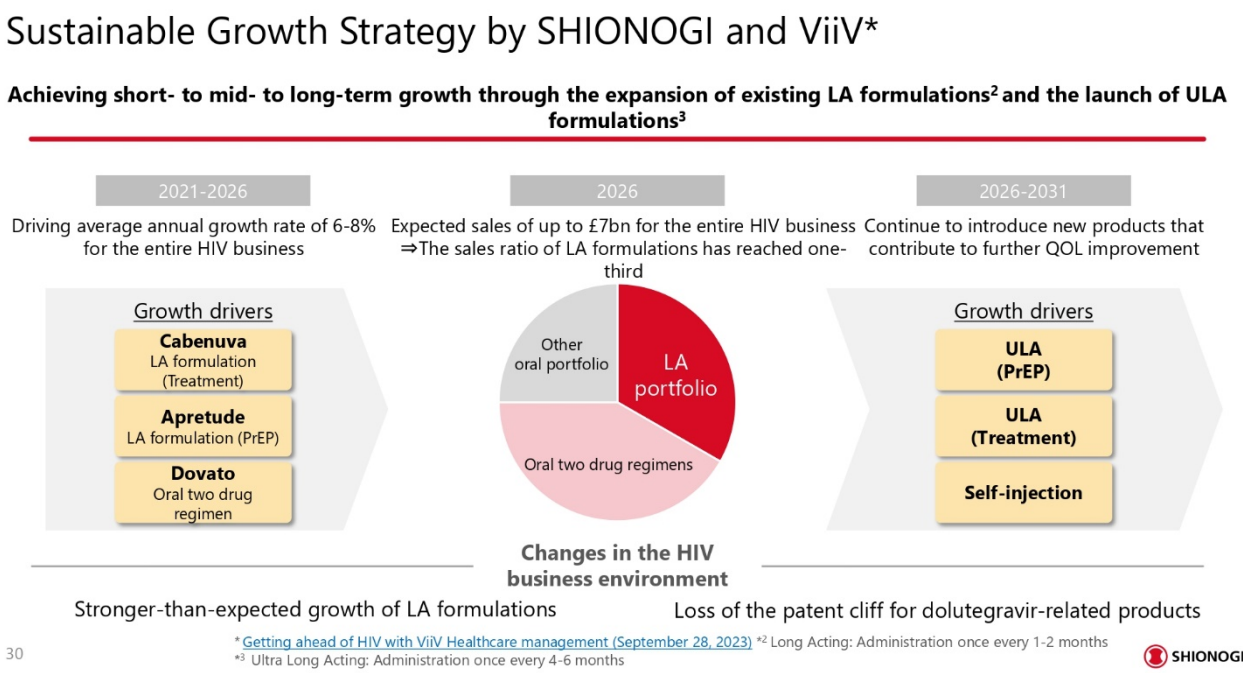
From now on, John, who is probably the most knowledgeable person on HIV, Uehara on development, and Iwasaki on domestic sales, will talk a little about each of them.



Keller: We are pioneers in the HIV business, especially in long-acting drugs, prevention, and treatment, and we have the support of patients and doctors. Not only is it easy to use, but we have seen very steady and robust growth in terms of not being known to others and living a life without being aware of HIV.

Although most of it is in the therapeutic area, it has grown to quarterly sales of 300 million pounds. Cabenuva itself has grown into this billion-pounds-plus one-year sales product. As we look further, we want to continue to streamline more and make this pie plan better for the convenience of our patients.

We are thinking from once a month to once every two months, and then once every four months is the next phase, and thereafter to once every six months. The once-every-four-months rule means that a patient only needs to think about HIV three times a year.



In this context, even with the current portfolio, ViiV's top-down investment in 2026 will amount to 7 billion pounds, one-third of which will come from the long-acting drug, LA formulation.

Looking to 2030 and beyond, we estimate that one-third of the total HIV treatment market will be long-acting, with LA drugs accounting for 80% or more. What is needed to accomplish this is for the pipeline to be expanded.

Sustainable Growth Strategy by SHIONOGI and ViiV: Growth Strategy for 2026-2031

Drive further expansion of the LA formulation market through the launch of new products that meet diverse unmet needs

Promising compounds (licensed from SHIONOGI to ViiV) and key milestones

Cabotegravir*
(Integrase inhibitor)

- Developed the current LA formulation market
- Positive data on efficacy and safety in real-world clinical evidence has been accumulated

S-365598*2
(Novel integrase inhibitor)

- High potency
- Demonstrated an excellent resistance barrier and has a resistance profile different from existing drugs

	Duration	Key drugs	Combination candidates	CY2026	CY2027	CY2028-2030
ULA (PrEP)	Q4M	Cabotegravir*		**File and launch**		
	Q6M	S-365598*2 is candidate			Registrational study start	**File and launch**
ULA (Treatment)	Q4M	Cabotegravir*	Rilpivirine was selected		**File and launch**	
	Q6M	S-365598*2 is candidate	Candidates under consideration	Regimen selection and registrational study start		**File and launch**
Self-administered formulations (Treatment)	-	S-365598*2 is candidate	Candidates under consideration	Registrational study start		**File and launch**

Q4M: ULA formulation administered once every 4 months, Q6M: ULA formulation administered once every 6 months

31

* Successful development of ULA formulations may extend patent protection period for cabotegravir for new LA medicines, formulations and regimens
*2 The third-generation integrase inhibitor (development code: VH4524184) licensed out by Shionogi to ViiV

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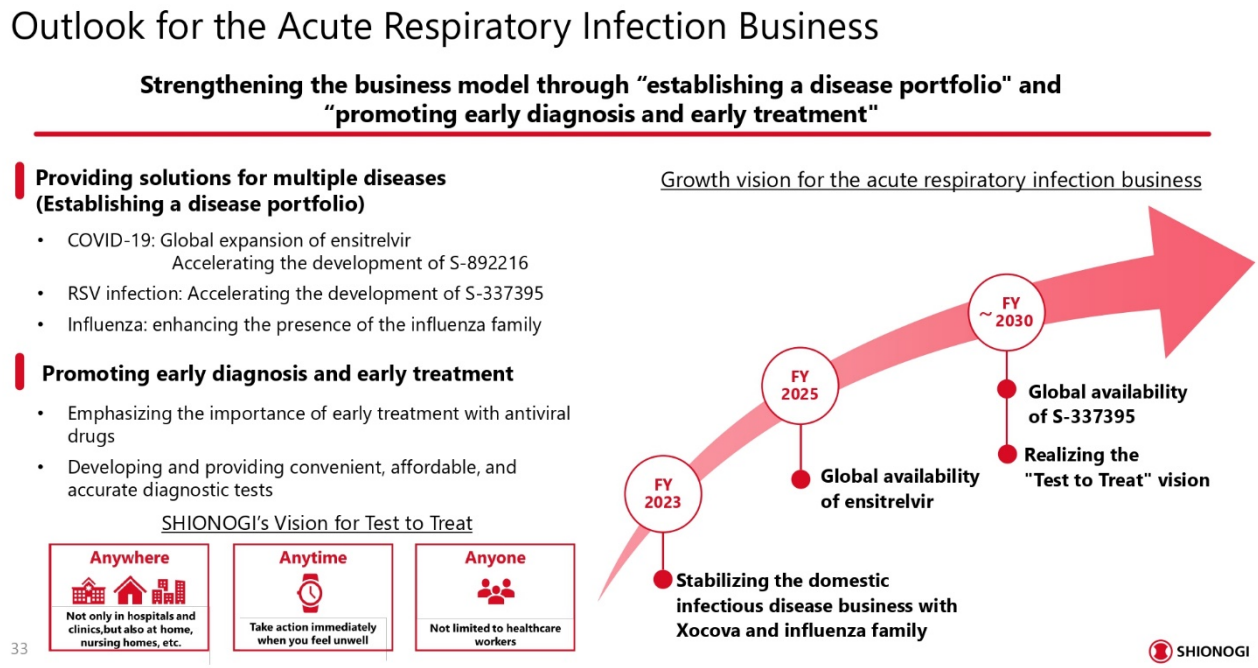
And as a next step, we are considering that every four months, not only cabotegravir alone, but also the combination. Cabotegravir for prevention and then again for treatment will come out in 2027. And we can also consider a formulation once every six months or so.

In addition to cabotegravir, we are also considering developing S-365598 as the key drug. This is every six months and is both curative and preventive. And we are also thinking of a convenient compound that allows us to do our own injections. We are now very much considering the idea of once every six months internally.

We intend to continue to expand our pipeline and further expand this position, this long-term formulation that we already have, into the future.

Thank you.

