SHIONOGI & CO., LTD.

3rd Quarter of Fiscal 2023 Financial Results Conference Call

January 31, 2024

Presentation

Kyokawa: I am Kyokawa, Vice President, Corporate Communications Department of SHIONOGI & CO., LTD. Thank you very much for joining us today despite your busy schedule.

We start SHIONOGI & CO., LTD.'s financial results briefing for Q3 of fiscal year 2023.

First of all, I would like to introduce today's speakers. John Keller, Senior Executive Officer, Senior Vice President, R&D Supervisory Unit.

Keller: I am Keller. Thank you.

Kyokawa: Toshinobu Iwasaki, Senior Executive Officer, Senior Vice President, Healthcare Business Supervisory Unit and Pharmaceutical Commercial Division.

Iwasaki: My name is Iwasaki. Thank you.

Kyokawa: Koji Hanasaki, Senior Executive Officer, Senior Vice President, Supply Supervisory Unit and Global Business Division.

Hanasaki: My name is Hanasaki. Thank you.

Kyokawa: Next, Takeshi Uehara, Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division.

Uehara: This is Uehara. Thank you.

Kyokawa: Lastly, Masako Kudou, Vice President, Finance and Accounting Department, Corporate Strategy Division.

Kudou: I am Kudou. Thank you.

Kyokawa: Now let's get started. Ms. Kudou, please go ahead.

Financial Results

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecasts Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	450.0	**336.8**	**74.8%**	338.3	**(0.5)**	**(1.5)**
Operating profit	150.0	**138.7**	**92.5%**	146.5	**(5.3)**	**(7.7)**
Profit before tax	192.5	**164.5**	**85.4%**	198.8	**(17.3)**	**(34.3)**
Profit attributable to owners of parent	155.0	**127.2**	**82.1%**	157.7	**(19.3)**	**(30.5)**
EBITDA*	-	**160.2**	**-**	157.0	**2.0**	**3.2**

- Revenue and all profit items are on track to achieve full-year forecasts
- Expanding sales centered on infectious disease drugs will alleviate the 100 billion yen impact from the Japanese government's purchase of Xocova recorded in the same period of the previous year

Exchange Rate (average)	FY2023 Forecasts (Oct. 31)	FY2023 Apr.-Dec. Results
USD($) – JPY(¥)	141	143.33
GBP(£) – JPY(¥)	173	179.59
EUR(€) – JPY(¥)	151	155.33

* 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.)

Kudou: I will now explain the overview of the financial results for Q3.

First of all, on page four, I will discuss consolidated financial results.

The results for Q3 of FY2023 were revenue of JPY336.8 billion, operating income of JPY138.7 billion, income before income taxes of JPY164.5 billion, and quarterly income of JPY127.2 billion. EBITDA, which was newly set as a KPI in the STS2030 Revision mid-term management plan announced last June, was JPY160.2 billion.

As for progress against the full-year forecast, we believe we are making steady progress in sales revenue and all profit items.

In addition, although both are negative as compared to the previous year, Q3 of last fiscal year included JPY100 billion from the Japanese government's purchase of Xocova. In Q3 of the current fiscal year, this JPY100 billion impact was absorbed and revenue was kept at 0.5% below the previous year's level. We see steady progress in expanding our own sales, especially of infectious disease drugs.

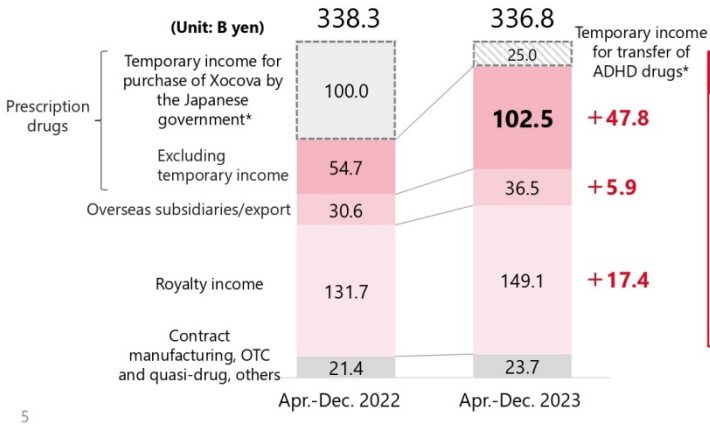
Each profit item has made a high percentage of progress toward the full-year forecast. We are positive that such strong progress is being made, but achievement of the top line will depend in part on the status of COVID-19 and the influenza pandemic in Q4, so at this time we are leaving our forecast unchanged.

