SHIONOGI & CO., LTD.

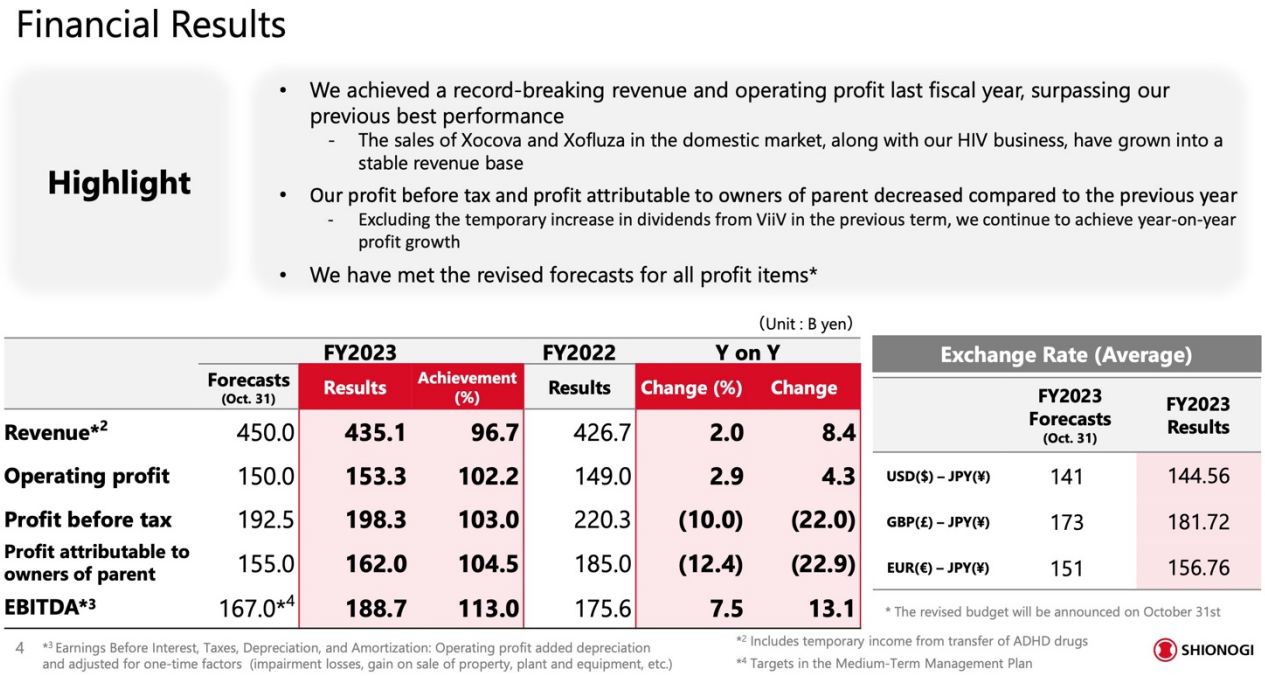
FY2023 Financial Results

May 14, 2024

Presentation

Kyokawa: Okay, it is now 10:30 AM and we will begin. My name is Kyokawa of SHIONOGI & CO., LTD. Thank you all very much for joining us today despite your busy schedules. We will now begin the briefing on the financial results for the fiscal year ended March 31, 2024, SHIONOGI. Today, Dr. Teshirogi will give an overview of the financial results, followed by a Question & Answer period. The end time is scheduled at 12:00 PM. Let me begin. Dr. Teshirogi, please.

Teshirogi: My name is Teshirogi. Thank you again for your joining us today. I would like to start by talking about the financial results and the pipeline, and then I would like to take questions from the audience. Thank you.



Financial Results

Highlight

- We achieved a record-breaking revenue and operating profit last fiscal year, surpassing our previous best performance
  - The sales of Xocova and Xofluza in the domestic market, along with our HIV business, have grown into a stable revenue base
- Our profit before tax and profit attributable to owners of parent decreased compared to the previous year
  - Excluding the temporary increase in dividends from ViiV in the previous term, we continue to achieve year-on-year profit growth
- We have met the revised forecasts for all profit items*

(Unit : B yen)

	FY2023			FY2022	Y on Y	
	Forecasts (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Revenue*2	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**
Operating profit	150.0	**153.3**	**102.2**	149.0	**2.9**	**4.3**
Profit before tax	192.5	**198.3**	**103.0**	220.3	**(10.0)**	**(22.0)**
Profit attributable to owners of parent	155.0	**162.0**	**104.5**	185.0	**(12.4)**	**(22.9)**
EBITDA*3	167.0*4	**188.7**	**113.0**	175.6	**7.5**	**13.1**

Exchange Rate (Average)

	FY2023 Forecasts (Oct. 31)	FY2023 Results
USD($) – JPY(¥)	141	144.56
GBP(£) – JPY(¥)	173	181.72
EUR(€) – JPY(¥)	151	156.76

* The revised budget will be announced on October 31st

4 *3 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.)

*2 Includes temporary income from transfer of ADHD drugs

*4 Targets in the Medium-Term Management Plan

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The first one, page four, is the financial statements. Revenue was JPY435.1 billion, up 2% from the previous year, and operating profit was JPY153.3 billion, up 2.9%, marking the second consecutive year of record revenue and operating profit since the Company's founding.

The sales revenue was JPY435 billion compared to JPY450 billion, which means that we missed the target by about JPY15 billion. This is true, but at the beginning of the fiscal year, we originally included a large amount of Xocova in Asia, especially in China, both in terms of sales and expenses. Once that was no longer available, we decided to try to do our best as much as possible, focusing on Japan. So, we left the JPY450 billion figure unchanged.

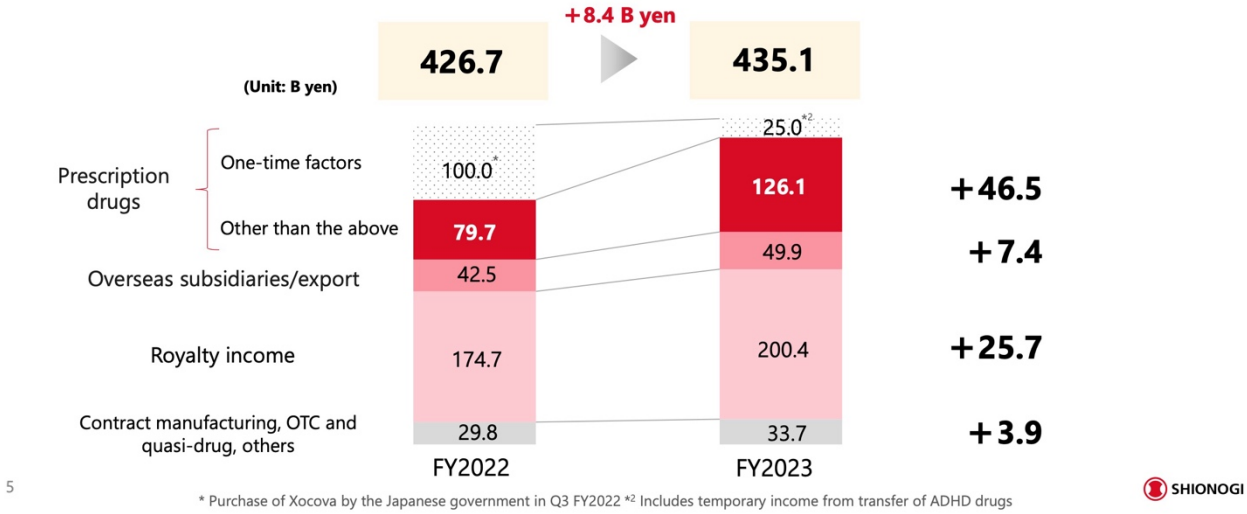
Although we fell short of the JPY15 billion from the plan, we feel very confident that our sales activities are beginning to show a very different strength, especially for domestic infectious disease drugs.

Profit before taxes was JPY198.3 billion and profit attributable to owners of parent was JPY162 billion, down 10% and 12.4% from the previous year, respectively. As you are all aware, in the financial balance sheet for FY2022, we received dividends five times from ViiV and a lump-sum payment for our share of Gilead's and ViiV's settlements, which together totaled over JPY22 billion. It is not good to say if only, but if not, profit

before taxes and profit attributable to owners of parent would have been on an upward trend. I think that the landing figures are reasonable number.

Growth of Topline

We achieved growth across all businesses, centered around a dramatic expansion in our direct sales



We have made it a little easier to understand this on page five. In FY2022, there was a JPY100 billion purchase of Xocova by the government, so it is very difficult internally to determine the impact of this purchase. In FY2023, there is a one-time payment of JPY25 billion for the transfer of ADHD, so looking at the difference, there is a difference of JPY75 billion in one-time payments. We had hoped to earn more than JPY75 billion from HIV in the US, Cefiderocol in Europe, and influenza and COVID-19 in Japan. I believe we have managed to achieve this goal.

If we take out the JPY100 billion of shadow portion and the JPY25 billion portion, we calculated how much we sold as our actual business. They were JPY326.7 billion for FY2022, and JPY410.1 billion for FY2023 after JPY250 billion. Comparing these two figures, sales increased by 26%, which of course includes royalties and exchange rates, but actual sales of infectious disease drugs both domestically and internationally grew by a certain amount. We believe that the actual sales grew considerably during the year.

Statement of Profit or Loss

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Revenue	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**
Cost of Sales	13.2 59.5	13.2 **57.6**	**96.8**	14.6 62.2	**(7.5)**	**(4.6)**
Gross profit	390.5	**377.5**	**96.7**	364.4	**3.6**	**13.0**
Selling, general & administrative expenses, R&D expenses total	51.3 231.0	47.4 **206.0**	**89.2**	47.8 203.9	**1.0**	**2.1**
Selling, general & administrative expenses	26.4 119.0	23.8 **103.4**	**86.9**	23.8 101.5	**1.9**	**1.9**
R&D expenses	24.9 112.0	23.6 **102.6**	**91.6**	24.0 102.4	**0.2**	**0.2**
Other income & expenses	(9.5)	**(18.1)**	**-**	(11.5)	**-**	**(6.6)**
Operating profit	33.3 150.0	35.2 **153.3**	**102.2**	34.9 149.0	**2.9**	**4.3**
Finance income & costs	42.5	**45.0**	**105.8**	71.3	**(37.0)**	**(26.4)**
Profit before tax	42.8 192.5	45.6 **198.3**	**103.0**	51.6 220.3	**(10.0)**	**(22.0)**
Profit attributable to owners of parent	155.0	**162.0**	**104.5**	185.0	**(12.4)**	**(22.9)**

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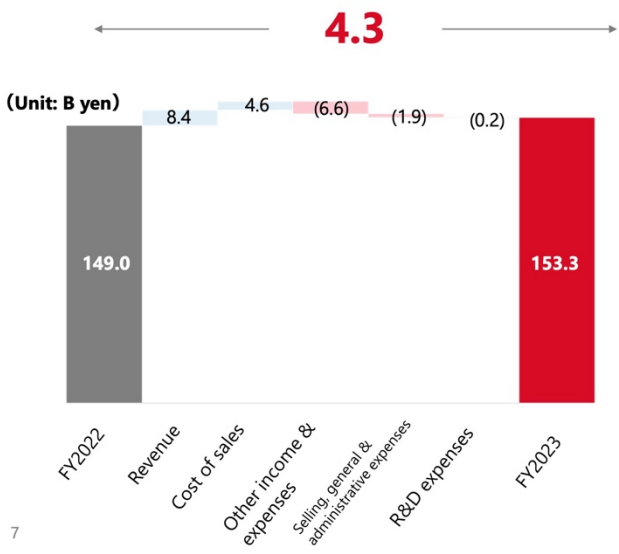
The next page is the P&L. On the right side of the graph show YoY comparison. Cost of sales decreased by 7.5% against an increase of 2% of sales. Of course, the manufacturing cost will vary slightly depending on how much and when Xocova or Xofluza are manufactured. So, we will have to subtract a little from the manufacturing cost.