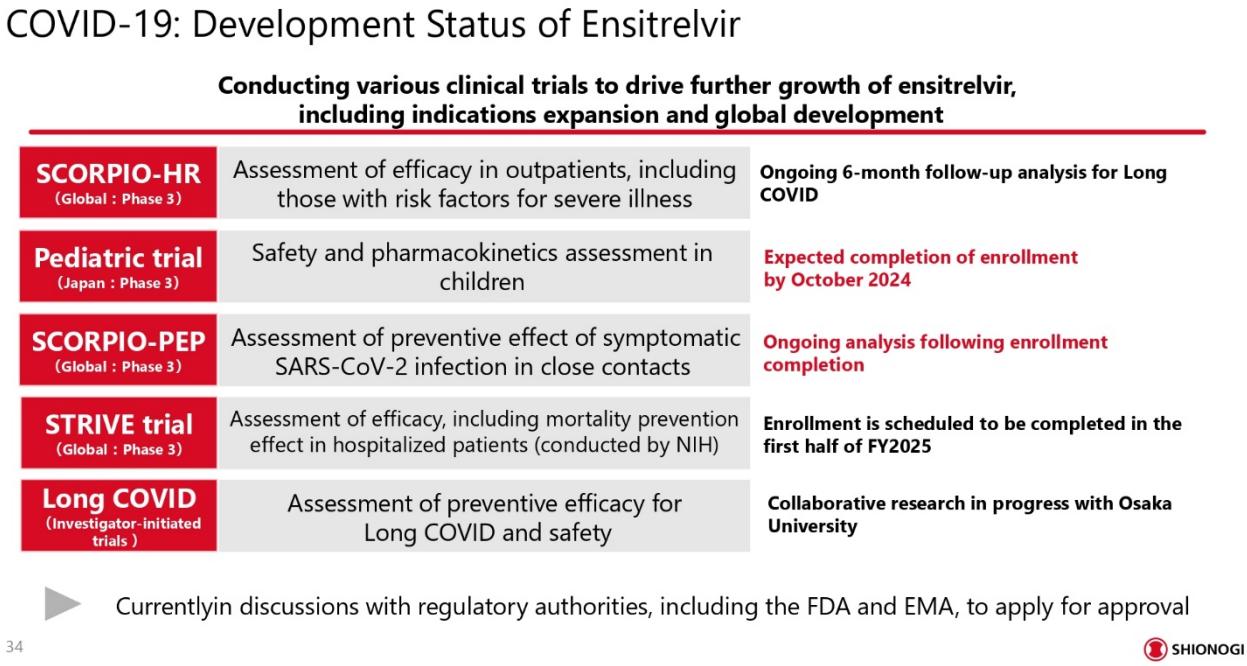


Uehara: I will now explain the outlook for the acute respiratory infection business, starting from slide page 33.

As you know, we have been developing drugs for the treatment of various viral infections and acute respiratory infections, including the Xofluza and RAPIACTA influenza families, as well as Xocova and even RS virus.

In addition to expanding our pipeline, as Teshirogi mentioned at the beginning of this presentation, diagnosis is becoming very important, and including providing diagnostic opportunities on a global basis, we consider three pipelines plus diagnostic drugs, our current vision is to further develop the acute respiratory infection business and provide various solutions to people in this way.

I will now discuss a few updates on each of these items on the following pages.



First, we have Xocova and ensitrelvir. Here is the press release delivered to your hand.

To give you some background on this, the results are really fresh and new. We were prepared to rush in and release the product at any time, and we released it immediately after seeing the results, so we were confident that we could deliver the results we were looking for.

This result is from the SCORPIO-PEP test, which is in the middle. Specifically, the trial showed that in families where there was a family member who had been infected with the disease, the trial was able to statistically and significantly confirm that the disease did not occur if the uninfected family member living in the same household, who may also be referred to as a "close contact," took the medicine.

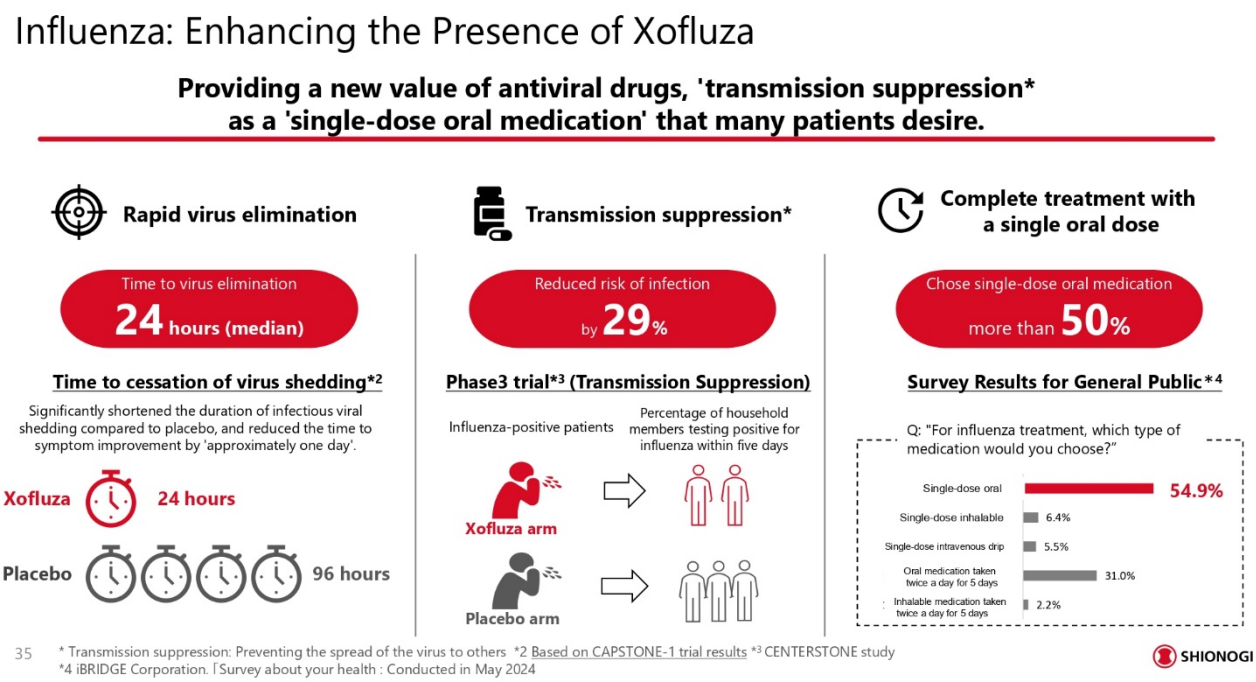
So, since this will add a Phase III trial and another application to the pivotal trial, we will have discussions with the FDA, EMA, and various other authorities regarding the global application.

The challenge with our ensitrelvir is that although some real-world data have shown a reduction in severity of illness, double-blind studies in actual clinical practice have not shown a statistically significant difference.

Naturally, compared to tests conducted before the Omicron strain became prevalent when there was no vaccine, our company's data is relatively close to actual clinical practice, and it clearly shows antiviral effects and symptom improvement in a situation where the Omicron strain is prevalent, and most patients have been vaccinated.

Now that Phase III trial results have been obtained showing that the antiviral effect of the drug suppresses the onset of the disease, we would like to submit all of this data to the regulatory authorities for discussion regarding future application or indications of the drug.

In addition, we have prepared a small tablet in Japan for pediatric clinical trial, which the registration will be completed this month. As soon as the results are obtained, we will aim for early approval of the drug in Japan. The trial seems to be smoothly progressing.



I would like to talk a little more about Xofluza.

Teshirogi spoke about this topic at the beginning of the meeting as well. About transmission suppression. It may be a little confused with prevention, it is expected that if taken, patients may not spread the virus around.

As you can see on the left side of this slide, in the Phase 3 trial of Xofluza, the virus had disappeared in more than half of the patients the day after taking the drug. So, when we think about what the benefit would be, we can expect that the virus would not be spread to the people living together.

It is scientifically promising, but no one has verified it in a Phase 3 trial in a real clinical setting. We are going to confirm it for the first time in the world.

With such high antiviral efficacy, we were confident that we could win, so we enrolled patients all over the world. As expected, the transmission of virus was reduced by 29% in the family members of those living with the patient who took Xofluza, which is also statistically significant. Therefore, the major progress this time is that we have been able to verify the result in the clinical trial, at the Phase 3I trial.

In this way, we will continue to grow various antiviral drugs and, although we didn't prepare the slides, we are now conducting the Phase 2 trial of a new mechanism of action against RS virus. We expect to have the results of this project in the near future, and as soon as we have them, we will explain them to you at the future meeting, along with our development plan for Phase 3 trial and beyond.