Regarding foreign exchange, the yen weakened more than expected, resulting in foreign exchange gains in each currency.

Expansion of In-house Sales Centered on Infectious Disease Drugs

Exceeded the previous year's revenue in all business segment (excluding temporary factors) due to sales growth of in-house developed infectious disease drugs

Revenue by Segment (Y on Y)



Main sales increase factors

- **Prescription drugs (Excluding temporary income)**
  - Sales of Xocova and Xofluza
- **Overseas subsidiaries/export**
  - Sales of cefiderocol (Fetroja, Fetcroja)
- **Royalty income**
  - Strong sales of ViiV's HIV franchise

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* Temporary factors that affected revenue

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Next, on page five, we discuss the expansion of in-house sales, particularly of infectious disease drugs.

The graph on the left compares cumulative sales revenue from April-December of the last fiscal year and April-December of the current fiscal year, including a breakdown by segment.

Excluding the JPY100 billion in revenue from the Japanese government's purchase of Xocova in the previous fiscal year and the JPY25 billion one-time payment associated with the transfer of the ADHD drug license in the current fiscal year, which was a one-time factor that affected revenue, domestic prescription drug sales nearly doubled from JPY54.7 billion in the previous fiscal year to JPY102.5 billion in the current fiscal year, a YoY increase of JPY47.8 billion.

As we will show again later in detail, the main reason for this is the sales expansion of Xofluza, an influenza treatment, and Xocova, a COVID-19 treatment.

In the overseas business, sales of cefiderocol Fetroja and Fetcroja in Europe and the United States, respectively, increased by JPY5.9 billion YoY due to their sales expansion. In terms of royalty income, ViiV's HIV franchise sales were strong, resulting in an increase of JPY17.4 billion in royalty income compared to the previous year.

As described above, all businesses exceeded the previous year's results, excluding one-time factors, due to the expansion of sales, mainly of infectious disease drugs discovered and developed in-house.

Statement of Profit or Loss

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	450.0	336.8	74.8	338.3	(0.5)	(1.5)
Cost of Sales	13.2 59.5	12.6 42.4	71.3	13.2 44.6	(4.9)	(2.2)
Gross profit	390.5	294.4	75.4	293.8	0.2	0.6
Selling, general & administrative expenses, R&D expenses total	51.3 231.0	43.6 146.9	63.6	43.9 148.4	(1.0)	(1.5)
Selling, general & administrative expenses	26.4 119.0	22.1 74.3	62.4	21.7 73.6	1.0	0.7
R&D expenses	24.9 112.0	21.6 72.6	64.9	22.1 74.8	(2.9)	(2.2)
Other income & expenses	(9.5)	(8.8)	92.2	1.1	-	(9.8)
Operating profit	33.3 150.0	41.2 138.7	92.5	43.3 146.5	(5.3)	(7.7)
Finance income & costs	42.5	25.7	60.6	52.3	(50.8)	(26.6)
Profit before tax	42.8 192.5	48.8 164.5	85.4	58.8 198.8	(17.3)	(34.3)
Profit attributable to owners of parent	155.0	127.2	82.1	157.7	(19.3)	(30.5)

Main Variation Factors (Y on Y)

Revenue
- Increase
  - Overseas subsidiaries /export, Royalty income
- Decrease
  - Purchase of Xocova by the Japanese government in Q3 FY2022

Other income & expenses
- Increase in expenses
  - Costs related to implementation of early retirement program in Q2 FY2023 (6.6 B yen)

Finance income & costs
- Decrease in income
  - Received dividend from ViiV (FY2022 dividend increased temporarily)

  ⇒ Dividends are progressing as planned, excluding temporary factors

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Next is page six, the consolidated statement of profit and loss.

As for the revenue from sales, it is as I mentioned on the previous page.

Cost of sales decreased 4.9% from the previous year, a larger percentage decrease than the 0.5% decrease in revenue, but this was due to an increase in the sales ratio of in-house developed products with a low cost ratio and royalty income with no cost.