However, sales of Cefiderocol, Xocova, and Xofluza, including Cefiderocol, have been increasing, which are our original products with low costs. Also, with strong royalties, we have been able to keep costs fairly low, resulting in a 3.6% increase in gross profit.

As you all know, until three or four years ago, our R&D expenditures were generally around JPY60 billion, with some years reaching JPY70 billion. At present, we have invested a great deal of necessary resources in the COVID-19 vaccine, Xocova, and the successor to Xocova, which is still ongoing which has reached to JPY100 billion level of R&D expenses since last year. In the current fiscal year, we have spent the same JPY100 billion in R&D expenses and have secured an increase in operating profit as a landing point.

Other income and expenses were negative JPY18.1 billion, an increase of JPY6.6 billion from the previous year. In the course of reviewing various items, we have taken some impairment losses in appropriate timings. We have recorded impairment losses of around JPY10 billion in the past year and the year before. In addition to this, there was the special early retirement of 300 employees, which amounted to about JPY7 billion. This time there was a large amount of JPY18.1 billion, but including this, we managed to secure an increase in operating profit.

Main Variation Factors of Operating Profit (Y on Y)



Revenue

Increase — Overseas subsidiaries/export, Royalty income

Decrease — Purchase of Xocova by the Japanese government in FY2022

Cost of Sales

Decrease in expenses
- Changes in product mix

Other income & expenses (One-time factors)

Increase in expenses
- Costs related to implementation of early retirement program
- Impairment due to revision of development plan of Zatolmilast (BPN14770) in Alzheimer's disease

※ Impairment charges were recorded due to a revision of the development plan in the previous term

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Moving on to the next page, here is a slightly schematized waterfall chart. We have put more detailed information about other income & expense area. As you know, for the 770 Alzheimer in Japan which is for a very old age group, we stopped development because we could not dispel concerns about the safety of this product.

There is actually a successor item at John's place, and we feel very good about this mechanism. We decided that it would be better to stop at 770, a little on the safety side, and for the elderly people. But we smelt faint about efficacy in the cases. We are hoping that the PD-4 mechanism, which has a high safety profile, will work and we have managed to create this as a backup, and now we are currently in the preparation stage for starting a clinical trial for it.

Revenue by Segment

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	167.0	**151.1**	**90.5**	179.7	**(15.9)**	**(28.6)**
Excluding temporary income	-	**126.1**	**-**	79.7	**58.1**	**46.4**
Temporary income	-	**25.0**	**-**	100.0	**-**	**(75.0)**
Overseas subsidiaries/export	49.2	**49.9**	**101.5**	42.5	**17.4**	**7.4**
Shionogi Inc.(US)	17.0	**17.9**	**105.6**	15.4	**15.9**	**2.4**
Fetroja	-	**14.5**	**-**	10.0	**45.4**	**4.5**
Shionogi B.V.(EU)	13.0	**13.6**	**104.3**	9.1	**49.9**	**4.5**
Fetcroja	-	**10.7**	**-**	6.6	**62.0**	**4.1**
Ping An Shionogi/C&O	12.1	**10.6**	**88.1**	12.0	**(11.3)**	**(1.4)**
Others	7.1	**7.8**	**109.7**	6.0	**29.8**	**1.8**
Contract manufacturing	16.4	**17.6**	**107.5**	15.3	**14.8**	**2.3**
OTC and quasi-drug	14.8	**14.6**	**99.3**	13.1	**11.6**	**1.5**
Royalty income	201.2	**200.4**	**99.6**	174.7	**14.7**	**25.7**
HIV franchise	196.5	**195.8**	**99.6**	168.5	**16.2**	**27.3**
Others	4.7	**4.6**	**96.6**	6.2	**(26.7)**	**(1.7)**
Others	1.5	**1.4**	**98.6**	1.3	**12.6**	**0.2**
Total	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**

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The next, page eight, shows revenue by business segment. As you can see, the domestic sales alone decreased by 15.9%, but excluding one-time factors, sales increased by JPY46.4 billion, or 58.1%. This includes the ADHD portion, which I will discuss later. In terms of anti-influenza and anti-COVID-19 for infectious disease drugs, we have increased revenues by approximately JPY70 billion, and I believe we have landed very strongly.

In the US and Europe, revenue increased 15.9% and 49.9%, respectively, for a total of JPY49.9 billion. It is a shy of JPY50 billion, but it shows a reasonable growth. As you can see, Fetroja and Fetcroja in particular, have grown to a combined value of a little over JPY25 billion.

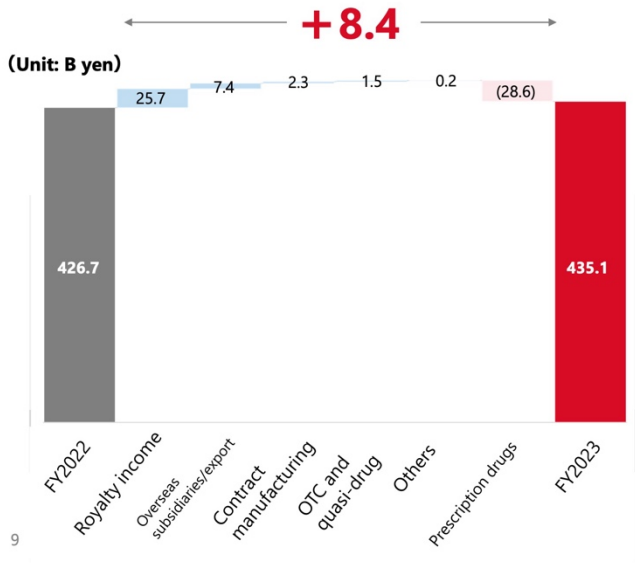
We would like to see a growth of more than JPY30 billion this fiscal year, and the fact that we are making strong progress in this area with our own products and through our own marketing suggests that we have passed one of the key points for our future sales activity. We are making a plan to develop Xocova and Xofluza overseas.

As a matter of fact, as of April 1, we have been handling overseas supplies under Dr. Hanasaki. However, from April of this year, all sales, including those in the US, Europe, China, and Japan, are under the control of Dr. Iwasaki, who will handle all sales.

This may seem modest, but the OTC pharmaceuticals business has been at its highest revenue level for the five consecutive years, with a YoY growth rate of 11.6%. Five years ago, we spun out our division, which we called the pharmaceutical and trading division, into a separate company called SHIONOGI Healthcare, and we have been managing the company quite actively since then. The amount of JPY14.6 billion in the last fiscal year was double as we spun out the division at JPY7.2 billion. Shionogi Healthcare has been recording its highest earnings for five consecutive years, so I believe that the business is performing very well.

Royalties, JPY195.8 billion for HIV franchise, an increase of JPY27.3 billion, of which about one-third is foreign exchange and two-thirds is actual business growth. We are promoting very solid growth. We believe that this will continue to be very strong in FY2024 and beyond.

Main Variation Factors of Revenue (Y on Y)



Prescription drugs

Increase
- Sales of Xocova and Xofluza
- Receipt of lump-sum income for transfer of ADHD drugs in Q1 FY2023 (One-time factors)
- Returns of Xofluza and Rapiacta in FY2022

Decrease
- Sales of ADHD drug
- Purchase of Xocova by the Japanese government in Q3 FY2022 (One-time factors)

Royalty income

Increase: Strong sales of ViiV's HIV franchise

Overseas subsidiaries/export

Increase: Sales of cefiderocol (US: Fetroja, EU: Fetcroja)

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Main variation factors for Revenue are on page nine. This is a waterfall chart of what I have just described.

I will explain on the next page, the third point is that there were almost no sales of Xofluza in FY2022 for the third year in a row. So we took all the inventory of Xofluza in the market, effectively reducing the market inventory to almost zero. We emphasized and announced our policy of not placing excess inventory on the market in the future, and we had a little complain from our front line.

That said, the inventories that were taken is inevitably no in terms of GMP, so we have to disposed them. This is not a right action in SDGs perspective, so we started making an action to not sell them excessively either to the market or wholesalers. Actual sales of Xocova and Xofluza were quite strong this year in real term, partly because we took this measure in FY2022, and the results were negative last year.

Prescription Drugs in Japan

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Infectious disease drugs	97.5	**82.9**	**85.1**	112.1	**(26.0)**	**(29.2)**
COVID-19 related products + Influenza franchise	88.6	**73.4**	**82.9**	103.6	**(29.1)**	**(30.2)**
Excludes purchase of Xocova by the Japanese government	-	**73.4**	-	3.6*	-	**69.8**
Cymbalta	4.2	**3.8**	**92.5**	5.4	**(29.3)**	**(1.6)**
OxyContin franchise	4.3	**4.2**	**97.1**	4.4	**(6.3)**	**(0.3)**
Symproic	4.9	**4.5**	**91.5**	3.4	**32.3**	**1.1**
Actair	1.0	**0.7**	**67.9**	0.5	**29.6**	**0.2**
Others	55.1	**55.0**	**99.7**	53.8	**2.2**	**1.2**
ADHD drugs (Intuniv and Vyvanse)*2	25.0	**25.0**	**100.0**	20.6	**21.4**	**4.4**
Prescription drugs	167.0	**151.1**	**90.5**	179.7	**(15.9)**	**(28.6)**

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

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

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

10

* Returns of Xofluza and Rapiacta (Recognized -5.3 billion yen in 2Q of FY2022)

*2 Includes temporary income from transfer of ADHD drugs

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Page 10. As I mentioned earlier, we have JPY73.4 billion in sales in the influenza family, with an incremental amount of about JPY70 billion, excluding the Xocova purchase by the Japanese government. The influenza related was certainly strong last fiscal, but I think we have started to move a little more positively in our sales, marketing, and M&A activities, all of which we are involved in.

By the way, you may ask Dr. Iwasaki later, but copayment is JPY9,000 on October 1, then returns to the standard rate of 30% after April. We could not anticipate fully how the prescribing rate would change each time. Although we had some concerns, we believe that it is performing better than expected at this point.

At the end of September last year, the percentage of all positive patients treated with antivirals, which was between 22% and 23% for all three drugs combined, dropped to 12% to 13% after the end of September and into October

The 10th wave was not as big as it was said. Since then, the rate has been 12% or 13% to 14%. We are wondering how much it will drop after April, when a regular 30% copayment returns. We have been thinking various patterns, but we believe that the overall prescription rate is performing a bit stronger rate than we expected, around 8% to 9%.

In this context, our market share has been very strong especially after April, including the fact that copayment is smaller than that of the other two drugs. Going forward, we believe our actions will have a strong impact on the market, positioning us well for the release of the oral COVID-19 treatment.

This April, Dr. Iwasaki and I were actually discussing how much it would decrease, but it is performing better than we anticipated. It has also been reasonably steady for April, which means that it will probably move reasonably well for the entire year. Of course, treating patients would be impossible without any patients at all, but cases are beginning to appear sporadically, and new strains with mutations are emerging in the US and starting to become problematic.

We will keep a close eye on it and continue to work on both influenza and COVID-19 in such a way that we can win alone in Japan.

