SHIONOGI & CO., LTD.

FY2022 Financial Results

May 11, 2023

Presentation

Kyokawa: SHIONOGI & CO., LTD. will hold a Financial Results meeting for the fiscal year ended March 31, 2023. My name is Kyokawa, Vice President, Corporate Communications Department of SHIONOGI. Thank you all very much for joining us today despite your busy schedules.

First of all, I would like to introduce today's speakers.

This is Dr. Isao Teshirogi, PhD, Chief Executive Officer. Next, this is Dr. John Keller, PhD, Senior Executive Officer, Senior Vice President, R&D Supervisory Unit and Vice President, Investment Strategy Department.

Next, I would like to introduce Toshinobu Iwasaki, PhD, Senior Executive Officer, Senior Vice President, Healthcare Business Supervisory Unit and Pharmaceutical Commercial Division.

Next, this is Dr. Ryuichi Kiyama, PhD, Senior Executive Officer, Senior Vice President, Corporate Strategy Division.

Next, this is Dr. Takeki Uehara, DVM, PhD, Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division.

Finally, this is Ms. Masako Kudou, Vice President, Finance & Accounting Department, Corporate Strategy Division.

Today, Dr. Teshirogi will give an overview of the financial results, followed by a question-and-answer session. The event is scheduled to end at 12:15 PM.

Please note that simultaneous interpretation is available for today's briefing.

Now, let me begin. President Teshirogi, please.

Teshirogi: Once again, my name is Teshirogi. Thank you for joining us today.

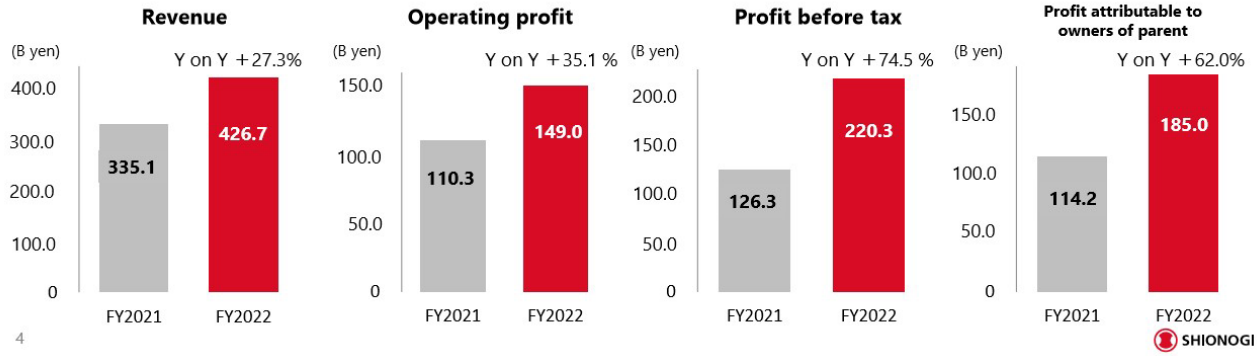
Now, I would like to present an overview of the financial results, but in addition to the numbers, I would like to explain our approach to R&D, sales, and other activities mainly, especially in the context of our guidance for FY2023 since many professional analysts are joining us today. Dr. John and Dr. Uehara will be present for R&D, and Dr. Iwasaki will be present for sales, so we would like to have the opportunity to answer your questions. Thank you.

Financial Highlights

Revenue and all profit categories exceeded record highs

- Revenue : **426.7 B yen** (420.2 B yen : FY2001)
- Profit before tax : **220.3 B yen** (174.0 B yen : FY2018)
- Operating profit : **149.0 B yen** (145.1 B yen : FY2018)
- Profit attributable to owners of parent : **185.0 B yen** (137.2 B yen : FY2018)

( ) indicate record high performance



Now, let's move on to page 4.

The numbers are listed as you see, but we have achieved a record-high performance since the establishment of the Company in terms of sales revenue and all profit items. Starting with a 27.3% increase in sales revenue to 426.7 billion yen, followed by a 35.1% increase in operating profit to 149 billion yen. Profit before taxes was 220.3 billion yen, a very large increase of 74.5%, which I will explain later. Accordingly, profit attributable to owners of parent was 185 billion yen, an increase of 62%.

From my personal point of view, I took office as president in 2008. Once we deliberated re-engineering the entire business between 2001 and 2004, sales dropped to around 200 billion yen in 2004. It had been difficult to renew the top line of 420.2 billion yen, including the wholesale business.

In terms of profit, we have continued to renew the profit margin by successfully combining Crestor and HIV royalties, and sales are finally beginning to follow. The big challenge for us is whether we will be able to make the same or higher sales in 2023, other than through purchases by the Japanese government. We are confident that we will be able to achieve this, and this reflects in our forecast for FY2023. That is the background.

Now, we feel that we are finally in a position to aim for a company that can generate a certain amount of sales.

Financial Results

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts revised on Jan.30	Results	Achievement (%)	Results	Change (%)	Change
Revenue	421.0	**426.7**	**101.4**	335.1	**27.3**	91.5
Operating profit	147.0	**149.0**	**101.4**	110.3	**35.1**	38.7
Core operating profit*	144.5	**158.5**	**109.7**	110.6	**43.3**	47.9
Profit before tax	210.0	**220.3**	**104.9**	126.3	**74.5**	94.1
Profit attributable to owners of parent	170.0	**185.0**	**108.8**	114.2	**62.0**	70.8

- **Year-on-year increases in revenue and all profit categories**
  - The commercialization of Xocova (ensitrelvir) and the growth of the base business contributed
  - Invested over 100 billion yen in R&D, the largest amount ever
- **Exceeded revised forecasts for all items**

Exchange Rate (average)	FY2022 Forecasts (Jan. 30)	FY2022 results
USD ($) – JPY (¥)	**135**	**135.51**
GBP (£) – JPY (¥)	**162**	**163.22**
EUR (€) – JPY (¥)	**140**	**140.99**

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* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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It was very difficult to predict the development trend of COVID-19, the vaccine, and its treatment, as well as the dialogue with the regulatory authorities and health authorities in each country, and how the approval process would proceed.

Normally, it was reasonable to aim for operating income to 140 or 150 billion yen. However, due to the situation I just told you about, I told you in May last year that we would like to start with 120 billion yen.

After that, in the fiscal year ended in September, the trends of Xocova and Vaccine became more visible, so we made an upward revision in November, and after Q3, when the government's purchase was finalized, we issued our final, latest estimate.

The revised forecast on the far left is the figure we released after Q3. YoY figures are shown on the far right, as it is also very important for us to see how we compare with the forecast.

We believe that it is very important for us to know whether our company can perform as projected when clarity rises. We have written this down as 101% to 109%, which means that we have managed to exceed the latest estimate.

Statement of Profit or Loss

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts Jan.30	Results	Achievement (%)	Results	Change (%)	Change
Revenue	421.0	**426.7**	**101.4**	335.1	**27.3**	91.5
Cost of Sales	15.7 66.0	14.6 **62.2**	**94.3**	16.5 55.4	**12.3**	6.8
Gross profit	355.0	**364.4**	**102.7**	279.7	**30.3**	84.7
Selling, general & administrative expenses, R&D expenses total	48.9 206.0	47.8 **203.9**	**99.0**	50.2 168.2	**21.2**	35.6
Selling, general & administrative expenses	24.5 103.0	23.8 **101.5**	**98.5**	28.4 95.2	**6.6**	6.2
R&D expenses	24.5 103.0	24.0 **102.4**	**99.4**	21.8 73.0	**40.3**	29.4
Other income & expenses	(2.0)	**(11.5)**	-	(1.2)	-	(10.4)
Operating profit	34.9 147.0	34.9 **149.0**	**101.4**	32.9 110.3	**35.1**	38.7
Core operating profit	34.3 144.5	37.1 **158.5**	**109.7**	33.0 110.6	**43.3**	47.9
Finance income & costs	63.0	**71.3**	**113.2**	16.0	**347.0**	55.4
Profit before tax	49.9 210.0	51.6 **220.3**	**104.9**	37.7 126.3	**74.5**	94.1
Profit attributable to owners of parent	170.0	**185.0**	**108.8**	114.2	**62.0**	70.8

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I would like to explain about the cost section and the financial income and expenses section. I would like to mention about the cost.

As for the cost of goods sold, sales were somewhat steady. The sales of Xocova were 104.7 billion yen. Since this is our original product, and we have been preparing for it, the cost of Xocova is still a little higher at this stage, but we were still able to keep the cost down to a fairly low level, and the sales amount was 62.2 billion yen, which is 94% of the forecast.

As you can see on the far right, sales increased by 27.3%, while cost of sales increased by only 12.3%, and gross profit increased by more than 30.3%. We have been conducting our business properly while controlling costs.

As for expenses, both SG&A expenses and R&D expenses are slightly lower than the latest estimate. However, as you can see on the right, R&D expenses exceeded 100 billion yen, which means an increase of 29.4 billion yen, or 40.3%.

Still, operating profit was 149 billion yen while using R&D expenses exceeding 100 billion yen. We have been able to deliver more than the promised figures, and I believe that the 100 billion yen for R&D expenditure will be a milestone for SHIONOGI in the future.

However, in order to be able to support this, the Company must have a corporate structure that can consistently generate sales of 450 billion yen or 500 billion yen. I believe this is what we need to show you in FY2023.

In the area of financial revenue, we see a very large increase of 55.4 billion yen, to 71.3 billion yen. As I am sure you have already understood, the 16 billion yen in FY2021 was only able to record three dividends from ViiV. Their closing date was moved to April 1. We could not record the dividend on April 1. The dividend in Q4 is the largest one, so that portion was gone and not recorded.