Selling, general, and administrative expenses and research and development expenses have progressed about 65% of the full-year forecast, respectively. Our approach to these costs is to manage them flexibly according to the top line landing.

As for other income and expenses, expenses were higher YoY due to the recording of JPY6.6 billion in expenses related to the implementation of a special early retirement program in the current period.

Regarding finance income and costs, Q1 of last fiscal year was below the prior year's level due to a one-time factor that resulted in an increase in dividends from ViiV, but dividends for the current fiscal year are generally on track as planned.

The full-year landing is also within our expectations, including the fact that the dividend from ViiV is usually largest in Q4 of the year.

As a result of the above, each profit item is on track against the full-year budget.

Revenue by Segment

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Prescription drugs	167.0	**127.5**	**76.4**	154.7	**(17.5)**	**(27.1)**
Excluding temporary income	-	**102.5**	**-**	54.7	**87.5**	**47.8**
Temporary income	-	**25.0**	**-**	100.0	**-**	**(75.0)**
Overseas subsidiaries/export	49.2	**36.5**	**74.3**	30.6	**19.4**	**5.9**
Shionogi Inc.(US)	17.0	**13.1**	**77.2**	11.5	**14.1**	**1.6**
Fetroja	-	**10.6**	**-**	7.3	**45.4**	**3.3**
Shionogi B.V.(EU)	13.0	**10.1**	**77.4**	6.6	**52.0**	**3.4**
Fetcroja	-	**7.9**	**-**	5.1	**56.0**	**2.8**
Ping An Shionogi/C&O	12.1	**8.3**	**68.8**	8.3	**(0.7)**	**(0.1)**
Others	7.1	**5.1**	**70.7**	4.1	**22.3**	**0.9**
Contract manufacturing	16.4	**11.7**	**71.7**	10.3	**14.2**	**1.5**
OTC and quasi-drug	14.8	**10.6**	**71.7**	10.1	**5.1**	**0.5**
Royalty income	201.2	**149.1**	**74.1**	131.7	**13.2**	**17.4**
HIV franchise	196.5	**146.1**	**74.3**	126.9	**15.1**	**19.2**
Others	4.7	**3.0**	**63.8**	4.8	**(37.1)**	**(1.8)**
Others	1.5	**1.4**	**93.8**	1.0	**33.2**	**0.3**
Total	450.0	**336.8**	**74.8**	338.3	**(0.5)**	**(1.5)**

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Main Variation Factors (Y on Y)

Prescription drugs

- Increase
  - Sales of Xocova and Xofluza
  - Receipt of lump-sum income for transfer of ADHD drugs in Q1 FY2023 **(Temporary income)**
- Decrease
  - Sales of ADHD drug
  - Purchase of Xocova by the Japanese government in Q3 FY2022 **(Temporary income)**

Overseas subsidiaries/export

- Increase
  - Sales of cefiderocol (Fetroja, Fetcroja)

Royalty income

- Increase
  - Strong sales of ViiV's HIV franchise

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The figures for domestic ethical pharmaceuticals indicated include those excluding transitory factors.

The total amount was JPY127.5 billion, JPY27.1 billion less than the previous year's JPY154.7 billion. Excluding the JPY100 billion in the previous year and JPY25 billion in the current year, which are transitory factors, the total for the current year was JPY102.5 billion, an increase of JPY47.8 billion from JPY54.7 billion in the previous year.

Overseas subsidiaries/exports totaled JPY36.5 billion this fiscal year, up JPY5.9 billion from JPY30.6 billion last fiscal year, due to sales growth of cefiderocol in Europe and the United States.

Royalty income totaled JPY149.1 billion this fiscal year, up JPY17.4 billion from JPY131.7 billion last fiscal year, due to strong sales of ViiV's HIV franchise, both in actual sales and in foreign exchange.

Overall sales revenue was JPY336.8 billion, well on track to achieve the full-year forecast, as contract manufacturing, over-the-counter drugs, and other sales also increased YoY.

