



SHIONOGI & CO., LTD.

FY2024 Financial Results

May 13, 2025

Presentation

Kyokawa: Now the time has come. Let's begin.

Thank you very much for joining us today despite your busy schedules.

My name is Kyokawa, Director of Corporate Communications Department of Shionogi & Co., Ltd. Now, we will begin the financial results briefing of SHIONOGI for the fiscal year ended March 31, 2025.

Agenda

01

Overview of FY2024 Financial Results

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Main Activities of STS2030 Revision Phase 2

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- ◆ Changes to STS2030 Revision Phase 2 KPIs
- ◆ Business investments aimed at new growth
- ◆ Growth of Existing Business
- ◆ Progress in pipeline

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FY2025 Financial Forecasts and Shareholder Return

(P.33-39)

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Kyokawa: Now, let me give you a brief explanation of today's process.

First, President Teshirogi will give an overview of the financial results.

Next, Dr. Teshirogi and the director in charge will explain about the STS2030 Revision Phase II initiative. Then, return to Teshirogi, he will give another presentation on earnings forecasts and shareholder returns, followed by a Question & Answer session.

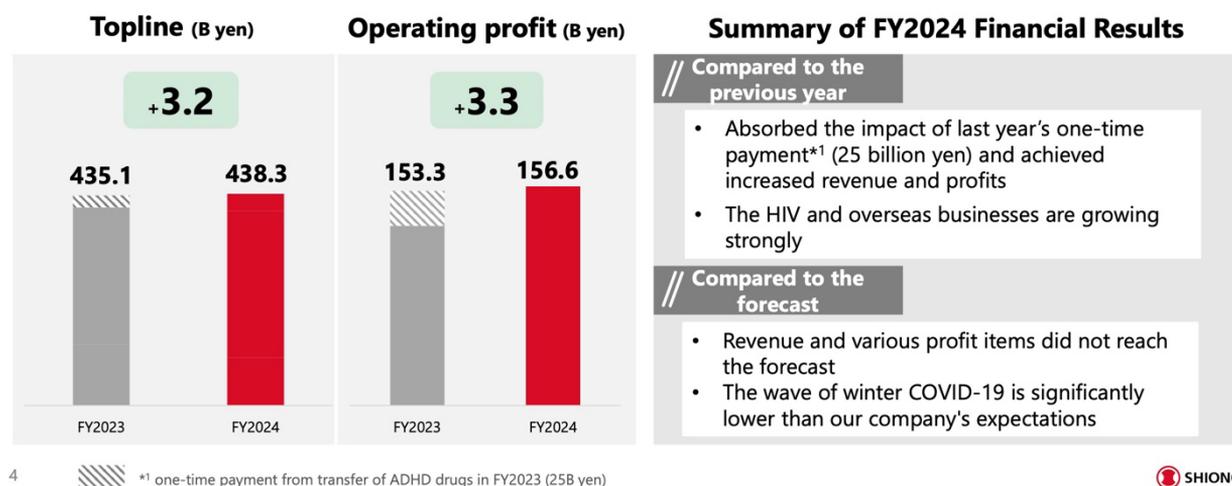
OK, I would like to move on to the explanation. President Teshirogi, please.

Teshirogi: I am Teshirogi. Thank you for joining us today.

I will start with the financial figures, which I'm sure many of you are already familiar with since they were announced yesterday. After that, John, Iwasaki, and Uehara will go over each section, including the questions some of you have already asked in advance.

Highlight

Revenue and operating profit have reached a record high for the third consecutive term



Page four.

Revenue was JPY438.3 billion, and operating profit was JPY156.6 billion. We continued to post record highs in both revenue and operating profit for the third consecutive quarter. However, revenue fell short of the forecast by just under JPY20 billion due to Xocova sales in Japan in February and March.

As for operating profit, we as a company feel deeply regretful that it fell short by about JPY8.5 billion. I will explain the details later, but while part of the reason lies in cost of goods and other factors, our usual approach has been to closely monitor Xocova sales in February and March and make necessary adjustments in expenses to ensure we meet our targets.

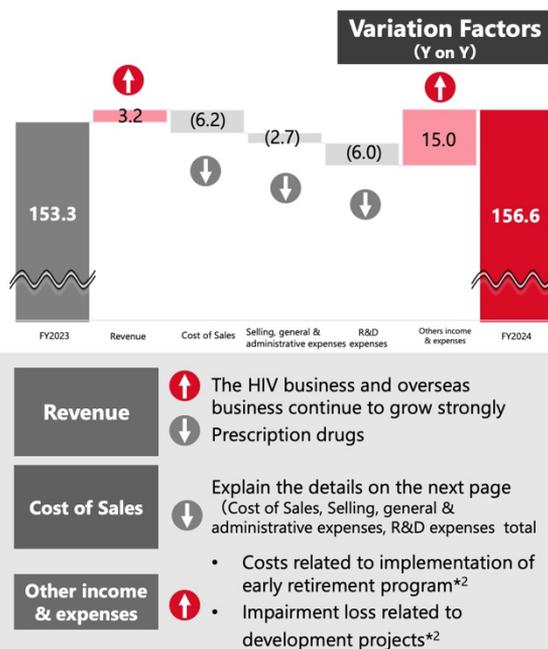
Xocova, or COVID-19 was too quiet, and cost control was slightly delayed, which is why we missed the large operating profit of JPY8.5 billion against the forecast.

We have been discussing internally how to make the most of this in FY2025 and FY2026. We have reaffirmed our determination as a company to ensure that our operating income will never again fall short of the announced figure.

Statement of Profit or Loss

(Unit: B yen)

	FY2024		FY2023		Y on Y	
	Forecast Full year	Results	Achievement (%)	Results	Change (%)	Change
Revenue	460.0	438.3	95.3	435.1	0.7	3.2
Cost of Sales	14.6	14.6		13.2		
Gross profit	67.0	63.8	95.3	57.6	10.8	6.2
SG&A*1, R&D expenses total	48.9	49.0	95.4	47.4		
Selling, general & administrative expenses	23.7	24.2		23.8	4.2	8.6
R&D expenses	25.2	24.8	97.3	103.4	2.6	2.7
Other income & expenses	116.0	106.1	93.6	102.6	5.8	6.0
Operating profit	(3.0)	(3.2)	105.8	(18.1)	-	15.0
Finance income & costs	35.9	35.7		35.2		
Profit before tax	165.0	156.6	94.9	153.3	2.1	3.3
Profit attributable to owners of parent	41.0	44.1	107.7	45.0	(1.8)	(0.8)
	44.8	45.8		45.6		
	206.0	200.8	97.5	198.3	1.2	2.5
	171.0	170.4	99.7	162.0	5.2	8.4



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*1 Selling, general & administrative: SG&A *2 Factors that occurred last fiscal year

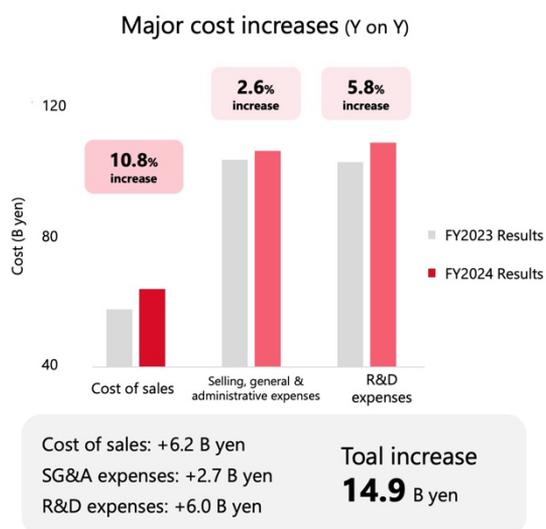


On page five. Statement of profit and loss.

The details of the increase in expenses will be explained later on page six. If you look at the YoY figures in particular, you will see that cost of sales was JPY6 billion and SG&A expenses were JPY8.5 billion. In fact, the impairment loss and early retirement recorded in the previous fiscal year have been eliminated. So, there should be a positive impact on other income and expenses, and that should be reflected in operating profit.

That is where we inevitably fell behind, and that is why we did not meet the operating profit target. We managed to achieve record sales, record profit, and record operating profit overall, but we are very disappointed that we could not meet your expectations that, given our capabilities, we should have at least achieved the announced operating profit.

Details of Cost Increases (Y on Y)



Cost of sales

- From FY2022 onwards, we have increased production and made investments in facilities in response to the expanding demand for antibiotics and other products
 ⇒The cost in relative terms has increased significantly for the FY2024
- Changes in product composition in relation to sales
- Increase in raw material and manufacturing expenses during the period

SG&A and R&D expense

- COVID-19 awareness activities and sales expenses for Xocova
- Acceleration of the development of acute respiratory infection drugs (COVID-19, RSV)
- Expansion of the U.S. research center and promotion of Qpex development products
- Preferential investment in late-stage development products

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Page six.

As for the cost, I don't mean to make excuses, but after 2019, we shifted various items to COVID-19. In 2021 and 2022, especially in areas related to Xocova, vaccines, and influenza, including Xofluza, we were forced to stretch the manufacturing process significantly and push it to the limit.

What we produced at that time hit us hard in 2024 in the form of standard costs, and that was the biggest reason why our cost target increased compared to the previous year. In a way, the cost we are seeing in 2024 is the result of the strain we put on our production in response to COVID-19 during 2022 and 2023.

We are a company that has always controlled costs well. So, unless something tricky things happens in 2025 or beyond, the scheduled cost will remain the same as in 2024 for 2025. Therefore, while the cost amount will rise as volume increases, we do not expect any impact on the cost ratio from 2025 onward.

In addition, there are drug price revisions by the Japanese government, rising costs of imported raw materials, and increasing labor costs. Not only us but the pharmaceutical industry as a whole is facing challenges in managing manufacturing costs. In 2025, we are implementing various measures to effectively manage this situation.

As for SG&A and R&D expenses, they were within our target. However, if we anticipate a shortfall of, say, JPY3 billion or JPY2 billion, we usually make adjustments in February or March. That's our usual pattern. This time, however, we used the budget without making those adjustments and ended up slight overspending.

One point worth mentioning is that after the acquisition of Qpex, particularly on antimicrobials, not only in addressing the AMR issue but also in targeting diseases such as TB and NTM. We have been exploring how to advance research focused on bacteria rather than viruses. The new laboratory at Qpex serves as a foundation for this effort. It is a fully equipped wet lab with a substantial number of researchers.

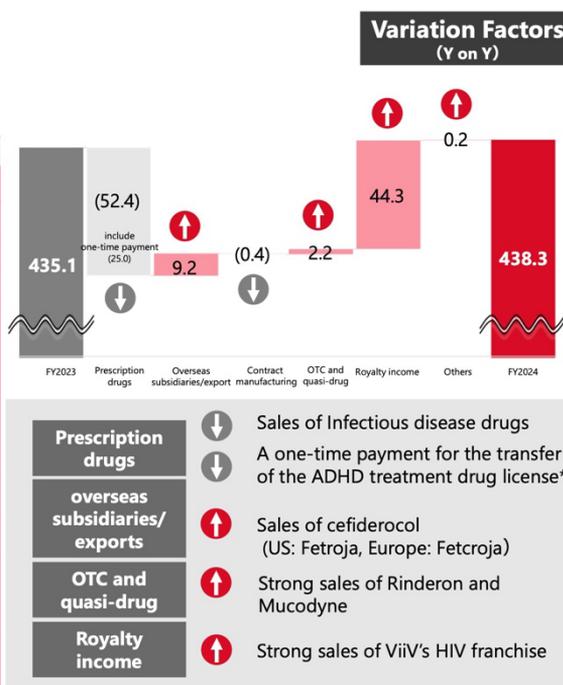
The opening of this lab was an epoch-making event for us in terms of promoting research on infectious diseases by effectively sharing study between Japan and the US. When we originally acquired Qpex, we had 14 people, including researchers and management, and now we have grown to 35.

20 of those are pure researchers. So, we are going to proceed with our research on antimicrobials little by little here. Although this has cost a certain amount of money, we recognize that we have taken a very big step forward in terms of how to divide drug discovery study between the US and Japan.

Revenue by Segment

(Unit: B yen)

	Forecast Full year	FY2024		FY2023		Y on Y	
		Results	Achievement (%)	Results	Change (%)	Change	
Prescription drugs	124.7	98.8	79.2	151.1	(34.6)	(52.4)	
Excluding temporary income	-	98.8	-	126.1	(21.7)	(27.3)	
Overseas subsidiaries/export	57.6	59.1	102.6	49.9	18.4	9.2	
Shionogi Inc. (US)	22.6	23.4	103.4	17.9	30.6	5.5	
Fetroja	-	20.0	-	14.5	37.7	5.5	
Shionogi B.V. (EU)	16.7	16.8	100.7	13.6	24.0	3.3	
Fetroja	-	12.9	-	10.7	20.4	2.2	
Ping An-Shionogi/C&O	9.1	8.7	95.3	10.6	(18.3)	(1.9)	
Others	9.2	10.2	111.0	7.8	30.3	2.4	
Contract manufacturing	16.5	17.3	104.6	17.6	(2.0)	(0.4)	
OTC and quasi-drug	16.6	16.8	101.3	14.6	14.8	2.2	
Royalty income	242.8	244.7	100.8	200.4	22.1	44.3	
HIV franchise	234.9	240.4	102.3	195.8	22.8	44.6	
Others	7.9	4.3	54.0	4.6	(6.8)	(0.3)	
Others	1.8	1.7	93.4	1.4	17.0	0.2	
Total	460.0	438.3	95.3	435.1	0.7	3.2	



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* Factors that occurred last fiscal year SHIONOGI

Let us turn to page seven.

As for sales revenue, even excluding the JPY25 billion from ADHD, domestic sales were negative JPY27 billion. JPY21 billion of them are Xocova-related, which means that the price of the drug, or older ones like Cymbalta, for example, have decreased to some extent.