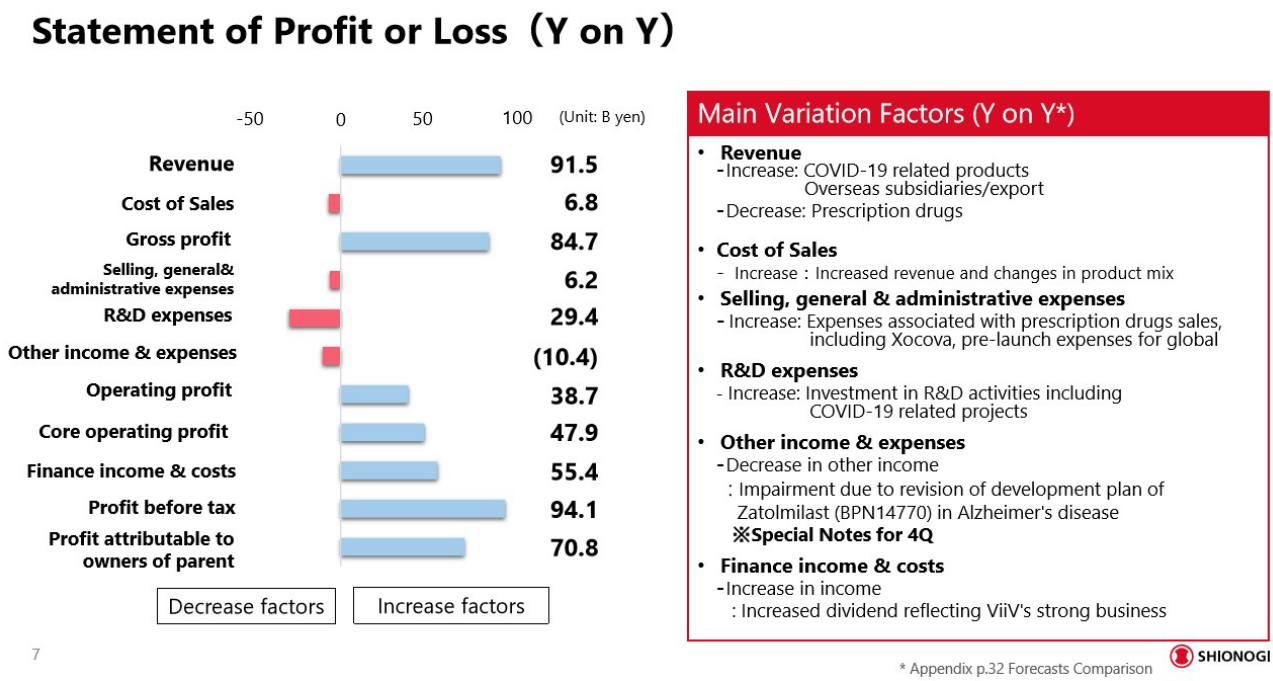
Last year, we received a lump-sum payment from Gilead Sciences for the settlement of the intellectual property rights of Gilead, ViiV, and SHIONOGI, and we recorded 50 billion yen as SHIONOGI's portion last year.

Naturally, since we have received 50 billion yen, ViiV has also received a considerable amount of money. This is reflected in the dividend, so a kind of special dividend was added on April 1. The total amount of both is about 25 billion yen.

Of the 71.3 billion yen, about 20 billion yen to 25 billion yen were dividends that should have been recorded in FY2021 but were shifted here.

In fact, we have set our financial income and expenses, including dividends forecast for FY2023, at 42 billion yen to 43 billion yen, which is almost a routine level, and we think it is a reasonable percentage for us to receive. Naturally, as ViiV's sales increase and profits rise, the dividend portion will also increase in the future, but based on the sales and cash position of GSK and ViiV for this fiscal year, 42 billion yen to 43 billion yen is a reasonable amount.

We are wondering if a certain model can be created to determine the amount of dividends that will be received by SHIONOGI after this fiscal year. Other than that, profits, etc., are as explained earlier.



Let's move on to page seven.

This is a chart version of what I just talked about, so there is not much to talk about. However, R&D is sticking out widely on the left side of the chart, and I wonder if we will be able to make sales that will allow us to spend 100 billion yen on R&D in the future. I know this may sound a bit wordy, but I am suggesting these points, and I would like to discuss them with you.

Revenue by Segment

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts Revised on Jan. 30	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	76.4	**75.0**	**98.2**	89.1	**(15.8)**	**(14.1)**
Overseas subsidiaries/export	39.3	**42.5**	**108.1**	34.4	**23.7**	**8.1**
Shionogi Inc. (US)	14.4	**15.4**	**107.0**	13.8	**12.2**	**1.7**
Fetroja	-	**10.0**	-	6.2	**59.5**	**3.7**
Ping An-Shionogi*/C&O	10.4	**12.0**	**115.3**	10.2	**17.7**	**1.8**
Shionogi B.V. (EU)	8.6	**9.1**	**105.6**	5.0	**81.4**	**4.1**
Contract manufacturing	14.8	**15.3**	**103.8**	17.4	**(12.0)**	**(2.1)**
OTC and quasi-drug	13.2	**13.1**	**99.2**	11.2	**17.7**	**2.0**
Royalty income	166.0	**174.7**	**105.2**	181.3	**(3.6)**	**(6.6)**
HIV franchise	159.9	**168.5**	**105.3**	174.0	**(3.2)*3**	**(5.5)**
Crestor	1.3	**1.3**	**100.0**	1.2	**15.4**	**0.2**
Others	4.8	**4.9**	**102.9**	6.1	**(20.0)**	**(1.2)**
COVID-19 related products*2	110.0	**104.7**	**95.2**	-	**-**	**104.7**
Others	1.2	**1.3**	**108.2**	1.8	**(28.8)**	**(0.5)**
Total	421.0	**426.7**	**101.4**	335.1	**27.3**	**91.5**

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* OTC and quasi-drugs also include in revenue of joint venture *2 Revenue from Xocova and S-268019
*3 Received royalty income from the conclusion of dolutegravir patent license agreement in FY2021

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Page 8. I will explain later on page 10 the domestic part of our business, but domestic and overseas, in general, has been firm.

Of course, foreign exchange rates have not had zero impact, but in the US in particular, despite the fact that a onetime payment of more than 2 billion yen for Fotamet was made in FY2021, this amount of growth has been achieved. This means that cefiderocol—the European name is Fetcroja—has been growing steadily.

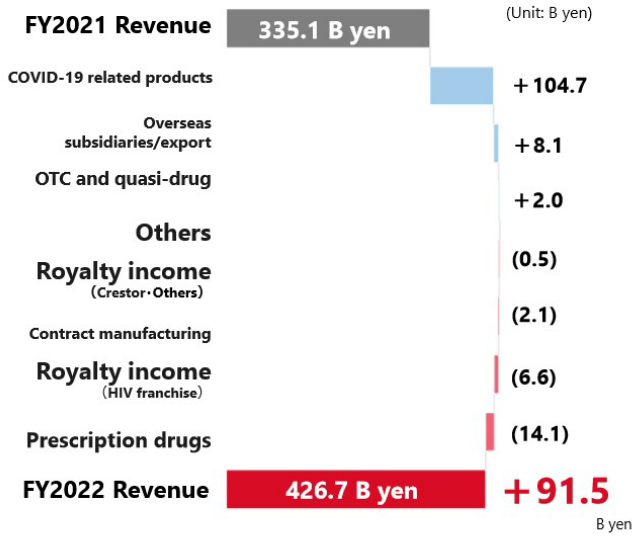
In the area of over-the-counter (OTC) pharmaceuticals, sales have been at an all-time high for four consecutive years, and our position in the industry has risen considerably. In the future, we will continue to promote this OTC drug, as we have a good product lineup.

As for the HIV franchise that I mentioned earlier, you can see on the far right side that the HIV franchise is down 5.5 billion yen, or 3.2%. This is a comparison with last year's royalties, which included the 50 billion yen onetime payment from the settlement with Gilead.

Conversely, the fact that the amount of the royalty payment was only reduced by 5 billion yen despite the 50 billion yen onetime payment recorded, this means that the actual royalty payment increased by 45 billion yen. This trend includes injectable drugs and now a two-drug therapy, and we hope to see strong growth in HIV in this area in the future. We believe we will be able to do so.

Then, COVID-19, as I mentioned earlier, 104.7 billion yen, 100 billion yen from government purchases and 4.7 billion yen from the sales after general distribution was accounted for.

Revenue by Segment（Y on Y）



Main Variation Factors (Y on Y*)

- **COVID-19 related products**
  - -Increase: Purchase of 2 million courses of Xocova by the Japanese government
    : Sales of Xocova in Japan through general distribution
    ※Special Notes for 4Q
- **Overseas subsidiaries/export**
  - -Increase: Sales of cefiderocol (Fetroja, Fetcroja)
- **Royalty income**
  - -HIV franchise
    - › Increase: Strong sales of ViiV's HIV franchise
    - › Decrease: Income from settlement agreement in prior year
    - ⇒ Excluding the one-time factor and the impact of exchange rates, royalty income from the HIV franchise grew 15% Y on Y
- **Prescription drugs**
  - -Increase: Sales of Intuniv and Vyvanse
  - -Decrease: Sales of Cymbalta, Returns of Xofluza and Rapiacta

* Appendix p.33 Forecasts Comparison

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I just wrote it down here, and it says that COVID-related products are 100 billion yen, and that's almost straight down to 91.5 billion yen.

Naturally, if we are to further expand this 91.5 billion yen and more this year, we will need to continue to produce and sales this amount of COVID-related products in 2023 and 2024.

Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts Full year (Jan 30)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Intuniv	20.0	**19.2**	**96.1**	16.4	**17.0**	**2.8**
Vyvanse	1.3	**1.4**	**112.3**	0.8	**81.2**	**0.6**
Infectious disease drugs	8.8	**7.4**	**84.7**	11.8	**(37.2)**	**(4.4)**
Influenza franchise	0.1	**(1.1)***	-	3.1	-	**(4.2)**
Cymbalta	6.1	**5.4**	**89.2**	15.9	**(65.8)**	**(10.5)**
OxyContin franchise	4.5	**4.4**	**98.8**	4.8	**(7.6)**	**(0.4)**
Symproic	3.4	**3.4**	**100.1**	2.7	**28.1**	**0.7**
Actair	0.6	**0.5**	**93.4**	0.5	**8.8**	**0.0**
Mulpleta	0.1	**0.1**	**81.6**	0.1	**(16.5)**	**(0.0)**
Pirespa	2.4	**2.5**	**106.8**	3.8	**(33.6)**	**(1.3)**
Others	29.4	**30.6**	**104.1**	32.4	**(5.5)**	**(1.8)**
Crestor	3.9	**4.1**	**104.1**	5.9	**(30.7)**	**(1.8)**
Prescription drugs	76.4	**75.0**	**98.2**	89.1	**(15.8)**	**(14.1)**

<Products categorized as infectious disease drugs>

- Xofluza
- Rapiacta
- Brightpoc Flu・Neo

Influenza franchise

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

* Sales of 4.2 billion yen recorded for influenza family in April-December. Approximately 5.3 B yen worth of products that expire this year were returned in the second quarter.

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In the domestic market, we have seen a negative figure of 1.1 billion yen for the influenza family but a certain amount of growth for Intuniv and Vyvanse, which were transferred to Takeda Pharmaceutical Company Limited on April 1. We have strengthened the ADHD franchise in our own way up to this point.

Although we have been criticized by many people as to whether our sales staff can really do their jobs, to a certain degree, I think we can say that we still have the ability to grow to this level even though it was the first time for us to enter the ADHD market.

We know you have already heard from us, but since October, we have collected all market stocks in wholesalers, and we have changed the way we sell only the necessary amount of influenza products.

The amount sold in this new form was 4.2 billion yen. Naturally, the inventory on the market and at wholesalers is almost manageable and has been reduced to the point where it could be said to be almost zero. If the influenza epidemic spreads again in the future, we will be able to sell products to wholesalers and sell the actual products, and all sales are pure to record.

Naturally, from the SDG perspective, pharmaceutical companies often try to make up for the recovered products with new products, but once the recovered products go to wholesalers or hospitals, they are under non-GMP, and there is no other way but to dispose of them.

We can't repackage them, so we have to dispose of all of them. It is not in favor of keeping such way of disposal from the industry point of view, no matter how low the cost or how high the selling price is. I think it is a very good initiative on our part that we have stepped in to optimize the situation, especially in this most difficult-to-read area of acute infectious diseases.

Symproic, Dr. Iwasaki is very particular about this, and I think we are starting to see some movement. We are still a very strong company in the area of medical narcotics, and we intend to continue to grow in this area in the current fiscal year and beyond.

FY2022 Results for Medium-Term Business Plan STS2030 KPIs

	KPI	FY2019 (Result)	FY2020 (Result)	FY2022 (Target)	FY2022 (Results)		FY2024	FY2030
Growth indications	Revenues	333.4 B yen	297.2 B yen	400.0 B yen	**426.7 B yen**	Achieved	500.0 B yen	600.0 B yen
	Core operating profit*	127.4 B yen	94.0 B yen	120.0 B yen	**158.5 B yen**	Achieved	150.0 B yen	200.0 B yen
	Core operating profit margin	38.2%	31.6%	Over 30%	**37.1%**	Achieved	Over 30%	-
	Overseas revenue ratio (excluding RYT)	18.5%	16.2%	Over 25%	**16.5%**	Unachieved	Over 50%	-
	Internally-discovered pipeline ratio	67%	71%	Over 60%	**61%**	Achieved	Over 60%	-
Shareholder return indications	EPS	395.71yen	365.03yen	Over 370 yen	**621.31yen**	Achieved	Over 480 yen	-
	DOE	4.0%	4.1%	Over 4%	**3.9% (planned)**	Unachieved	Over 4%	-
	ROE	15.5%	13.9%	Over 13%	**17.8%**	Achieved	Over 15%	-

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* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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On page 11, the SHIONOGI Transformation Strategy 2030 was created in 2020, and the third line from the left shows the goals for 2022.

Sales were 400 billion yen, operating profit 120 billion yen, and so on.

The ratio of overseas sales to KPI for 2022 was 16.5%, which was below the target, but the overseas sales themselves increased. Since overall sales, including Japan, increased, the ratio of sales to total sales is lower than expected.

We have achieved everything else, but the overseas sales ratio and the goal of a DOE 4% or higher.

We are planning to unveil the STS2030 revision on June 1, and we believe that 2022 was a good year for us as a preliminary step towards this.

Results for FY2022

Progress of COVID-19 projects

- Domestic commercialization of Xocova, building foundations for global expansion, progress in trials
- Domestic approval application for COVID-19 vaccine

A paradigm shift in the HIV franchise

- Extension of HIV franchise due to rapid growth of long-acting formulations

Development of growth drivers

- Shifted resources from COVID-19 to other growth drivers
- Progressed 6 pipeline products into the next stage of clinical development*

Exceeded record high performance and built a foundation for further growth

* A list of products that have made progress is listed on Appendix p.37

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The content on page 12 is what I just mentioned. We will explain a little about the second growth driver, the staging of clinical trials for the six products under development, one by one later.

Direction for FY2023

Accelerating global expansion with the new infectious disease products created in FY2022

Top-line growth through global sales expansion

- Expand sales of Xocova in Japan and Asia
- Promoting initiatives in the infectious disease area
  - Development of government stockpiles and subscription model
  - Building a foundation for global supply

Establishment of growth drivers that can be deployed globally

- Aggressive investment to advance global self-developed products
- Strengthening in-licensing to expand development and product portfolio
- Domestic launch and global expansion of vaccines

Transform into a company that can expand globally on its own

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Let me move on to page 14.

Not only in FY2023, but also in the STS2030 revisions that we will be submitting in the future, the same themes are important to us.

This is, after all, COVID-19-related products that we have been working hard to make for three years. The number one priority is how to sell these products on a global scale, including Japan, and how to establish actual sales, including Xofluza, in terms of respiratory tract infections.

We have high expectations for AMR products, including cefiderocol, to be presented at the G7 Summit to be held in Hiroshima this year, and we are highly expecting that the G7 countries statements will go one step further than in the past. Ms. Sawada, who is our director and vice chairperson, met directly with the Prime Minister and discuss these issues with him and the parties involved. We hope that we can make significant progress in the area of subscriptions in Japan and in the G7.

Even if we make progress in this area, our sales are not on par with those of Xocova or vaccines, so we are aiming for a business model in which AMR products can bring in, say, 10 billion yen or 20 billion yen. I believe that we can aim for this, but the major issue is how to develop the other top lines.

In addition, while we are offering oral drug, we also continue to offer prophylaxis, pediatric, and Long COVID follow-up, and I am proud to say that we are probably the only company in the market that does so.

It will cost a certain amount of money, but one of the themes of 2023 is changing a gear, what we need to do for the next stage, so I wonder how much people, money, and things we can affix there to support the next growth of SHIONOGI. This is the direction we will be taking in 2023 and beyond.

Earnings Forecast

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	**450.0**	**217.0**	426.7	5.5	23.3
Operating profit	**150.0**	**80.5**	149.0	0.7	1.0
Core operating profit*	**150.0**	**80.5**	158.5	(5.4)	(8.5)
Profit before tax	**192.5**	**98.0**	220.3	(12.6)	(27.8)
Profit attributable to owners of parent	**155.0**	**78.0**	185.0	(16.2)	(30.0)

- **Achieved higher sales and profits due to top-line growth from expanding global sales of infectious diseases products**
- **Aggressive investment for global expansion and establishment of growth drivers**

Exchange Rate (average)	FY2023 Forecasts	FY2022 Results
USD ($) – JPY (¥)	130	135.51
GBP (£) – JPY (¥)	160	163.22
EUR (€) – JPY (¥)	140	140.99

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* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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So, as you can see on page 15, the forecast for the full year is 450 billion yen for FY2023 and 150 billion yen for operating profit. So far, an increase in sales and profit.

Regarding profit before taxes and net income, as I mentioned earlier, there is a gap of more than two tens of billion yens in terms of the normalization of dividends, and we are unable to keep tracking with that, so the full-year forecast of 192.5 billion yen and 155 billion yen, or 12% and 16% decrease in profits, respectively, appears to be the result. I am sure you understand better than we do that this depends on the top line, how much we can go, and how much we spend on SG&A expenses, and R&D expenses.

It is the same for last year's start from 120 billion yen, but we are showing you where the minimum operating profit line is that we can promise to you, even if sales do not increase or R&D expenses are higher than necessary. Our message is that we would like to start from 150 billion yen.

Forecast: Revenue by Segment

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Prescription drugs	**134.1**	**87.4**	179.7**	(25.4)	(45.6)
Overseas subsidiaries/export	**96.6**	**28.0**	42.5	127.3	54.1
Shionogi Inc. (US)	**13.6**	**6.7**	15.4	(11.7)	(1.8)
Shionogi BV (EU)	**11.5**	**5.4**	9.1	27.2	2.5
Ping An-Shionogi* /C&O	**58.0**	**13.2**	12.0	384.8	46.0
Others	**13.4**	**2.7**	6.0	122.9	7.4
Contract manufacturing	**13.8**	**7.3**	15.3	(10.1)	(1.5)
OTC and quasi-drug	**15.0**	**6.8**	13.1	14.2	1.9
Royalty income	**189.5**	**86.9**	174.7	8.5	14.8
HIV franchise	**185.0**	**86.0**	168.5	9.8	16.5
Others	**4.5**	**0.9**	6.2	(27.4)	(1.7)
Others	**1.0**	**0.5**	1.3	(21.6)	(0.3)
Total	**450.0**	**217.0**	426.7	5.5	23.3

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* OTC and quasi-drugs also include in revenue of joint venture ** Includes income from purchase of Xocova by the Japanese government

SHIONOGI

Page 16.