SHIONOGI's COVID-19 Vaccine Portfolio

Promoting the vaccine business through both platform establishment※ and universal vaccine development

Project	Antigen	Status	Remarks
COVGOZE	Wuhan	Approval (FY2024 1Q)	-
S-268023	XBB1.5	Primary endpoint* not achieved (FY2024 2Q)	Follow-up data currently being collected (evaluation of persistence of neutralizing antibody titers)
S-268024	JN.1	Phase 3 in preparation (FY2024 4Q)	We are currently conducting the manufacturing, process validation, and preclinical trials of the investigational drug
S-567123	Sarbecovirus (Universal vaccine)	Phase 1 in preparation (FY2024 4Q)	We are currently conducting clinical trial design under consideration and preclinical trials of the investigational drug

※ Platform
For vaccines that have been established as a platform, if there is a commitment to obtain data on quality, efficacy, safety, and immunogenicity after marketing, it is possible to apply for a complete change to the current recommended strain with the latest quality and preclinical test results

* Geometric mean titer of neutralizing activity and antibody response rate against the XBB.1.5 strain on Day 29 after vaccination

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I would like to talk a little bit about the COVID-19 vaccine.

We have written about four pipelines of vaccines here. As you are aware, we have successfully received approval for the production and marketing of COVGOZE against the originating strain.

However, as you are aware, the prevalent strains have already changed from the originating strain to Omicron strain. In this ever-changing world, new vaccines are being newly created every year. In order to do so speedily, it is necessary to be recognized as a platform and to have authorization.

In order to be recognized as a platform, the mutant strain must be created once again, meet quality requirements, and provide preclinical data. If the mutant strain meets the requirements of the Phase 3 validation test, then both the origin strain and the mutant strain will be comprehensively approved, and we do not need to conduct Phase 3 trials every time we make a new strain. That is the current idea.

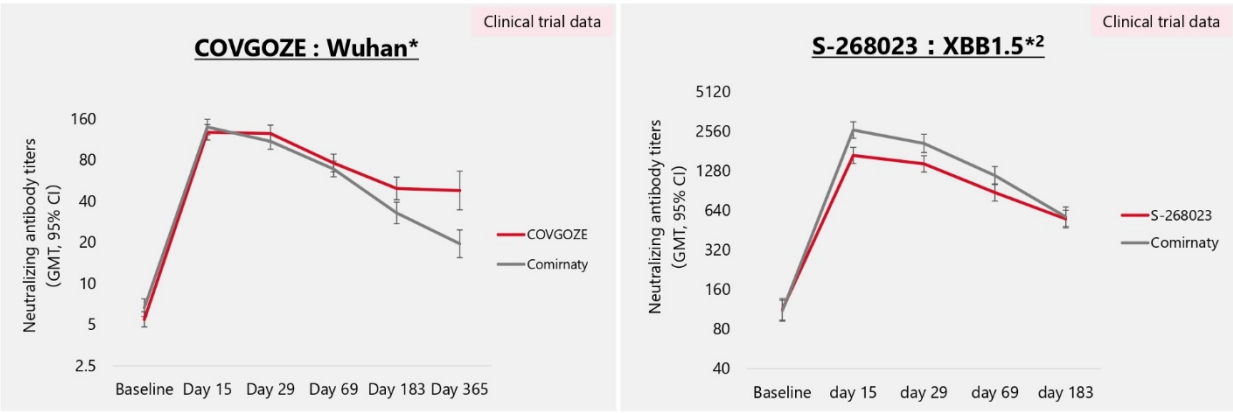
The second compound, S-268023, was tested in clinical trials last year on XBB1.5 strains, but unfortunately the primary endpoint was not met. In this context, we are now producing a new vaccine against the JN.1 strain. This one is in the process of being finalized, with plans to conduct Phase 3 trial by the end of this year.

In this context, I will show a few results on the next slide to answer a few questions about why the new vaccine and what about the previous data.

Towards the Realization of a Vaccine Platform

- Characteristics of SHIONOGI's First Vaccine -

Over a period of six months to one year, the neutralizing antibody titers remained high compared to pre-vaccination levels



* The S-268019 additional immunization comparative trial for individuals who have received two doses of Comirnaty intramuscular injection (Data presented at the joint conference of the 97th Annual Meeting of the Japanese Society of Infectious Diseases, the Academic Lecture Meeting, and the 71st Academic Meeting of the Japanese Society of Chemotherapy in 2023). Additionally, this study is supported by AMED under the project number JP21nf0101626 and by the Ministry of Health, Labour and Welfare / Regarding additional immunization, COVGOZE is not yet approved

38 *2 Evaluation of the safety and clinical efficacy of S-268023 in subjects aged 20 years and older who have completed initial immunization, and verification of non-inferiority to Comirnaty RTU intramuscular injection (monovalent: XBB.1.5). This study is supported by AMED under project number JP21nf0101626, as well as by the Ministry of Health, Labour and Welfare.

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The 38th slide, on the left, shows the results when boosting COVGOZE.

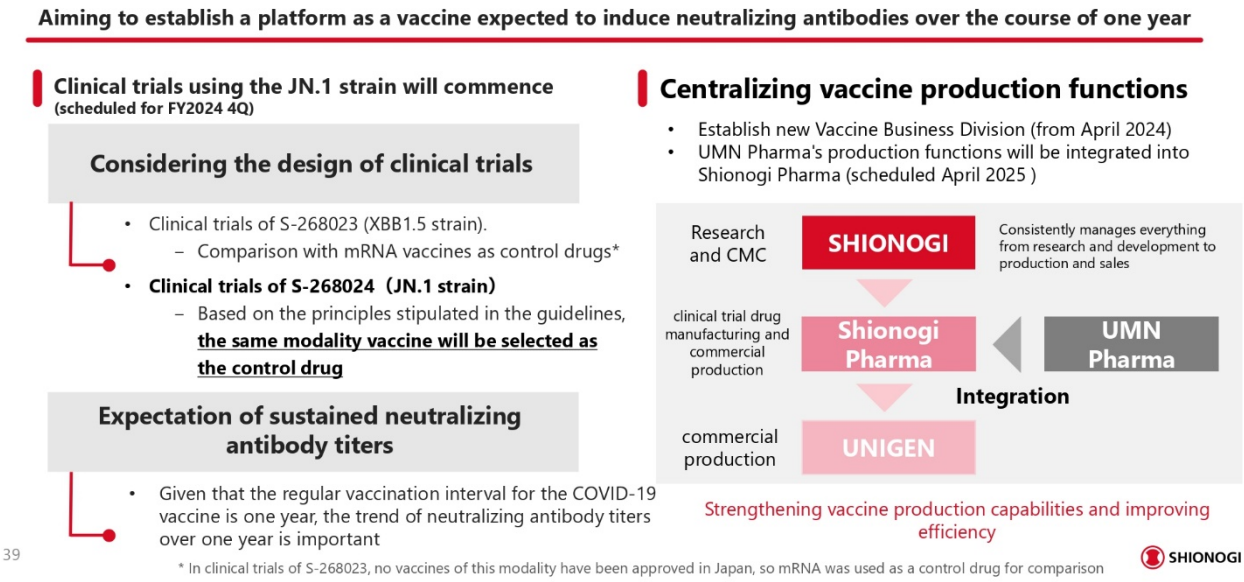
Specifically, if a person who has received two doses of vaccine, Comirnaty from Pfizer is given our vaccine for the third dose, or three Comirnaty doses. So, as you can see, we are still showing non-inferiority with COVGOZE and Comirnaty as of day 29, and we are slightly above them numerically.

Characteristically, the data were obtained on this day 183 and day 365, which would be expected to show a tendency for neutralizing antibodies to persist. In the midst of all this, we decided that this S-268023 was still a good one, and we wanted to study the mutant strain as well, so we designed a new trial in the same way.

Various primings, mostly Comirnaty, primed multiple times. This time, when our S-268023 vaccine was boosted there again while it has been boosted multiple times, three times or four times, unfortunately, the neutralizing antibodies were a little low on the day 29 primary. It was that non-inferiority could not be confirmed.

We have also obtained data that suggest that our recombinant vaccines may have some characteristics that make them more likely to be sustained.

Towards the Realization of a Vaccine Platform: Future Strategies



What we are going to do again in JN.1 this time is to show non-inferiority of the vaccine with the same modality in terms of guidelines, which is the regulated way. We did not have any available at that time, so we used Comirnaty for non-inferiority.