The damage on the long-listed patients who have been receiving selected treatment since October has been much greater than we had expected. We should have made more effort to fill the loss.

On the other hand, regarding overseas, I would say that they are really doing very well, especially in cefiderocol. As Dr. Iwasaki will explain later, the US saw a 30% increase and Europe a 24% increase. As for Ping An-Shionogi, including C&O, we purchased the remaining 49% from Ping An as of the end of March, and officially launched Shionogi China on April 1.

We are in the transition of this new drug model, with the launch of cefiderocol this fiscal year and Naldemedine next fiscal year, so we expect that sales will be a little tough. We aim to achieve significant growth beyond the current fiscal year.

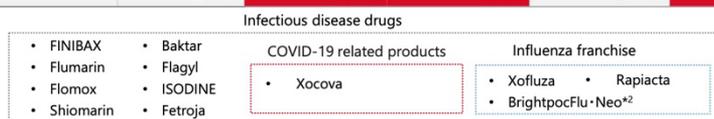
OTC drugs may seem modest, but they have been recording the highest sales for six consecutive years. We are gradually seeing that they will be ranked among the top ten in the industry. The profit level is around 15% in terms of operating profit margin, which I believe is one of the very strong businesses. We will continue to work on to grow this area.

In terms of royalties, HIV sales were extremely strong, increasing by 22.8% to JPY240 billion. ViiV's business is strong. Of course, the weak yen has had an impact, but I believe the business itself is strong. Volume growth accounted for just under two-thirds of the total, while the foreign exchange effect accounted for just over one-third.

Prescription Drugs in Japan

(Unit: B yen)

	Forecast Full year	FY2024		FY2023	Y on Y	
		Results	Achievement(%)	Results	Change(%)	Change
Infectious disease drugs	83.4	61.4	73.6	82.9	(26.0)	(21.6)
COVID-19 related products + Influenza franchise	72.3	51.8	71.6	73.4	(29.5)	(21.6)
Symproic	5.9	5.0	85.1	4.5	11.1	0.5
OxyContin franchise	5.0	4.3	85.0	4.2	2.4	0.1
Actair	1.3	0.9	66.0	0.7	22.9	0.2
Cymbalta	3.3	2.1	64.1	3.8	(44.7)	(1.7)
Others*1	25.8	25.2	97.4	55.0	(54.2)	(29.8)
QUVIVIQ	3.0	0.8	26.5	-	-	0.8
Prescription drugs	124.7	98.8	79.2	151.1	(34.6)	(52.4)



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

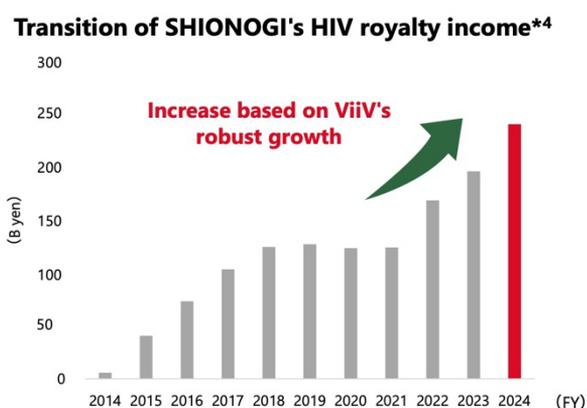
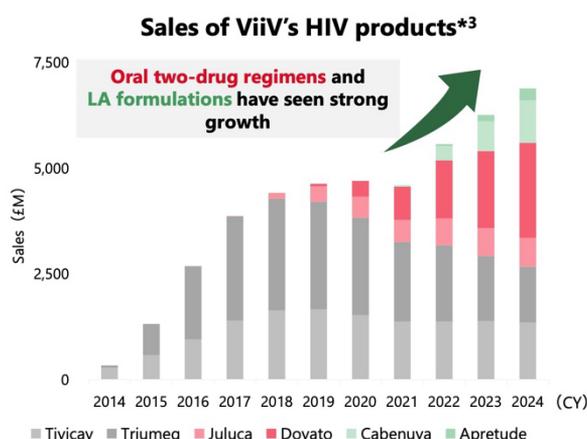


Speaking of domestic prescription drugs, results were JPY51.8 billion, falling short of the forecasted JPY72.3 billion by around JPY21 billion. Looking back, we initiated this franchise with the goal of reaching a minimum of JPY50 billion, regardless of fluctuations in epidemics such as influenza or COVID-19. Now, with Iwasaki achieving this JPY50 billion baseline, it represents a significant and powerful shift for us.

QUVIVIQ looks small, marking JPY0.8 billion against the forecast of JPY3 billion. However, the dosage is still limited to two weeks, and although two competitors are aggressively promoting their products, we have received very favorable feedback from doctors who use the drug. We have high expectations for this drug.

Progress of HIV Business by ViiV (FY2024)

The HIV business is experiencing strong growth due to the expansion of the oral two drug regimens*1 and LA*2 formulations



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*1 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



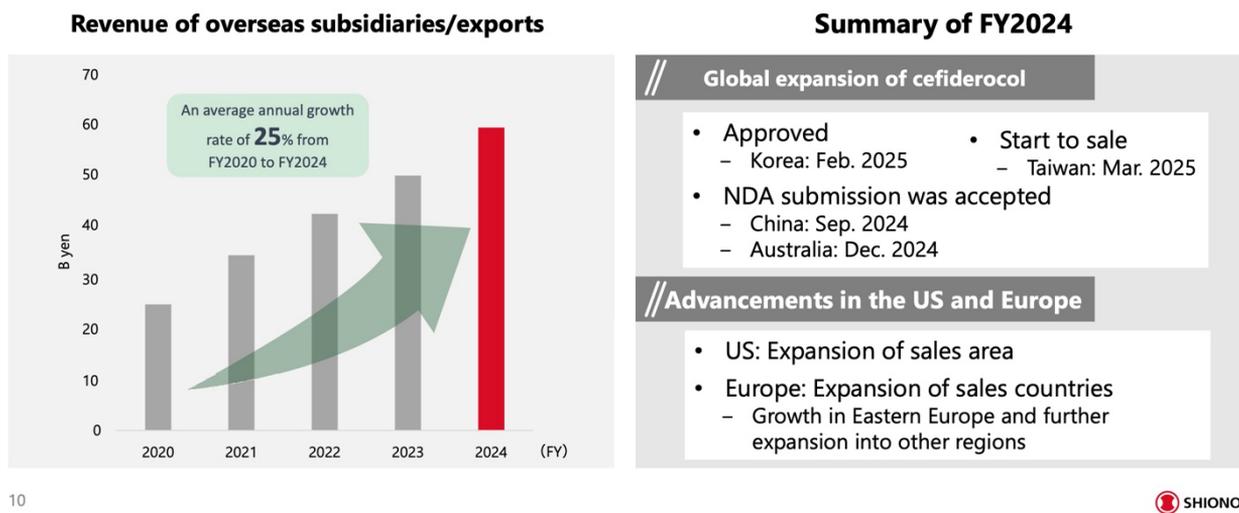
Next, but not least, HIV.

As I mentioned earlier, we receive royalties. The two oral drug regimens, especially Dovato, has the largest market share in Europe, and the oral form is growing. The long-acting injectable form is also growing very rapidly.

John will explain the details later. This means that royalties are also strong.

Progress of Overseas Business (FY2024)

The overseas business has achieved a record high for the fourth consecutive term, due to the stable growth of cefiderocol



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SHIONOGI

For cefiderocol, it has continued to maintain a CAGR of nearly 25% over the past three to four years. To be honest, when we first launched cefiderocol globally five years ago, few people expected it to become a JPY40 billion to JPY50 billion franchise.

In particular, Medical Affairs has steadily built-up data and explained where and how the AMR compound can be used. At the same time, each country has allowed us to set prices for this AMR compound that are somewhat different from those of conventional antibiotics.

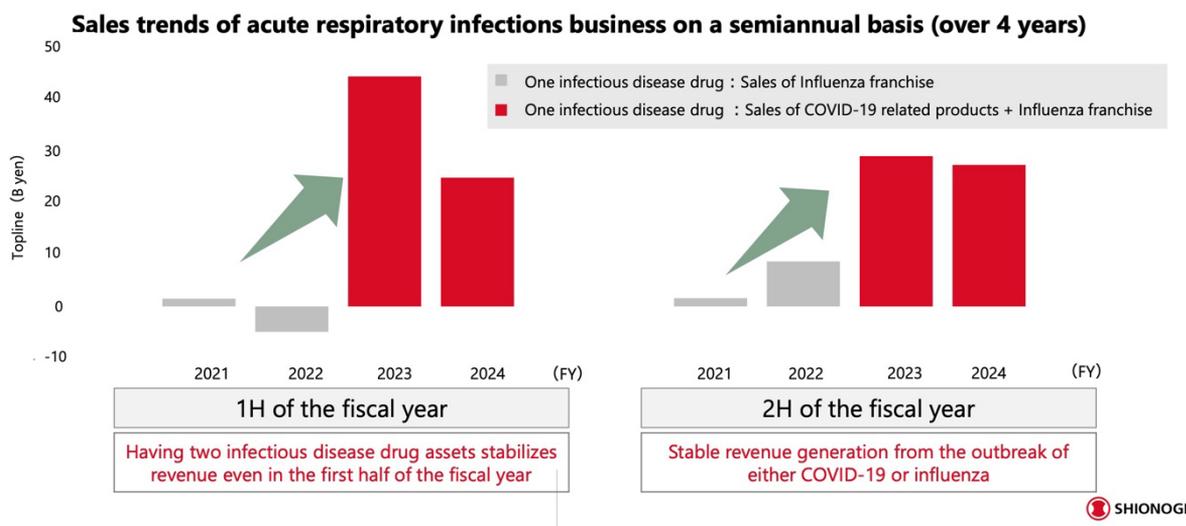
Germany, Italy, and other countries have also offered better pricing in the antibiotic area than we had expected, reflecting their stances to carefully nurture this compound. Combined, these factors have led to the creation of a fairly large JPY50 billion franchises for the next fiscal year.

We are committed to ensuring the proper use of this product. We do not want to create a situation of cefiderocol resistance, so we are not simply pursuing volume, but we are committed to proper use of the product. That said, we also need to expand horizontally. We have a partnership with Sobi in Eastern Europe and, more recently, with a new company called Link in Australia.

In China, we will continue to expand sales based on the experience we have accumulated in the US and Europe.

Progress of Domestic Business (FY2024)

**With two infectious disease drug assets,
the acute respiratory infection business contributes steadily to performance throughout the year**



As I mentioned earlier, in Iwasaki's area, there will be times when influenza is widespread in Japan, and times when COVID-19 is more widespread. Still, we want to aim for the minimum of JPY50 billion.

Our concept for the anti-infective drug and acute viral infection franchise was to aim for the JPY50 billion mark globally, and we have managed to build it up to that level, especially in H2, even though COVID-19 was largely absent in January, February, and March.

Through various initiatives such as so-called "disease awareness" and the Private insurance for the use of COVID-19 treatments that we are implementing with PayPay Insurance Service and Sumitomo Life Insurance, the prescription rate among all positive patients is finally showing a slight movement.

The rate has now managed to reach the 14% range. By continuing these efforts, we believe that we will be able to achieve our goal for this fiscal year if we can overcome the first hurdle, which is 20%.

Progress of Main Pipelines for the Current Fiscal Year (FY2024)

Multiple pipelines are making steady progress, achieving various approvals and submissions for approval

Infection diseases		QOL diseases with high social impact	
S-268019 COVID-19 vaccine	Approved in Japan	ENDEAVORRIDE ADHD (pediatric)	Approved in Japan
Ensirelvir COVID-19 Post-Exposure Prophylaxis	Submitted in Japan Rolling submission started in US	Zuranolone Depression	Submitted in Japan
S-268024 COVID-19 vaccine	Phase 3 started	SDS-881 Dementia (AI program for cognitive function testing)	Phase 3 started
S-337395 RSV infections	Achieved primary endpoint in Phase 2 trial	SASS-001 Sleep Apnea with a Central Component	Phase 2 started
S-892216 COVID-19 treatment (Oral)	Phase 2 started	Zatolmilast Jordan syndrome*1	Phase 2 started

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*1 Phase 2/3 trial for zatolmilast in the treatment of fragile X syndrome is ongoing



John or Uehara will talk about the pipeline later, but first of all, we started a rolling submission as the Ensirelvir and PEP trials were very good.

In addition, the S-892216 that we are working on with BARDA, which is at the bottom of the list, has successfully started Phase II. I believe that things in the infectious disease area are moving smoothly.

In the area of QOL diseases, it is very significant that we were able to properly proceed with the application approval for Zuranolone. The Phase II/III results for Zatolmilast are expected in the fall and winter of this fiscal year. We have received many requests from patients, and we have started a clinical trial for Jordan's syndrome. We hope to make the PDE4D mechanism a major pillar of our business.

To this end, in addition to the successful progress of Fragile X, we are already receiving requests from patients and patient groups to do something about Jordan Syndrome, which is truly ultra-rare. I think this is a very good thing.

Results for FY2024

Achieved growth surpassing last year's one-time payment (25B yen) and achieved increased revenue and operating profit

 <p>The topline and operating profit has reached a record high</p>	<ul style="list-style-type: none"> • HIV Business ↑ +44.6 B yen (Y on Y +22.8%) • Overseas Business ↑ +9.2 B yen (Y on Y +18.4%)
 <p>The financial results did not meet the full year forecast</p>	<ul style="list-style-type: none"> • Implemented strict cost management in the second half, but the winter COVID-19 surge significantly undershot our company's expectations • Continue to invest in necessary activities for future growth
 <p>Continued proactive investment in growth drivers</p>	<ul style="list-style-type: none"> • Based on the results of the clinical trials, a reassessment of priorities will be made • Initiate Phase 2 and Phase 3 of the next-generation development products

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In summary, on page 13, I would like to reiterate that HIV business overseas was very strong. We are determined to make improvements in the areas, including falling short in Japan and making timely adjustments to cost control in FY2025.