Prescription Drugs in Japan

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Infectious disease drugs	97.5	**69.0**	**70.8**	102.9	**(32.9)**	**(33.8)**
COVID-19 related products + Influenza franchise	88.6	**62.0**	**70.0**	96.2	**(35.6)**	**(34.2)**
Excludes purchase of Xocova by the Japanese government	-	**62.0**	**-**	(3.8)*	**-**	**65.8**
Cymbalta	4.2	**3.1**	**75.4**	4.4	**(29.5)**	**(1.3)**
OxyContin franchise	4.3	**3.3**	**77.7**	3.5	**(5.3)**	**(0.2)**
Symproic	4.9	**3.3**	**67.3**	2.6	**27.5**	**0.7**
Actair	1.0	**0.5**	**50.5**	0.4	**28.4**	**0.1**
Mulpleta	0.1	**0.1**	**53.7**	0.1	**(19.9)**	**(0.0)**
Pirespa	1.9	**1.6**	**81.3**	2.0	**(23.3)**	**(0.5)**
Others	53.1	**46.6**	**87.7**	38.7	**20.3**	**7.8**
ADHD drugs (Intuniv and Vyvanse)**	25.0	**25.0**	**100.0**	15.8	**57.8**	**9.2**
Prescription drugs	167.0	**127.5**	**76.4**	154.7	**(17.5)**	**(27.1)**
Excluding temporary income	-	**102.5**	**-**	54.7	**87.5**	**47.8**

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

* Returns of Xofluza and Rapiacta (Recognized △5.3 billion yen in 2Q of FY2022) ** Includes temporary income from transfer of ADHD drugs

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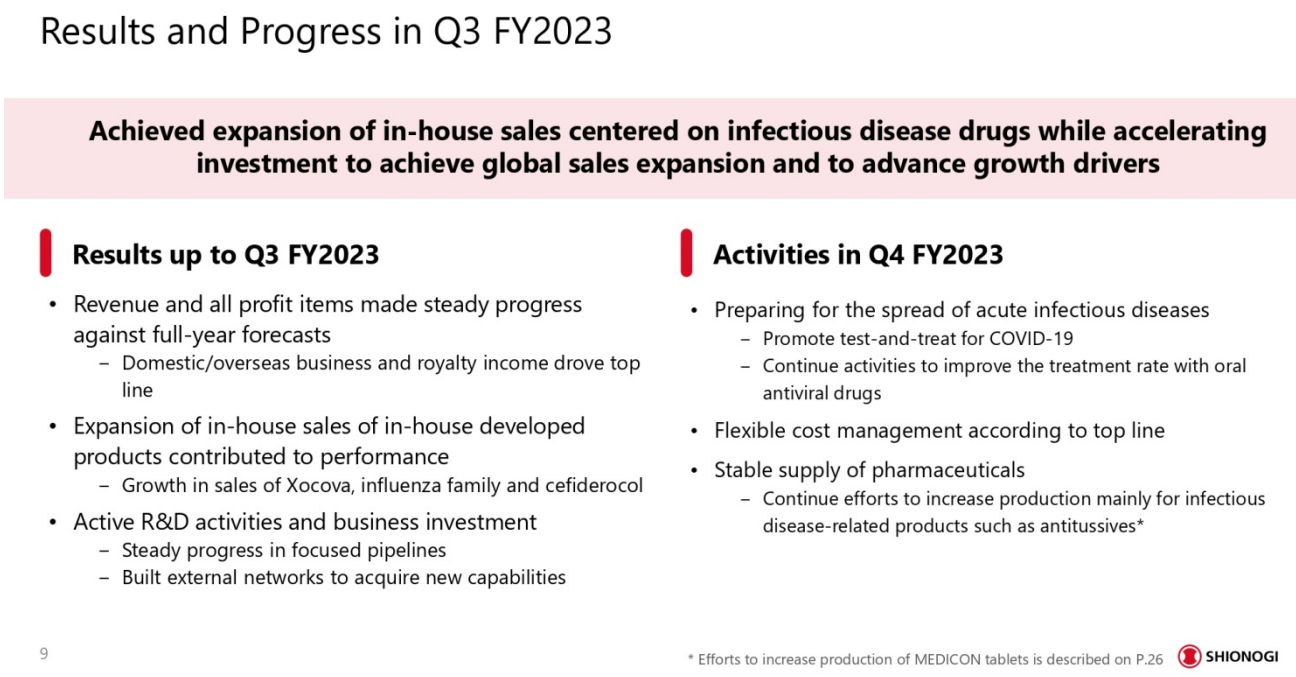
Continuing on page eight, we detail revenue from prescription drugs in Japan.