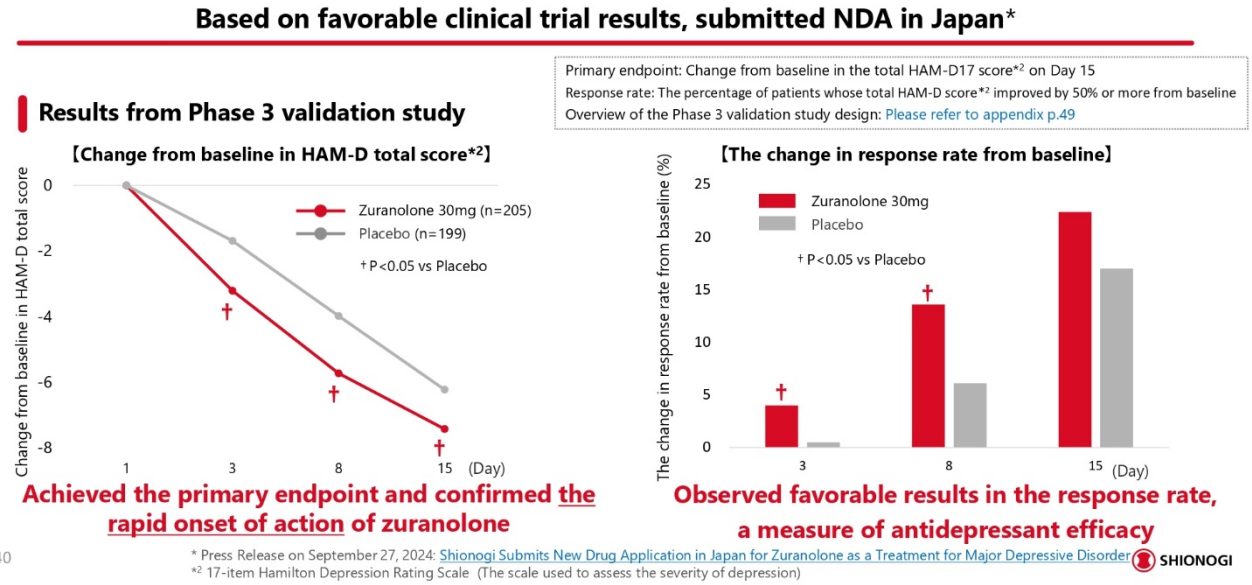
We have once again created a recombinant peptide vaccine using JN.1. Therefore, we will continue to conduct the Phase 3 trials with a different trial design in order to deliver a better and safer vaccine that will also be sustained.

In addition, the production base for vaccines will be transferred from UMN Pharma to Shionogi Pharma, and the vaccine business division, today we have Hanasaki here, is gradually building a system that will enable Shionogi to conduct R&D and manufacturing under Hanasaki's leadership.

I would like to ask you to go back with a few slides. On the 37th page, we discussed the fact that it was time to stop constantly reformulating the universal vaccine against the Sarbecovirus every time, and we used a little scientific technology to acquire an antigen that has the potential to induce neutralizing antibodies against various mutant strains.

The various Sarbecoviruses also include SARS-CoV-1. If we can induce neutralizing antibodies against highly pathogenic Sarbecovirus, which is highly lethal, and if we can make a broad-spectrum vaccine, we may be able to deviate from the competition to make a new vaccine. The current status of the vaccine business and research and development is that we are preparing for the Phase 1 trial globally.

Zuranolone: New Drug Application (NDA) in Japan for Major Depressive Disorder



Now, the 40th slide, about zuranolone.

We have talked about the results of the previous R&D day and other occasions, but once again, these are the features of our zuranolone. The speed of effect is a very important feature of this product.

We are re-posting the results of the Phase 3 validation study on the left side, and we see that there is a significant difference after day 3. I think it is very important for those who are very troubled and suffering from depression to come to the clinic and see immediate results after taking the drug. In fact, there are many existing drugs for depression, but to my knowledge, there is no such drug that shows a significant difference from the third day.

Zuranolone: Unmet Needs in Antidepressant Treatment and Characteristics of Zuranolone

As a new treatment option, aim to become "a novel therapy, rapid acting therapy for the acute treatment* of depression"

Key unmet needs in antidepressant treatment

The onset of effect can be slow

- Many antidepressants take 6 to 8 weeks to show effects

Low pharmacotherapy response rate

- Discontinuation of administration due to insufficient efficacy or the occurrence of side effects

Characteristics of the novel antidepressant zuranolone

Rapid onset

- Start to show its effects from Day 3 (after taking the medication twice)

Ease of use

- No dose adjustment required, and administration is completed in two weeks
- Post-treatment management can be flexibly determined based on symptoms and shared decision-making (SDM)*2

Safety

- Demonstrated good tolerability
- Results from the observation period of up to 52 weeks showed no dependency

* Acute phase of depression: From the start of treatment after diagnosis to remission (disappearance of depressive symptoms) (Source: Depression Treatment Guidelines, Key Points of Depression Treatment-10)

*2 The process in which healthcare professionals and patients share scientific evidence and, while considering the patient's preferences and values, determine the best treatment method

SHIONOGI

Therefore, we have submitted data to the PMDA and are currently under review by them in order to deliver a new depression medication with a new mechanism of action and a good response rate, one that is both fast-acting and convenient, and that maintains safety.

I have rushed a bit to talk about the progress of our representative programs, but the remaining two pages are a summary of the progress of our development pipeline.

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	→		**Analyzing the 6-month follow-up for Long COVID**
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	→ Complete enrollment (FY24 2Q)	Phase 3 topline results (FY24 4Q)	**Registration expected to be completed: October 2024**
	Ensitrelvir	COVID-19 (prevention)	Phase 3	→ Complete enrollment (FY24 2Q)	Phase 3 topline results (FY24 3Q)	**Recruitment completed and under analysis**
	S-892216	COVID-19	Phase 1	Phase 2 start (FY24 4Q) →	Topline results (FY25 3Q)	
COVID-19 vaccines	**COVGOZE (S-268019)**	COVID-19 (Wuhan, Vaccine)	Approval			
	S-268023	COVID-19 (XBB1.5,Vaccine)	Phase 3	→		**Phase 3 interim analysis completed**
	S-268024	COVID-19 (JN.1, Vaccine)	Preclinical	Phase 2 start (FY24 4Q) →	Topline results (FY25 2Q)	
	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)	**Received Fast Track designation from the FDA: October 2024**
	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)	**Achieved FPI for Combination Phase 1: September 2024**

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As you already know, I have talked a lot about the pipeline of infectious diseases that I mentioned earlier in the introduction.

Progress of Major Development Products - QOL Diseases with High Social Impact -

※ 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
QOL Diseases with High Social Impact	SDT-001	ADHD	Submission	Approval (FY24 4Q)		
	Zuranolone	Depression	Submission	Submission (FY24 2Q)	Approval (FY25 2Q)	Submitted in Japan : September 2024
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3		Submission (FY25 3Q)	
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline (FY25 1Q)	Submission (FY25 3Q)	
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2			
	S-309309	Obesity	Phase 2	Considering future development strategies		
	S-600918 + Drug X	Sleep apnea syndrome	Phase 2	Phase 2 start (FY24 3Q)	Phase 2 topline (FY25 3Q)	IND application* in US : October 2024
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start (FY24 2Q)		Achieved FPI in Phase 2 part : September 2024
	S-151128	Chronic pain	Phase 1b	Phase 1b topline (FY24 2Q)		
	S-606001	Pompe	Phase 1		Phase 2 start (FY25 1Q)	

43

* Investigational New Drug Application

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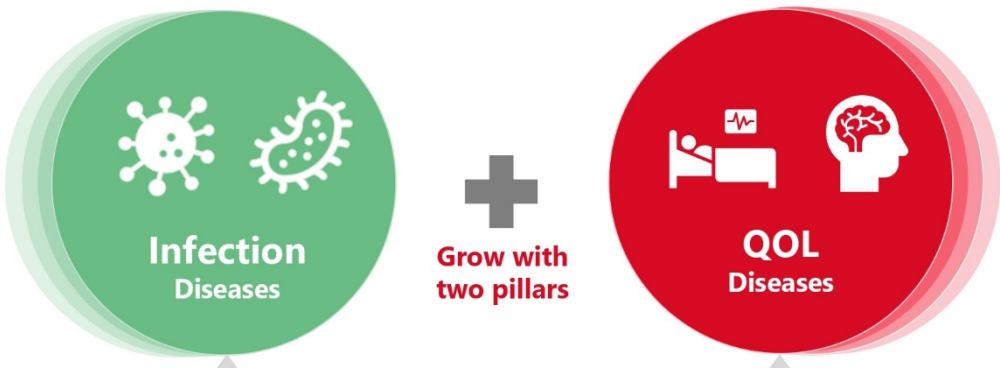
In the area of quality of life, QOL-related diseases, which we believe will become another mainstay of our business and which have a high social impact, we are making steady progress with various products, as shown here. If there is anything in here that needs to be addressed, please check back later. That is all.

SHIONOGI will Grow with the Two Pillars of Infectious Diseases and QOL Diseases

In addition to the stable growth of its infectious disease business, SHIONOGI is seriously committed to tackling QOL diseases



The pillar of SHIONOGI's business

・Stabilization and further growth through the evolution of the business model.
・Evolve the infectious disease business by realizing "Test to Treat."

The new pillar of SHIONOGI

・Continuously introduce new products.
・Raise to the same level as the infectious disease business

44

SHIONOGI

Iwasaki: I, Iwasaki, in charge of our domestic business, would like to explain about the domestic business.