Changes to KPIs in "STS2030 Revision Phase 2"

Although the main KPIs of STS2030 Revision Phase 2 have been revised downward, FY2025 will be a year of significant growth

	FY2024 Results	FY2025 Previous Targets*2	FY2025 New Targets
Revenue	438.3 B yen	550.0 B yen	530.0 B yen
EBITDA	179.3 B yen	200.0 B yen	196.0 B yen
Overseas sales CAGR*1 <small>Starting from FY2022</small>	17.9 %	50 %	Reviewed the growth plan ⇒Consequently, we plan to reset our KPIs to align with anticipated growth in the coming fiscal years

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*1 CAGR (Compound Annual Growth Rate)

*2 [Presentation materials](#) for Medium-Term Business Plan SHIONOGI Transformation Strategy 2030 (STS2030) Revision announced in June 2023



Now next, on page 15.

Our new target for FY2025 is sales revenue of JPY530 billion and EBITDA of JPY196 billion. As for the overseas sales CAGR, as you all know, the domestic sales ratio will temporarily increase due to the M&A, including Torii

Pharmaceutical. At the same time, the contribution of Ensitrelvir to earnings and sales, which we had planned to start in 2025, will inevitably be shifted to 2026.

How to think beyond 2026 is a very big theme in the Company right now. Naturally, as you can imagine, there are two opinions. One approach is to position the next three or four years view beyond 2026, as the final phase of STS2030. Or, since there was an M&A, Xocova is progressing, and the situation with Ping An is shifting slightly, we consider ourselves to be in a different stage. From that perspective, another approach is to envision how we want to move forward over the next 35 to 40 years, and then treat the initial few years starting from 2026 as the first phase of a new mid-term business plan.

We are currently discussing our focus on the four key divisions. We will announce later which approach we will take, but you may see that we will fall slightly short of the original STS2030 targets of JPY550 billion and JPY200 billion.

That said, although there's no point in emphasizing it, our internal budget is actually set above these figures. However, since sales and operating profit fell short of the forecast this time, we disappointed the market. Therefore, we would like to present figures that we can confidently achieve and commit to, JPY530 billion in revenue and JPY196 billion in EBITDA.

Operating profit is JPY175 billion, but we would like to proceed with this as a minimum line.

Background of New KPI Setting

Progress of major businesses is smooth towards achieving Phase 2 KPIs and realizing the 2030 Vision

	Initial assumptions	Current Progress
Overseas subsidiaries/exports	<ul style="list-style-type: none"> Global expansion centered on in-house developed infectious disease drugs 	<p>Ensitrelvir</p> <ul style="list-style-type: none"> Delay in the start of sales in the US due to the failure to meet the primary endpoints of the SCORPIO-HR trial ⇒ Accelerate global expansion starting with US approval based on favorable results from the SCORPIO-PEP*1 trial <p>Revenue from overseas subsidiaries/exports</p> <ul style="list-style-type: none"> Achieved an average annual growth rate of 25% between fiscal years 2020-2024 <p>⇒ Steady growth centered on in-house sales of cefiderocol</p>
HIV business	<ul style="list-style-type: none"> Expansion of sales of new products (LA formulations, oral 2-drug regimens) 	<ul style="list-style-type: none"> Sustained stronger-than-expected growth <p>Development of next-generation growth drivers is progressing smoothly</p>
New products and new businesses	<ul style="list-style-type: none"> Growth towards realizing the 2030 Vision through aggressive investment (R&D, business investment) 	<ul style="list-style-type: none"> Acquired new revenue base through M&A <p>Continue to make aggressive investments based on priorities</p>

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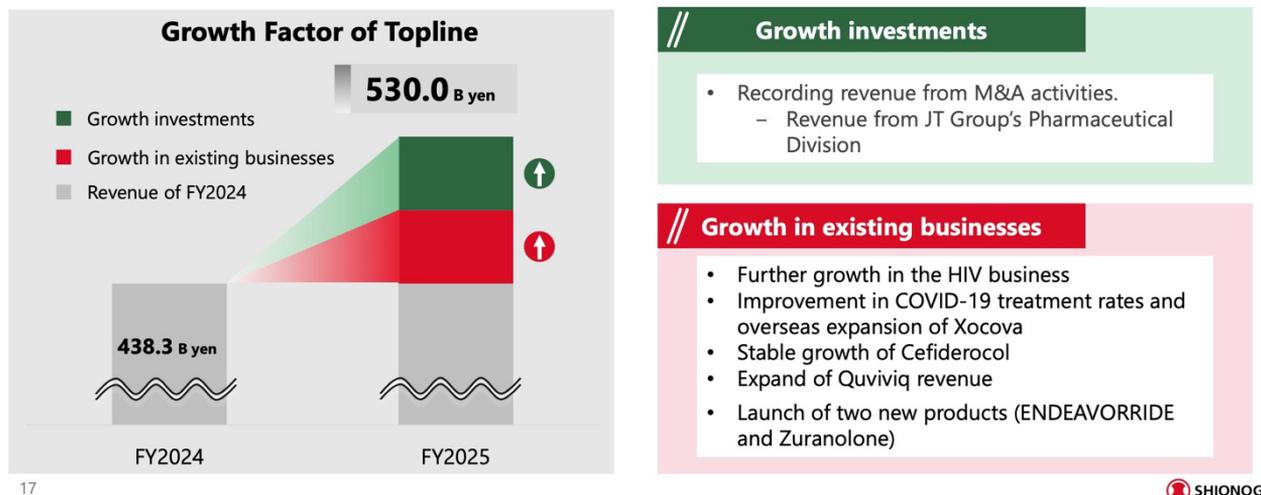
*1 PEP: Post-Exposure Prophylaxis 

Page 16, but including that, how do you plan to develop this year's focus. Ensitrelvir, and then the overseas subsidiaries, especially cefiderocol in exports. In terms of the HIV project, as John will say later, S-365598 is doing very well. How to develop it is a major theme for this fiscal year, FY2025.

We have no concerns about the base sales, but this year will be very important in terms of what we can see in 2025 that will lead to the next stage of development. We will complete the new products, new business and M&A of JT's pharmaceutical division, including PMI. Then, we consider the next development, which is currently underway, during this year.

For Achieving STS2030 Revision Phase 2

We will achieve the KPIs for FY2025 through "growth investments" and "growth in existing businesses"



On the next page, the existing business, the red part below, the HIV business will grow. We are taking a firm and conservative approach, but we will see how the business above, especially Xocova and Xofluza, will move.

We are taking a little bit firm approach in our commitment to achieve an operating income of JPY175 billion or more, as I mentioned earlier. We expect that HIV, Xocova, Xofluza and global expansion of Xocova, as well as further solid growth of cefiderocol.

And, Quiviviq in Japan, and Zuranolone that we are confident get an approval. The red part of the chart reflects the growth of JT's pharmaceutical division and Torii Pharmaceutical, which together have a combined sales volume of approximately JPY100 billion.

This fiscal year, we will consolidate about half of that portion, and by fully contributing from the next fiscal year, we aim to grow the top line which accounts for about half of the total, within this fiscal year.

Growth investments aimed at realizing our 2030 Vision

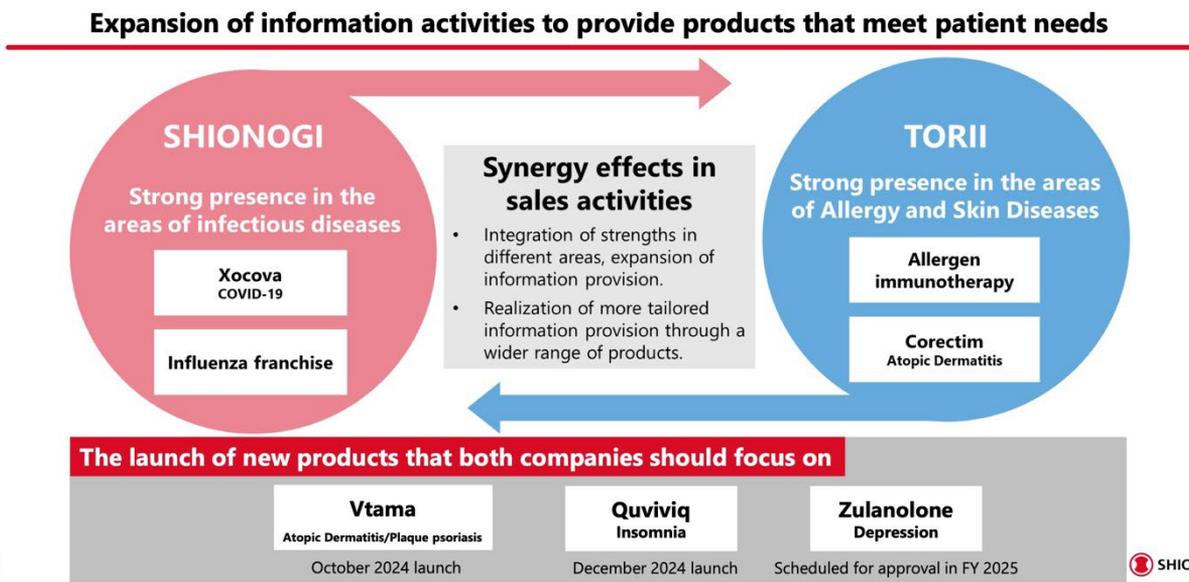
Through the M&A of JT Group's Pharmaceutical Division, SHIONOGI has strengthened our R&D capabilities as well as our domestic product assets



As for JT and Torii Pharmaceutical, there may be many different ways of thinking, but we recognize that these three elements, including Akros, are really functioning as one company.

I believe that it is not just Torii Pharmaceutical, JT's pharmaceutical division, or Akros individually, but the organic combination of all three that has driven the pharmaceutical business so far. We intend to strengthen this structure, including PMI, where all three elements are in place.

Maximizing the value of domestic product assets



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On page 19, I think Iwasaki can explain, but we believe that the synergies in sales activities are quite large.

The year before last, when we implemented early retirement, we reduced the number of MRs by about 200 or so as part of our effort to reconsider how to revamp our domestic sales structure. As I mentioned earlier, with Xocova’s prescribing rate at 13% to 14%, there has been missed sales opportunities.

One of the major target departments is otolaryngology, and Iwasaki’s division has always wanted to focus on otolaryngology for both Xocova and Xofluza. Torii Pharmaceutical also has about 230 MRs mainly in dermatology, but they are also strong in otolaryngology.

We are also using an IgE compound from a company called Funpep for CEDARCURE. I believe hay fever in this country has great potential as a market and is also a type of social issue.

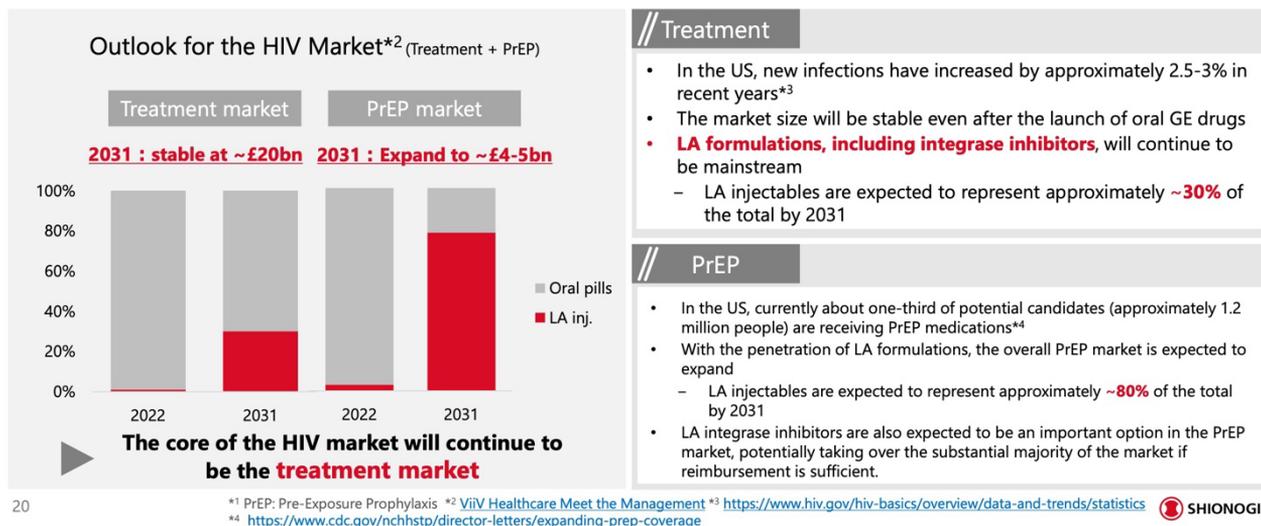
We believe this area can grow further with our participation. In order to expand the new drugs Vtama, Quviviq, and Zuranolone, I believe that the combination of these two companies will work very well together.

From here, John will explain the process.

Growth Outlook for the HIV Market (Treatment + Prevention)



In the treatment and PrEP*1 market, LA formulations will continue to drive growth



Keller*: Thank you very much. About HIV. First of all, regarding to how the LA formulations will going forward. There are two markets, treatment and prevention markets for long term formulation, and the distinction between these two is significant..

Treatment is accounted for 90% of all HIV. It is GBP20 billion, and I would say it is stable. Furthermore, the number of patients is increasing in the US and EU. In the US, the number is increasing by approximately 35,000 patients annually. A similar increase is seen in Western Europe, while the rise is even greater in Eastern Europe. Long-term formulations are becoming more and more important. I believe that one-third of the total, by 2031, will be these long-term formulations.