Achievements in FY2023

Achieved revenue and profit growth through top-line growth and meticulous cost management

Top-line growth

Domestic business: Successfully expanded our own sales mainly in the category of infectious disease drugs

- Revenue from domestic business increased by **46.5 billion yen from the previous fiscal year excluding non-recurring factors**

Royalty income: Oral two-drug regimens and LA formulations grew dramatically

- Increased by **25.7 billion yen from the previous fiscal year as ViiV achieved steady business growth**

Overseas business: Steady progress in Cefiderocol

- Revenue increased by **7.4 billion yen from the previous fiscal year mainly through growth in the European and US business**

Profit growth

Flexible cost management in response to changes in top line

- Achieved growth in operating profit after recognizing several non-recurring expenses
- Invested aggressively toward establishing growth drivers*

* The results of the major development projects for FY2023 are described on page 39

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On page 11 describes what I just said. Our three pillars of business, namely, infectious disease drugs in Japan, royalties, and Cefiderocol overseas, have all been performing well. Our ability to generate operating profit, even with sales and R&D expenses exceeding JPY100 billion, is an area where we excel. I believe we have successfully created operating profits that provide the market with a sense of security.

Reflections on First Year of STS2030 Revision Phase2

The KPIs set forth in the STS2030 Revision have shown a promising start in alignment with the objectives of STS Phase2

	STS Phase2			STS Phase3
	FY2023 (Target)	**FY2023 (Results)**	FY2025	FY2030
Revenue	**450.0 B yen**	**435.1 B yen**	**550.0 B yen**	**800.0 B yen**
Overseas sales CAGR*	–	**17.4%** Starting from FY2022	**50%** Starting from FY2022	**15%** Starting from FY2025
EBITDA	**167.0 B yen**	**188.7 B yen**	**200.0 B yen**	–

* CAGR (Compound Annual Growth Rate)

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We released the STS Revision in June of last year, and although sales revenue fell short by JPY15 billion to JPY435.1 billion, we made a solid start in terms of overseas sales growth rate and EBITDA. We believe that we are steadily getting ready to achieve our goals for FY2025 by preparing various items in this FY2024.

Ensitrelvir: Summary of Results on the SCORPIO-HR trial

Primary endpoint	**Symptom improvement effect**	• Although ensitrelvir demonstrated a numerical reduction in the time to symptom resolution compared to placebo among participants treated within 3 days of symptom onset, the difference was not statistically significant. → A pre-defined supportive analysis of resolution of six symptoms for one day using a statistical method similar to that used in the SCORPIO-SR Study (Phase 3 part of the Phase 2/3 study of ensitrelvir conducted in Asia) yielded a significant difference ($p<0.05$) in the time to resolution of symptoms
Secondary endpoints	**Effect for Long COVID**	• Ensitrelvir did not demonstrate a statistically significant reduction in the proportion of participants with post COVID-19 symptoms (Long COVID) at three months, but there was a tendency for a higher proportion of participants to report "having returned to pre-COVID health" and "felt no fatigue" compared to placebo. → Further detailed analysis is planned, including additional follow-up at six months.
	Antiviral effects	• Ensitrelvir demonstrated a potent antiviral effect for both viral RNA and culture, compared to placebo. • Symptomatic viral rebound was not observed in this study, supporting previous findings from SCORPIO-SR.
	Hospitalization and death prevention	• No deaths were observed in either group up to Day 29 of follow up, and very few cases of COVID-19 related hospitalization were observed in either arm.
Safety		• No new safety concerns were identified. • Ensitrelvir had similar tolerability to placebo and there were no reports of taste disturbance.

14 SHIONOGI

Now, I would like to talk about the results of the ensitrelvir once again, which we disclosed yesterday, in terms of the efforts and the results in in FY2023 and FY2024.

One prerequisite that we have to share with you is this study was funded by the NIH and NIID and conducted under the auspices of the NIH. Frankly speaking, we can use the results in our application for approval, but since the NIH is responsible for disclosing and communicating the trial results and how to do it, we cannot fully incorporate our intentions.

Additionally, about the press release we issued yesterday, to the best of our ability, we have clarified the nuances of how and by whom the trial was conducted.

In that regard, the primary endpoint was not met, but the NIH is preparing to publish the results at an academic conference or in a paper. This publication will detail how much the primary endpoint was missed and whether there was a significant difference, using the same statistical method as the SCORPIO-SR study conducted in Asia. We have already begun communicating with the FDA and other health authorities in the hope that they will show understanding to our discussions with the NIH and allow us to apply for approval.

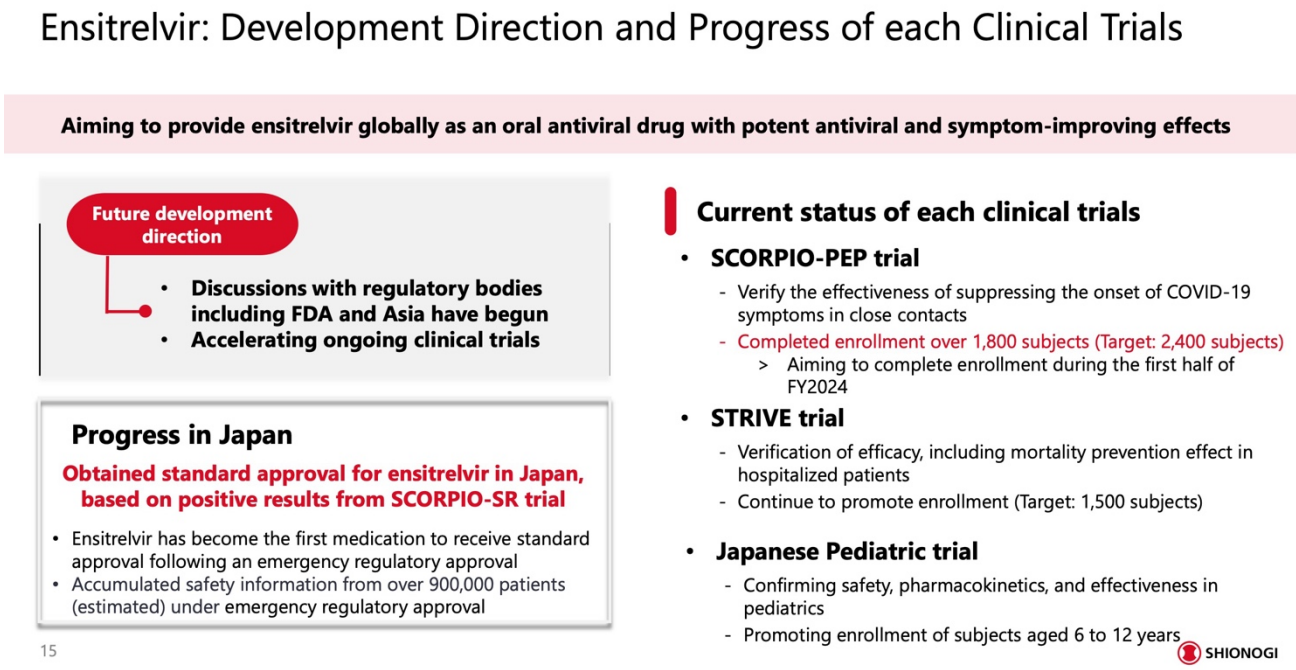
It also goes for the Long COVID. This is for three months and all 15 symptoms. Overall, there is no significant difference, however, as with the SR study conducted in Asia, some symptoms are strongly suppressed while others are not, showing considerable variability.

At this point, we can observe that while some patients have returned to their pre-COVID-19 health, others are experiencing severe fatigue and difficulty resuming their daily lives as long-term COVID-19 patients. It is encouraging that patients who took the drug have shown favorable results. We plan to conduct a six-month follow-up and will analyze the results, including those from the follow-up.

For the same reason as before, I cannot say what the level of antiviral effect is, but the amount of virus at the start of the trial has been considerably reduced compared to previous clinical trials. The fact that it has decreased considerably means that it is difficult to lower further from the point where it has decreased. In this situation, the effectiveness of the antiviral drug is clear. Therefore, we believe that its impact is significant, and our company can help people.

Another point to consider is that SCORPIO-HR, which stands for high-risk, did not enroll as many hospitalized or high-risk individuals as we hoped, despite numerous requests specified in the protocol. In effect, although the study is named SCORPIO-HR, it essentially functions as the GLOBAL SCORPIO-SR study. Therefore, I believe the results are predominantly applicable to standard risk situations.

In terms of safety, it is really safe that there is little difference compared to placebo. When we received the official approval more than a year later, we are now more confident that the drug is very safe, which of course is strictly monitored in Japan.



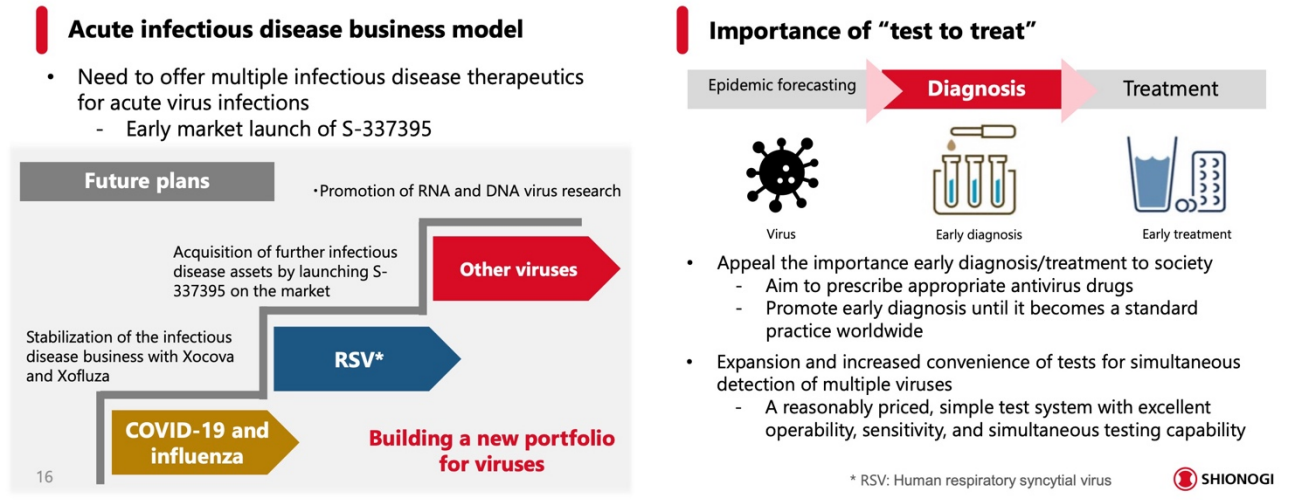
In response to this, I have already said but we have begun communication with the authorities. Of course, we would like to update you at times for feedback we receive. From our point of view, we are steadily working on it.

We are conducting a global prevention study, or prep study. Additionally, we are carrying out the STRIVE study, which specifically targets hospitalized patients. We have long considered this approach in patients with severe illnesses.

Also, for domestic pediatric patients, we are addressing the increasing number of domestic pediatric patients, where Mr. Uehara is facing challenges but we are working on this bit by bit. We are striving to differentiate our products from those of other companies globally, as they typically do not offer products for the rare age group of children between 6 and 11 years old.

Toward Further Stabilization of Acute Infectious Disease Business Model

Aim to realize a "diagnosis and treatment" paradigm with a comprehensive virus treatment portfolio



Page 16. On the left side, including what I said. For the first item of Xofluza, Mr. Iwasaki had struggle in sales activities due to no outbreak of influenza this year. I believe it was a significant advantage for us to be able to engage with doctors on various occasions and discuss both, especially during an epidemic like influenza, involving treatments such as Xofluza, Rapiacta, and Xocova.