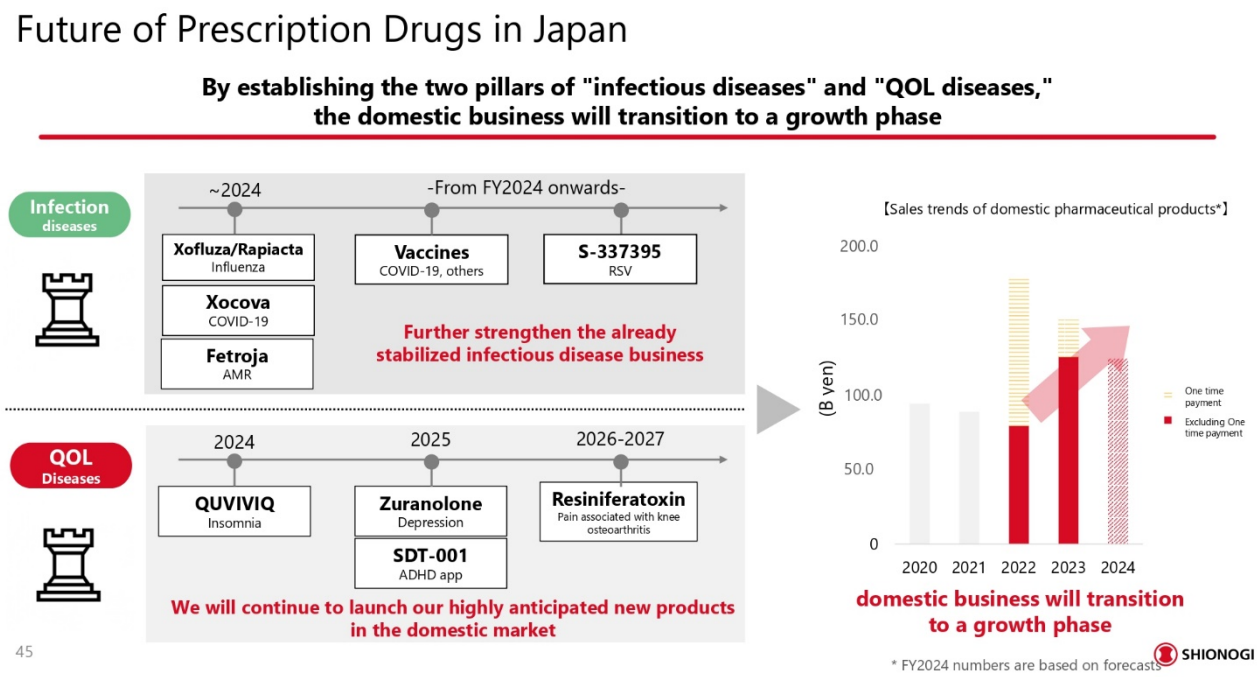
SHIONOGI will continue to focus on the two pillars of growth: infectious diseases and quality of life-related diseases in the future. As you are aware, we have been involved in infectious diseases for many years.

Until two years ago, we had only one influenza virus, so our sales were zero or 100 depending on the epidemic. With the entry of COVID-19's Xocova, last year, the monthly average was JPY6 billion, and this year, at the end of H1, JPY25 billion, although the influenza did not spread, so we have established one stable business model, with either of these diseases becoming more prevalent.

This is not only for business, but also for resources that we can forecast. Since we are now able to better predict how much resources to devote to infectious diseases, we are also able to better predict our overall activity plan, and I believe that we will be able to focus even more on our other pillar, quality of life-related diseases.

In the case of acute infectious diseases, the test-to-treat rate for COVID-19 is still only 10%, and we must aim for 20% or 25% at a minimum. As Uehara mentioned earlier, there was some negative information about the evaluation of the cost-effectiveness of the preventive results, there was also some misinformation that it might not work.

We are currently accumulating data on the results of prevention trials and on the suppression of sequelae and severe disease in Japan, mainly through the efforts of medical affairs. We hope to achieve stable business in the infectious disease field in H2 or in the future by disclosing this kind of information or results as soon as possible and raising awareness of the need for treatment and to realize this.



At the same time, it is important that we realize the growth to quality of life-related diseases at the same level as the infectious disease business.

First, regarding infectious diseases, in addition to Xofluza, RAPIACTA, and Xocova, we are also reviewing Fetroja, Finibax, and Flumarin, to once again demonstrate SHIONOGI's presence in the entire field of so-called infectious diseases at hospitals.

Then the vaccine S-337395 for RS virus infections, and acute infection, and then AMR, these two axes. In the hospital business and general practitioner business, we will assign MRs mainly to develop business in these areas.

On the other hand, in the area of quality-of-life-related diseases, we are now able to market QUVIVIQ by ourselves, which has made it easier for us to formulate a sales plan and strategy. We reviewed a part of the sales forecast. We will also work on QOL-related diseases related to the central nervous system with zuranolone, SDT-001, and resiniferatoxin, which was introduced by Grunenthal and others, and which is used to treat pain.

In this area, we are not only using resources, but also the digital web, and are considering a hybrid sales approach that combines people and digital technology. In addition, although the number of MRs was reduced by 200 last year, we have been working to improve the efficiency of our sales activities by consolidating and closing sales offices and using outside consultants to provide information in a way that matches the characteristics of doctors and regions.

We are also collaborating with M3 to launch a company called Stream-I, where we are working on an activity called digital detail. Thus, we will focus on both of these infectious diseases and quality of life-related diseases, both human and digital, to achieve further growth.

Kyokawa: Thank you very much.

Question & Answer

Kyokawa : Now, let's move on to the question-and-answer session. Mr. Yamaguchi from Citi.

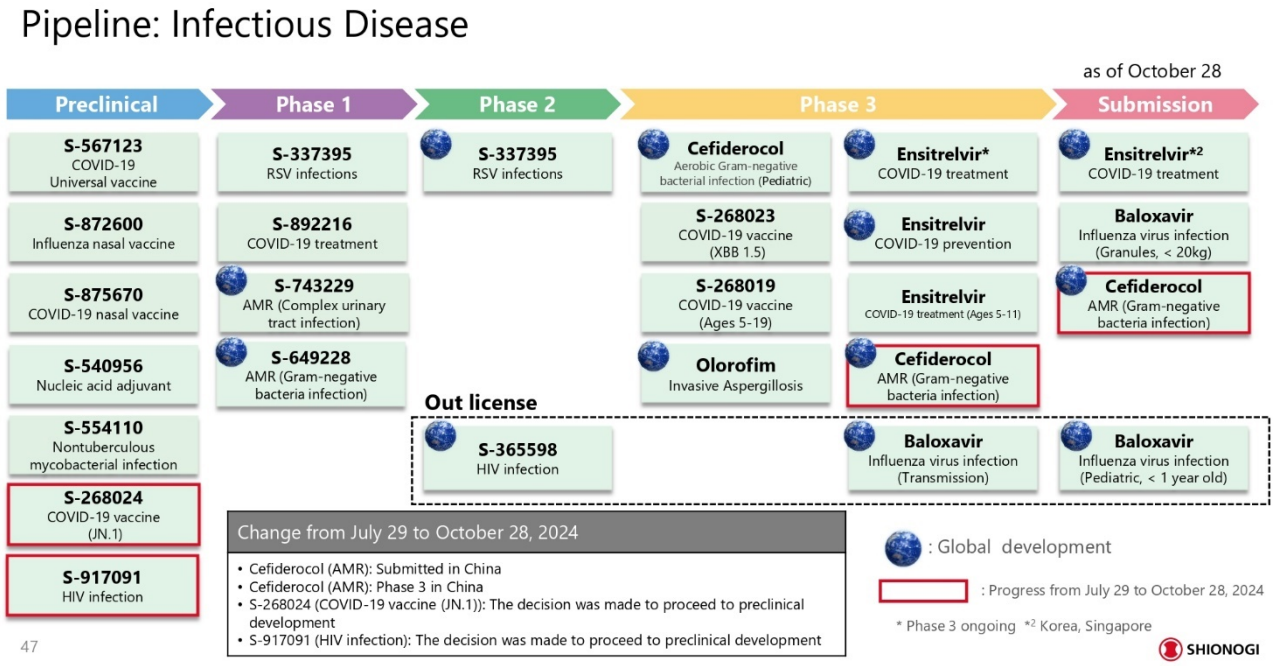
Yamaguchi : This is Yamaguchi from Citigroup Global Markets. Thank you. The first question is about the revised chart on page 27. I think there were arrows and things before, so I'm sorry, I think the revised, I think the message was like this before, but do you mean new information in the sense that the vertical axis is more quantitative? Sorry if I don't understand something new there. Please explain that again.

Teshirogi : Thank you, sorry. We have heard from some of you that this is a very confusing picture, especially with respect to 2025 to 2030, and how much, whether qualitative or otherwise, will it really grow, remain flat, or decline.