This is the revenue forecast that is a basis of what I just talked about.

The third line from the left, 179.7 billion yen, is a fair comparison because it includes 100 billion yen of government purchases and 4.7 billion yen is actual sales. In that sense, the point is how much we can grow from 79.7 billion yen. A simple comparison shows a 25% decrease in revenue from 179.7 billion yen to 134.1 billion yen, but in reality, our target is to increase revenue from 79.7 billion yen to 134.1 billion yen.

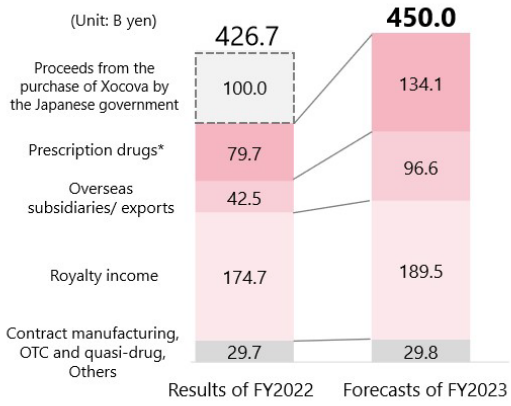
Overseas, our focus is on cefiderocol in the US and Europe, and we have been making significant sales of Xocova (encitrelvir) in China and other Asian countries, including Korea, especially in H2. The total amount of the project is to be increased from 420 billion yen to 450 billion yen. We are sure you will agree that most of the growth will come from Xocova and vaccines, and in Japan and other Asian countries including Southeast Asia.

We are currently considering a royalty rate of 185 billion yen, an increase of approximately 10%. This reflects the fact that both GSK and ViiV are currently projecting sales growth of approximately 10%. We think that ViiV probably wants to grow further more, excluding the factor of the exchange rate. So, we are going to make some changes accordingly.

Global Top-line Growth

Achieve top-line growth through our own sales of Xocova in Japan, expansion overseas, and growth of base business

Revenue Forecast by Segment (Y on Y)



- **Forecast includes 105.0 B yen in Xocova and COVID-19 vaccine sales**
- **Prescription drugs : +54.4 B yen**
  - Xocova, COVID-19 vaccine, Influenza franchise
- **Overseas subsidiaries/ exports : +54.1 B yen**
  - Xocova : China, South Korea, Taiwan
  - Cefiderocol
- **Royalty income :+14.8 B yen**

* Includes sales in Japan after Xocova goes into general distribution

SHIONOGI

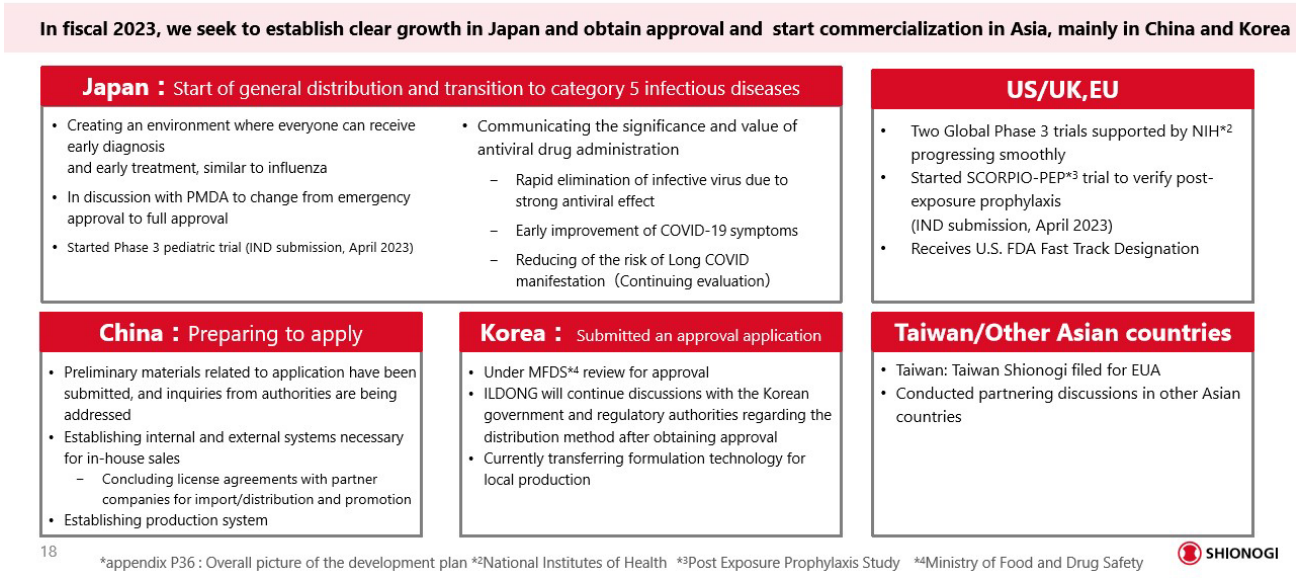
The bottom part on page 17 shows that royalty income will increase by 14.8 billion yen. HIV is accounted for 16.5 billion yen of it. Royalty for Crestor was finally reduced to zero in FY2022, so there will be a decrease in some areas but HIV alone will increase by 16.5 billion yen.

Most of the reason that 426.7 billion yen becomes 450 billion yen is COVID-19-related oral drugs and vaccines. Regarding influenza, we made 4.2 billion yen in Japan in FY2022, and Roche's sales in the US and Europe were not so strong.

Whether you agree or not, we, both on the sales side and the R&D side, are feeling a bit suspicious about the influenza. In particular, human and animal infections are beginning to appear here and there. It's hard to tell how much of this is real.

However, cap-dependent endonuclease inhibitors work for all avian/human and swine/human influenza that we have. We have both cap-dependent endonuclease inhibitors and neuraminidase inhibitor, and we need to be prepared for influenza. Our expectations for influenza are also included in these figures.

Xocova (Ensitrelvir): Global Expansion*



Regarding Xocova on page 18.

For the US and Europe, which are in the upper right corner, we have agreed on clinical trials and protocols with the FDA, and they are progressing at a very rapid pace. We consider it is going well. We hope to apply for and obtain approval in the US and Europe.

In the United States and Europe, we are not as clear as we are in Japan regarding the need for prevention and pediatric indications, but we are proceeding with development. Naturally, we think the fast-track adaptation in the US is a tailwind.

Also, regarding China and South Korea, there may have been some changes in their perceptions of therapeutic drugs and vaccines after China changed and lifted its zero-corona policy around February and March. So, after about two domestically produced drugs were approved, no new drugs were approved. However, we think that the number of patients may be gradually increasing.

Especially in February and March, 80% to 90% of our employees were actually infected with COVID-19, and it happened nationwide, so neutralizing antibodies rose once. Neutralizing antibodies against Omicron start to decline after about 4 to 5 months, so we think it's not surprising that people who were infected sooner or later get re-infected.

We heard that XBB.1.16 is starting to appear in China. At this week's press conference, Dr. Ozaki said that the positive rate of PCR was in the single digits before Golden Week, but last week it rose to 15%, so we wonder if there are signs of a slight increase in Japan as well. We think, of course, there is a possibility that the same situation will occur in China and South Korea. We would like to receive approval in the first half of the year and then start full-scale deployment from the second half.

Xocova (Ensitrelvir): Latest Data* from Phase 3 Part of Phase 2/3 Trial

Positive date, attributed to strong antiviral effects, continue to be generated

Reduced risk of Long COVID manifestation*2

- Significantly reduced risk of manifestation of Long COVID in severely symptomatic patients versus placebo
  - 45% reduction in the proportion of patients with longer-term presence of any of the 14 symptoms characteristic of COVID-19
  - 33% reduction in the proportion of patients presenting with the four most commonly reported post-acute neurological symptoms

Mukae H. et al,. Precision Medicine 2023.6(4):291.

Regarding viral rebound and symptom recurrence*3

- Symptom recurrence was rare and was not associated with viral RNA rebound
- Although RNA rebound was observed in a small number of patients, there was only one case of (1/310) low level viral titer positivity in follow up, suggesting no concerns for infectivity or transmission.

The 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID)

*post hoc analysis *2 the 30th CROI: Phase 3 part of Phase 2/3 trial result、CROI 2023 Follow Up Meeting
*3 SHIONOGI Press Release：ECCMID2023: Phase 3 part of Phase 2/3 trial result

SHIONOGI

For page 19, we would like to express the fact that we have accumulated such a large amount of data, since we, as a specialist in infectious diseases, will continue to be the number one materiality in infectious diseases field.

As for Long COVID and rebounding which has been talked about a bit with other drugs, we are collecting data in depth.