As with the description of prescription drugs in Japan on page seven, figures are also shown excluding transitory factors. Infectious disease drugs are broken down by COVID-19-related products and influenza family together.

Overall sales of infectious disease drugs totaled JPY69 billion this fiscal year, down JPY33.8 billion from JPY102.9 billion last year. However, if we exclude the purchase of Xocova by the Japanese government, which is a one-time factor, sales increased by JPY65.8 billion YoY, and you can see that we have greatly increased our own sales.

Overall sales of prescription drugs in Japan, including the impact of the license transfer of ADHD drugs, a one-time factor in the current fiscal year, amounted to JPY127.5 billion for the current fiscal year, representing 76.4% of the progress against the full fiscal year.



Please see page nine. This is a summary of what we have reported so far.

As results and progress through Q3, we have achieved expansion of in-house sales, mainly of infectious disease drugs, while accelerating aggressive investment for global expansion and establishment of growth drivers.

As for the results through Q3, to reiterate, sales revenue and each profit item progressed steadily against the full-year forecast. All businesses performed well, and in particular, the expansion of in-house sales of Xocova, influenza family, cefiderocol, and other in-house products contributed to our performance, and we believe that we are making steady progress in strengthening in-house sales as stated in STS2030 Revision.

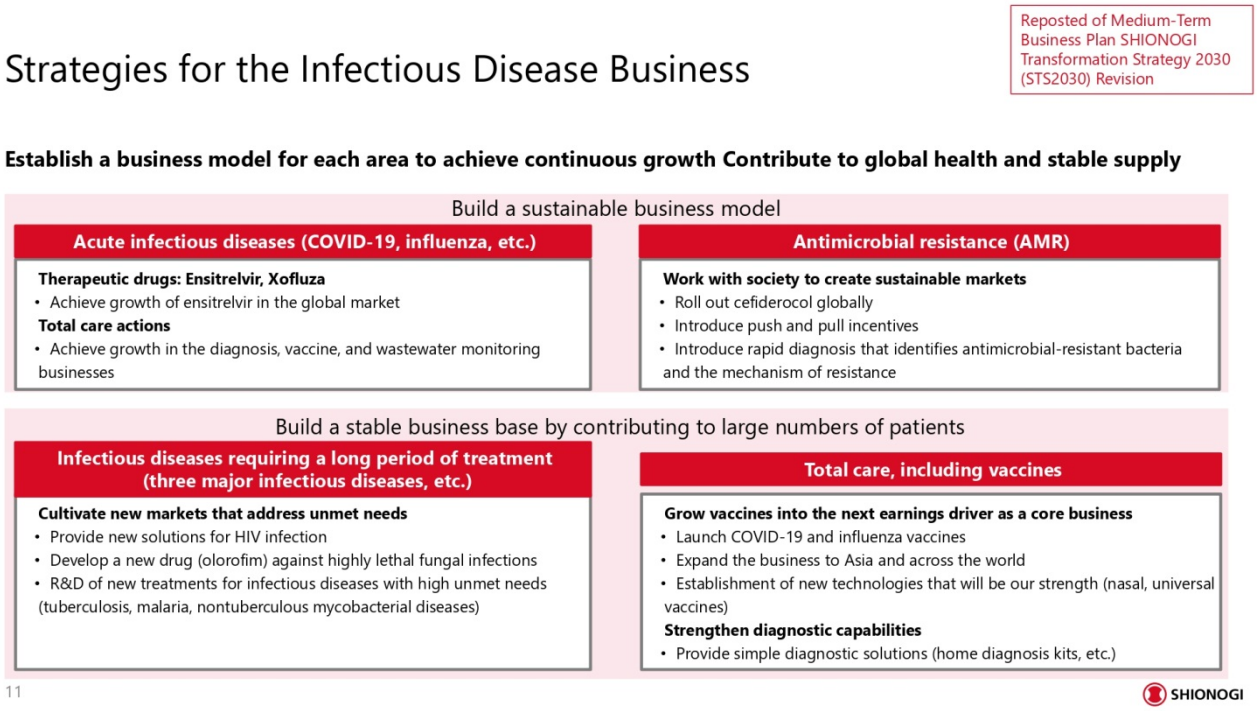
In line with our policy of active investment, we have steadily promoted our focused pipeline and made necessary business investments for the future.