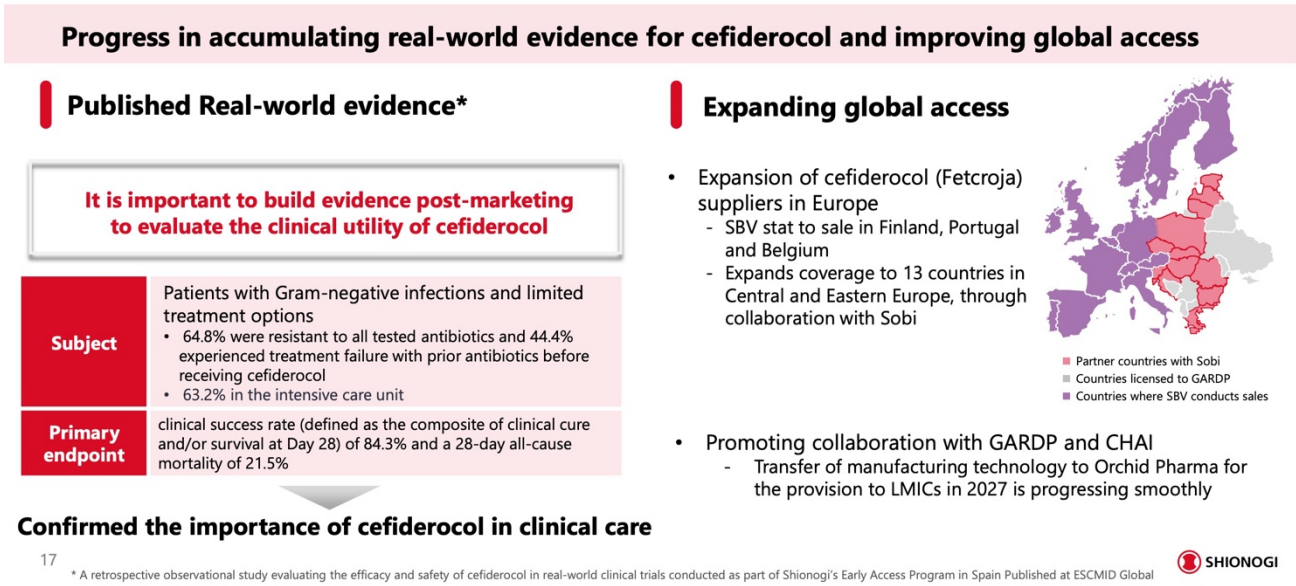
At John and Uehara's, we have also started the Phase II challenge study for RSV. Once the three respiratory infectious diseases, influenza, COVID-19, and RSV, are all in place, I believe that our business will become much more stable, and we will work to expand it globally as soon as possible.

On the right side. However, when we do this, one of the primary issues in the US and Europe is that the number of people who go to see doctors is low. Everyone got tests during the pandemic, but now they rarely get a test anymore.

If you have a test and find out that there is a virus, could be influenza or COVID-19, many people think they have to do something about it, but most people don't get a test. This is partly because taking a sample in a nasal cavity for an antigen test is still a very big hurdle.

We are collaborating with several diagnostic agent venture companies that are innovating to simplify and enhance the accuracy of diagnostics. We are exploring ways to make diagnosis easier and more cost-effective, potentially through methods that do not involve nasal swabs.

Addressing the global issue of AMR



I am sure that you have read about this real world evidence, since you, analysts are experts on Cefiderocol. We have received very high praise from doctors for achieving such good results in a place where there are many patients with AMR, multidrug resistance, and severe disease.

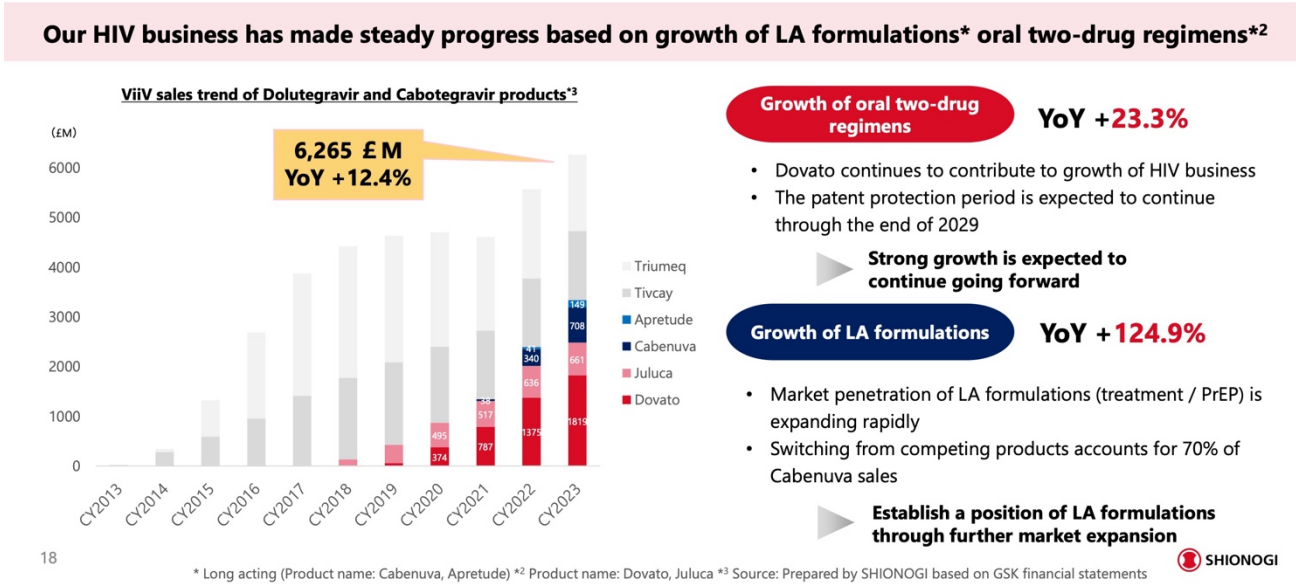
We also believe it is encouraging that the data from real world evidence is better than the clinical trial. We have to ask for stewardship or proper use of this in the end, of course, but I believe it is very encouraging to have such good data in the Real World Evidence.

Also, in that sense, we are talking in GARDP/CHAI and LMICs, but how to cover those areas in between, for example, Eastern Europe, Middle East, and so on. It is difficult for our SHIONOGI Inc. or SHIONOGI B.V., to cover everything.

However, as I mentioned earlier, we had to sell the product properly in stewardship, so we spent more than a year talking with Sobi about how we would really sell it, and we offered to sale in 13 countries.

We believe that we have chosen a very good partner, and we would like to continue to expand our business in the future.

Progress of HIV Business by ViiV

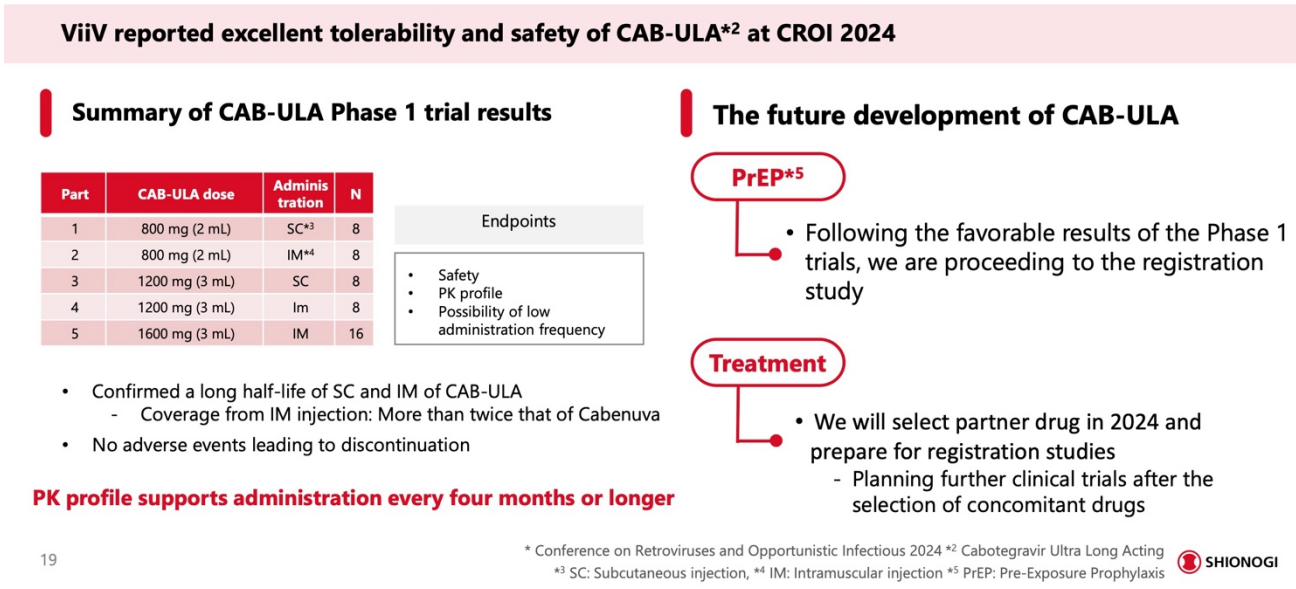


Page 18, ViiV. ViiV's sales have risen to GBP6.2 billion, or just under JPY1.3 trillion in today's yen rate. I think that the scheme of royalties has become really stable along with that.

Especially with the LA formulation has increased 125% or to 2.25 times. Excuse me, I said this straight out, but I think Gilead is probably working on three or four integrase LAs in parallel.

We acknowledge that there are very capable companies that might catch up with us, but currently, we hold a significant lead. We aim to expand this market as quickly as possible to capitalize on our current advantage.

CROI 2024* Update



So that's what we're trying to do. As for CROI's 24, I think it is very encouraging that we submitted the actual data of CAB one time in four months.

Of course, we are aware that the next integrase, including CAB and Gilead's integrase, will require even higher resistance hurdles and even longer acting time.

As for integrase, we have already released 598 integrase products after the CAB. We are not stopping there, and we are continuing our research on the third and fourth generations of integrase products.

Rilpivirine as a NNRTI is a good drug, but whether it will last forever, a possibility to build resistance against Rilpivirine is not completely zero. So, we are doing research as a partner drug.

We hope to contribute to the next generation of integrase and the next generation of partner drugs in co-operation with ViiV.

Progress of Major Development Products - Infection diseases -

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

	Pipeline	Indication	Current stage	FY2024	FY2025
COVID-19 Family	S-268019	COVID-19 (Vaccine)	Submission		
	Ensitrelvir	COVID-19	Submission・Phase 3 Phase 3 (Pediatric)	Phase 3 topline results (FY24 4Q)	
	Ensitrelvir	COVID-19 (prevention)	Phase 3 † Data analysis in progress	Phase 3 topline results (FY24 3Q)	
	S-268023	COVID-19 (XBB1.5,Vaccine)	Phase 3		
	S-892216	COVID-19	Phase 1	Phase 2 start (FY24 2Q) topline results (FY24 4Q)	
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	Phase 1/2 start (FY24 4Q) topline results (FY25 2Q)	
Infection diseases	Olorofim	Invasive aspergillosis	Phase 3		
	S-337395	RSV infections	Phase 2		
	S-743229	AMR (Complex urinary tract infection)	Phase 1	Phase1 (combined use) topline (FY24 3Q)	
	S-649228	AMR (Gram-negative bacteria infection)	Preclinical	Phase1 (combined use) start (FY24 2Q) topline results (FY24 3Q)	

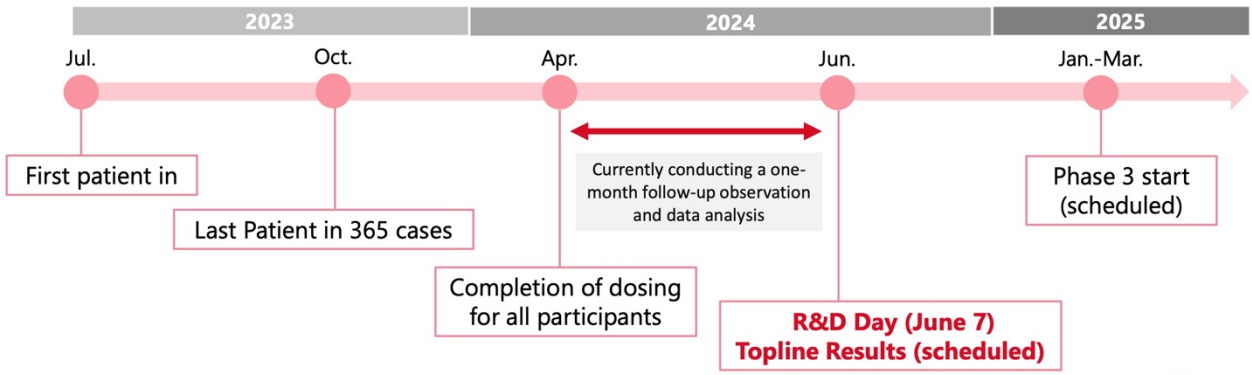
20 SHIONOGI

This is the pipeline.