That this market will remain stable in the future. We believe we can significantly mitigate the impact of generics if and when they emerge. As for the 10% of the market, we believe that this long-acting injection formulation will grow in the future to double its current scale. However, prevention and treatment are different.

This is especially different in the US in this area of insurance reimbursement. At present, even in Europe, insurance reimbursement is not yet available for prevention. I believe that there will be a considerable increase in reimbursement for prevention in the future, unlike treatment.

As for this long-acting injection formulation, I believe that the one contains an integrase inhibitor will become a mainstream.

Outlook for HIV Business by FY2025



Data on the LA formulations has been accumulating as LA contributes increasingly to HIV business growth

Real World Evidence at CROI 2025 *1, 2

Phase 2a trial data for S-365598 (oral)*3, *4

// **Cabenuva**

High adherence and long-term efficacy in clinical practice

One-year continuation rate of Cabenuva treatment

Percentage of participants with ultimately suppressed virus

Approximately **80%**

Approximately **95%**

// **Apretude**

High selectivity and efficacy in clinical practice

Percentage of participants who voluntarily chose Apretude (vs oral)

Number of new HIV infections during the follow-up period

Approximately **83%**

0 cases

// **S-365598**

Acquired PoC for the first time in HIV patients

Maximum change from baseline in plasma HIV-1 RNA, mean (SD), log₁₀ c/mL

Group	Week 10 Mean Change (log ₁₀ c/mL)	SD
S-365598 10mg Q3D (N=6)	-0.28	0.37
S-365598 50mg Q3D (N=6)	-1.17	0.46
S-365598 300mg Q3D (N=6)	-2.15	0.25
Placebo Q3D (N=3)	-2.31	0.46

- Confirming equivalent efficacy to dolutegravir
- No drug resistance mutations were observed, and there are no concerns regarding tolerability and safety
- Currently conducting Phase 1 trials of the long-acting formulations (injectable) to evaluate pharmacokinetics, etc.

21 *1 Conference on Retroviruses and Opportunistic Infections *2 [ViiV Healthcare Press release](#) and [ViiV Healthcare Press release](#) *3 Conference on Retroviruses and Opportunistic Infections; March 9-12, 2025; San Francisco, Announced by ViiV Healthcare in California (Luise Rogg et, al) *4 For information on an overview of the Phase 2a trial, please refer to 46



And as for our business in 2025, the growth of Cabenuva and Apretude and the excitement of doctors and patients is very high. One-year continuation rate of Cabenuva treatment is 80%. And the percentage of participants with ultimately suppressed virus is 95%. The percentage of participants who chose Apretude is 83%, and the number of new HIV infections during the follow-up period is 0 cases. And S-365598, which ViiV calls VH4524184, will be the next-generation platform.

This is a platform of ViiV portfolio of SHIONOGI. And its antiviral efficacy is comparable to that of dolutegravir, which is the benchmark. And it is very safe, and it also has a completely unique ability. It is excellent for viral resistance, as no drug resistance mutations were observed.

So, I believe that LA's capabilities will lead to the next platform and the Ultra LA formulation. It means six months in the office and also at home. This is also an important factor in terms of prevention.

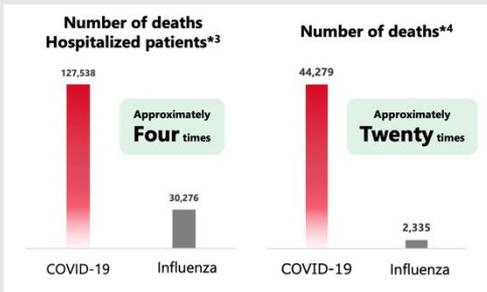
Growth of Xocova in Japan

Continue to promote initiatives to improve the treatment rate of COVID-19

Variable Factor	FY2023	FY2024	FY2025
Number of positive confirmed case	Annual average of fixed points 8.0	Annual average of fixed points 5.2	Assuming the same level as FY2024
Average Share Xocova	Approximately 50%	Approximately 65%	↑
Treatment Rate* ¹ Average value of the most prevalent month	21.4%	13.1%	>20%

// Improve treatment rates

COVID-19 is an infectious disease with higher rates of long-term effects and severe cases compared to influenza



Disease	Hospitalized patients	Number of deaths
COVID-19	127,538	44,279
Influenza	30,276	2,335

COVID-19 is approximately **Four** times higher for hospitalized patients and **Twenty** times higher for deaths compared to Influenza.

- Number of infected individuals: FY2024 saw relatively fewer infections, especially during the winter season
- Share: FY2024 experienced significant growth in market share
- Treatment rate: FY2023 had a high treatment rate due to public funding for treatment costs*²

^{*1} Treatment rate with oral antiviral drugs, created by our company from JAMIDAS data
^{*2} April to September 2023: No out-of-pocket expenses due to full public funding. October 2023 to March 2024: Out-of-pocket expenses of 6,000 to 9,000 yen depending on the out-of-pocket percentage
^{*3} The total from October 2023 to December 2024
^{*4} National Institute of Infectious Diseases, Infectious Disease Surveillance Weekly Report Download 2024 (Calculated and plotted based on the data accessed on January 16, 2025)
^{**} The total from May 2023 to August 2024 is also included.
^{***} The Ministry of Health, Labour and Welfare's Vital Statistics Survey Summary (accessed on January 16, 2025) was also referenced.



Iwasaki: Next, from page 22 onward, I, Iwasaki, who is in charge of the healthcare business, will explain our business initiatives in Japan and overseas.

I would like to begin by explaining our Xocova initiatives.

As I mentioned in the results section, Xocova's share of the market through activities in FY2024 is steadily increasing and has reached about 65%, according to various data sources.

On the other hand, the treatment rate with antiviral drugs remains low at 14%, still in the 10% range. So, the goal for the current fiscal year is how to raise this rate.

However, looking only at the numbers, they may appear quite stretched. However, based on this fiscal year's KPIs and fixed-point observations, assuming conditions similar to last year, we are projecting an average share of 70% and a treatment rate of at least 20%.

When we talk about raising the treatment rate, it was around 20% in 2023 when it was publicly funded. So we believe it's not unrealistic for the rate to return to that level or even exceed it, as it had already reached that point before.

However, we believe the most important issue for our activities this year is how to accomplish this in a short period of time, and that raising disease awareness is key.

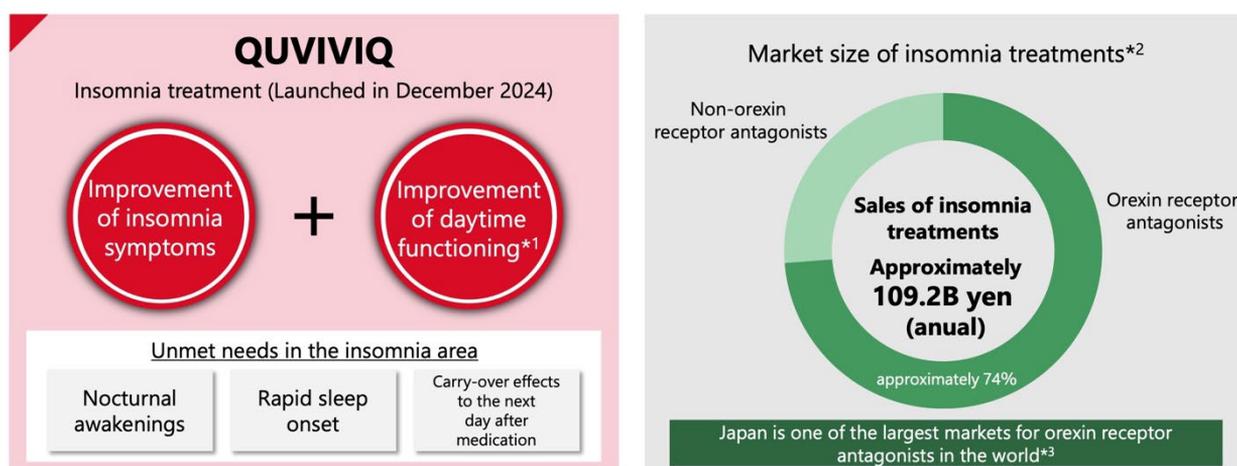
As shown on the right-hand side of this slide, the number of hospitalized COVID-19 patients is approximately four times higher than that of influenza, and the number of deaths is about twenty times higher. Due to these risks, many medical specialists are prescribing antiviral medications. Therefore, we believe it is essential to raise awareness of the disease to ensure early treatment with antiviral drugs is widely understood and adopted. In addition, we are currently conducting clinical research in collaboration with Osaka University and the Tokushukai Medical Group, and we expect to publish data on long COVID later this fiscal year. Through these efforts, we aim to highlight the importance of treatment and improve the treatment rate.

Moreover, it is not only the treatment rate that needs to be addressed, but also the diagnosis rate. We believe it is important to encourage people to visit medical institutions and receive proper diagnosis. If public perception shifts to thinking that “COVID-19 is no longer serious,” this could lead to negative consequences given the risk of severe illness, as previously mentioned. While we may not reach the same level of attention as influenza, we aim to improve diagnosis rates and, at minimum, achieve a 20% treatment rate.



Characteristics of QUVIVIQ and the Insomnia Market

Maximize product value early to address unmet needs in the field of insomnia



23 *1 [Lancet Neurol 2022; 21: 125-39](#). *2 Permission for publication by IQVIA is being confirmed. Copyright © 2025 IQVIA. Created by our company based on IQVIA JPM April 2024-March 2025 years (Unauthorized reproduction prohibited) *3 [Nxeira Pharma Co., Ltd. Corporate presentation in April 2025](#)

I will then describe the characteristics of the new insomnia drug, Quviviq, and the insomnia market.

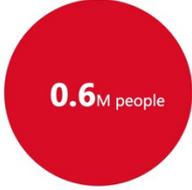
Quviviq, an orexin receptor antagonist, is characterized by its short elimination half-life and low carryover effect.

In addition, Quviviq has shown improvement in insomnia symptoms by alleviating excessive arousal. Furthermore, insights gained from the global Phase 3 trial have confirmed improvements in daytime functioning scores, including reduced daytime sleepiness, enhanced alertness and decision-making, and greater emotional stability. These findings underscore the product's key features, and we aim to accelerate its market launch accordingly.

In December of this year, the current two-week prescription restriction will be lifted. However, at this point, the two-week limitation remains a barrier to broader prescription. For the time being, we will continue our current information dissemination efforts, and once the restriction is lifted, we plan to expand promotion activities. Despite strong competition from two rival products, we intend to allocate resources effectively, increase our share of voice, and drive broader adoption of Quviviq.

Launch of Zuranolone and ENDEAVORRIDE

Accelerate the growth of our business in Japan through the launch of innovative new products

<h2 style="text-align: center;">ENDEAVORRIDE</h2> <p style="text-align: center;">Digital therapeutic App for pediatric patients with ADHD (FY2024: Manufacturing and marketing approval obtained)</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">  <p style="text-align: center;">Pediatric ADHD market (estimate)</p> <div style="text-align: center;">  <p>0.6M people</p> </div> <p style="text-align: center;">Potential number of patients</p> </div> <div style="width: 50%;"> <ul style="list-style-type: none"> • A new option of program medical devices that can improve ADHD*¹ symptoms </div> </div>	<h2 style="text-align: center;">Zuranolone</h2> <p style="text-align: center;">Depression treatment (FY2025: Scheduled for manufacturing and marketing approval)</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <ul style="list-style-type: none"> • No dosage adjustment needed, and effectiveness determined in two weeks • Contributing to the unmet need for early treatment in depression patients </div> <div style="width: 50%;"> <p style="text-align: center;">Depression market (estimate)</p> <div style="text-align: center;">  <p>5M people</p> </div> <p style="text-align: center;">Potential number of patients</p> </div> </div>
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*1 ADHD: Attention Deficit Hyperactivity Disorder  SHIONOGI

Next, on page 24, I would like to introduce ENDEAVORRIDE and Zuranolone, which are scheduled to be launched in the current fiscal year.

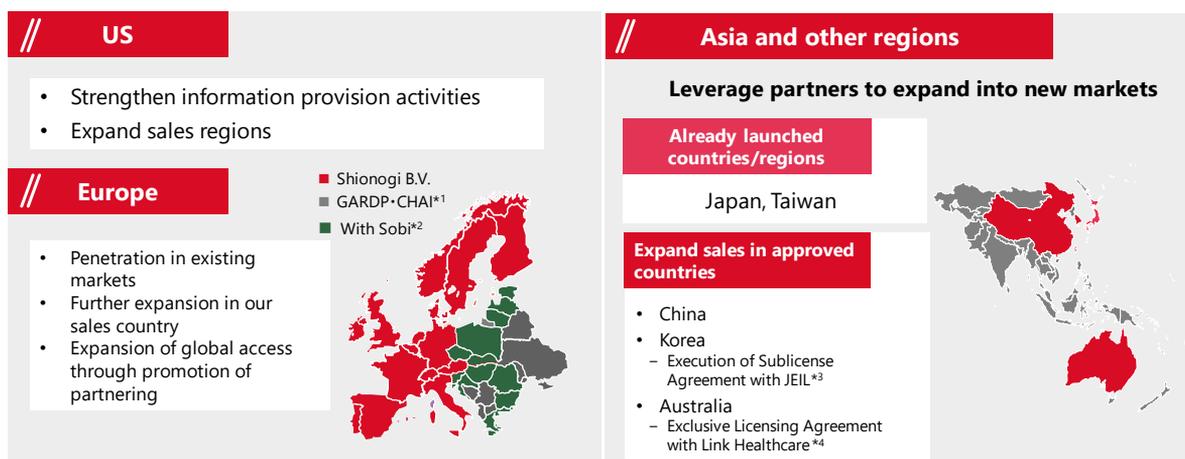
This ENDEAVORRIDE is a digital therapy application that improves ADHD symptoms in children. We have obtained manufacturing and marketing approval for this ADHD-targeted treatment application, as it is the first of its kind in Japan.