As for our efforts in Q4, we will continue our vigorous activities to promote the spread of early diagnosis and treatment and to improve the treatment rate with oral antiviral drugs to prepare for the spread of acute infectious diseases.

We will also implement flexible cost management both above and below the line, depending on the top line.

Furthermore, strongly recognizing our responsibility as a pharmaceutical company to ensure a stable supply of pharmaceuticals, we will first work diligently to increase production of antitussives, Medicon, and will also continue to consider ways to increase production of other infectious disease-related products.

That is all from me.

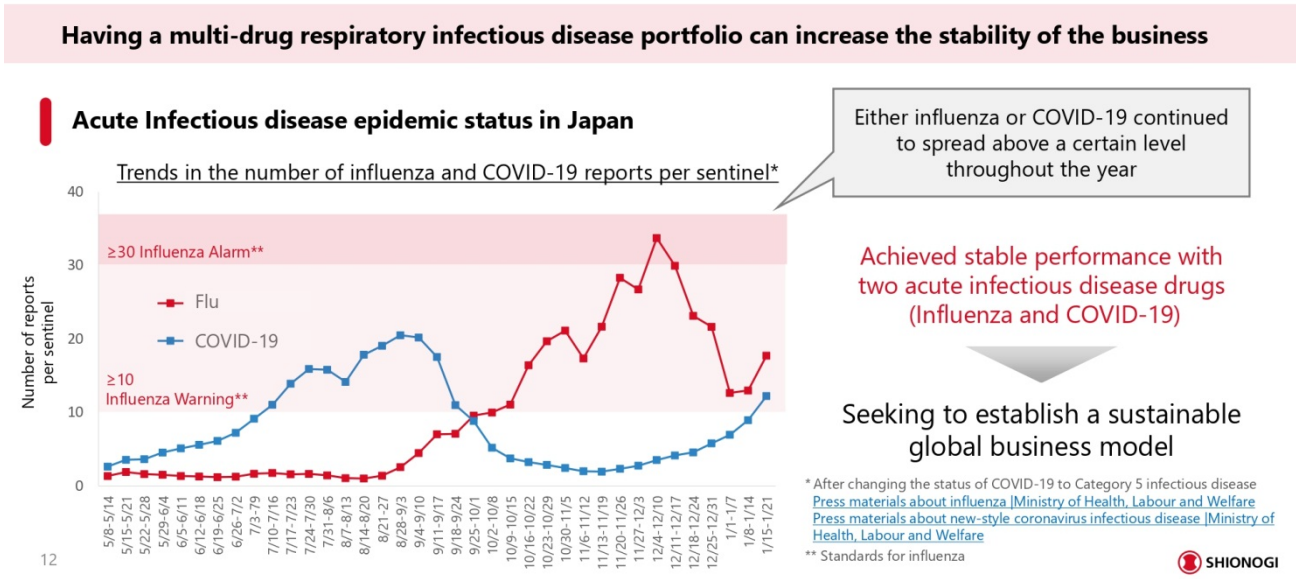


Iwasaki: Now, Iwasaki will talk about our strategies for infectious disease business.

This slide shows SHIONOGI's strategies for infectious disease business. In the medium-term business plan SHIONOGI Transformation Strategy 2030 STS2030 Revision released last June, we indicated that we would establish four major business models, including acute infectious diseases, antimicrobial resistance, which is referred as AMR, infectious diseases requiring a long period of treatment, and total care, including vaccines to achieve sustainable growth and realization of these business models.

From these four perspectives, we present the main results for Q3 of this fiscal year and our initiatives for future growth.

Acute Infectious Diseases: Establishment of Sustainable Business



First, let us discuss acute infectious disease. Please see page 12.

It is about establishment of a sustainable business model for acute infectious diseases.