S-309309 Development Progress

Top-line disclosure is scheduled for R&D Day

Status of progress



22 SHIONOGI

Now let me move on to QOL diseases. The follow-up for S-309309, for which you are all looking forward, will be completed on May 15, or tomorrow or the day after tomorrow. One-month follow-up for the last patient will be completed. We will do our best to analyze and submit the data in time for R&D Day.

At that stage, based on the results if possible, we would like to have a suggestive discussion about what we will do afterwards, although it is not completely definite.

Introduction of MZE001, a New Therapeutic Drug Candidate for Pompe Disease

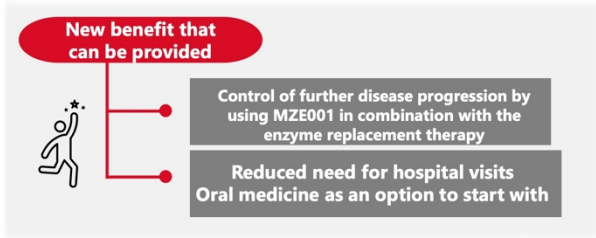
Aim to cause a paradigm shift by a low-molecular therapeutic drug for Pompe disease whose unmet needs are high

What is Pompe disease?

- A genetic disorder characterized by dysfunction of acid α-glucosidase
  - It causes an accumulation of glycogen in cells due to a deficiency in glycolysis
    - > Symptoms include motor dysfunctions, respiratory disorders, and cardiac dysfunctions
- Enzyme replacement therapy (intravenous drip) is the only existing therapy
- The market size for therapeutic drugs is estimated about $1.0 billion and is expected to increase going forward

Characteristics of MZE001

- Novel oral GYS1* inhibitor
  - It inhibits the synthesis of glycogen, which is the cause of accumulation in cells
- The only small molecular drug in the clinical development stage
  - As its mechanism of action and route of administration are different from those of the existing therapy, it may be able to provide new benefit to patients

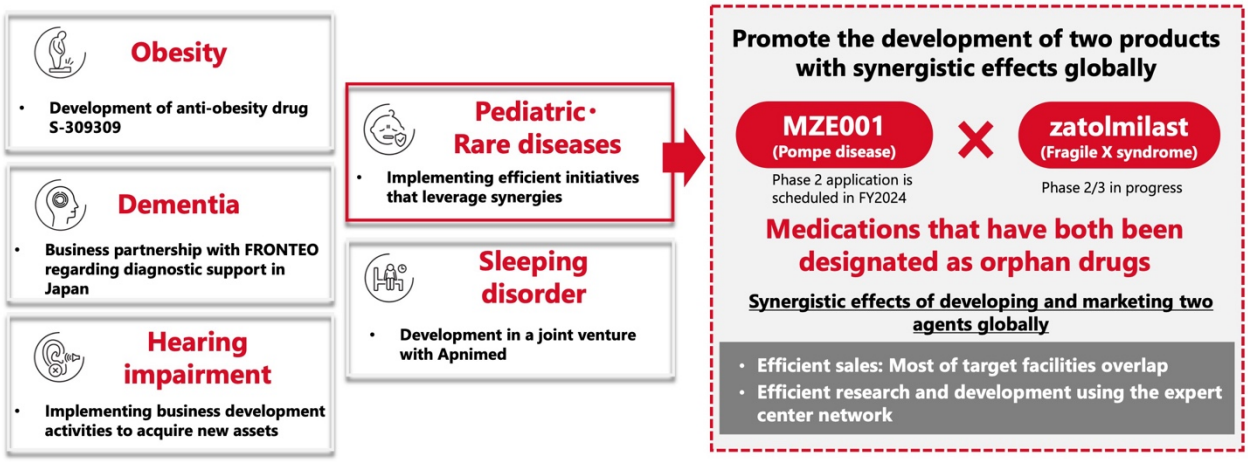


* Glycogen synthase1 *2 Can genes influencing muscle function affect the therapeutic response to enzyme replacement therapy (ERT) in late-onset Type II Glycogenosis? *3 Questionnaire survey on home enzyme replace therapy for lysosomal storage disease patients (N = 23, 2020)

SHIONOGI

Promoting the global development of treatments for diseases affecting QOL

Progress in global initiatives for pediatric diseases and rare diseases



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Introduction of MZE001 for Pompe disease. You may wonder what is going on all of a sudden, but we have been in talks with Maze since the end of last year. There are two points. One is that we have always been saying that we do pediatric. Of course, we have been working on pediatric development in infectious diseases, and I have actually been invited as a panelist at pediatric conferences. Symbolically, for instance, converting Baktar tablets into mini tablets is unlikely to be profitable. However, we would like to try hard for doing what is necessary for children.

We are aiming to make pediatrics the next cornerstone of our business. This is an oral drug for Pompe disease which is small molecule. Currently, we are collaborating with two companies to develop a substantial market in the field of enzyme replacement therapy, which you will likely see emerging soon.

We hope that we can somehow contribute to this area by replacing enzyme replacement therapy, or even if we cannot replace it, we hope that we can reduce enzyme replacement by using the combination. We think we can contribute to this area.

We believe that Maze possesses strong capabilities in the area of low-molecular weight. After discussing with them, we have found them to be a truly interesting company. They were originally looking for a partner for this Pompe disease, as they are renal specialists and wanted to specialize more in the renal area.

The BPN14770, zatolmilast, is a fragile X, which is used for both young children and adolescents, and we are seeing good results in this area as well. I have a feeling that we could obtain a good pipeline for a rare disease in children to franchise it.

At the R&D Day, I would like to delve a little deeper into Pompe disease, and I would like to be able to discuss with you what we are talking in terms of marketing.

Regarding obesity and dementia, as you may have seen in today's online news, we are collaborating with FRONTEO to diagnose mild cognitive impairment (MCI) and mild dementia through AI, by engaging in dialogue and conversing with patients. We believe this is an intriguing project with a high degree of applicability.

Including this, it is very interesting mechanism in the Alzheimer's part, BPN14770, as I mentioned earlier. We had to stop because of safety concerns with an elderly person. We have managed to create a backup compound for this and are now in the final stages of preclinical testing. So, we would like to somehow get this started. For this purpose, we would like to promote the diagnosis of dementia and MCI.

We are working with Apnimed to start clinical trials for OSA in the middle of this fiscal year, and we are also in talks with several companies about partnerships for hearing loss. We are currently making steady progress in the five areas, obesity, dementia, hearing loss, rare diseases in children, and sleep disorders, in the past year and this year.

We would like everyone to see what we are really doing as much as possible, and what our next milestone should be, including the R&D Day.

So let me move on to the forecast for FY2024. Page 27. For the next fiscal year, as I mentioned earlier, we have already begun discussions with the FDA and other health authorities regarding Xocova and Ensitrelvir. Although we have received fast-track status from the FDA, completing the timeline will take eight months. Therefore, even if successful, it may not be ready by March 2025 or within FY2024

This is the best estimate, so we do not include sales in this fiscal year. The current three pillars, drugs for acute respiratory infections in Japan, including Xocova and Xofluza, global expansion including Cefiderocol.

l, which Sobi has spread in 13 countries, plus sustained growth of the HIV business. As for the top line, we are trying to build sales as much as possible around these three pillars.

As I mentioned earlier, we are proceeding with the consolidation of all sales under Mr. Iwasaki. As part of this transition, we have decided to offer early retirement to 300 employees in Japan. I believe we need to quickly establish not only a domestic but also a global headquarters, which includes strategizing on how to attract the next generation of talent.

In fact, since the end of last year, we have been seriously and actively working to transform our corporate headquarters into a global headquarters. First, for the accounting and finance and the HR functions, we do not plan to explore overseas but rather, we would like to invite key young employees from the US and Europe come to us to build these functions. At the same time, we are also actively seeking new career opportunities.

Domestic Business Progression in FY2024

Aiming to further grow domestic business by continuously introducing new products to the market

Focus items

Xocova — COVID-19 treatment

Xofluza — Influenza virus infecion treatment

- Promote early diagnosis and treatment
- Aim for continued stable growth as an important asset for acute respiratory infections

Fetroja — Various infectious diseases treatment

- Obtain regular domestic approval in FY2023
- Providing a new option for patients suffering from infections caused by drug-resistant bacteria

Symproic — Opioid-induced constipation

- Expanding market share through switching from other drugs
- Promoting efforts to raise awareness of opioid-induced constipation

NEW

Daridorexant — Insomnia Treatment

Sales Timing	**Sales are scheduled to begin in the second half of 2024**
Mechanism	A dual orexin receptor antagonist that selectively blocks the binding of wake-promoting neuropeptides
Product Characteristics	There is a possibility that it could become a best-in-class treatment that meets the unmet needs of insomnia patients

After Nxera Pharma Japan obtains manufacturing and sales approval, we will begin sales together with Mochida Pharmaceutical*

28

* Announcement of the Sales Partnership Agreement in Japan between Shionogi and Mochida regarding Insomnia Treatment Drug Daridorexant

SHIONOGI

This is the domestic business. Page 28. As I mentioned earlier, in addition to Xocova, Xofluza, and Fetroja, the three infectious disease drugs, Iwasaki's group is seeing a steady growth in painkillers, especially a narcotic, including Symproic, although we are still working on OxyContin. We will focus on these four drugs, and we will also plan to work with Mochida on Daridorexant, an orexin compound, which we have looked at a number of things and think is best in class. I am not saying that there are no competitors, but I believe that we can compete with them because they are good products.

Enhancing Global Sales System

Further accelerate globalization by unifying sales systems in both in Japan and overseas

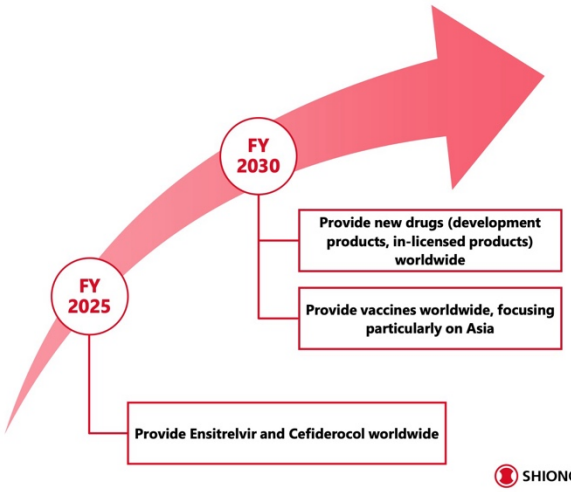
FY2023

- **Domestic sales**
  - Achieved growth and stabilization of profit with Xocova and the influenza family
- **Overseas sales**
  - Established a presence in the infectious disease area through the growth of Cefiderocol

Future Initiatives

Integration of our global sales system into the Healthcare Business Supervisory Unit

- Centralization of various functions from marketing to sales on a global basis
- Global maximization of product value by sharing product sales knowhow centered on Ensitrelvir and Cefiderocol



29

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Regarding our global business, this is a continuation of what I mentioned earlier, but we aim to establish a headquarters system by FY2024 that can compete internationally. Following that, starting from 2025, we plan to set specific targets for overseas expansion, including for Xocova and Xofluza.