Currently, psychosocial treatment such as counseling and drug therapy are the mainstay of treatment, but patients are not receiving sufficient treatment due to lack of resources currently. This can be substituted with a therapeutic app, and from that perspective as well, we believe that ENDEAVORRIDE can be widely adopted and contribute to the treatment of many patients.

Zuranolone is a novel drug for the treatment of depression with unique characteristics. It means that no dose adjustment needed, such as titration treatment. And effectiveness determined in a short period of time, two weeks.

Another important point is that the drug begins to show effects from the third day of administration. This is highly significant. While typical antidepressants are generally evaluated after about four weeks, this medication delivers a noticeable effect in just three days. We believe this will be a very impressive result for patients, and that the product will contribute to domestic sales immediately after its launch. In addition to acute respiratory infections, we hope to further expand the growth of our domestic business through the launch of these two new products or Quviviq.

Promote appropriate use and further expand global access to cefiderocol



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^{*1} Press release June 2022 ^{*2} Press release Dec. 2023 ^{*3} Press release Jul. 2022 ^{*4} Press release Apr. 2025 

Next is the outlook for our overseas business.

First, with regard to overseas business, we will aim to further expand global access in Europe, the US, Asia, and other regions, starting with cefiderocol, a product created in-house, as a pioneer.

In promoting the expansion of global access, the promotion of appropriate use is also a prerequisite. With the expansion of access, we would like to contribute to patients by collaborating with partner companies who can promote the appropriate use of our products together with us.

It is growing well in the US and Europe, but we need to work on horizontal expansion, as President Teshirogi mentioned earlier. As you can see here, we have received approval in Korea and have filed an application in Australia. So, from this fiscal year onward, in effect, we will be essentially working with JEIL in Korea, then Link in Australia, and then Sobi in Eastern Europe.

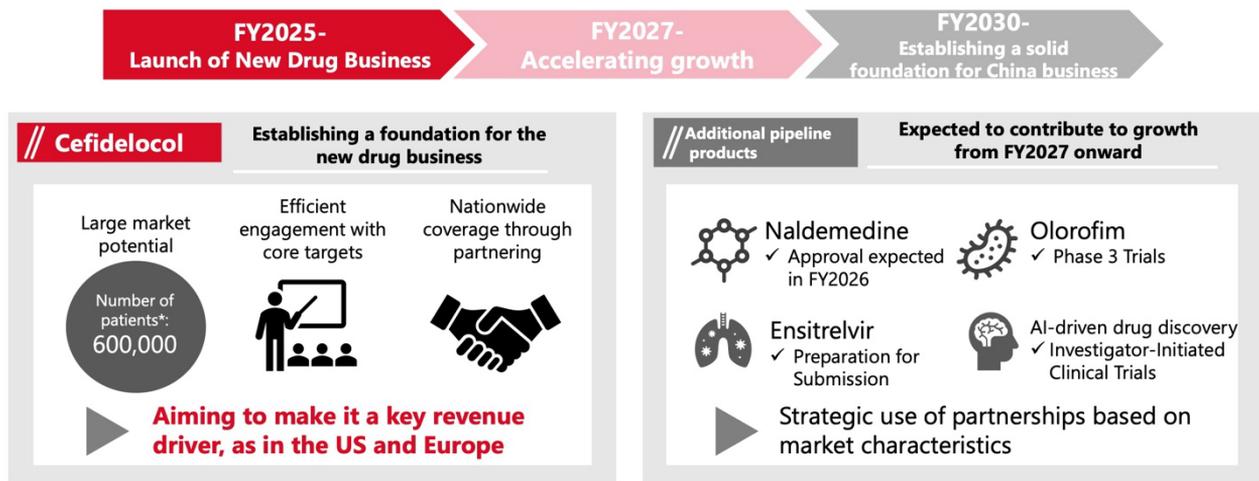
We would like to expand our horizontal development in cooperation with these countries, and in the future, we would like to work with ASEAN and the Middle East, which are also countries that have a high interest in AMR. We are currently considering whether to do this on our own or in cooperation and partnership with our partners.

We will further accelerate our global expansion centered on cefiderocol in the current fiscal year.

We have already applied for approval in China, and we plan to launch the product as soon as possible after receiving approval this fiscal year.

Future Business Development in China

Under the new structure as Shionogi (China) Co., Ltd., we will accelerate the development of our new drug business in China



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*1 Annual number of AMR-related deaths in China (2019): [Burden of infectious diseases and bacterial antimicrobial resistance in China: a systematic analysis for the global burden of disease study 2019 - The Lancet Regional Health – Western Pacific](#)

I would like to talk about our China business in future. In our previous financial results presentation, we reported on the dissolution of the merger with Ping An Insurance. Today, I would like to explain our future outlook.

In April 2025, we will launch a new structure as Shionogi (China) and begin full-fledged development of our new drug business in China. In the medium to long term, we plan to expand our business in stages along three phases, as shown here on the slide.

First, in 2025, we will promote the new drug business, starting with the launch of cefiderocol. As for cefiderocol, we are aiming to obtain approval within this fiscal year. In China, however, infections caused by multidrug-resistant bacteria have become a very serious social issue, and the need for this drug is extremely high, with an estimated 600,000 patients. We believe that there is already sufficient visible demand.

In addition, since these diseases will be treated mainly at priority facilities, we are preparing to develop the infectious disease business in China by allocating our own resources, allowing us to move forward without committing a large number of additional resources.

We will make various decisions on whether to develop the business on our own or with a partner, while keeping an eye on the situation. In addition, we are preparing to submit an application for Naldemedine and expect to obtain approval in the next fiscal year. We will consider expanding our business in China through licensing with a partner.

In any case, as a new business in China, we will focus on cefiderocol, an infectious disease that can be managed with fewer resources, for severe infectious diseases.

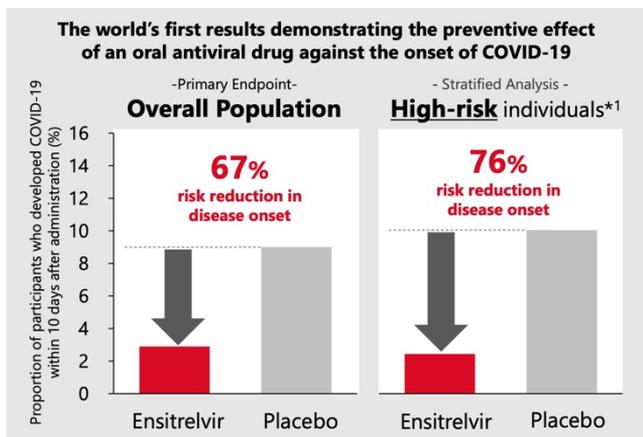
That is all for my part.

Global Expansion of Ensitrelvir

Accelerating global rollout based on positive results from the SCORPIO-PEP study

- Phase 3 Trial Results of Ensitrelvir (SCORPIO-PEP)-

- Development status by country-



- United States**
 - Initiated a submission to the FDA for approval of the prophylactic indication (rolling submission)
 - Ongoing discussions toward submission for treatment indication
- Europe**
 - Preparing for submission for both treatment and prophylaxis indications
- Japan · Asia**
 - Japan:**
 - Application submitted to add prophylaxis indication
 - Planned to submit the pediatric treatment indication application within Q1
 - Expanding to other Asian countries

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*1 Key representative high-risk factors: BMI ≥30 kg/m2, smoking (current or former), age (≥65 years), heart disease, diabetes (type 1 or type 2); high risk is ≥1 risk factor

Uehara: Continuing on, I, Uehara, would like to talk about the progress of the development pipeline.

Slide 28. For Xocova, or Ensitrelvir, as Teshirogi mentioned at the beginning of this presentation, the Phase III results were very encouraging and clear, as shown in the bar graph on the left.

We have confirmed that administering ensitrelvir in advance to household members or cohabitants of COVID-19 patients—before the onset of symptoms—can reduce the risk of developing symptoms by 67% in the overall population. Naturally, elderly and high-risk patients are more likely than the general population to benefit from prevention with these drugs, so we have provided data specifically on high-risk patients. We are in discussions with various regulatory authorities, as we have very clear data showing that the drug prevents disease onset even in clearly high-risk individuals.

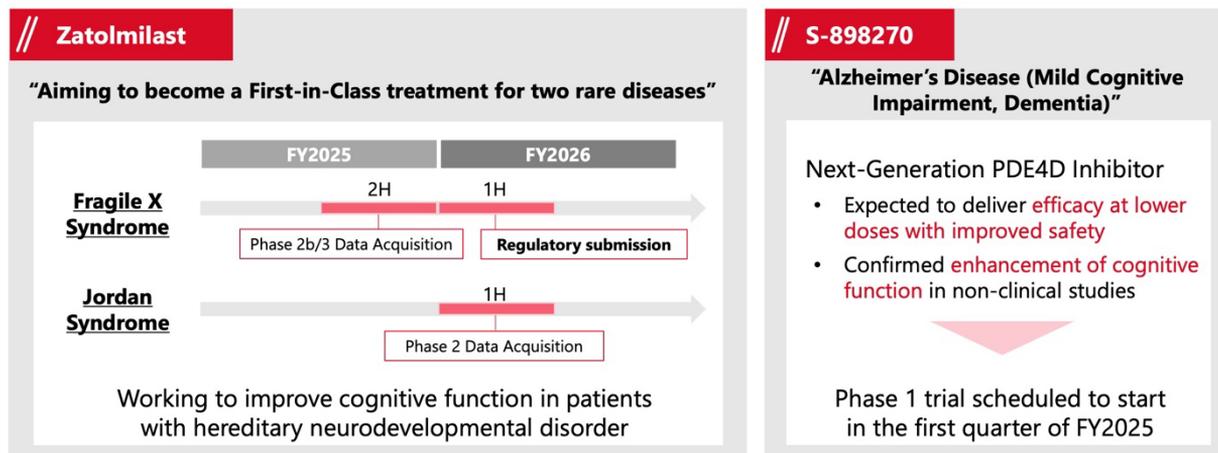
We have received requests from the US to submit the application as soon as possible, and we have already completed the rolling submission. We are on schedule to complete the submission of all remaining modules soon.

In the US, the first step is to obtain the indication for prophylaxis, but in Europe, we have been requested to submit applications for both prophylaxis and treatment. We plan to submit applications for both packages in the US and Europe, and the regulatory authorities will discuss the final approved indications.

As you are aware, we have already completed the application for prophylaxis in Japan, and we are now in the process of applying for pediatric indications for small tablets.

Development Zatoilmilast / S-898270

Accelerating the development of two PDE4D inhibitors expected to improve cognitive function, aiming for the early delivery of solutions



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SHIONOGI

Now, continuing on, slide 29. Zatoilmilast or S-898270, is a new drug.

This is a PDE4D inhibitor, which means that the drug inhibits the breakdown of the second messenger cyclic AMP in the brain.

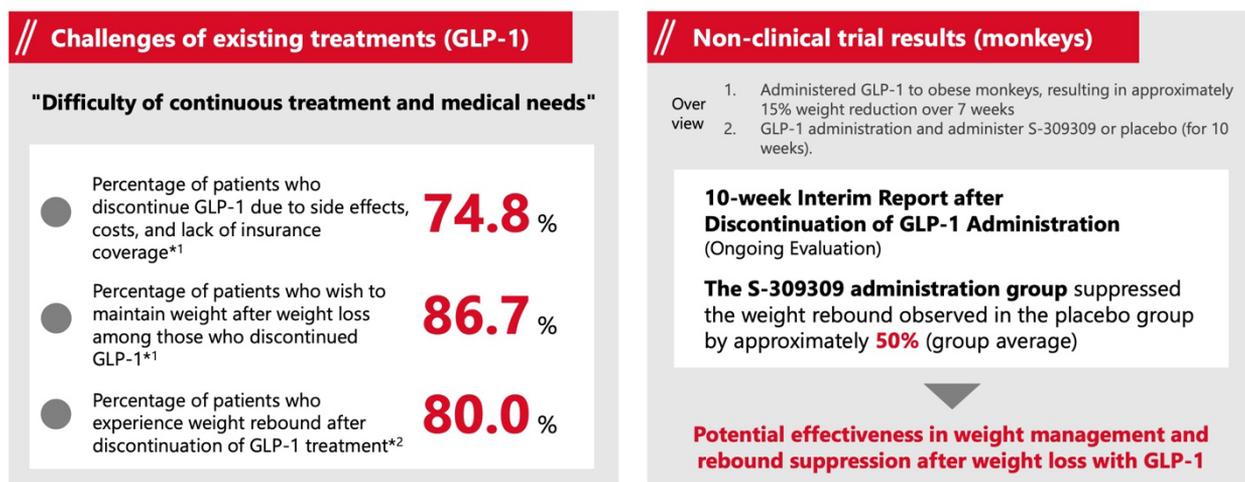
This has clearly been shown to improve cognitive function in animal studies. Also signs of cognitive activation have been observed in brain signals in humans.

Regarding the development for Fragile X Syndrome, favorable results were obtained in the Phase 2 study, and we are currently conducting two Phase 2b/3 trials as well as an open-label Phase 3 trial. Of the two Phase 2b/3 trials, one has already completed enrollment and is now in the follow-up stage. As for the remaining trial targeting adolescents, once we reach the target number of cases, we plan to move forward with the database lock process. As soon as we get the results, and if the results are favorable, we will proceed to the US application.

In addition to Fragile X Syndrome, we have also received inquiries suggesting that this drug may be effective in treating Jordan Syndrome. Based on that, we are currently exploring development in that area as well. In addition, since it is a cognitive function, it could be used for Alzheimer's disease, which is naturally a high hope. In Alzheimer's disease, there are a combination of various medications and liver function. We are now in the process of preparing a new Phase I for S-898270 with enhanced activity and safety profile that can be taken by people who are weak. The Phase I study will begin this fiscal year.