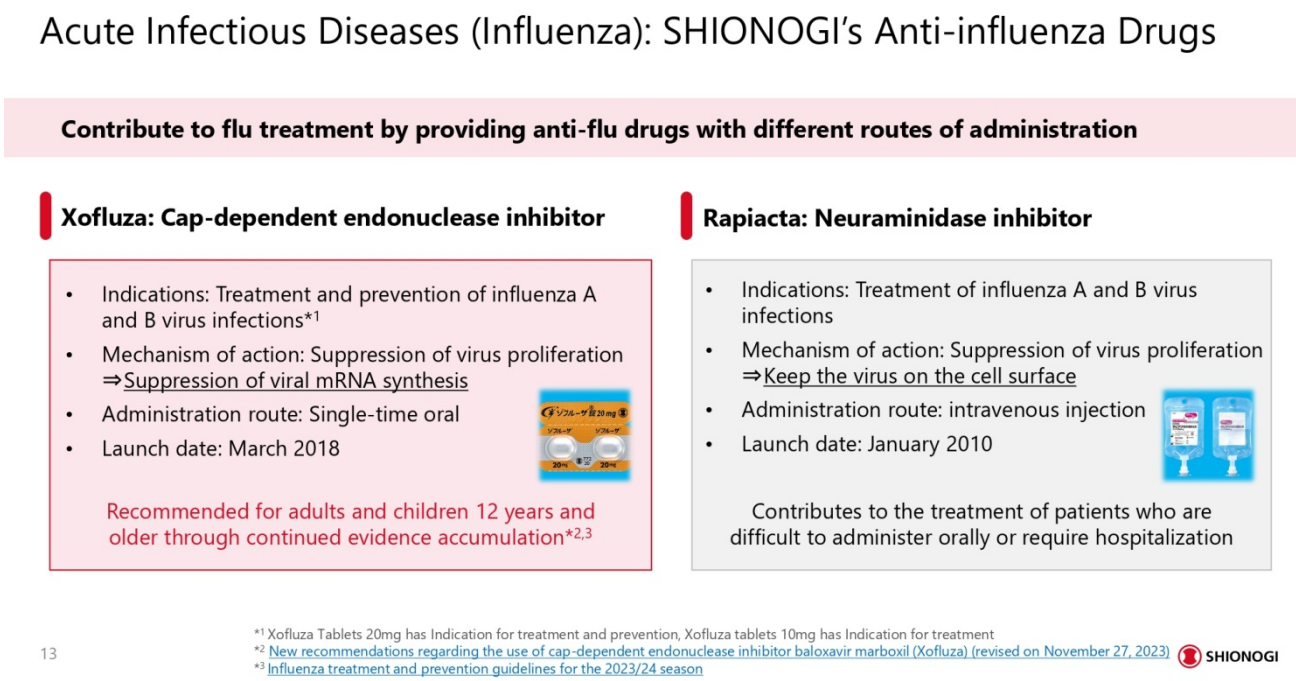
The graph on the left shows the epidemic status of influenza and COVID-19, major acute respiratory infections in Japan, based on the number of cases reported per fixed point by the Ministry of Health, Labor and Welfare.

For influenza, a fixed point exceeding 1 is defined as an epidemic, a fixed point exceeding 10 as an alert, and a fixed point exceeding 30 as a warning. The graph is colored 10 and 30 or more as an indication of the scale of the epidemic.

We hope you can confirm that since May, when COVID-19 was placed and changed to a Category 5 infectious disease, either influenza or COVID-19 has continued to be prevalent to a certain degree.

As reported earlier in our business results, with two infectious disease drugs, an anti-influenza drug and a COVID-19 treatment, we will proceed to build a stable revenue base in the acute infectious disease field, which is recognized as an unstable business.

In terms of revenue, in addition to the expected revenue generation in this manner, we will work toward building a sustainable business model for acute infectious diseases that is not affected by the size of the epidemic by adding RSV drugs to our portfolio in the future and by expanding this initiative to the global arena.



Page 13. This shows anti-influenza drugs possessed by SHIONOGI.