Vaccine Business: Building a New Business Foundation

Establish vaccines as a medium- to long-term growth driver, including domestic launch of S-268019

COVID-19 vaccine: S-268019

- Under review by MHLW and PMDA for approval
- Accelerate preparations for domestic supply
- Efforts toward LCM to maximize value
  - Adolescents, school children, adult booster (4th vaccination)
  - Omicron strains
  - Expression of Interest (EoI) filed with WHO for S-268019 to be placed on the Emergency Use List (EUL)

Establishment of a production system for recombinant protein vaccines

- Initial supply from UMN Pharma
- Ongoing efforts toward mass production at UNIGEN
- Partnering for multiple production options

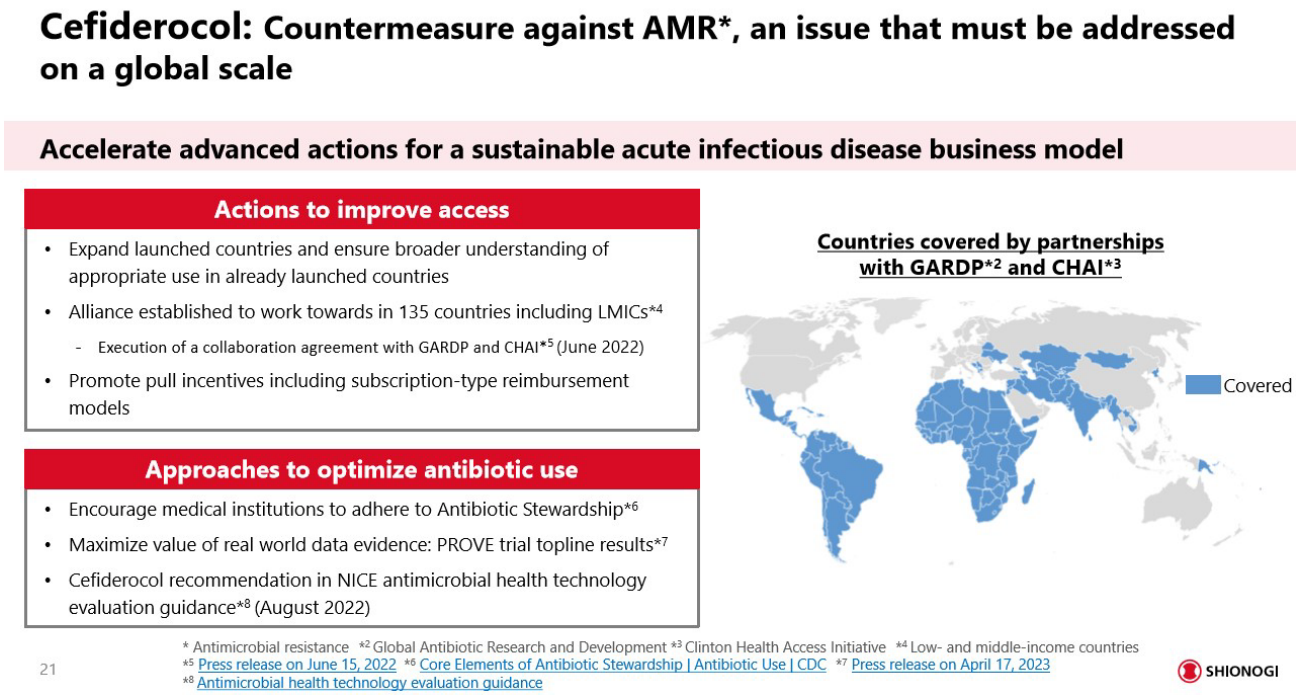
Expansion of vaccine business

- Development of influenza vaccines
- Building a foundation for the development of nasal vaccines and universal vaccines

SHIONOGI

As for vaccines, we applied for approval of the vaccine in November of last year, and the review process is progressing smoothly. Naturally, we cannot comment on the progress of the review process, but if you think about it, it is the timing when our S-268019 will be included in the approval schedule, and when we will receive approval based on that schedule will be visible to us and to everyone else.

From our point of view, at this point in time, we are aware that the screening process is proceeding smoothly and vigorously.



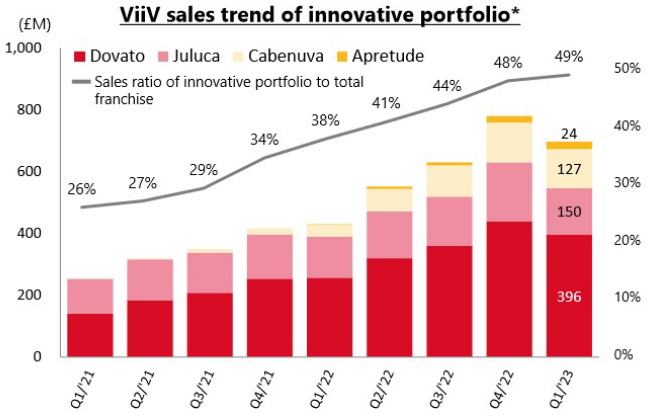
Page 21.

We think we don't need to tell much about cefiderocol. Although it sells well for some extent in the US and Europe, I often talk with John about this, and I think we need to start thinking about how well stewardship is being observed, especially in southern Europe. It is not enough if it keeps selling well.

If cefiderocol resistance was to appear, it would take another 20 years for us to produce the next antibiotic. So, I think we are in the phase of making good use of the various antibiotics we have, such as Avycaz and Recarbrio, and I think it is very important to enhance pull-type incentives.

Progress of HIV Business by ViiV

Paradigm shift due to growth of oral 2-drug regimens and LA formulations and accelerating of next-generation pipeline development



Further growth of top line

- Dovato: Driving growth in overall HIV franchise sales
- Cabenuva: About 90% of clinical trial participants prefer Cabenuva therapy over daily oral pills*2
- Apretude: Growing sales in US with launch to follow in Europe (Expected EMA approval in late 2023)

Development of next-generation pipeline

- S-365598*3: Phase 1 trial ongoing
- N6LS (combination candidate for ultra LA): Expect to begin a phase 2b trial

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* Source: GSK financial statement *2 GSK press release *3 ViiV development numberVH4524184

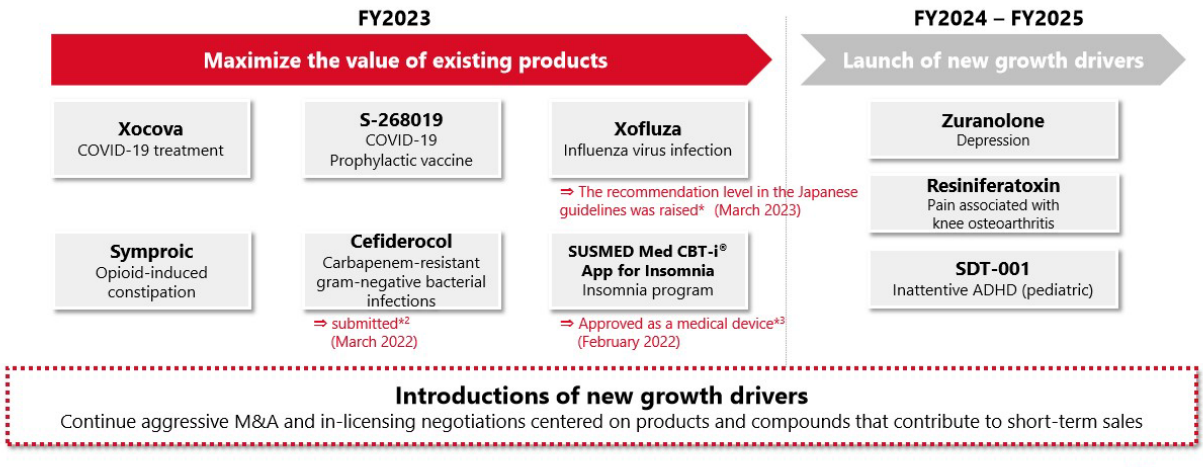
SHIONOGI

Page 22.

We talked about HIV in the last HIV meeting. There is nothing new, but we would also like to cooperate with ViiV, including on Phase I of S-365598, as well as the ones once every three months or longer and the once-a-week orals.

Direction of Domestic Business

Continue to expand sales and portfolio for sustainable growth in focus areas



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* New recommendations for the use of Xofluza by the Japanese Association for Infectious Diseases *2 SHIONOGI press release *3 SUSMED press release

SHIONOGI

Page 23 is about domestic business.

It shows short term and long term but FY2024 and FY2025 in particular, Chris Wiebacher of Biogen have clearly stated that lecanemab and zuranolone for Alzheimer's disease are the two products that they are most excited about.

For this zuranolone, Phase III in Japan will be key open soon. I personally expect that we will be able to achieve good results with zuranolone based on the results of Phase II, and I am very excited about the prospect of developing this in Japan.

We are in Phase III of resiniferatoxin, and olorofim, and we would like to launch them with NDA as soon as possible.

On the left side, we have Xocova, vaccine, Xofluza, Symproic, Cefiderocol, and SUSMED's app for insomnia. We are working with Idorsia on a sleeping pill, so we will also be developing in the area of sleep and depression.

Milestones of Major Development Products

Selection and concentration on growth drivers addressing unmet medical needs

Disease area	Pipeline	Indication	FY2022	FY2023	FY2024
Infection	Olorofim	Invasive aspergillosis	Phase 3	Phase 3 Completion of case registration (4Q)	
	S-337395	RSV infections	Phase 1	Phase 1 topline results	
	S-892216	COVID-19	Phase 1	Phase 1 topline results	
Psychiatry/ Nervous/Pain	Zuranolone	Depression	Phase 3	Phase 3 topline results (3Q) Submission (4Q)	
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	Submission (4Q)	
	SDT-001	ADHD	Phase 3	Submission	
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline results (2Q) Submission (3Q)	
	S-151128	Chronic pain	Phase 1	Phase 1 topline results	
New growth area	S-309309	Obesity	Phase 2	Phase 2 topline results (4Q)	
	S-531011	Solid tumor	Phase 1b/2	Phase 2 (4Q)	
	Redasemtide	Dystrophic epidermolysis bullosa	Phase 2	Submission (3Q)	
		Acute cerebral infarction	Phase 2b		

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

SHIONOGI

On page 24, we have the newly opened products under Phase I, the second from the top, S-337395 which RS virus, and S-892216 which COVID-19, S-151128 which the pain medication. Regarding S-892216 which I'm going to say because there's no need to hide them. we are aiming for protease inhibitors that have no DDI and no pregnancy effects. Also, the resistance profile is different from that of our Xocova and the other 3CL protease, so resistance has not been a major problem so far.

I am personally very excited about the fourth one from the bottom, S-151128, the pain medication, and I think it is a very good one. The difficult part of pain meds is how to obtain approval and what kind of drug price to charge. I think it is a very interesting product.