However, no matter how much of an image it is, by putting this out to ViiV, no, we don't want to be at the level where we have to put something like that out. We have discussed more in more detail. We are now trying to find out if it is comfortable with respect to the growth of the Company in a qualitative rather than a quantitative manner. If this is the case, they will now make a public announcement and consider it as their business plan, and that they have converted it into royalties for SHIONOGI, which means that this figure is extremely appropriate, and that is why we have made it clear that they will grow this time.

Yamaguchi : Thank you very much. It is only a qualitative part. Thank you. I have two more minor questions on HIV. In terms of royalties by quarter, Q1 was high and Q2 was flat. As I recall, there was a bit of a special part in Q1, but am I correct in understanding that this was not the case in Q2?

Teshirogi : Exactly. While it may not be necessary to dive into every detail each year, growth has been steady at a rate of around 13% to 14%, assuming there are no extraordinary factors impacting results.



Yamaguchi : On page 47 of our development pipeline, it's noted that we have an HIV compound, S-917091, currently in the non-clinical stage. Could you provide some insight into this compound and what it entails?

Keller : S-917091 is an internally developed pipeline compound; however, at this stage, we are not disclosing specific details regarding its mechanism. For long-acting therapies, a key drug like an integrase inhibitor is essential, but additional partner drugs are also required for effective treatment. S-917091 is one of the candidate compounds we are advancing as a potential partner drug.

Teshirogi : We are working for oral, and now the PK exam to see if it will last six months, we have said this many times, but we have to wait six months. We will have the results of those six months around the beginning of next year.

In any case, for both Gilead and us, PrEP is one drug, but when we really need at least two drugs for treatment, we really need a partner drug that lasts for six months. They are thinking about neutralizing antibodies, but John and the rest of us think that we need a very solid partner drug, such as a small molecule. We were allowed to make the compound in-house, and it turned out to be quite good.

Yamaguchi : I understand. Thank you. Finally, sorry, I know this is a totally different subject, but maybe there is no specific update on S-309309, but if there is, could you please say something including partnering as well?

Keller : As previously discussed, we need to consider both our own findings and the current treatment landscape for GLP-1 receptor agonists. There remain unmet needs in GLP-1 therapy; many patients discontinue treatment relatively early after initiation. Although next-generation GLP-1 combination therapies are emerging, fundamental challenges persist.

Our compound, S-309309, is being investigated in preclinical studies to determine if its unique characteristics can address these challenges. Initial studies were conducted in rodents, and we have now progressed to studies in primates. We anticipate that results from ongoing studies will become available within this fiscal year, allowing us to outline our future direction based on these findings.

Yamaguchi : So, you are waiting for the results. You are waiting for the results before talking to other companies?

Keller : That's right. We consider both other companies and ourselves.

Kyokawa : Mr. Ueda from Goldman Sachs.

Ueda : This is Ueda from Goldman Sachs. I would also like to know about the mid-term outlook, first of all.

This time, the assumption has been changed from a slight decrease to an increase through to 2030, but I would like to know the background to this.

Regarding long acting, since last year, there has been some very good data on cabotegravir. Also, as you explained, the two-drug fixed-dose combination and oral drugs are progressing well, while in the area of prevention rather than treatment, I think we are seeing good data from the competition. I'd like to know what kind of changes in this area have deepened your company's confidence.

Also, I think there will probably be another cliff just ahead of 2030, where we will probably have to switch to two oral drugs, so I would like to know how you think about this area in the long term.

Teshirogi : John will add the details later. I think it is a very significant progress that the realization of Cabenuva once every four months has increased considerably. As John said, at this point, HIV patients, the viral status has to be checked every three months to four months, which is in line with this cycle, so once every four months, rilpivirine is also going to go if it goes that far. This is a very big advantage as a treatment here.

There are still some things we don't know, and I don't intend to under-estimate, but given that the competition, whether it is once every six months there or once every four months, the treatment in the form of integrase plus one is not going to be there yet, I think that 2030 I believe that we will be able to compete on our own in the treatment market, at least in LA, until close to 2030.

As for prevention, of course, lenacapavir has good results, and even if there are a few problems such as a trace of subcutaneous injection once every six months, the results are very good. I guess this would probably become a competition. If we can extend it to once every four months, or eventually once every six months, I wonder what level it could be.

However, the PrEP market is very large in countries such as the US, us, and perhaps Gilead as well, so we need to make it very large. They are predicting that the size of the market will be much larger by an order of magnitude. Even if we do not go that far, the market will be so large that it will be different from the current level. I don't know if it will be 50-50, but we will have a certain amount of competition, and that market will grow as well. As for the LA market, I think we can almost read the movements with certainty.

Also, I believe that Juluca, then Dovato, and formulations, among the so-called orals, will remain until about the early 2030s, as Mr. Ueda just mentioned. After that, it is difficult to predict how the oral drug market itself, including our competitors' market, will develop.

They are also projecting that about a third or half of Dovato, which is what they are saying at the current peak, will remain. Although we have included a certain number of these drugs, we have discussed with both companies the possibility of constant growth centered on long-acting injections and prophylaxis and have calculated royalties based on this.

Also, this may be a raccoon dog's way of saying that 598 and other integrases are very important to us. Our competitors say that they are planning to use something else as backbone therapy, but we think it will be difficult to do so.

However, we really want to create an "integrase plus one" program, so we have stepped up our efforts since last year and are now working on it at John's place, and we are now seeing the possibility of having a once-every-six-months program.

If ViiV were to take these treatments as they are, both of the main treatment regimens would leave our company, which we believe would be a very big plus for us.

Keller : Currently, treatments represent 90% of the market. While Gilead's efforts are likely to expand this market, we believe integrase inhibitors will continue to play a pivotal role. Although Gilead has shown significant commitment in early-stage preclinical and clinical development, they currently do not have any compounds in late-stage clinical development within this pipeline.

ViiV estimates that one-third-plus of the market would be LA. In 2030 and 2031. It is very similar to the current top line. And we believe this is due to us. As for therapeutic drugs. Therefore, we would like to maintain this.

And I think it is difficult for the government or payers to switch back patients from LA to oral. Therefore, we believe that what we are focusing on is speed. In terms of market share, we are growing about 2 percentage points YoY. Gilead is at about 0.6 points. And we are taking from other regimens. We believe this is due to the strength of LA.

Ueda : The second point I would like to ask is about your expectations for domestic business.

I would think that with the exception of infectious disease drugs, you have had a bit of a difficult period in terms of performance so far. As you explained today, while I think that infectious diseases are now on a fairly solid base, and new items have been introduced for quality of life-related diseases, I also think that it will take some more time for our own products.

Can you please explain how you see the importance of domestic business in the 2030 Vision, and whether it can be positioned as an important revenue driver other than HIV royalties?

Teshirogi : What we are hesitant about is that the market in this country is still very important. We have already mentioned the scope of what we can see now, including QOL diseases, at Iwasaki's place, but I think we need to further strengthen this area.

We are considering a major turning point in the framework of investment for growth, so we would like to include this area in our business plan for the next fiscal year, and after that, we would like to eventually have 50 sales overseas and 50 sales in Japan.

However, since there are 50 in Japan, I am sure that we will be able to provide an answer in the not-too-distant future as to the costs and benefits of investment for growth in this area.

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

Kyokawa : Ms. Haruta from UBS.

Haruta : This is Haruta from UBS Securities Japan Co., Ltd. I'd like to talk about the R&D part. We think that there are still a few issues to be addressed in terms of quality-of-life-related diseases and obtaining PoC, such as obesity and the chronic cough area.

What do you think is needed to increase the success rate of QOL diseases to the same level as infectious diseases? There are many ways to do this, such as JV with Apnimed, utilizing outside resources, and strengthening translational research in the non-clinical and clinical areas. Once again, what measures are you taking to increase the certainty of success of your company's products in the future for QOL diseases?

Uehara : Thank you. As you mentioned, I think you understand well. One is that it would be faster to look at sleep apnea, for example, in humans than to look at it in animals anymore. In such a situation, there are some diseases that take a strategy to confirm the proof of concept in humans.

In addition, when considering translational research from animals to humans, proof of concept is always focused on the use of biomarkers and, although it may be a bit cliched, what kind of data can be obtained from the preclinical stage to bridge the gap to humans.

If the drug is finished and advances to the Phase I trials, even at a relatively early stage and before a large-scale Phase II trial, it should be possible to confirm that such biomarkers are clearly working, and that can be good evidence to proceed.

Therefore, in order to increase the accuracy of the PoC, we are proceeding with various R&D efforts from the perspective of weeding out those with low PoC accuracy as quickly as possible.

Keller : Regarding sleep apnea syndrome, with the help of our partner company Apnimed, which has expertise in this field, we have been able to advance development by combining S-600918 with compounds that have different mechanisms from S-600918. By repurposing existing compounds in this way, we may be able to accelerate our development progress.