Initiatives to Become a Globally Competitive Leader

Strengthening the company platform and human resources in order to be a globally competitive leader

Strengthening the company platform

- **Strengthen global corporate functions**
  - Change in the structure of the Corporate Strategy Division
    It now also oversees also the Human Resources Department to globally manage the effective use of budgets and human capital

Building a platform to support group-wide optimization of management resources of the SHIONOGI Group in response to the globalization of its business

×

Strengthening human resources

- **Reform of the human resources system**
  - Ensuring appropriate treatment by re-grading all employees
  - Competitive compensation plans
- **Implementation of a special early retirement program**
- **Securing and retaining human resources necessary for growth**
  - Enhancing mid-career recruitment
    Hiring excellent human resources related to globalization, establishment of vaccine business, and digital transformation

SHIONOGI

The next page 30. As for corporate functions, the Board of Directors met yesterday, and we have been given strict guidance on our corporate governance and sustainability, both qualitative and quantitative. I believe that we are making strong efforts as a company to address these issues.

In this context, our significant challenge is to develop our human resources while strengthening our management base. Reflecting on the purpose behind the 300 early retirements, I realize that we aim to enhance our head office functions to transition to the next stage; conducting global R&D and sales.

Financial Results

Earnings forecast

- **Both revenue and operating profit are expected to achieve record highs for the third consecutive year**
- **We plan to increase profits in all profit items**
  - **Profit before tax and profits attributable to owners of parent will also post increases**
- **Investment toward achieving STS2030 will be accelerated further**

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	455.0	210.0	435.1	4.6	19.9
Operating profit	160.0	69.0	153.3	4.4	6.7
Profit before tax	200.0	82.5	198.3	0.9	1.7
Profit attributable to owners of parent	163.0	66.5	162.0	0.6	1.0
EBITDA*	-	-	188.7	-	-

Exchange rate (average)

	FY2024 assumptions	FY2023 results
USD ($) – JPY (¥)	145	144.59
GBP (£) – JPY (¥)	178	181.72
EUR (€) – JPY (¥)	155	156.76

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

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This is a consolidated forecast. We plan to achieve record highs for the third consecutive fiscal year, with sales revenue of JPY455 billion and operating profit of JPY160 billion, up 4.6% and 4.4%, respectively. I don't know if it is appropriate to say this, but our internal budget is considerably higher than this. I would like to spend the second year of Revision properly communicating to everyone that we will definitely be able to deliver.

In the meantime, we plan to make various preparations, and we are working to achieve the figures for FY2025.

We are considering a slight increase in profit before taxes and net profit, respectively, compared to the previous year.

Statement of Profit or Loss

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change (%)	Change
Revenue	**455.0**	**210.0**	435.1	**4.6**	**19.9**
Cost of Sales	**66.0**	**28.5**	57.6	**14.6**	**8.4**
Gross profit	**389.0**	**181.5**	377.5	**3.1**	**11.5**
Selling, general & administrative expenses, R&D expenses total	**226.5**	**111.0**	206.0	**9.9**	**20.5**
Selling, general & administrative expenses	**106.5**	**52.0**	103.4	**3.0**	**3.1**
R&D expenses	**120.0**	**59.0**	102.6	**16.9**	**17.4**
Other income & expenses	**(2.5)**	**(1.5)**	(18.1)	**-**	**15.6**
Operating profit	**160.0**	**69.0**	153.3	**4.4**	**6.7**
Finance income & costs	**40.0**	**13.5**	45.0	**(11.1)**	**(5.0)**
Profit before tax	**200.0**	**82.5**	198.3	**0.9**	**1.7**
Profit attributable to owners of parent	**163.0**	**66.5**	162.0	**0.6**	**1.0**

SHIONOGI

This is the P&L for sales revenue, etc. We set cost of goods sold a little high, an increase of 14.6%, or JPY8.4 billion. It will probably be a little lower than the previous budget but I would like to start the budget in this area.

Then there is JPY120 billion for R&D. We have S-309309, which I mentioned earlier, MZE001(Pompe disease), zatolmilast (BPN14770), and S-005151. Most of our development activities are centered in the US and Europe. Most pharmaceutical companies, the weak yen will significantly impact our development activities in the US and Europe. Therefore, while we continue to conduct our activities, we are setting somewhat higher monetary targets.

At this point in the current fiscal year, we do not expect to incur any special expenses. Therefore, we believe that we will be able to achieve JPY160 billion in operating profit.

Revenue by Segment

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change(%)	Change
Prescription drugs	**134.9**	**58.0**	151.1	**(10.7)**	**(16.2)**
Overseas subsidiaries/export	**53.7**	**24.7**	49.9	**7.6**	**3.8**
Shionogi Inc. (US)	**20.6**	**10.0**	17.9	**15.1**	**2.7**
Shionogi B.V. (EU)	**14.4**	**6.8**	13.6	**6.1**	**0.8**
Ping An Shionogi/C&O	**11.2**	**4.7**	10.6	**5.5**	**0.6**
Others	**7.5**	**3.2**	7.8	**(4.2)**	**(0.3)**
Contract manufacturing	**15.5**	**6.5**	17.6	**(12.0)**	**(2.1)**
OTC and quasi-drug	**16.6**	**8.0**	14.6	**13.3**	**2.0**
Royalty income	**232.5**	**112.2**	200.4	**16.0**	**32.1**
HIV franchise	**224.6**	**111.2**	195.8	**14.7**	**28.8**
Others	**7.9**	**1.0**	4.6	**72.6**	**3.3**
Others	**1.8**	**0.6**	1.4	**25.3**	**0.4**
Total	**455.0**	**210.0**	435.1	**4.6**	**19.9**

33

SHIONOGI

In terms of revenue by business segment, domestic sales were negative JPY16.2 billion because we think we will be unable to cover the JPY25 billion one-time ADHD payment in FY2023. If we do not have the one-time payment of JPY25 billion, it means that we will have an increase about JPY10 billion in actual performance.

It shows the below, but the plan is to increase revenue by JPY6.7 billion mostly with COVID-19 and influenza drugs in Japan.

As I mentioned earlier, we now have the results of the Xocova revenue for April and the first week of May. Our analysis of patient trends, market usage of Xocova, and how it's being used indicates that achieving our goals would be very challenging if no patients appear at all. However, we have developed a plan based on the assumption that patient numbers will match those of the 10th wave or a regular wave.

SHIONOGI Inc. will increase by 15.1% and SHIONOGI B.V. increase by 6.1%. Total sales of overseas subsidiaries will be JPY53.7 billion or 7.6 % increase. We would like to achieve this by growing overseas sales, and after all, I believe that Fetroja and Fetcroja have been performing well.

We are aiming for the highest sales of OTC drugs for the sixth consecutive fiscal year, while we are looking at royalties a little conservatively. However, with an increase of 14.7% or JPY28.8 billion, we are aiming to surpass JPY200 billion, the first actual figure for an HIV franchise. This target is not unrealistic considering ViiV's current sales forecast.

Prescription Drugs in Japan

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change(%)	Change
Infectious disease drugs	**91.2**	**37.6**	82.9	**9.9**	**8.2**
COVID-19 related products + Influenza franchise	**80.1**	**32.7**	73.4	**9.1**	**6.7**
Symproic	**6.5**	**2.9**	4.5	**43.9**	**2.0**
OxyContin franchise	**5.0**	**2.3**	4.2	**20.4**	**0.8**
Actair	**1.4**	**0.5**	0.7	**100.4**	**0.7**
Cymbalta	**3.3**	**1.8**	3.8	**(13.7)**	**(0.5)**
Others	**27.5**	**12.8**	55.0*	**(49.9)**	**(27.4)**
Prescription drugs	**134.9**	**58.0**	151.1	**(10.7)**	**(16.2)**

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

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

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

34

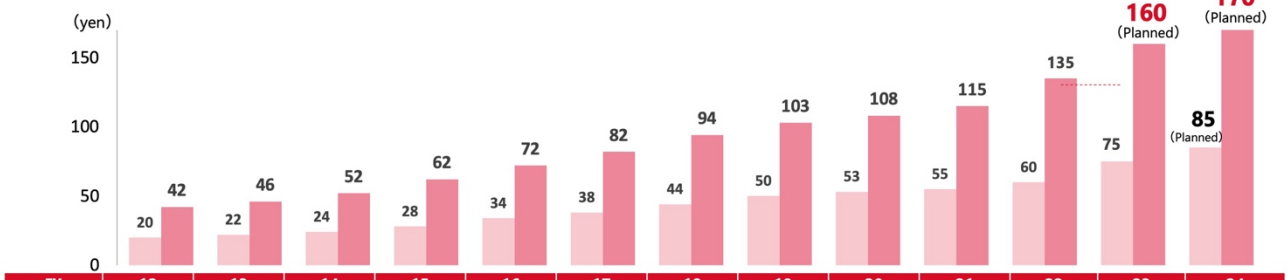
* Includes temporary income from transfer of ADHD drugs

SHIONOGI

Regarding the domestic in P.34, I just explained.

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
- FY2023 is the largest annual dividend increase (+25 yen)
- Plan to increase dividend again for the 13th consecutive year in FY2024



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

36

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

*2 Resolution passed on July 31, 2023, and treasure shares cancelled on April 17, 2024

Values calculated based on IFRS after 2019

SHIONOGI

Finally, it is about shareholder returns. We will propose a dividend of JPY85 at the upcoming general meeting of shareholders. If this is approved, we plan to increase the dividend by JPY25, or JPY160 for FY2023, which is the largest increase we have ever planned.

In response, we have decided to start FY2024 with a DOE of 4%, setting initial targets at JPY170, JPY85, and JPY85. After aiming for the best possible results at the year-end, we will consider the possibility of increasing the year-end dividend. This will be discussed further in Board of Directors meetings and other relevant forums.

That's all I have to say. Thank you very much.

Kyokawa: Thank you very much.

Question & Answer

Kyokawa : Let's move on to the Question & Answer session. Mr. Ueda, go ahead.

Ueda : My name is Ueda from Goldman Sachs. For my first question, I would like to ask you about Xocova. Can you give us some background on the failure to meet the primary endpoint in this HR study, including whether it is a difference in patient enrollment or a difference in the primary endpoint? I would also like to ask your comment on how you plan to achieve practical application on a global scale. Thank you.

Uehara : Thank you for your question. Uehara will answer your question. One thing is this is an antiviral drug, and the patient's own viral load was lower than the study under SCRPIO-SR. Even before the medication is taken, the amount of virus is quite low at a baseline, although I will avoid specific numbers. Even under this condition, we were able to confirm that those who took the medication, we confirmed that viral load was clearly and significantly lowered. So, we were able to confirm the so-called antiviral effect of the antiviral drug.

In such a situation, the question is how the symptoms are improving and how quickly. The endpoints we have established for this study are aligned with the global standard, which dictates that symptoms must disappear completely from body across all 15 symptoms and be maintained for 48 hours.

In fact, as I am sure you all do, it is not easy to have a morning when everything is completely fine in your body, without fatigue, headache, cough, nose, and so on. Therefore, even when patients are actually cured, they are typically required to monitor their symptoms daily. Consequently, the number of patients who meet the criteria for complete symptom disappearance remains small. Given these considerations, it becomes difficult to make a difference from a statistical point of view.

In contrast, if we use the definition of SCRPIO-SR from Japan and Asia, the result clearly falls below the 0.05 criterion from a planning perspective. The results show that there was no significant difference in the pre-defined main evaluation, although there was a clear trend in the effect.