Olorofim, at the top of the list, zuranolone, and resiniferatoxin are in Phase III. S-309309, which is at the bottom, has started Phase II, and redasemtide has started Phase II-b. As for the S-531011 solid tumorst, it is quite interesting, and we would like to push it strongly.

Forecast: Statement of Profit and Loss

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	450.0	217.0	426.7	5.5	23.3
Cost of Sales	15.3 69.0	14.5 31.5	14.6 62.2	10.8	6.8
Gross profit	381.0	185.5	364.4	4.5	16.6
Selling, general& administrative expenses, R&D expenses total	50.9 229.0	47.7 103.5	47.8 203.9	12.3	25.1
Selling, general& administrative expenses	28.9 130.0	24.9 54.0	23.8 101.5	28.1	28.5
R&D expenses	22.0 99.0	22.8 49.5	24.0 102.4	(3.3)	(3.4)
Other income & expenses	(2.0)	(1.5)	(11.5)	-	9.5
Operating profit	33.3 150.0	37.1 80.5	34.9 149.0	0.7	1.0
Core operating profit	33.3 150.0	37.1 80.5	37.1 158.5	(5.4)	(8.5)
Finance income & costs	42.5	17.5	71.3	(40.4)	(28.8)
Profit before tax	42.8 192.5	45.2 98.0	51.6 220.3	(12.6)	(27.8)
Profit attributable to owners of parent	155.0	78.0	185.0	(16.2)	(30.0)

SHIONOGI

We know this may sound over-repeating, but since SG&A expenses were totaled for 130 billion yen, and 54 billion yen of it is budgeted in H2, you can easily understand that they are extremely weighted in H2. This is not unrelated to where we will sell Xocova in H2, and there is a connection between this and the 130 billion yen in SG&A expenses that we have never used before.

At this time, we are still maintaining a research and development budget of 100 billion yen. As I mentioned earlier, we have a pipeline that must support the next SHIONOGI, including Phase I, Phase II, and Phase III, and it is our intention to proceed even if we have to spend 100 billion yen.

We would like to continue to have a dialogue with you on how to manage the total P&L.

Repost of P.16
(Partially revised)

Forecast: Revenue by Segment

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Prescription drugs	**134.1**	**87.4**	179.7	(25.4)	(45.6)
Overseas subsidiaries/export	**96.6**	**28.0**	42.5	127.3	54.1
Shionogi Inc. (US)	**13.6**	**6.7**	15.4	(11.7)	(1.8)
Shionogi B.V. (EU)	**11.5**	**5.4**	9.1	27.2	2.5
Ping An-Shionogi* /C&O	**58.0**	**13.2**	12.0	384.8	46.0
Others	**13.4**	**2.7**	6.0	122.9	7.4
Contract manufacturing	**13.8**	**7.3**	15.3	(10.1)	(1.5)
OTC and quasi-drug	**15.0**	**6.8**	13.1	14.2	1.9
Royalty income	**189.5**	**86.9**	174.7	8.5	14.8
HIV franchise	**185.0**	**86.0**	168.5	9.8	16.5
Others	**4.5**	**0.9**	6.2	(27.4)	(1.7)
Others	**1.0**	**0.5**	1.3	(21.6)	(0.3)
Total	**450.0**	**217.0**	426.7	5.5	23.3

Assumptions for forecasts

- **Prescription drugs**
  - Sales revenue of Xocova and COVID-19 vaccine in Japan included in forecast
  - Recorded 100.0 billion yen in income from the purchase of Xocova by the Japanese government in FY2022
- **Overseas subsidiaries/export**
  - **Shionogi Inc.**
    > Decrease in sales year-on-year due to change in Osphena sales scheme**
  - **Ping An-Shionogi/C&O**
    > Sales revenue of Xocova in China and South Korea included in forecast
  - **Others**
    > Sales revenue of Xocova in Taiwan included in forecast

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* OTC and quasi-drugs also include in revenue of joint venture
** Sales forecast decrease due to change in sales scheme for Osphena, but profit forecast remain unchanged

SHIONOGI

Page 27. This is a breakdown of that.

In this sense, what I explained earlier has been written again, and it may sound repetitious, but with overseas sales growing so rapidly, the focus of Shionogi Inc. in the US and Shionogi B.V. in Europe will be on Cefidelocol, and in Asia is on Xocova, and I hope a portion of vaccines will also be involved. Overall, COVID-19-related is our main focus.

Forecasts: Prescription Drugs in Japan

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Infectious disease drugs	**65.7**	**40.0**	112.1	(41.4)	(46.4)
Covid-19 related products + Influenza franchise	**57.3**	**35.8**	103.6	(44.7)	(46.3)
Cymbalta	**4.2**	**2.1**	5.4	(23.5)	(1.3)
OxyContin franchise	**4.1**	**2.1**	4.4	(6.6)	(0.3)
Symproic	**4.9**	**2.3**	3.4	44.6	1.5
Actair	**1.0**	**0.4**	0.5	91.0	0.5
Mulpleta	**0.1**	**0.1**	0.1	25.9	0.0
Pirespa	**1.9**	**1.1**	2.5	(24.4)	(0.6)
Others	**52.1**	**39.3**	51.2*	1.8	0.9
Lump-sum income from transfer of ADHD drug	**25.0**	**25.0**	-	-	25.0
Prescription drugs	**134.1**	**87.4**	179.7	(25.4)	(45.6)

<Products categorized as infectious disease drugs>

- Xocova
- COVID-19 vaccines
- Xofluza
- Rapiacta
- BrightpocFlu・Neo
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE

28 COVID-19 rerated products Influenza franchise

* Includes sales of Intuniv and Vyvanse in FY2022

SHIONOGI

On page 28, there are two points worth mentioning in this regard: COVID-19 and influenza are for about 57 billion yen for the full year and 36 billion yen in H1.

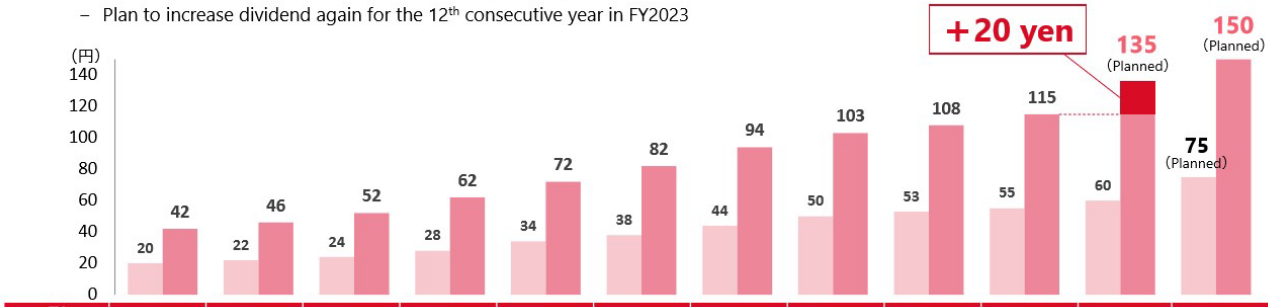
Especially for Xocova, we were asked by the media yesterday. The government's share of drug costs is clear until the end of September, but after that it is not yet clear. Considering this factor, we have a larger projection in 1H.

The total of oral drug, including the other two drugs, the prescription rate is still less than 10%. How to bring it up to 20% or 25%. If we can get to that level, I think it would be a really easy number, so the question is how smoothly the expansion of prescriptions will proceed.

At the bottom, we have included 25 billion yen as a round figure for this fiscal year as a onetime payment for the transfer of ADHD. As you know, it does not reach 25 billion yen, including both Intuniv and Vyvanse put together. However, we have been growing for a long time, and we will make up for the loss with 25 billion yen, which is a round figure.

Flexible and Prompt Capital Strategy

- **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
  - FY2022 is the largest annual dividend increase (+20 yen)
  - Plan to increase dividend again for the 12th consecutive year in FY2023



FY	12	13	14	15	16	17	18	19	20	21	22	23
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	-
Treasury stocks: Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	-
DOE (%)	3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9(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	13.5 (expected)

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020 Values calculated based on IFRS after 2019

SHIONOGI

Lastly, shareholder returns.

As you can see on page 30, the Board of Directors approved the agenda for the General Meeting of Shareholders yesterday, and it is our intention to increase the dividend for 2H of the current fiscal year by 15, and since we increased the interim dividend by 5 for 1H, we would like to increase the full-year dividend by 20, to 135. The 20 dividend increase is the largest increase in our 145 years of history.

We will start the current fiscal year with 75, 75 of 150, but this is subject to favorable financial results, etc. We will consult with the Board of Directors regarding the dividend for H2 of the fiscal year.

With regard to share buybacks, we will continue to be flexible and make decisions as we have in the past, always keeping in mind that we will do so when we have to.

This is a brief explanation of the financial results. Thank you for your attention.

Question & Answer

Kyokawa : I will now move on to the question-and-answer session.

Now, Mr. Kohtani please.

Kohtani : My name is Kohtani from Nomura Securities. I have a couple of questions.

The first question is on page 17. In this top-line growth in domestic prescription drugs, 54.4 billion yen is probably a significant portion of Xocova, of course. Before I go any further, I would like to know your thoughts on vaccines. Sorry, this is my own thought, but it would make sense for the government to purchase the same quantity as the flu vaccine.

You don't have a vaccine for the Omicron variant, so most will go to Pfizer and others, but since the government is investing to some extent, I don't see why they don't buy anything. I believe that a shy of 10% will be directed to domestic vaccines.

I think the amount is quite small as far as I can see from the figures, so I wonder if there is a clear reason for this. Or if the Ministry of Finance is actually trying to narrow it down to such a small amount that they don't have to buy any more vaccines since they have such a large surplus.

But simply because it hasn't been approved yet, you are being very modest. Could you please explain this a little?

This is the first question.