Future Development Policy for S-309309

Considering the potential development of a highly safe anti-obesity drug that suppresses weight rebound after discontinuation of GLP-1 administration



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*1 Omada, 2024, GLP-1 Discontinuation: Real-World Perspectives on a Complex Journey *2 The STEP 4 trial, JAMA. 2021;325(14):1414-1425



Now, the next slide, 30. S-309309.

As I mentioned earlier, in the Phase II study of the single agent in obese patients, we were not able to achieve our weight loss goal.

However, some interesting effects are visible in some people. Because of such data, when we consider the current unmet need, we cannot expect the same level of weight loss with the S-309309 single agent as with GLP-1 based on the Phase II results.

However, although GLP-1 is used in a large number, we have heard that many people stop taking it in the middle of treatment due to side effects or the high cost of drug. Many of those who stopped taking the drug gained weight again shortly afterward. And then they lost muscle but regain the fat.

There is still a great deal of unmet need for such social issues. So, we experimented with obese monkeys to see if perhaps we could use them there. We gathered a group of slightly overweight monkeys in China and gave GLP-1 for losing weight. In the experiment, about 15% of body weight was added to the monkeys, and then they were given either a placebo, no treatment, or switched to our S-309309 compounds.

We observed clear suppression. Therefore, the non-clinical data provide strong evidence supporting the concept that our compound may effectively suppress the increase in appetite that often occurs after discontinuing GLP-1 treatment. Since this data was obtained not in rats but in monkeys, a species closer to humans, we believe it may open up possibilities for exploring new uses. We are currently discussing how to move forward with development in this direction.

S-151128: Phase 1b Trial Results

Although a favorable safety profile was confirmed with repeated administration, the expected efficacy was not observed

// Phase 1b Trial Overview		// Phase 1b Results	
In addition to safety and pharmacokinetics during repeated administration, exploratory efficacy was evaluated		Safety (Primary Endpoint)	
Country	Japan	<ul style="list-style-type: none"> No issues with tolerability 	
Subjects	Countries of Implementation: Patients with Osteoarthritis of the Knee (patients otherwise healthy except for knee pain)	Efficacy (Exploratory)	
Trial Design	Multicenter, Randomized, Placebo-Controlled, Observer-Blind	<ul style="list-style-type: none"> Analgesic effect for osteoarthritis of the knee was not confirmed 	
Dosage and Administration Number of cases	Treatment Groups: Active Drug, Placebo Total 76 Cases* ¹ Two intermittent intravenous administrations at 28-day intervals (30 minutes each)		

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*¹ The sample size is not sufficient to detect a statistically significant difference between the active treatment group and the placebo group in terms of WOMAC pain scores 

Now, let me also update you on one last drug.

S-151128 is a drug candidate targeting Nav1.7, which we had high hopes for as a potentially highly effective analgesic. We initially conducted a Phase 1 study in patients with osteoarthritis (OA). The results showed a favorable pharmacokinetic (PK) profile and good safety, and at that point, the data were considered positive.

However, in real-world clinical settings, OA patients typically manage their pain with NSAIDs, and within such a patient population, we were unable to observe a clear analgesic effect. As a result, we concluded that it would be difficult to continue development for this specific patient population. That is the current status of the program.

R&D Milestones Planned for FY2025

※Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2025 1H	FY2025 2H
Infection Diseases	Ensitrelvir	COVID-19 treatment	Submission	Submission (EU)	
		COVID-19 PEP	Submission	Submission (US, EU)	Approval (Japan)
		COVID-19, Pediatric (Treatment and prevention in under 12 years of age)	Preparation for global submission	Submission (Japan)	
	S-268024	COVID-19 (JN.1Vaccine)	Phase 3	Phase 3 Topline results	
	Cefiderocol	AMR Pediatric (Gram-negative bacteria infection)	Phase 3	Phase 3 Topline results	Submission (US, EU)
	S-892216	COVID-19 treatment (Oral)	Phase 2		Phase 2 Topline results
	S-743229	AMR (Complex urinary tract infection)	Phase 1		Phase 1 Topline results
S-649228	AMR (Gram-negative bacteria infection)	Phase 1		Phase 1 Topline results	
QOL Diseases with High Social Impact	Zuranolone	Depression	Submission	Approval (Japan)	
	Zatolmilast	Fragile X syndrome	Phase 2/3		Phase 2/3 Topline results
	SASS-001 (S-600918 + Drug X)	Sleep Apnea with a Central Component	Phase 2		Phase 2 Topline results
	S-531011	Solid tumor	Phase 1b/2		Phase 1b/2 Topline results
	S-606001	Pompe disease	Phase 1	Phase 1 Topline results	
	S-740792	Gait disorders associated with multiple sclerosis	Phase 1		Phase 1 Topline results

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Now, we have one last slide. The pipeline, which is shown on slide 32.

We have already touched the pipeline of infectious diseases. Other vaccines. Here is the Phase III boosting trial of the JN.1-compatible vaccine, which has also completed patient enrollment.

As soon as the results are obtained, we are continuing to develop a Japanese-made recombinant protein COVID-19 vaccine that can be used as a platform.

Others are global pediatric expansion of cefiderocol. Or AMR drugs in collaboration with Qpex. We are making progress of various pipeline for infections.

I also touched earlier about other quality of life diseases, the approval of Zuranolone, and Zatolmilast. As for future developments, we are in the process of creating new drugs for various diseases such as sleep apnea syndrome, cancer, Pompe disease, and multiple sclerosis.

That is all.

Budget assumptions

// Revenue	// Cost
Prescription drugs <ul style="list-style-type: none">• Growth in the domestic Acute Respiratory Virus Infection Treatment• Growth of Quviviq• Launch of new products (Zuranolone, Endeavoride)• Adding the revenue from JT Group's Pharmaceutical Division	Cost of Sales <ul style="list-style-type: none">• Increase in costs due to acquisition of domestic products and sales growth• Controlling cost ratio through further growth of products with lower cost ratios
Royalty income <ul style="list-style-type: none">• Further growth expected in ViiV's HIV	SG&A expenses <ul style="list-style-type: none">• Expansion of information activities due to the increase in domestic focus products• Building a foundation for the launch of new products overseas• Promoting globalization
Overseas subsidiaries/export <ul style="list-style-type: none">• Volume expected to reach a record high, but revenue is projected to decline year-on-year due to foreign exchange impact	R&D expenses <ul style="list-style-type: none">• Continuing active investment in globally developed in-house products

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SHIONOGI

Teshirogi: At the last, I would like to take a few moments to talk a little bit about the budget for FY2025. On page 34, there are some mixed topics as budget assumptions, where you might have few questions.

As Iwasaki mentioned, growth in the domestic acute respiratory virus infection treatment area is key to this budget, based on the same level of outbreak, and to achieving the treatment rate of 20% and market share 70%. We believe this is achievable.

In terms of royalties and overseas business, we believe that there is relatively little risk. We believe that this is achievable.

As for expenses, there has been no significant increase in costs compared to last year. We believe that at least not for our company's own products. Even if JT Corporation's or Torii Pharmaceutical's R&D expenses are included later, we believe we will be able to properly control SG&A and R&D expenses by applying the same prioritization framework we have used so far, deciding what priority, in which country, for which disease, and how to proceed with development.

Financial Results

Earnings forecast

- Sales revenue and operating profit are expected to reach record highs for the fourth consecutive term
- All profit items are expected to increase
- Investment towards achieving 2030 Vision will be further accelerated

(Unit: B yen)

	FY2025			FY2024	FY2025			FY2024	FY2025			FY2024
	Full year	Change	(%)	Results	1H	Change	(%)	1H Results	2H	Change	(%)	2H Results
Revenue	530.0	91.7	20.9	438.3	233.0	19.0	8.9	214.0	297.0	72.7	32.4	224.3
Operating profit	175.0	18.4	11.7	156.6	82.0	6.1	8.1	75.9	93.0	12.3	15.2	80.7
Profit before tax	222.0	21.2	10.6	200.8	102.0	8.2	8.7	93.8	120.0	13.1	12.2	106.9
Profit attributable to owners of parent	180.0	9.6	5.6	170.4	86.0	2.9	3.4	83.1	94.0	6.7	7.7	87.3
EBITDA*1	196.0	16.7	9.3	179.3	93.0	6.3	7.3	86.7	103.0	10.4	11.2	92.6

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*1 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.)



Based on this assumption, going to next page, the consolidated forecast on sales revenue is JPY530 billion, an increase of about 21%. Below, operating income is JPY175 billion, an increase of about 12%. Profit before tax is JPY180 billion, an increase of 5.6%.

Profit before tax showed a smaller percentage increase, as it reflects the fact that this year's net profit grew significantly due to the incorporation of tax effects and other factors.

Normally, I don't give a detailed explanation of H1 and H2, but after September 1, we will incorporate Torii Pharmaceutical and the incorporation is scheduled by December 1 at the latest, although we are trying to move this forward if possible. The pharmaceuticals division of JT Corporation, which is mainly royalties, is a little different in terms of the balance between H1 and H2. Therefore, we are talking this area a bit in detail this time.

What I would like to emphasize is that we aim to increase both revenue and profit in H1 and H2 in all items compared to the previous year.

Statement of Profit or Loss

(Unit: B yen)

	FY2025			FY2024	FY2025			FY2024	FY2025			FY2024
	Full year	Change	(%)	Results	1H	Change	(%)	1H Results	2H	Change	(%)	2H Results
Revenue	530.0	91.7	20.9	438.3	233.0	19.0	8.9	214.0	297.0	72.7	32.4	224.3
Cost of Sales	88.0	24.2	37.9	63.8	33.0	2.9	9.5	30.1	55.0	21.3	63.3	33.7
Gross profit	442.0	67.6	18.0	374.4	200.0	16.2	8.8	183.8	242.0	51.4	27.0	190.6
SG&A*1, R&D expenses total	263.0	48.3	22.5	214.7	116.0	9.3	8.7	106.7	147.0	39.1	36.2	107.9
SG&A expenses	131.0	24.9	23.5	106.1	58.0	8.1	16.2	49.9	73.0	16.8	30.0	56.2
R&D expenses	132.0	23.4	21.5	108.6	58.0	1.2	2.1	56.8	74.0	22.2	42.9	51.8
Other income & expenses	(4.0)	(0.8)	-	(3.2)	(2.0)	(0.8)	-	(1.2)	(2.0)	(0.1)	-	(1.9)
Operating profit	175.0	18.4	11.7	156.6	82.0	6.1	8.1	75.9	93.0	12.3	15.2	80.7
Finance income & costs	47.0	2.9	6.5	44.1	20.0	2.0	11.3	18.0	27.0	0.8	3.1	26.2
Profit before tax	222.0	21.2	10.6	200.8	102.0	8.2	8.7	93.8	120.0	13.1	12.2	106.9
Profit attributable to owners of parent	180.0	9.6	5.6	170.4	86.0	2.9	3.4	83.1	94.0	6.7	7.7	87.3

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*1 SG&A: Selling, general & administrative 

If I could just focus on a few points here, please take a look at the percentage increase for H1, all the way from the top, it is 8.9%, 9.5%, and 8.8%. SG&A expenses are a little larger, but you can see that the numbers are generally similar from top to bottom.

This reflects our usual pattern. As sales increase, costs such as COGS and SG&A may also rise slightly, but we aim to land operating profit at the planned level. We will follow through with this approach.

As for H2 of the fiscal year, to be honest, Torii Pharmaceutical is currently in a fables state, with most of its manufacturing outsourced. From our perspective, we feel the costs are bit higher.

Of course, whether we can quickly add new manufacturing sites depends on the product, but as you can see, a 30% increase in sales appears to be accompanied by a 60% increase in cost of goods. The first key point for synergy is how we can quickly and effectively control this to generate synergy.

Then, with regard to SG&A expenses and R&D expenses in particular, R&D expenses appear to have increased by 43%. At this stage, we have consolidated JT's and Torii Pharmaceutical's SG&A expenses schedules as they are. In our opinion, both are a little high.

I am sure synergies will come up quite a bit at Iwasaki's area and John's area from time to time with occasional check ins. However, we have not had a chance to look at everything from the beginning, so at this stage we have added them as they are.

The operating income rise and fall in response to this is JPY82 billion for H1 and JPY93 billion for H2. So, I think you can see that we are not that unreasonably dependent on H2 of the fiscal year.

The last one, which I did not mention earlier, is the financial income and expenses, which are mostly dividends from ViiV Healthcare Ltd.. In the back of this package, I have written the forecast for the exchange rate, and we expect that the yen will swing slightly stronger. As a result, we set JPY47 billion, which is an increase of about JPY3 billion over last year. We believe that ViiV's base business is strong enough to increase dividends.