Regarding our next steps, one approach is that we have a successful SCRPIO-SR that met its primary endpoint. We are currently discussing with various authorities the possibility of applying for approval based on the data from this SCRPIO-SR. As a result, many agencies have responded that if we are conducting another test, they would like to evaluate comprehensively based on the results of such a test.

We have one successful study and the trend has been confirmed in global patients this time. So, based on the many safety data we have received in Japan, we are now in the process of discussing with the respective authorities what they think about this drug as an antiviral agent.

Ueda : Thank you very much. My second question is in the area of HIV. I would like to know the significance of the data presented at the CROI this time and your thoughts on it. If it can be administered at intervals of four months or longer, it will be possible to administer the drug in conjunction with hospital visits, and I think that this will considerably increase the convenience of treatment and prevention. Can you share your thoughts on the positive impact you expect this LA formulation to have on market penetration and its significance?

Keller : Thank you very much. It has been shown that with the new formulation of cabotegravir, administration is possible at least once every four months. This could also align well with the timing of viral testing. For patients, this means that instead of taking medication daily, they would only need to visit the clinic three times a year.

Additionally, we need to select combination candidate drugs for treatment by the end of this year. We are considering partners, such as those offering broad-spectrum neutralizing antibodies. Our goal is to obtain approval for the preventive administration every four months by 2026, and for the treatment by 2027.

Kyokawa : Mr. Hashiguchi.

Hashiguchi : My name is Hashiguchi from Daiwa Securities. I would like to know your opinion on how you think the results of the Xocova SCRPIO-HR will affect the willingness of Japanese doctors to prescribe the drug. If you think there is an impact, I would appreciate your comment on what data and what ideas are affected, including the reasons.

Iwasaki : I will answer your question. I spoke with doctors in Japan, and they have very different ideas about therapeutics. For example, we do not see impact from doctors who believe that simply having an antiviral effect is sufficient for an antiviral drug. The HR test shows the same result of symptoms as SCRPIO-SR. So as far as standard risk, I, myself, do not think it has much of an impact.

Another point is that specialty doctors understand the difficulty of accurately demonstrating potential under such clinical trial. Therefore, if we focus solely on data interpretation and antiviral effects, I personally do not see any significant impact. More importantly, I believe it is crucial to convince doctors who initially think that antiviral drugs are unnecessary, in order to increase the treatment rate.

One more thing, for that reason, I think it is nonsense to argue if it works or don't work at all with current trials. For example, in the Medical Affairs section, we have data on Long COVID from our collaboration with Osaka University, Tohoku University has indicated that COVID-19 poses a higher risk of death and serious illness compared to influenza. Or efficacy under actual trials conducted by the medical association. As I mentioned earlier, it is crucial for doctors to understand which symptoms improve on which days, rather than focusing solely on the total number of days.

If I can explain the true potential of Ensitrelvir, including clinical trials in Japan and case reports, I would not say that it will have no impact on the domestic market, but I do not think it will have a negative impact.

Teshirogi : Sorry, just one thing. The use of antivirals varies greatly from country to country.

As Mr. Iwasaki mentioned, we are currently running trials for Long COVID, hospitalization, and disease severity control with a considerable number of hospitals and doctors involved. We will continue to run such trials so I have little concern about how the drug will be used in Japan, beyond how it is used globally.

Hashiguchi : Thank you. Just one more point, I would like to confirm Mr. Teshirogi's statement in his explanation about the plan for royalties. When you say that royalty is a little conservative and HIV is not so strange, did you make a distinction between the two? Or did you mean HIV is a little conservative? Or did you say that there is some conservative element outside of HIV?

Teshirogi : No, sorry. We are unable to make HIV sales forecasts, so we have to make royalties based on ViiV's opinion, so we have to be firm in that area.

Hashiguchi : So, it does not mean that anything other than HIV is conservative.

Teshirogi : No. Sorry.

Hashiguchi : My apologies. Thank you very much.

Teshirogi : No, not at all.

Kyokawa : Thank you very much. Now, Ms. Haruta.

Haruta : I am Haruta from UBS Securities. Thank you. I would like to confirm about S-309309. I would like to know more about the Phase II data, which will appear in the R&D Day. I would like to get some more suggestions from you there. Looking at the R&D expenses, will your company start Phase III immediately and then proceed with partnering activities from there? I would like to know how you proceed with partnering there.

Also, I believe that the 8% to 10% weight loss targeted by this 309309 is aimed at people who do not need to urgently address their obesity. I would like you to clarify what such a target group looks like, more so than before. I had the impression that you were saying that you were going to target Asia. What is the regional profile you have in mind?

Keller : I'll start with the budget. The budget plan, Phase III, is the first thing we are going to do on our own. If we get results that support, it. And I expect it will take about nine months to find a partner. We do not want to delay Phase III, so we are planning with that in mind.

As for the profile, we are not focusing exclusively on Asians. This GLP-1 weight loss was too fast, and it was too great. For example, that there is a change in the face and a loss of muscle strength.

I think there are some people who need to reduce it this greatly, or some who are very sick. However, for normal obese patients, this is a too match, which means it is not healthy, in many ways. Some doctors do not prescribe GLP-1 to the elderly very often. The reason for this is that muscle weakness occurs.

And then an additional profile that should be considered, as a form of combination therapy, is to lower the dose and reduce the side effects of the GI. I meant the gastrointestinal symptoms related to this GLP-1.

Then there is maintenance. For those who do not tolerate GLP-1 well or do not like injections, if they stop, the muscle will not return immediately, but the fat will. Then it would be possible to make up for that with more tolerable and less expensive drugs.

Haruta : Are you including GLP-1 combinations in Phase III, right?

Keller : We will start the first Phase III, and then the combined use will start at the end of the year. I believe that this would begin by working with a partner.

Haruta : Regarding the expansion of this portfolio in acute infectious diseases, I think the development of vaccines for RS virus is becoming more active worldwide. What do you envision the combination use with the therapeutic drug and the vaccine? Could you tell us about the competitive environment for RSV drugs and what you see as the strengths of your RNA polymerase inhibitors?

Uehara : I, Uehara, will answer. The widespread adoption of vaccines will not eliminate the need for therapeutic drugs. The virus is smart, so if humans immunize against it, it will get smarter and infect them again. Even if a person has been immunized or vaccinated, they can become infected again.

So, perhaps the segment may get smaller. Although the severity of RS virus infections is not likely to increase or it becomes a rare disease, we believe that RS virus infections will never disappear from the world.

In such a situation, what our drug can do is polymerase inhibition from the viewpoint of mechanism of action, so it is not entry inhibition. Although this is pre-clinical data, the antiviral effect seems to be strong. Rather than actually stopping the growth of the virus from increasing, the conditions resemble a person who has reached the peak of the virus. The virus will continue to grow until the person actually starts to show more

and more symptoms. Non-clinical studies have demonstrated that the virus can be rapidly reduced with outstanding effectiveness.

From that perspective, I think this drug would be interesting if it can produce a clear antiviral effect, coupled with data from the challenge trial the one we are conducting now.

Haruta : I understand. Thank you very much.

Kyokawa : Thank you very much. Mr. Mamegano.

Mamegano : My name is Mamegano from BofA Securities. I would like to know about Xocova in Japan. I think you mentioned that April was stronger than expected. When I look your plan, with Xofluza, I am not sure, but I think you are looking at about the same level as last year. Do you expecting the current number of COVID-19 patients and the overall number of patients to be about the same as last year, or are you taking a more conservative view and expecting to gain market share? Since other medications are also expensive, are you assuming that patients will shift from them? Could you please inform me about this?

Iwasaki : I, Iwasaki, will answer. Although we have been unable to accurately predict the epidemic, we essentially anticipate that the baseline will be the same as last year. Even if COVID-19 does not outbreak, we will try to balance the market share of COVID-19 with that of influenza, for example. Basically, we still believe that it comes down to how to increase the treatment rate.

Kyokawa : Mr. Wada.

Wada : SMBC Nikko Securities, this is Wada. Thank you very much. I wanted to ask you what is happening with the vaccine. The conventional expectation was that the plan would be ready in time for the next outbreak around early fall. Can I ask whether the COVID-19 vaccine is in your plan this time around?

Teshirogi : It is not included. It has already been announced to the May 24 meeting that the original will take. In the area of vaccines, if we first obtain the original approval and then obtain clinical data on a mutant strain and have it approved as a platform. Then, we can generally use CMC from that point forward.

JN.1 is now under WHO recommendation, but what we are doing is BA, or XBB for a clinical trial. So, we will use the data to obtain approval as a platform once again before moving on to the next stage. In reality, we aim to produce against a mutant that will be announce for April of next year, which is targeting the 2025 winter season.

On the other hand, I don't mean to be negative, but the COVID-19 vaccine has been spreading for a long time, as if mRNA was the sole winner, or rather the only one. By now, I wonder if the world is gradually recognizing the value of having options, especially for those who are severely affected by adverse reactions and questioning whether there truly no concerns about medium to long-term safety are.

The recently announced partnership between Novavax and Sanofi exemplifies the global environment, where a certain percentage of recombinant proteins, including fixed-dose combinations with influenza, will be utilized. As for safety, I feel very comfortable with recombinant proteins because they have been used for a long time.

As routine vaccinations become more widespread, inactivated vaccines may be used in some cases, not solely for mRNA. It would be advantageous if inactivated, recombinant protein, and mRNA vaccines were made available to offer patients a choice.

Of course, at the time of the next pandemic, we do not yet know which of the three will be best for the virus. In some cases, viruses that are less likely to produce mRNA may become prevalent. In that sense, I believe that it is not a bad for human to have three options.

Wada : Thank you very much. One more item, bariatric drug, S-309309. I would like to confirm that the data from Phase I, which was based on mice, showed GLP-1-like effects. I can observe feeding inhibition, and the weight suppression effect seems stronger than merely affecting the fat area.

I would like to inquire about the extent of feeding suppression observed in the Phase I data, and whether any GLP-1-like effects are present. One common side effect associated with this is gastrointestinal toxicity. I am interested in knowing if such side effects are absent even at high doses.

Uehara : Thank you for your question. First of all, regarding the weight in Phase I, as you know, most of the medications in Phase I are given to normal healthy adults. We are taking data from some healthy obese patients for verification purposes. For the purpose of looking at blood levels and safety.

We have actually collected data, but the period of stay is really limited, and the hospitalization environment forces patients to live properly. So, to speak, they lose weight just by being hospitalized. So, I have to admit that this data is difficult to read. It is really difficult to measure appetite quantitatively. Therefore, it is our opinion that nothing can be said from Phase I.

We have started Phase II, and the non-clinical data are similar to those of GLP-1. There have been no problems with gastrointestinal disorders so far. We are in a situation where adverse events are occurring in balance, including with the actual drugs. However, there is no data indicating that the number of patients discontinuing medication due to gastrointestinal symptoms was particularly high in the actual drug group.

Wada : Thank you very much.

Kyokawa : Mr. Akahane.

Akahane : I am Akahane from Tokai Tokyo Securities. We would like to confirm your performance. I am looking at pages seven, eight, and nine, and the financial results that have been completed, the gross profit margin is almost the same, the profit margin is the same, and there was Xocova in the previous year, and this is gone, and the royalty has increased but the gross profit has not changed. It is because, as the president explained earlier, Xocova, Xofluza are your own products, and their profit margins are very close to, if not identical to, the royalty rate, is that correct?

Teshirogi : Royalties are also zero cost. We have a large number of our own products with costs that are really in the single-digit range, so this is working well for us.

Akahane : Even the average gross profit is 87%, so really, it's almost like a profit. I understand. In response to that, in the assembly of the results, you said that you are looking this fiscal conservatively and you cannot make forecast for HIV at your company. Do you expect the profit margin to deteriorate by about 1.3 percentage points as well as sales? My understanding that the number is pretty conservative but internal target is to generate a little more profit. Is it correct?