Teshirogi : The reason is not that. It is our problem. The manufacturing capacity has not caught up that much. That is the main reason.

Kohtani : You mean that you are still struggling a bit with the expansion of culture in terms of manufacturing capacity.

Teshirogi : That is correct.

We think the government side is quite positive about the situation, as Mr. Kohtani just mentioned. However, since we are really still a newcomer to vaccines, how much confidence we can always have and deliver them, we believe that it is unacceptable to overpromise and fail to deliver the vaccine at the end. We are still talking with the government about a highly accurate figure, and it will be based on this.

We would like to quickly increase our capability to include this and produce the numbers they asked, but unfortunately we have not reached that point yet.

Kohtani : Perhaps it will still take some time to resolve this issue by the end of this fiscal year. Is this about the right figure?

Teshirogi : As for the manufacturing capacity, if it increases, the factory will have to add more products. So, I wonder how long it will take to get the data and approval after the addition.

As for the capability, I think we are getting closer to a very good point. Our current thinking is that we would like to have the ability to produce all the numbers we are told to produce in, say, early next fall, including taking data, stability, and site qualification.

Kohtani : Okay, the second question is about the domestic demand for COVID-19 treatments. First of all, I think the last disclosure of this is as of March 31, which is 3,578 facilities prescribing it. I wonder how this is going now.

Can you tell us if there are any areas that you think are a little different than you expected after May 8 when COVID-19 lowered to Class 5? I personally think that the prescription rate is very low. It is quite surprising to me that people seem to take this infection disease lightly, which is a more severe infection disease than influenza. I would like to know something about that as well.

Teshirogi : I will let Dr. Iwasaki add his comments from the site, but I think you are right.

How to really seize the flow of patients after moving to Class 5 [is important], especially as it is often discussed on TV whether people will take the test when they are charged for it in the first place.

In the usual way of thinking about influenza, if the test is positive, in most cases, treatment and antiviral drugs are prescribed. At present, 80% to 90% of antivirals are prescribed, including Xofluza, Inavir, Tamiflu, and generics.

At the current stage, it is only a single-digit percentage. Doctors have been talking with patients to manage symptoms with acetaminophen for a long time, so I think the biggest hurdle is to change the prescription pattern from "we have always managed to use it" to "there is this good product, so we can use this, and it will be slightly better."

There are all kinds of stories about it being an emergency approval, or a lot of paperwork. When we asked doctors who use it, they said it is a hassle, but not that much. In short, we are aware that many people say that the concept that COVID can be cured with antivirals is still too weak or too little developed. I think that has to be raised anyway.

Iwasaki : As Teshirogi just mentioned, the number of facilities has steadily increased from 3,500 to 5,000, but in the end, we should be able to cover around 40,000, looking at the facilities where Xofluza and other drugs are delivered.

Since the need for checklists, etc. is no longer necessary with general distribution, so that complication has been eliminated. The rate of prescribing has definitely increased. Still, the three drugs are below 10%, so the first thing to do is to raise this level.

To do so, we are not only collecting data from professors in academia and science, but also from clinical practice from clinical doctors. We publicize the clinical effects of our products using those data. In fact, we have seen a significant improvement in fever and sore throat in a single day after use. We are hoping to expand the use of this product to other areas.

The definition that it can only be shortened by one day of symptomatic status had been spread without sufficient definition, so we would like to work more carefully on this point. Another thing is that, unlike influenza, doctors are not yet fully aware of the risks associated with COVID-19 and Long COVID. We would like to accelerate the need for early diagnosis and treatment, including such data as presented at the recent ECCMID and other conferences, although.

Kohtani : Finally, this may be a difficult question to answer. Right now, the XBB.1.16 variant is coming up as a COVID-19 variant. As a scientific basis, a scientific explanation, is it possible to have a scenario where the 9th wave will be not occurring?

That is what I wanted to ask the infectious disease professionals. It would be helpful if you could tell me about how to look at the possibility of COVID-19 going to really settle down, with no more waves after the ninth.

Teshirogi : I don't know if John or Uehara think differently, but I don't think so. It is going to be difficult to grasp the accurate number of new infected patients or infected patients as it will be identified through fixed-point observation. In fact, the sewage epidemiology in both the US and Europe shows that the number is increasing.

I think it probably won't be zero. What we are interested in looking at is that influenza has 100 years of history that it is prevalent almost exclusively in the winter, that is, when the temperature is low and the humidity is low. If you look at the first through eighth waves so far, COVID-19 shows a wave of bimodal mountain, always coming once in the summer and bumpy every six months.

So, we would like to find out whether the so-called ninth wave will peak in the summer, which is what everyone, including us, is thinking of, or whether it will be slightly delayed and peak in early fall or winter. We would like to see if it is the same or different from the past. At this point, it is difficult for us to think of an option that the coronavirus, including mutations will not spread.

Kyokawa : Mr. Ueda

Ueda : My name is Ueda from Goldman Sachs.

First of all, I would like to ask you about Xofluza. Now that the recommendation has been raised in the official domestic guidelines, I wonder what positive effects can be expected in this area. In terms of your plan, could you tell us about the prevalence status, market share, etc., and what your assumptions are about those?

Iwasaki : There was an impression that the I38 mutation was unusable for pediatric patients. According to the new guideline, the age group is 12 years and older, so children are included in this age group. I think that's where we can expect to see the development, such as children six years and older, etc., who make up a very large 20% of the population. In fact, there have been cases where we have been able to promote to hire [ideas] by doing so.

In light of this, we would like to aim for a 40% share of the market, given the once-a-day requirement.

Ueda : Thank you very much.

The second one is about the new drug, S-337395 for RS virus infections. Can you tell us what is the concept of this drug? I would like to know how this drug will be positioned clinically, as I believe that vaccines are being developed for this disease, and there are also antibody drugs and others that are ahead of it.

Keller : I don't think you can go 100% coverage, even with vaccines. The severity of the disease is still continuing. I believe that this drug will provide a very strong benefit because it has this mechanism of action, such as being effective and rapidly reducing the number of viruses. I think this is a very important contribution for this treatment.

Kyokawa : Now, Mr. Hashiguchi.

Hashiguchi : My name is Hashiguchi from Daiwa Securities.

I think the rate of prescriptions for antiviral drugs, including Xocova, will go up with the efforts you mentioned earlier. Considering whether the current pace is sufficient to achieve this plan, do you expect some kind of trigger to occur at some point that will cause a sudden increase? If there is such a thing, would you be able to share with us when you think the prescription rate will increase dramatically?

For my part, I would imagine that the evidence for lowering the risk of severe disease, for example, or the recently published data on Long COVID is also encouraging, but I wonder if there will be an update with a higher level of evidence or something like that. Please let us know what your company thinks.

Iwasaki: I think this is a difficult question to answer, but I would like to set a goal of actually achieving 20% prescription rate. The number of patients is increasing, so we are wondering how much we can increase the number of patients at this time of year. To be honest, I don't think we have a specific thing that I can say that I wish I had.

However, on the other hand, to hit back, there were Long COVID data and 40,000 units of post-marketing PMS, so I really think that there are not safety issues. Another thing is that not only scientific evidence, but also so-called checklists and consent documents under emergency approval, as I mentioned earlier, can be complicated, so obtaining regular approval is one of them.

The other thing is that this packaging for four people, and the drug price is also expensive, so there is a situation that people are a little hesitant to purchase it. Against this, we are promoting a single package in early fall. So, at this point, we need to disseminate the Long COVID data, and then remove complications through regular approval, and then individual packaging.

I think these three are some of the key points. We are considering how to move these points forward.

Hashiguchi : What would normally be required to obtain regular approval? When do you have an idea that it will be ready?

Uehara : As a pre-condition for emergency approval, there is a proviso that an application for regular approval must be submitted within one year, so we are planning to apply for regular approval by November when we received approval.

We are currently in the process of submitting all the actual data, and since various procedures, such as inspections at various facilities, are required for approval, we are currently implementing such procedures in an appropriate manner.

Hashiguchi : Thank you very much.

One more point I would like to ask is that in your explanation of SG&A expenses, when you mentioned that there is a big difference between H1 and H2, I don't think you mentioned it clearly, but it sounded like you were assuming that you would have to spend costs when you sell Xocova overseas. Is that correct?

What kind of activities does your company consider to be costly? What are your current thoughts on how you plan to divide up the roles of your partners?

Teshirogi : Thank you very much.

I think it’s probably been implied, but we have teamed up with Chia Tai Tianqing Pharmaceutical Group for sales in China, as they have the ability to sell strongly throughout China, and also with Shanghai Pharmaceutical to see how much can be distributed.

I am sure that everyone has a rough idea of how much distribution and promotion fees are charged when working with such partners in China. If you consider it in that context, I think you will understand that the numbers are not that strange.

Hashiguchi : So, rather than your company doing the hands-on work, you are putting in the money to pay the partner.

Teshirogi : That is correct.

Kyokawa : Anybody has questions? Mr. Mamegano.

Mamegano : Mamegano of BofA Securities. Thank you for taking my questions.

I would like to ask you about the research and development of S-309309 and resiniferatoxin, which seems to be a little behind schedule. I think the 100 billion yen for the current fiscal year was roughly in line with expectations in terms of R&D expenses. I was wondering if there is any possibility that the 100 billion yen level of R&D expenses will continue in the next fiscal year and beyond.

Teshirogi : I will talk about macro issues, and Dr. Uehara will talk about the practical details, but we would like to consider 100 billion yen as a standard for the next few years. Of course, we must continue to sell 450 billion yen or 500 billion yen, but it will be difficult if we don't do this much for the next phase.

This is a very detailed story, but the more overseas clinical trials increase, the more the depreciation of the yen will have an effect, so if overseas clinical trials increase in the latter part of the fiscal year, it will have a modest effect. So, I think that 100 billion yen is going to be one of the standards.