Revenue by Segment

(Unit: B yen)

	FY2025			FY2024	FY2025			FY2024	FY2025			FY2024
	Full year	Change	(%)	Results	1H	Change	(%)	1H Results	2H	Change	(%)	2H Results
Prescription drugs	183.0	84.2	85.3	98.8	62.0	14.3	29.9	47.7	121.0	70.0	137.3	51.0
Overseas subsidiaries/export	54.9	(4.2)	(7.1)	59.1	25.7	(2.6)	(9.3)	28.3	29.2	(1.6)	(5.1)	30.8
Shionogi Inc. (US)	22.6	(0.8)	(3.3)	23.4	10.9	(0.3)	(2.8)	11.2	11.7	(0.5)	(3.9)	12.2
Shionogi B.V. (EU)	16.9	0.1	0.5	16.8	8.3	(0.0)	(0.1)	8.3	8.6	0.1	1.0	8.5
Shionogi China	7.0	(1.7)	(19.3)	8.7	3.5	(0.7)	(16.6)	4.2	3.5	(1.0)	(21.9)	4.5
Others	8.4	(1.8)	(17.7)	10.2	3.0	(1.6)	(35.0)	4.6	5.4	(0.2)	(3.5)	5.6
Contract manufacturing	13.2	(4.1)	(23.5)	17.3	6.5	(1.3)	(16.2)	7.8	6.7	(2.8)	(29.4)	9.5
OTC and quasi-drug	18.5	1.7	10.0	16.8	8.9	0.7	9.2	8.2	9.6	0.9	10.8	8.7
Royalty income	257.9	13.2	5.4	244.7	128.7	7.2	5.9	121.5	129.2	6.0	4.9	123.2
HIV franchise	244.8	4.4	1.8	240.4	125.8	6.2	5.2	119.6	119.0	(1.8)	(1.5)	120.8
Others	13.1	8.8	207.2	4.3	2.9	1.0	52.7	1.9	10.2	7.8	331.2	2.4
Others	2.5	0.8	48.8	1.7	1.2	0.7	131.8	0.5	1.3	0.1	11.8	1.2
Total	530.0	91.7	20.9	438.3	233.0	19.0	8.9	214.0	297.0	72.7	32.4	224.3

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SHIONOGI

Among the business segments, one that I think deserves a special mention is Shionogi. Cefiderocol itself plans to grow by about 15% plus or minus on a volume basis.

Then, I wondered why this is happening. It is not just the impact of yen appreciation. This is going back quite a while, but the license-out agreement for Osphepa sold by Shionogi expired last fiscal year, FY2024. As a result, about JPY2 billion in revenue from that will no longer be recorded from this fiscal year, which makes it appear as though the US business is in a slightly negative situation.

As for our baseline, cefiderocol, we expect growth of over 15% in the US and over 5% in Europe. We expect these businesses to remain solid.

We are aware that the royalty rate for the HIV franchise is estimated to be quite firm, since we have made certain hedges last year and this year as well, while considering that the yen may appreciate slightly. We think that we see a little more upswing here.

Prescription Drugs in Japan

(Unit: B yen)

	FY2025			FY2024	FY2025			FY2024	FY2025			FY2024
	Full year	Change	(%)	Results	1H	Change	(%)	1H Results	2H	Change	(%)	2H Results
Acute Respiratory Virus Infection Treatment	85.8	34.0	65.7	51.8	31.0	6.1	24.7	24.9	54.8	27.9	103.4	26.9
Quviviq	9.3	8.5	-	0.8	1.2	1.2	-	-	8.1	7.3	-	0.8
Symproic	8.1	3.1	61.4	5.0	3.9	1.5	65.2	2.4	4.2	1.5	58.1	2.7
OxyContin franchise	5.6	1.3	31.7	4.3	2.9	0.8	40.4	2.1	2.7	0.5	23.5	2.2
Others	74.2	37.3	101.1	36.9	23.0	4.6	24.8	18.4	51.2	32.7	177.2	18.5
Prescription drugs	1,830	84.2	85.3	98.8	62.0	14.3	29.9	47.7	121.0	70.0	137.0	51.0

- Acute Respiratory Virus Infection Treatment-

- COVID-19 Treatment : Xocova
- Influenza Franchise : Xofluza, Rapiacta

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Next, we will discuss about Japan.

Acute respiratory virus infection treatment is JPY85 billion, which is about JPY30 billion in H1 and JPY55 billion in H2. Regarding this, as I mentioned earlier, if we see the same level of infection outbreak as last year, or an epidemic, we believe we can manage the situation.

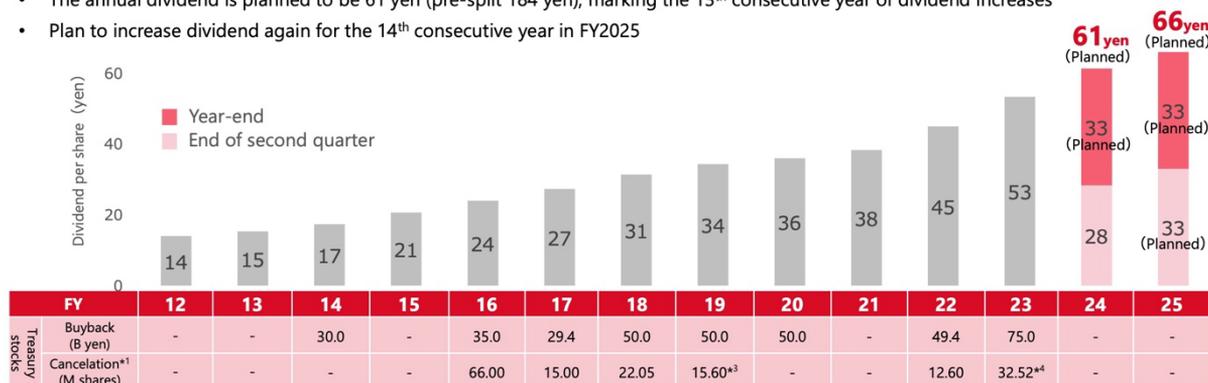
It may seem surprising to you that Symproic is expected to grow by 60%. In fact, our pain management franchise turned positive for the first time in quite a while in the last year. The steady efforts we have been making are finally starting to bear fruit.

Especially in H2, when we will be able to utilize Torii Pharmaceutical's 230 MRs, we believe we can allocate more resources to the pain management area. With that in mind, we aim to achieve this positive result.

Shareholder Returns

Shareholder return policy through which shareholders can feel our growth

- Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
- The year-end dividend is planned to increase by 4 yen per share from the previous forecast, resulting in 33 yen*1 (pre-split : 99 yen)*2
- The annual dividend is planned to be 61 yen (pre-split 184 yen), marking the 13th consecutive year of dividend increases
- Plan to increase dividend again for the 14th consecutive year in FY2025



39 *1 Effective October 1, 2024, Shionogi has implemented a 3-for-1 stock split of its common stock. Dividends and Treasury stock's Cancellation are calculated based on the assumption that the stock split was implemented at the beginning of the FY2012 *2 [Press Release April, 2025](#) *3 Resolution passed on March 30, 2020, and treasury shares cancelled on April 6 *4 Resolution passed on July 31, 2023, and treasury shares cancelled on April 17, 2024



Lastly, shareholder returns.

I have two points. As of now, the dividend is JPY66, or JPY198 before the pre-split into three. Apparently, my head is still a bit pre-split mode, but the previous year was JPY160, and we increased the dividend this year to JPY184, which is a JPY24 increase before the three-quarter split. The year before that, the dividend was increased by JPY25, from JPY135 to JPY160.

For the JPY198, JPY33 in H1 is a start point. We have been discussing with the Board of Directors the possibility of a further increase in dividends for H2, while keeping an eye on the landing point. We would like to continue our efforts in this area.

As for the share buyback, the landing point for JT Torii Pharmaceutical's share buyback in FY2024 was a little delayed than we had expected. We had hoped to complete it by the end of last fiscal year, but there was a slight delay.

Thus, in FY2024, we increased dividends, but we prioritized M&A rather than share buybacks.

As for FY2025, we currently have two or three projects in progress. While we prioritize growth investments in terms of how we allocate funds, we expect to have a clearer view by around September to see whether the next M&A opportunity will materialize within the fiscal year.

At that point, taking into account discussions with the Board of Directors and our cash balance, we will consider whether to implement a share buyback as part of shareholder returns. If we do proceed, we intend to continue discussions on the appropriate scale of the buyback.

It is getting long, but this is all from me. Thank you for your attention.

Kyokawa: Thank you very much.

Question & Answer

Kyokawa : I will now move on to the Question & Answer session.

Now, we will take questions from the audience. Mr. Ueda.

Ueda : My name is Ueda from Goldman Sachs.

I would like to start with the first question. The acquisition of JT Group's pharmaceutical business. I would like to know how it will contribute to your company's drug discovery capabilities.

I think you mentioned that one of the purposes of this acquisition was to strengthen your small molecule drug discovery capabilities. What did you find attractive about JT in that respect? Please also share your thoughts on your company's strengths and the potential for future synergies.

Teshirogi : I will ask John to add his comments on this, as he communicates with them quite a bit.

Since last year, and the year before, we faced some challenges, especially when looking at infectious diseases. HIV, for example, for this S-365598, I discussed it with John, and we decided to make a new long-acting drug after all. We were quite serious about it.

With the development phase of Xocova and S-892216 settled down, we have been able to focus more on HIV. We have also been working on synthesizing new partner compounds. So, once we decide to move forward, we are confident we can develop a good product fairly quickly. Then, there are the next HIV partner compounds, which we have already announced, but we believe there will be more to follow.

In terms of viruses, we have a viral library that includes both RNA and DNA viruses. Developing a therapeutic drug for something like Dengue or West Nile from that library, deciding which compound to advance, requires a significant number of resources.

As I mentioned earlier, among the three major infectious diseases, we want to do both malaria and TB NTM. To be honest, we have not been able to keep up. While people may say we are a specialized infectious disease company with strong capabilities, the reality is that we are not in a position to fully cover everything. For example, we have hardly touched the area of fungal infections. That is why we have also felt the need to allocate more of our existing resources to the infectious disease areas we are already engaged in.

On the other hand, we have allocated a significant number of our chemists to areas like sleep apnea and hearing loss. We also allocated a significant number of our chemists to the vaccine area, so we have been seriously short on chemists for so-called QOL-related diseases. As a result, there has been ongoing competition within the research center, with different projects constantly vying for chemists.

In terms of AI drug discovery, we have confirmed during our due diligence that the level of AI drug discovery is much higher than ours. I believe that chemists are very strong in the areas, especially in allergy, immunology, cardiovascular, and renal as QOL diseases.

It may be the case that, by shifting some of our own chemists more toward the infectious disease side, we look to JT to play a key role on the QOL side with their chemists. We are hoping that this will considerably increase the depth of our second pillar, which is QOL diseases.

Our chemists also read a lot of papers, so they keep a close eye on what kind of patent information and research results are coming out from chemists at various companies in Japan, and what kind of compound structures are being reported in those papers.

From the perspective of our own chemists, JT's chemists are highly skilled. We believe that if we can work together on a single project, there's strong potential for a synergy where one plus one becomes three or even five.

Keller : I'm being specific, but practical applications of AI, this is not a dream, but actual use of AI. JT is very much ahead of the curve when it comes to accelerating drug discovery and making choices.

When it comes to specific target molecules such as kinases or chaperonins, we did not have particular strengths in those areas, but JT has very strong capabilities. JT has focused on up to early development and has excellent technology in clinical evaluation.

They are very good in toxicology, DMPK, in vitro and in vivo techniques. They are very strong in small molecule drug discovery because they have a very high ability to identify which compounds have more potential. We consider these elements to be highly complementary to our future initiatives in small molecule drug discovery.

Ueda : Thank you very much. Second, I would like to ask you about the market environment for HIV.

Given the increasing uncertainty in the business environment, such as US drug pricing policies, how do you view the associated risks? Also, where there is no change in the market outlook.

In addition, your company appears to have a broad lineup, including oral two-drug regimens and long-acting injectables. Could you also share your thoughts on how these strengths might come into play going forward?

Keller : Thank you very much. To answer your second question, we have two elements in that portfolio. Having oral two-drug regimens and LA formulations is becoming a major advantage for us.

In Europe, where pricing pressure remains high, oral two-drug regimens have demonstrated particularly strong growth, while long-acting formulations are experiencing rapid expansion in both the United States and Europe. Even our long-acting formulations are offered at a lower price point than competing oral therapies. Overall, ViiV is taking a very conservative approach.

Regarding the US market, there are two elements.

One is the recently announced executive order concerning the MFN pricing policy.

At this point, it is difficult to determine which elements are intended to drive price negotiations, which are aimed at excluding PBMs, and which are designed to encourage price increases in other countries.

We will continue to closely monitor these developments and work in close coordination with relevant stakeholders to ensure the best possible outcomes for people living with HIV.

The other point concerns the PrEP market.

The growth of the PrEP market has historically depended on Medicaid reimbursement, and it remains uncertain whether this support will continue in the future.

While this may not have a significant direct impact on the businesses of ViiV or Shionogi, it is an important issue in terms of how rapidly the PrEP market can grow compared to the treatment market.

Kyokawa : Mr. Hashiguchi.

Hashiguchi : My name is Hashiguchi from Daiwa Securities. I have several questions. I would like to start with M&A. During the next three or six months, we talked about acquiring various possible opportunities, while keeping in mind the STS2030 sales target. We have had many such discussions with your company.

This time, you announced the projects with Torii Pharmaceutical and the JT Group. I was wondering, are the projects we have heard about so far still ongoing? In our previous discussions, I understood that you had in mind two or three projects that could have a significant impact on sales in the near future.

Has it not changed there? You mentioned that you expect to have a clearer picture by the end of H1, but I would like to confirm once again whether the remaining items can be considered based on the discussions we have had so far.

Teshirogi : Thank you very much. It is exactly as Mr. Hashiguchi described. Nothing has changed.

Of course, some US venture companies are in rather difficult situations, and we receive many inquiries and proposals. However, that does not mean these are currently at the top of our serious consideration. Rather, we see them as potential future opportunities and continue to keep the dialogue open.

We have cleared one out of our three and are continuing the conversation around the other two, which are the ones that will have a large positive impact on sales.

Hashiguchi : Thank you very much. However, my understanding was that this was a project intended to contribute to achieving the FY2025 sales target by securing a certain level of visibility during H1 of the fiscal year.

This time, it was a slight, but the target has been revised downward. It takes time until H1. During H1, it still takes a little more time. How should we understand the reason behind this apparent slight delay?