Teshirogi : It's not all good, and as for why there, especially with John and the current research headquarters, we are working on that now, including reorganization, but the pharmacology is still weak. We are strong in synthesis, and we are also strong in infectious disease pharmacology, but we are weak in pharmacology in the area of bridging from animal pharmacology to human pharmacology, and in biological pharmacology, which I think we must admit. We have to speed up about it.

It may sound strange, but I am aware that the accuracy of this area will not improve unless the pharmacology department is redone, including bringing in considerably younger people at the top of the list. There, as for small molecule, synthetic, infectious disease, we are objectively strong. We have a very strong infrastructure and a large number of people, so it is a very big issue for us how to improve the pharmacology part of this area, and we are working on this as quickly as possible.

Haruta : I understand. Thank you. Secondly, this may be a reminder question, but I was wondering if you could reiterate your thoughts on strategic investment in the area of capital allocation.

You mentioned before that the scale could be up to JPY400 billion or JPY500 billion, but I don't think your company is necessarily looking to maximize the scale, so I am wondering if your priority is to promote the global development of infectious diseases or to strengthen the QOL-disease pipeline. Of course, it depends on the timing of the meeting, since there is a partner, but again, what are your thoughts on this?

Teshirogi : Thank you for the question. In terms of the scale, as I mentioned earlier, if it is JPY400 billion to JPY500 billion, including the cash balance that we have now, and more importantly, as Mr. Ueda and Mr. Yamaguchi mentioned, I personally feel that the level of confidence has risen to a very high level. The flow of HIV royalties is becoming more and more certain until the year 2030 or even beyond.

In other words, the part about cash flow that is not removed is getting much stronger. The order of magnitude and confidence in how much can be spent on investment for growth, including this, has risen considerably, which is quite different from what we have seen in the past.

In this context, Japan still needs more goods and people in terms of establishing a very strong business that is not influenced by so-called fads, especially in the area of quality-of-life-related diseases. As I said before, the number of medicinal chemists in the country as a whole is drastically decreasing, even though, as I said before,

we have our own research headquarters and small molecules. We are down to about two-thirds of our peak, and there are not so many researchers. We really want to make this point stronger.

In the US and Europe, the late-stage pipeline is very expensive, but we are focusing on rare diseases, Pompe disease, and Fragile X syndrome. The reason why cefidelocor has been successful is that we have concentrated our resources in areas where we can handle them well, such as hospitals, severe infectious diseases. If we can add something that fits in with the current resources available to us, something that we are selling now at a real late stage, it would not have to be extremely high expensive, but it would be within our reach.

Looking at the total of these areas, as I mentioned earlier, I would like you to think that we are now running two or three parallel projects while keeping in mind the JPY400 billion to JPY500 billion figures in mind.

Haruta : Thank you very much.

Kyokawa : Mr. Mamegano.

Mamegano : My name is Mamegano from BofA Securities. Thank you. First, congratulations to SCORPIO-PEP. I think it is a wonderful result.

I believe that you are currently negotiating with the FDA on the SCORPIO-HR matter as well. I was wondering if the success of this PEP trial has any positive impact on that side. I guess it is still difficult to make a comment on this, but could you tell me about it? Thank you.

Uehara : Thank you. As you are probably aware, Pfizer and Merck have conducted similar studies on two oral drugs. Since neither of the drugs meet the primary, this is the first drug in the world to successfully perform the Phase III of post-exposure prognosis with an oral agent.

As we wrote in the press release, we are proud to say that we have obtained very encouraging data from the fact that no particular safety concerns have been identified.

In this context, as I mentioned in my explanation, the world focuses on reducing the severity of illnesses. How hospitalizations were made and how mortality rates were reduced. The background to this is that the guidance on emergency use authorization, which states that if a drug meets this definition, it should be approved as an emergency drug, has been misunderstood to the extent that if it does not meet this definition, it is not a drug at all.

What we should now take in actual clinical trials is clinical evidence such as the antiviral effect and improvement of symptoms and suppression of disease onset by the antiviral effect, as we have been able to do. Therefore, we would like to create an environment where our data can be presented and used around the world, including by experts, in an effort to create a new stone from what has been considered in the current stream of emergent use.

Mamegano : I understand. Thank you.

Kyokawa : Okay, we will now close the floor for questions from the audience in the venue, and we will take questions from those who are participating via the web. Mr. Hashiguchi from Daiwa Securities Co., Ltd., please go ahead.

Hashiguchi : I'm Hashiguchi. Thank you for giving me this opportunity. I have a question about the slide on page 27.

Do you think it is possible to achieve this growth in sales revenue only with the items that are currently being developed and marketed? I feel that there is a discrepancy, especially if FY2025 is an extension of the current

situation, but I would like to know to what extent you are assuming the introduction of new products from outside.

Teshirogi : Things are not decided until they are decided. For our part, as Uehara mentioned earlier, we are continuing to talk with the FDA and EMA about Xocova and ensitrelvir, for example, and we will continue to have new conversations, including this PEP study. I think it is a very big theme that within FY2025, how much infectious disease drugs will contribute to the overseas market.

Now that we are considering our landing point of 460 B yen, if you are asking how much more we can add to that, we may say that we can go that far, but that it would be difficult to explain all FY2025 KPI 5,500 B yen. We are in the process of aiming for that, but we are also always looking for ways to add other things to supplement it.

This is our growth image, and this is how we would like to grow, but for FY2025, the breakdown to be announced this coming April, we are proceeding with a balance while considering this.

Hashiguchi : Thank you. Can you provide any additional comments on the progress of Xocova's FDA and other efforts to file for approval in various foreign countries? It has been a little while since the top-line results of the Phase III trial were released. What would be required after this to make the application possible? If you have one or two clarifications as to what we should wait for, could you please let us know?

Uehara : Thank you for your question. I may be repeating myself a bit, but the point that is being sought now is how much evidence there is in the real world for the control of serious illness, including the fact that it is so widely used in Japan.

We have submitted one paper, but in terms of submitting it to the regulatory authorities, we have a different approach than a paper. So, one point is that we need to work on those areas.

In the meantime, new Phase 3 trial results have come out, so if we proceed with the approval application based only on the data we have submitted to the authorities so far, we won't be able to provide the new data. Therefore, when we thought about it, the results from PEP trial came up, so we are now negotiating to have the entire package, including post-exposure prophylaxis data, submitted for approval.

Hashiguchi : Thank you very much. That is all.

Kyokawa : Next, Mr. Wakao from JPMorgan, please.

Wakao : I'm Wakao from JPMorgan. Thank you. From me, it is the domestic Xocova for acute respiratory infection business. I would like to know about the 19th slide.

What I would like to know is how to achieve the quantitative targets for H2. In H2, you are aiming for about JPY47 billion for COVID-19 or influenza in the infectious disease category. If we exclude influenza, should we assume that this cannot be achieved unless the treatment rate of infectious diseases in H2 is at the same level as in the previous year, FY2023, and the epidemic is at the same level as in H1 of FY2023?

After all, I think that sales were very large in H1 of the previous fiscal year, and in order to achieve the plan for H2 on par with H1 of the previous fiscal year, that is how I see it from the graph here. Is my understanding correct?

In addition, I wonder if you could give us some more specific strategies or details on how to increase the treatment rate in H2.

Iwasaki : Iwasaki would like to answer your question. As for our goals, we have divided them into hospitals and clinics. As for clinics, since patients are less of having high-risk factors, we already have a market share of nearly 80% in this area, so we will focus our efforts on increasing the treatment rate.

There are two ways to increase the treatment rate. The first is to educate the general public. The first step is to raise the diagnosis, and one way to do this is to increase access to diagnostics or the OTC supply of diagnostics.

The other is to use mass media to raise awareness of the disease, as we did with SNS in the summer, and to further strengthen it by having people go to hospitals.

As for the hospitals, we are also working on the Long COVID data, etc., so we will increase the value of Xocova through such evidence, and this time we will increase the market share, which is now 40% to 60%, with Lagevrio now at the top of the market.

We will approach the hospital business in two ways: by presenting such data and by increasing our market share.

Wakao : Am I correct in understanding that this will be achieved if the number of infected patients is as prevalent as in H1 of the previous year, while the treatment rate there is being increased?

Iwasaki : That's right. As for disease awareness, we are now working on some concrete ideas, and when they are ready, we will be able to present them before the next winter season.

Wakao : Thank you very much. The second question is about HIV royalties. I think Mr. Yamaguchi asked the first question, but could you please elaborate a little more? The reason I ask is that at the time of Q1 briefing, the landing was supposed to be on par with the plan H1, but that ended up being an upward swing, and I wonder if the landing for Q2 has changed in any way from the time of Q1 briefing. As Teshirogi CEO explained earlier, you mentioned that H2 is also somewhat conservative. Normally, I saw H2 as a continuation of Q2 trend and an upward swing, is my understanding correct?