Uehara : Although it is hidden in the shadows under two COVID-19-related products, but in fact, we are giving top priority to S-309309, an anti-obesity drug, in particular as a next-generation growth driver.

As I have already mentioned, we have confirmed favorable safety and blood concentration profiles, and we have already started Phase II trials in the US at top speed. Even though this is Phase II, we have set the number of cases to be more generous in order to obtain comprehensive results. We are not delaying because we cannot invest in R&D due to a lack of funds.

As for resiniferatoxin, our partners have already implemented it all, and we are updating the latest status according to their progress.

Mamegano : Thank you. May I make one more point?

Regarding Xocova in Europe and the US, I would like to know about the status of the SCORPIO-HR trial.

Uehara: We have already received final approval from the FDA for the design of the trial, and the accumulation of cases in the trial is progressing well.

We are currently accumulating many patients from various countries in the US, Africa, Europe, and Asia. In this trial, as in the Phase II and Phase III trials conducted in Asia, we will also collect Long COVID data, and we are accelerating the accumulation of cases in order to obtain the same evidence on a global level.

Mamegano : Thank you. One point that concerns me is that I think there was a history of change in the endpoint setting in Japan. As for this SCORPIO-HR, I think there are many things that you can't talk about, but if you have something to share, I would appreciate it.

Thank you.

Uehara: Regarding the endpoints, as I mentioned earlier, we are currently in a situation with the FDA. For example, the time from the onset of illness was initially planned to be within five days.

The data from the Asian trials confirmed that it is virologically and clinically appropriate to evaluate patients within three days of the onset of symptoms, so the primary segment should be a group of patients within three days.

Naturally, we have made some changes to the study design with the authorities based on the evidence from the Asian trials. However, since the change in protocol is still in the very early stages of the trial implementation, there have been no particular problems, and all of the authorities have accepted the change.

Mamegano : Okay. Thank you very much.

Kyokawa :

Mr. Yamaguchi of Citigroup Global Markets.

Yamaguchi : My name is Yamaguchi. Thank you very much. I would like to confirm a few things about Xocova in China.

First of all, what do you think about the earnings forecast, since it includes an increase in revenue of about 46 billion yen, and I think a large part of this is related to Xocova. How much profit will eventually fall to your company if that is sold there? I wonder if you could tell us again about that, including what happens to these sales.

Teshirogi : We will explain as much as we can disclose, but as I mentioned earlier, we are working with Shanghai Pharmaceutical and Chia Tai Tianqing Pharmaceutical Group on the premise that they will expand their selling activities vigorously, so there is a portion that we pay to them.

The relationship between cost and sales price is based on a number of models, which I will not disclose at this time.

Naturally, our current assumption is that the total P&L operating profit margin that we should be aiming is secured.

Yamaguchi : Thank you very much. Just to confirm one thing, are these Ping An-Shionogi sales are the same as those sold by them in China?

Teshirogi : In accounting terms, this is true in principle. Profit attributable to Ping An Life Insurance will be adjusted at the bottom of the PL as net profit attributable to non-controlling interests.

Yamaguchi : Okay, the amount sold is listed here, so if the sales are going to appear here, that means we can look at it there, right?

Teshirogi : Yes, that is true.

Kyokawa : Mr. Muraoka from Morgan Stanley MUFG Securities.

Muraoka : Hi, this is Muraoka of Morgan Stanley MUFG Securities. Sorry, I would like to continue what you just said about China.

If we assume that sales have increased by about 46 billion yen, and SG&A expenses have increased by 28 billion yen, a large portion of the YoY increase is in this area. I'm sorry, but I have the impression that the payment portion of the SG&A expenses looks too much. Could you please explain more?

Teshirogi : I have already mentioned to Mr. Yamaguchi that we would like to realize this level of operating profit in China. I would like you to think that the rest of the SG&A expenses will be used in some other way other than Xocova in China.

Muraoka : Okay. Thank you very much. In other words, if there is a delay in the approval or launch in China, for example, the SG&A expenses will be automatically reduced to some extent, is my understanding correct?

Teshirogi : Yes, that's fine.

Muraoka : Thank you very much.

Also, Sivopixant, and this time the development has been discontinued. GSK bought BELLUS's competitive products, and I am wondering if there is a similar offer for Sivopixant.

Teshirogi : Our decision not to do Phase III for chronic cough and the licensing and deployment of 918 are two completely different things. We will continue to work hard on it vigorously.

Muraoka : Is it likely that there will be attractive offers?

Teshirogi : John's group is working very hard on this. Naturally, we would like to out-licensing them because we have good data on safety and other factors. However, as I mentioned earlier, even if we spend all 100 billion yen on R&D, it would be very costly to do one or two Phase III trials in the US and Europe, while we have so many other things we want to do.

It's not that we are naturally happy to discontinue it, but rather that when we consider the priority of various things, there are more important things than this for us. We have not had many experiences, including S-770108, where we had to stop something we wanted to do because we did not have the fund to do so. The pipeline is that large, so we have prioritized this area and decided to drop it.

Kyokawa : Ms. Kumagai.

Kumagai: My name is Kumagai from Mitsubishi UFJ Morgan Stanley Securities.

The first question is about Xocova. I remember that the Korean approval for Xocova was supposed to be granted a little earlier than you explained. Are there any reasons for this delay?

Teshirogi : As the state of emergency declarations have become more gradual, I have the impression that the authorities are becoming more cautious in their reviews. Both reviews in China and Korea have really started to move in May, so there may be movement spreading COVID-19 more widely there than we can see. We are asking to examine and prepare now for the next time when it grows larger. It has been difficult to take such action, and if next pandemic comes again, the screening process will be accelerated.

Kumagai : I understand very well. Thank you very much. One more point.

The 10% increase in royalties related to HIV is expected to be mainly due to the increase in the sales of Dovato and Cabenuva, is that correct? Is it correct to view Apretude as a limited contribution?

Thank you.

Keller : Yes, proportionately Dovato and Cabenuva, which have already achieved significant sales, are the main contributors. Apretude is also doing very well compared to the beginning, so a big increase is expected in the future.

Kyokawa : Next, Ms. Haruta.

Haruta : My name is Haruta from Credit Suisse Securities.

I may be persistent but about the China part of Xocova. I see that the application is under preparation, but what is the status of the application? Can we see the application from your press release when it achieves? I wonder if you have to go through the approval process then you can sell Xocova?

What is the process here, and How early in H1 would you be able to apply?

Teshirogi : That is a very difficult story, we do not fully understand it. Our current perception of our partners is that it takes about a week from application to approval. The timing of the application is what happens, so the pattern is completely different from other countries.

In Korea, the review process begins the same way it does in Japan, but after a great deal of discussion, once application is granted, the process is very smooth. I am aware that the process is very smooth from that point on.

Kyokawa : Mr. Sakai, please go ahead.

Sakai : This is Sakai from Credit Suisse Securities.

About Long COVID, I don't think the definition has been defined yet medically, but some people have said that the characteristic of this coronavirus, or the characteristic of the virus, is that there may be a pool of the coronavirus in the body, and I think this was described as reservoir.

I think that Xocova has the strongest effect on that. In other words, it's the expulsion of the virus from the body. If some form of clinical data can be obtained in this area, I expect that Xocova will become widespread . What is your view on this area?

Teshirogi : Let Uehara explain a little bit about what we are actually doing now.

Uehara : As you have already pointed out, there is a great deal of interest in the antiviral effects of Xocova, especially from overseas doctors.

As you commented, we have received comments and expectations that the drug would be most effective, and although we have not yet reached the stage of starting specific trials at specific overseas facilities, we are currently in the final stages of discussing the design of the trials.

As you mentioned, there are patients who have been infected with COVID-19 and have completed treatment but still do not feel well, and when we take a closer look, we find particles of the virus in their blood or feces. Therefore, we are now planning clinical trials to see if the symptoms of such patients will improve even a little by taking the drug.

Keller : The important thing is to prevent the onset of Long COVID, and to that end, it is important to suppress the proliferation of the virus at an early stage. From that point of view, I think Xocova can make a great contribution. Regarding reservoir, we would like to conduct various investigations in future clinical trials.

Kyokawa : Mr. Akahane, please go ahead.

Akahane : Excuse me, this is Akahane of Tokai Tokyo Research Institute.

I would like to make one point regarding the performance of the current fiscal year. It's a little confusing. If you look at page 17, I don't know if this kind of analysis is good, but royalties are 189.5 billion yen, and operating profit is 150 billion yen, so if you subtract royalties, you have a 49.5 billion yen deficit.

The last fiscal year was 149 billion yen in operating profit with royalties of 174.9 billion yen, so a deficit of 25.7 billion yen. Then, I wonder if I should exclude royalties, but the deficit will be double this fiscal year. Can this be explained simply by the fact that some of Xocova's domestic lines are being moved to China? Or is it simply conservative?

There are various expenses, such as R&D expenses and sales promotion expenses, but in the big picture, how should we think about this large increase in the deficit, excluding royalties?

Teshirogi : You are right, and one thing is that the Xocova portion I mentioned earlier, if the Japanese portion is halved and the overseas portion is roughly halved, we recognize that the cost ratio is higher overseas, so the profit margin is not as high as in Japan. That is one point.

As for SG&A expenses, we have never spent such a large amount as 130 billion yen, but we have included various plans, including those for Xocova in Asia-China and South Korea—Japan, and, as Mr. Hashiguchi mentioned, how we will take measures to expand our business in the country.

We are very conservative in our SG&A expenses, including how much money we will spend to make it happen. As I said, my thought is that we could start at 150 billion yen. We would like to make our utmost efforts to land on the top.

Akahane : You are saying that it is almost entirely explained by the calculation of Xocova and promotional costs.

Teshirogi : You are right.

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

Kyokawa : Thank you very much. This is the end of the financial results presentation of SHIONOGI. Thank you all very much.

Teshirogi : Thank you very much.

[END]