Teshirogi : It is difficult to say, but to put it straight, this is our first M&A exceeding JPY100 billion in 16 years. We formed a strong SWAT team, making good use of FA, legal experts, and others, but the core members or the so-called aces, were all relatively young, including Fujiwara, who is around his age. The team members were around his age.

Unfortunately, it is true that a few unexpected issues did come up, and that did cause some delays. We wanted to complete the Torii Pharmaceutical's case by the end of last year, but it was delayed by three or four months.

That said, we are not foolish. We have gradually become able to build a solid team for this kind of work. So next time, in terms of speed and thoroughly addressing any gaps or oversights, I believe our capabilities have improved significantly. I am sure that the young people, in particular, have gained confidence that they can do this.

Hashiguchi : So, it is taking a little bit of time for the same reason regarding the other two cases.

Teshirogi : That is more of the other party's situation.

Hashiguchi : I understand. That is all. Thank you very much.

Kyokawa : Mr. Sakai.

Sakai : My name is Sakai from UBS Securities. I was curious about John's earlier comment regarding the growth of PrEP and what the key drivers for that growth will be going forward.

One is the Trump administration's gender policy, how do you read the impact of this? My understanding is that PrEP is mostly covered by private insurance, so government policy may not have much impact. However, during 1.0, Mr. Trump did announce a policy aiming to eradicate HIV by 2030. How should we view or interpret that now?

I think the most important point is the growth of PrEP but how do you view this matter?

Keller : Treatment is important for our future, of course. That is the biggest segment for us.

However, regarding prevention, one-third of the US population are receiving PrEP. But about 70% of gay white men are covered by PrEP.

African Americans, Hispanics, minority men, women, and Black individuals do not have insurance. Because of this, the current PrEP market is unlikely to be significantly affected. However, when discussing the possibility of the market doubling or tripling in the future, I believe that growth will be slower

Regarding President Trump's statements, it is uncertain what will happen. At this point, there are many unknowns.

Sakai : There are two things that caught my attention at the briefing about JT and Torii Pharmaceutical. You mentioned that you want to enter the renal area.

What does it mean by that? I don't think Torii Pharmaceutical or JT have many compounds in the renal area. Is the idea, then, to bring in such assets from outside in the future, whether they are in early stages or already under development? Or are you considering some kind of internal strengthening or capacity building in that area? I would like to ask about that first.

Keller : I am thinking of early-stage development. And I am also thinking of a specialty area.

Over the years, we have been interested in the kidney market. This is an important medical need, and the market potential is huge, but we had no experience in the mechanism, development, or commercialization in this area.

We can move forward in this area under JT's lead, and we also intend to explore external area as part of our expertise. There have been two or three cases in the past with potential for interesting in-licensing.

In the past, we were not able to bring in assets in the kidney area because we lacked the in-house expertise to properly evaluate them.

Sakai : Regarding Quiviviq, we have heard that inquiries have been very strong. I asked Nxera Pharma, and they told us that they have been accumulating a considerable amount of inventory, and that the production volume is not keeping up with the demand.

So, your company, I think you mentioned that you have a little extra production and factory capacity, but do you have any ideas on how to make effective use of it?

Iwasaki : As you mentioned, we initially distributed the product, and fortunately, it has been significantly consumed, especially in psychiatry. As of now, there is no stock left.

Regarding production, we are asking to speed up the manufacturing of the 50 mg dose, since 50 mg is needed to ensure effectiveness, with 25 mg used for dose reduction. We still had 25 mg in stock, but we were going to manufacture and supply 50 mg. So, we asked them to hurry up with the production of the 50 mg.

At present, there is no concern about a shortage, and we are planning to be able to supply sufficient quantities of 50 mg tablets.

Teshirogi : Actually, regarding manufacturing, we are hoping to do it somewhere around the end of this fiscal year. Maybe it would be easier to understand if we put out a ten-year plan or so.

We manufacture Xocova, Xofluza, dolutegravir, and Cabenuva. If asked how much of a backup plan we have in place in case of a natural disaster, we do have a BCP. However, we cannot say with certainty that we would be able to immediately supply high-quality drugs in sufficient volumes to the Japanese population 100%.

It usually takes 4 to 5 years to build a new factory, qualify it, and achieve stability. Currently, we are planning what to produce in Japan, and we need 3 to 4 capital investments. Therefore, I believe it is necessary to propose this.

We do not manufacture Quiviq in Japan at this time. In fact, Zuranolone is being imported as tablets under the initial deal. We would very much like to manufacture it in Japan in the future. We are considering what kind of products, in what form, and in what place, if any, to reorganize production in Japan, even if it does not involve the production of all products.

Since the amount involved is quite large, we have been discussing it at management meetings, and I believe it will be important to share this information with analysts going forward.

Sakai : Thank you very much.

Kyokawa : The last questions from the venue, Mr. Matsubara.

Matsubara : My name is Matsubara from Nomura Securities. Thank you very much.

Two things about Xocova, please. First of all, you have set a target of a 20% domestic treatment rate for this fiscal year. You mentioned that this rate is expected to increase through the use of services like PayPay Hoken. Although it has only just begun, could you share the current percentage of those covered by insurance and the likelihood of achieving the 20% target?

Iwasaki : We cannot directly advertise or sell the COVID-19 insurance "Private insurance for the use of COVID-19 treatments" However, as a sponsor of the insurance, we are considering ways to help increase awareness. If awareness expands, combined with other disease awareness initiatives, we believe that a treatment rate of 20% can be achieved.

Matsubara : Okay. Thank you very much.

The second is the development in the US. I have heard that if a person is infected with COVID-19, a COVID-19 treatment drug is prescribed in the US. The prescription rate is higher than in Japan.

On the other hand, I wonder what will happen with regard to this prevention. How many of the infected patients do you see prescriptions for prophylaxis? Please let me know what you see as the market expectations here.

Iwasaki : It is difficult to understand the premise, since there is no drug indicated solely for PEP. However, I believe that the need for facilities such as nursing care health facilities in Japan will be quite high.

Matsubara : You mentioned that you applied because you wanted PEP in the US and Europe. What do the FDA or EMA expect in that matter?

Uehara : It is difficult for us to hear directly from the authorities about what they are expecting. Nevertheless, None of the other oral medications have achieved the primary endpoints for this indication, so there is definitely a need. We have received the message that they want to create an environment where it is the only medication that can be used. Naturally, the key issue for any therapeutic is how to prevent severe cases, and this is a global perspective. As you are well aware, people do not become severely ill if they do not develop symptoms after infection. So, from that standpoint, it may be more effective for high-risk individuals to start taking the drug early, right after close contact, to prevent viral replication. We believe this represents a new approach, and the focus is on how Ensitrelvir can be used globally in this context.

We are now looking to develop this product globally while exploring its market and usage.

Matsubara : I understand. Thank you very much.

Keller : in addition, the response to the PrEP data for the FDA and EMA has been very positive. I felt the reactions were strong and energetic.

Kyokawa : Thank you very much. We have about eight minutes left, and we will take questions from those participating online.

Mr. Yamaguchi of Citigroup, please ask your questions.

Yamaguchi : My name is Yamaguchi. Thank you very much. Two simple questions, please.

The President mentioned at the beginning of the presentation that there was a small gap compared to the assumption in the previous fiscal year. The decline in Xocova's sales and the control of SG&A expenses did not go well in February and March as a result.

I am sure that there will be some seasonality in the future, but you said that you will not cause such problems after this fiscal year. If you have any suggestions on how to create a system to prevent this from happening, please let us know. This is the first.

Teshirogi : Predicting the outbreak situation for January, February, and March is very difficult. This time, we expected it to come in February or March, but it didn't. Therefore, we need to consider how to control costs as a contingency when the outbreak doesn't occur and how to implement this mechanism.

Previously, the cycle was once a month or once every two months, but now, with Kudo and Fujiwara, we need to shorten this cycle and monitor it on a weekly basis.

From an operational standpoint, there is no choice but to speed up the cycle. We have had quite a painful experience with this, so I believe we are moving towards significant improvements.

Yamaguchi : Thank you. And simple answer would be good enough for another one, but for JT and Torii Pharmaceutical, you mentioned JPY100 billion collectively. I think the difference between Torii Pharmaceutical and JT is JT's royalty. In any case, JT's profit is about JPY4 billion, too, for the full year. I think around JPY4 billion for Torii Pharmaceutical as well.

Will the royalty portion from JT contribute to the profit of your company now or not? Please let me know how much in terms of amount, if any.

Teshirogi : Royalties are royalties. So, that is where the top line would normally be reflected in operating income. In short, we are going to review how much of our R&D and SG&A expenses we spend and where we spend it.

Research and development expenses are used differently by both companies, so the main issue is how John, the new research team, and Uehara's development team can control and manage their spending in a way that fits our scale.

As for JT, since they will be consolidated since around December, it may not be reflected as a full year. That said, they have also started discussions with John on how to design a new operation if they are going to work with us.

We believe the synergies there are quite significant.

Yamaguchi : Thank you. That is all.

Kyokawa : Okay, next, Mr. Muraoka from Morgan Stanley MUFG Securities, please.

Muraoka : Thank you very much. Muraoka of Morgan Stanley MUFG Securities.

I would like to talk a little bit about JT, Torii Pharmaceutical's R&D expenses, and also royalties.

JT probably spends around JPY30 billion a year on R&D, and I assume that less than half of that is fixed personnel costs. That suggests they are putting a significant amount into clinical development, especially Phase I and Phase II. From what I have seen, some of those projects seem aligned with what your company would like to pursue, while others do not appear to be a major focus for you.

What I would like to ask is this that, if you move forward with a thorough selection of the pipeline, I get the impression that streamlining alone could easily generate, perhaps not easily, but around JPY10 billion in profit from the R&D side. Is my view a bit too optimistic?

Teshirogi : Regarding things other than personnel costs, I and John closely examine them down to the research level, so I think more will come out.

Muraoka : Okay. Thank you very much. Also, with JT and Torii Pharmaceutical now part of the consolidated group, I believe a significant portion of JT's royalty revenue comes from Elvitegravir. That is, royalties from Gilead and Novartis' MEK inhibitor are large.

Apologies if I am not fully informed, but my understanding is that the LOE for these might occur around 2030. If that is the case, they may expire around the same time as your oral drug. Is there any information on this that can be shared?

Teshirogi : We are not in a position to comment on the specifics of LOE and the like, we expect this situation to continue for at least the next few years. I would appreciate it if you could understand that this is as much as we can share at the moment.

Muraoka : Okay. Thank you very much. That is all.

Kyokawa : One minute left. I'll have the last one. Ms. Sogi of Sanford C. Bernstein, please.

Sogi : Thank you very much. I too have a question regarding M&A. As for the JT and Torii Pharmaceutical acquisitions this time, I think the main result will basically be to increase domestic sales.

In this context, how do you think Akros, for example, will contribute to the globalization of your business, which you have been talking about for a long time?

Also, one more thing. From what Mr. Iwasaki mentioned, I get the impression that you will use Torii Pharmaceutical's sales force to further increase your reach to customers.

On the other hand, I think that the merging of organizations in Japan this time will create a lot of synergy. In this regard, is it reasonable to expect that there will be cost synergies following an organizational change, which I understand is likely to take place after 2026?

Teshirogi : Iwasaki will speak about latter question, but as for the former, this is how we think.

As John mentioned earlier, JT's pharmaceutical division has traditionally focused on moving quickly through to around Phase IIa, and then out-licensing them to major pharmaceutical companies at a good price.

They have been quite specialized in this approach. What sets us apart is that if a compound is truly promising, we are prepared to take it through Phase IIb and Phase III on our own with Uehara's team leading the effort and eventually build a pipeline we can commercialize ourselves.

This is actually a very encouraging direction for JT's pharmaceutical division of JT, as eventually we can develop and obtain approval for products on our own. It is crucial to establish a research and development organization that can see the process through to the end, which I believe is important for their motivation.

Therefore, the principle for Akros is that the team at Uehara will primarily handle the latter part of Phase 2 and 3 trials. As the costs for Phase 2 and 3 trials naturally increase, it becomes important for the R&D committee to focus on narrowing down and specializing the pipeline, as mentioned in the previous question, and make concentrated investments.

Going forward, it will be crucial for John and Iwasaki, who are responsible for sales, to streamline and decide the sequence in which we allocate our human, financial, and material resources.

Iwasaki : In terms of synergy with Torii Pharmaceutical, as mentioned earlier by Teshirogi, our product lines do not overlap. Moreover, acute infectious diseases such as Xofluz and Xocova are commonly prescribed in the field of ENT as well.

We were unable to delve deeply into the field of ENT. Starting from September, I want to first focus on the medical department and determine which items to target for our business.

Currently, I have heard that Torii Pharmaceutical Corporation has around 200 specific sales reps, but I would like to know more about their functions and who else is involved. Moving forward, I would like to work on narrowing down these aspects and, naturally, consider the right person for the right position.

At the very least, with Torii Pharmaceutical's specialization in ENT and dermatology, with 200 representatives, we are hopeful for significant synergy effects where our products can also be promoted.

Sogi : Thank you very much. Sorry for one last thing.

Based on what you just said, should we understand that the current plan is to fully integrate the organizations? Or is the assumption that Torii Pharmaceutical or the JT side will continue to operate separately as their own organizations?

Teshirogi : Of course, over time, the ideal would be to move toward the most optimal organizational structure. However, we still need to work out the timeline in more detail.

It is simply not realistic to complete everything in one or two months. This is also tied to issues such as where the products are manufactured and how we handle the MAH. At the very least, we would like you to

understand that we are thinking in terms of a timeline of around a year to consider how best to optimize the structure and implement the necessary changes.

Sogi : I understand. Thank you very much.

Kyokawa : Sorry, we run over time a bit.

This concludes the financial results briefing for the fiscal year ended March 31, 2025, for SHIONOGI.

Thank you all for your time today.

Teshirogi : Thank you very much.

[END]