Teshirogi : With regard to royalty, I'm sorry, but we can't make it too strong on the predictions basis and let it go down, so we're usually going to make it quite conservative. GSK's earnings announcement is scheduled for tomorrow or the day after tomorrow, and we are making proper adjustments with ViiV and GSK in that area as well, so I think it is correct with your current understanding, Mr. Wakao.

Wakao : Is it my understanding that this landing in Q2 is also within the expectation of the landing, as you just mentioned the last time conservatively?

Teshirogi : Yes, and especially now, when thinking in terms of Japanese yen, so I also incorporated a little bit that we don't know what will happen with the exchange rate. Even though most of it is hedged, the exchange rate still went relatively stable, so I think that was a slight positive factor as well.

Wakao : I understand. Finally, I would like to understand the marketability of the PEP study, which has just been announced as a success. As for this one, I am not sure what kind of patient, or I don't know if I can say patients, you are referring to, but what kind of label are you aiming for?

So, what specific labels are you aiming for, such as prevention within 24 hours of a family member becoming infected, and how much marketability do you actually expect?

In the US, it seems that there are a large number of approved drugs and patients, but it is difficult to see whether they will be covered by insurance or whether patients will use them in the first place. Please let me know about that point.

Uehara : Thank you for your question. First, regarding labeling, of course this is a matter of negotiation with the authorities, so it is not up to us to decide. Basically, the labeling will be based on the design of the Phase III trial, so the labeling will be determined in real clinical practice.

The drug is supposed to be taken immediately after the onset of the disease, or after contacting a patient, and if the patient with onset has been in close contact with someone for a certain period of time, such as 72 hours, then this drug is supposed to be taken.

So, the issue is if you really want to limit it to the actual actual clinical situation, where they are family members living together. This is also true for Xofluza, for preventive indication, but it is not limited to family members. In the event that the drug is used in a nursing home, it could be used in a variety of ways, for example, in a nursing home where certain people are living together and the disease occurs, it could be taken by the person living in the same room in order to eliminate nosocomial infection, or in some cases, patients in the same room in a hospital.

In this context, I would like to reiterate that there is no drug that has been applied to COVID-19 for prophylaxis yet, so from the standpoint of actual drug prices and usage, we are going to release the most affordable drug for use in the US and Europe, and we are now in the process of finalizing such details.

We are still not in a position to give specific details, although we are expanding various ideas, such as the idea of keeping a stock file of the one and only drug in a national way.

Wakao : I understand very well. Thank you. That is all.

Keller : Additionally, as previously mentioned, our current discussions with the FDA and EMA encompass all data. This includes the SCORPIO-SR trial, SCORPIO-HR trial, real-world evidence, and the recently announced SCORPIO-PEP trial. Rather than considering each approval and indication independently, we are approaching this comprehensively. However, apart from that, various applications can be considered based on the results of these clinical trial studies.

In the US, preventive coverage is quite good. Insurance coverage is 100% or, for example, prevention of other antiviruses is 100% covered by commercial private insurance. Although the government has expressed some concern about HIV, I think it can be said that insurance coverage is excellent and high.

Kyokawa : Next, Mr. Tsuzuki from Mizuho, please.

Tsuzuki : I'm Tsuzuki, Mizuho Securities. Thank you. I was wondering if you could tell us about QUVIVIQ.

Regarding this QUVIVIQ, I believe that your company is expecting sales of about JPY3 billion in three months amidst the current competition, but I would like to know more about your strategy, such as how to win here, or how you think about peak sales.

Iwasaki : Belsomra, Dayvigo, there is very much competition. However, we would like to focus on clinic, as we believe that the unique and uniquely recommended drugs in European guidelines, etc. and the high level of daytime function are our characteristics.

In addition, as I mentioned Stream-I earlier, we would like to increase the coverage of target doctors by making full use of digital technology.

Another thing is that not only so-called orexin-based drugs, but also benzodiazepine drugs and non-benzodiazepine drugs are still using, but we would like to appeal the safety aspects such as safety or carry-over effects, we would like to promote the safety of the drug and its carry-over effect, not only for competing products, but also for switching from drugs with other mechanisms.

In light of the JPY110 billion market, we believe that JPY3 billion is a figure that is well within our grasp, since we can formulate all sales strategies, from clinic to hospital, and we have the resources to do it all ourselves.

Tsuzuki : Thank you very much. Is there anything quantitative you can tell us about how much you are aiming for in terms of peaks, if this is the case? Even if you have no such figures, it will be fine.

Iwasaki : Right now, the sales of competitor is JPY40 billion. So we are aiming for JPY20 billion first. I think my mission is to peak at JPY20 billion and how quickly we can get there.

Tsuzuki : Thank you very much. As for the developing products, I think the timing of the preliminary report on the results of S-151128, chronic pain, was already over, but I would be glad to receive any comments from you. Since this is a chronic disease area, it is getting more and more attention, including overseas, so if you have any information on this, please let me know.

Uehara : We are currently in the process of analyzing the data and will report back to you as soon as we have decided on the future strategy as well.

Tsuzuki : What sort of opportunities do we have? Like a briefing session, or press release? I guess it will be briefing.

Uehara: I would like to hold an R&D meeting or some other appropriate form of meeting like the financial results briefing, to explain it.

Tsuzuki : I understand very well. Thank you.

Kyokawa : Thank you very much. Continuing on, Ms. Sogi of Bernstein, please.

Sogi : Thank you. I have two questions. First, I would like to know your thoughts regarding Xocova.

We have been looking at Xocova's actual COVID infections, as well as the treatment rates you are presenting and market share. I believe the actual cases themselves grew by more than double from Q1 to Q2. According to your report, the treatment rate itself has increased by a factor of 1.3, and the market share has increased by a factor of 1.1.

Considering this, I think sales themselves will probably triple between Q1 and Q2. Your sales have actually increased more than fivefold, but I would like to know if there is anything that we are overlooking here.

Iwasaki : There are many ways to look at it, but the prevalence of patients is not at all predictable, so Q1 is much lower than predicted. If we use that as a base, I think we're stretching ourselves quite a bit, as you said. We believe that the number of patients is on par with last year's, and that a treatment rate of 20% to 25% and a market share of 80% are sufficient numbers to achieve our goal.

Rather than our own analysis, I think that the gap in the forecasted figures may be due to the way the figures are interpreted or the way the forecasts are made.

Sogi : I understand. Thank you. Then I would like to ask about vaccines. In this case, the vaccine did not reach the primary endpoint against the Omicron strain. Also, I understand that you are about to start a clinical trial for this new mutant strain.

If so, what is your company's current assumption regarding the actual commercialization of vaccines, and when do you assume which timing you will have actual sales?

Hanasaki : Thank you for your questions. Hanasaki will answer your question. On page 42, we have a pipeline schedule. Now, for S-268024 subject to JN.1 shares, Phase III will start during this fiscal year, so we should be able to bring it to application by the end of FY2025.

After that, we will consult with the authorities to finalize a schedule for obtaining approval.

Sogi : This one, of course, was approved for the first vaccine against the Wuhan strain, so I think it was a follow-up to that. If so, is it possible that the actual review period would be shorter than for a regular application?

Uehara : Yes. We want to believe so. However, we will be providing them with a variety of data, so asking them to look at it in another three months is obviously not the way to go. Basically, the process involves a thorough reading of the data and screening by the platform, so we recognize that it will take a reasonable amount of time.

Sogi : Then, realistically speaking, would it be correct to think that the actual sales will begin to stand in 2026?

Uehara : I can say that we will probably not make it in 2025 from a sales perspective a little bit.

Sogi : I understand. Thank you.

Kyokawa : We will now take the last questions. Mr. Matsubara from Nomura Securities, please go ahead.

Matsubara : My name is Matsubara from Nomura Securities. Thank you. I have one question. Regarding zuranolone. I think the effect on page 40 seems to be quite good. I think overseas sales would be good, too. I think it is very difficult to find patients with postpartum depression in Japan. If you have a strategy for discovery of patients that you are currently considering, or if you have a sense of what you envision for post-sale start-up formulations, could you please share that with us?

Uehara : Thank you for your question. I may have explained a little inadequately. The graph that I am showing on the 40th slide is for clinical study results of major depression, so it is not limited to postpartum depression. Sage has already been approved in the US for clinical trials for postpartum depression and is sold as a drug for postpartum depression, but our strategy is to use the drug for major depression as a whole, including postpartum depression.

Naturally, after the product is put on the market, we plan to work on such initiatives, having obtained evidence in various patients with postpartum depression, but we would like to target a larger segment of the population.

Matsubara : Thank you very much. If so, is it correct to say that the start-up will go smoothly?

Uehara : Yes.

Matsubara : I understand. Thank you.

Kyokawa : Thank you very much. This concludes the financial results briefing for Q2 of FY2024 for SHIONOGI & Co. Thank you for joining us today despite your busy schedule.

[END]