Teshirogi : That is correct.

Akabane : I understand very well. Sorry, it’s last one and briefly. I know this may sound insistent. he obesity treatment drug is indeed a challenging area, especially considering the partnerships and the delicate yet significant domestic market in Japan. While there are opinions against the use of anti-obesity drugs in Japan, there is also a substantial patient population in China, with over 200 million people. Your company faces tough choices with drugs for COVID and HIV, despite having effective treatments. President Teshirogi, how do you

perceive the market in Japan, Asia, and globally, especially given the government's reluctance to expand the market? It seems like a vague situation, but it's a critical one.

Teshirogi : I think it is close to the GLP-1 concerto at the moment. I think the world will settle down at some stage. For example, in the case of people with BMI of 40 or 45 who need to lose weight to regain mobility and regain their lives, there is a need for them to lose weight at a very rapid pace.

For instance, a normal BMI of 35, or 30 in Japan, might be considered overweight, but BMI of 30 is not considered obese at all in the US. As John mentioned, the needs of these individual for losing 25% of their weight in six months, potentially including muscle loss, are not aligned with the needs for bariatric drugs.

Therefore, it is important to consider how to lose weight healthily. Losing weight can have a favorable effect on cardiovascular disease and, in some cases, mental health issues. Overall, I believe that losing weight is beneficial. I believe there is no global consensus on which population should lose weight, by what means, and to what extent. We are just beginning to explore this issue. I am sure that there will be a market for what we are trying to achieve, which is safe, hard to rebound, and at an affordable price.

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

Kyokawa : Thank you very much. Mr. Yamaguchi from Citi, please.

Yamaguchi : I am Yamaguchi from Citigroup Global Markets. I would like to ask you two simple questions. First of all, I understand that you don't have the details of the Xocova trial results yet, but in the domestic trial, it was positive for the five symptoms. I think you are also looking at various other symptoms as well. I don't think you did not get positive results for all of symptoms domestically, but I think there were some symptoms that were less likely to be seen domestically, like neurological things. I wonder how are SCRPIO-HR went and did it show similar tendency? Sorry, this is a detailed question. Is there anything you can comment on when compared domestic and overseas?

Uehara : Thank you for your question. Regarding SCRPIO-SR data, as you mentioned, there is a significant difference in the five symptoms. It is a bit more detailed, but there is no significant difference in 12 symptoms, and there is a significant difference in 14 symptoms. So, we are going back and forth on this boarder.

The reason why the 14 symptoms identified in SCRPIO-SR are considered 15 internationally is that one symptom, nasal congestion, has been split into two categories: nasal congestion and runny nose. Thus, what was categorized as 14 symptoms in Japan is now evaluated as 15 globally. Therefore, the results indicate that the 14 symptoms in Japan show a significant difference, but they appear differently on a global scale.

The neurons and neurological symptoms that you mentioned is not included in this 14 or 15. symptoms. In fact, neurological symptoms are often taken as post-COVID-19 symptoms like Long COVID, such as brain fog and poor concentration.

The primary results of this evaluation of acute respiratory infections were based on 15 symptoms, including respiratory symptoms, general symptoms, gastrointestinal symptoms, taste, and sense of smell.

Yamaguchi : I understand. Thank you very much. Secondly, just to confirm, the development schedule for the S-309309 remains unchanged from previously. The top-line timing is now set for R&D Day. The dates for Phase III and related timelines are as originally disclosed. From this consistent schedule, can we infer whether the project is progressing well or not?

Uehara : As you commented. Since we are still running the entire trial, the timing is just before the R&D Day when we will be able to completely clean up and lock up all the data for disclosure. So, there is no change at this time in our activity plan for this fiscal year, including Phase III.

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

Kyokawa : Thank you very much. Now, please continue Ms. Sogi of Sanford C. Bernstein.

Sogi : I am Sogi. Thank you very much. I have two questions. First of all, you have kept the STS Phase II target of JPY550 billion in sales by 2025. I understand that the revenue will grow by about JPY100 billion from FY2025 and beyond when compared to the 2024 guidance. I think this is what President Teshirogi was referring to when he said that the bullets will be loaded next year, and that the JPY100 billion will grow for 2025. What makes you confident that the JPY100 billion growth will be achieved for 2025?

Teshirogi : Of course, I cannot share the details, but we are thinking of expanding Xocova globally, as I mentioned earlier, in part. We have been making quite a few moves, including other things. So, we think that some of those moves will go far enough to achieve the sales growth. I'm sorry, it's not something I can say, but I am being quite proactive right now.

Sogi : Thank you very much. If you do so, I think this globalization of Xocova becomes a key. However, as was mentioned in yesterday's announcement and in today's discussion, the primary endpoint of SCORPIO-HR was not met. Then, I think that would be a significant increase in uncertainty. What are your thoughts on this?

Uehara : Thank you for your question. There was an enough possibility of uncertainty even before the results came out, so in that sense, I would say that uncertainty is uncertainty, and we will proceed based on this.

Incidentally, as for the treatment indications, there are two bullets that can be loaded, and the rest is data from the Real World Evidence in Japan. In other indications, there is no drug that is covered by prophylaxis in the oral formulation. The third phase of this project is already reaching its climax.

Therefore, we would like to draw your attention to the various activities involving Xocova and encourage you to look data from a comprehensive perspective.

Sogi : I understand. Thank you very much. And one more point. In the 2023 results, the top line was slightly below target while the bottom line was high. I understand from looking at the numbers that you were able to keep SG&A and R&D costs down. Was there a cost reduction this time, or was something planned to be postponed due to the cut?

Teshirogi : I may get in trouble when I say this, but we have always been pretty firm on the cost side. So, I don’t think there is anything we didn't do at all, or that we did everything we should have done, especially since the Board is concerned that we are spending too much money.

We are relatively good at how to land a project, including that. So, we are trying to find a good combination of the two as we continue to search for a landing point. In terms of activities, we are almost always doing at full strength.

Sogi : I understand. Thank you very much.

Teshirogi : Thank you very much.

Kyokawa : Thank you very much. Next, JP Morgan, Mr. Wakao, please.

Wakao : My name is Wakao from JPMorgan Securities. Thank you very much. Let me briefly review a few things. The first one is Xocova. Based on these results globally, you are now consulting with the authorities. Can you please let us know if there is anything regarding the timing that might clarify whether or not the application is possible? In particular, if you know when you will know the eligibility to apply for the FDA, or if you have any assumptions, I would appreciate if you can comment on this.

Uehara : Thank you for your question. We are in the process of starting consultations, so it is not our decision to make and we cannot make any promises. I think we can see some kind of future policy in the range of a few months, well within the range of one hand, or two to three months, speaking from the average range.

Wakao : I understand. Thank you very much. You commented that this year's operating profit of JPY160 billion is the minimum achievable level. This will depend on the status of the infectious disease outbreak, so in the case outbreak is not as severe as you had expected, I wonder if it may or may not be possible to go ahead with the cost control.

Based on your earlier answer, if outbreak did not happen this year, is it correct to assume that the JPY160 billion is still solid because there will be a certain degree of buffer through cost control?

Teshirogi : It would be problematic to claim that there were zero cases of influenza and COVID-19, but we have budgeted about JPY80 billion in anticipation of a reasonable wave occurring. Even if it goes a little lower, I believe we can still reach the JPY160 billion line.

Wakao : I understand. On the other hand, on R&D, if this S-309309 goes well, you will start Phase III. So, may I have an impression that there is not much room for reduction? Can I think that you have more leeway on SG&A?

Teshirogi : No, it's just that R&D is not a sanctuary either. Naturally, we prioritize and fund R&D that is more important and valuable. For projects that are less critical, we have effectively managed costs by seeking collaborations with other companies or partners. I believe we have a strong track record in this area. We would like to land on the goal by considering what areas, including SG&A, and administrative expenses, are our priority and cannot be dropped.

Wakao : Thank you very much. Finally, I would like to ask about the S-309309 data you will be presenting at R&D Day. I assume that the weight loss rate at 24 weeks will be given, but as mentioned earlier in the Q&A, will you be able to disclose data on lean body mass or other such data at the time of R&D?

Uehara : We have yet to see the results of the trial, so we will be working hard to determine what and how to announce.

Wakao : I understand. I consider that the main theme will be the rate of weight loss at 24 weeks. Thank you very much.

Kyokawa : Thank you very much. Now, one more person from the Web, Mr. Tsuzuki from Mizuho, please.

Tsuzuki : My name is Tsuzuki from Mizuho Securities. Thank you very much. I think you mentioned that the prescription rate for Xocova is now at 8% to 9%. I would like to know what kind of change in market share was created for standard risk and high risk, respectively, and what kind of change was seen in the process of moving from this March to April. And for the pediatric application, when is the target date for this? These are my questions.

Iwasaki : I, Iwasaki, will answer the prescription rate. Although we do not have a detailed analysis, the treatment rate of 20% to 30% for the elderly, e.g., 75 years and older. For the 8% to 9% of the total, which is treatment rate has been maintained since April. I think 4% or 5% for young people, of course.

On the other hand, in the area of standard risk, we have a share of more than 80% based on some of our data sources. For the elderly, Lagevrio had emerged as the clear winner. One reason was that their tablets were difficult to swallow for elderly compared to ours, and our drug price, including the copayment, is half that. This cost advantage has worked well, and we now hold a 50% market share in the elderly group. Consequently, we have the top market share in both demographics.

Therefore, to reiterate, we believe that the domestic target figures will be achievable if we can raise and maintain the treatment rate.

Uehara : We are currently conducting a clinical trial for pediatric drug development. We are still short on the number of patients who can join the trial. So, as soon as the patient data is collected, we will submit it to the authorities and will move on from there.

During the pandemic, it could have been considered an emergency approval process as soon as the data was submitted. However, given the current post-pandemic situation, there has been a strong market demand to deliver pediatric drugs as soon as possible, however, regarding the speed of delivering the drug in Japan, we honestly believe that it will be challenging to meet the timeline for this winter.

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

Kyokawa : Mr. Sakai please. I think this will be the last one.

Sakai : I'm sorry. I would like to ask the president something that has nothing to do with financial results at all. You are talking about globalization quite strongly this time.

I believe that ViiV might become a bottleneck for your company's overseas expansion and global development. The better ViiV gets, how will you handle this ViiV revenue? I mean, based on what I've observed over the past 20 years, your royalty model appears to have a destiny that is difficult to deviate from.

Including this, I wonder if there will be an opportunity at some stage for you to clearly or strategically explain your company's international and global expansion plans to us. Especially after R&D. I am hoping that when the future of obesity drugs, Xocova, and vaccines become clear, you will be able to talk about it to us for some extent.

Teshirogi : I would very much like to do so. Let’s say assign John to take the responsibility for R&D. For instance, a while ago, we acquired a company which had Tetra's BPN14770. Then I asked him what PMI had conducted after the acquisition. After he joined, he established a new R&D structure. I also asked him about the PMI processes following our acquisition of Qpex. The difference in PMI outcomes was vast, the integration proceeding with Qpex went exceptionally well.

Of course, there are drugs for infectious diseases, including antibiotics, but we need to diversify our research and development efforts, especially in the US, or it will be very difficult to keep up with the current situation.

When considering how to expand globally and how much dynamism is there, we need to focus on the US and Europe. Otherwise, it is tough to develop so we do not have many choices here.

We would like to have an opportunity to discuss with you how we are planning our operations for FY2025 or FY2030, regardless of what form we may take.

Kyokawa : Thank you very much. The time has come and this concludes the briefing on the financial results for the fiscal year ended March 31, 2024, of SHIONOGI. Thank you very much for your participation today.

[END]