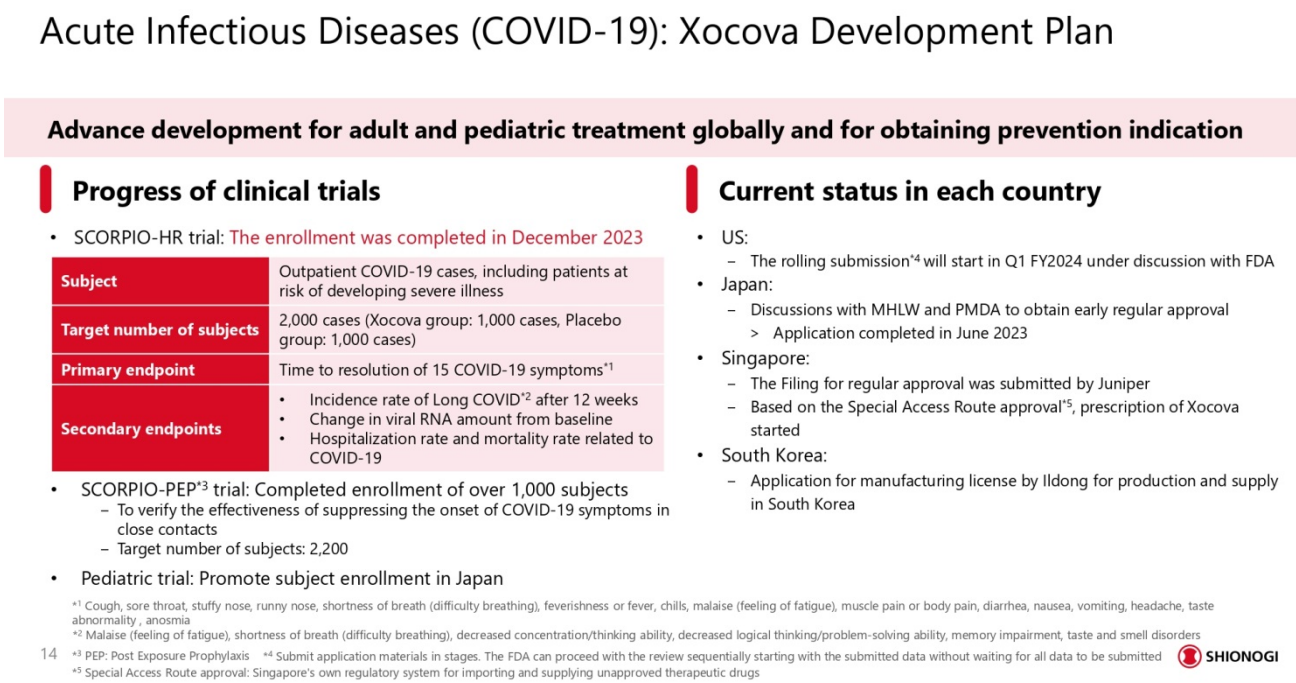
By providing a standard drug for influenza treatment with different routes of administration, we aim to contribute to the treatment of a large number of patients.

The first is Xofluza, a cap-dependent endonuclease inhibitor, and the second is Rapiacta, a neuraminidase inhibitor. The product profiles for each are shown here; both drugs have the mechanism of inhibiting viral proliferation in a broad sense, but Xofluza, which has a novel mechanism of action, is characterized by suppressing viral mRNA synthesis, which is the early stage of the viral proliferation process. The drug is expected to be easy and reliable to take, with treatment completed with only one pill dose.

As a special note for this season, through the continuous accumulation of evidence since its launch, we have received a recommendation from the Japanese Society of Infectious Diseases for patients aged 12 to 19 years and adults, and a recommendation from the Japanese Academy of Pediatrics for children aged 12 years and older.

Rapiacta is an injectable drug that is expected to be administered reliably and to provide antiviral treatment in cases where, for example, tablets cannot be taken orally. Like Xofluza, it is characterized by excellent antiviral efficacy and safety.

We will continue to fulfill our responsibilities as an infectious disease manufacturer, including in terms of production, and will continue to provide appropriate information so that these two drugs can continue to be used safely for influenza patients.



Uehara: I would like to continue with the current status of Xocova 's development plan.

First, market conditions. I am writing about the situation in each country and Japan. We have already applied for approval of this product and submitted the materials in June 2023, so we are currently working with the authorities to obtain approval.

In addition, as we move forward with our global expansion, one of the projects is the SCORPIO-HR trial, a global Phase III study. As it is stated in red, we have completed the enrollment of over 2,000 cases in December 2023. For the primary endpoint, the time to resolution of all COVID-19-related symptoms, all 15 symptoms, was determined after consultation with the FDA.

In addition, we have obtained data on the suppression of the incidence of Long COVID, so-called sequelae, at 12 weeks, and we are verifying this as well in SCORPIO-HR trial. We are keeping the data up to three months under blind, so we expect to be able to present our results to you in April on these results as a topline after a three-month follow-up starting in December.

In the field of prevention, which will continue to be in high demand in the medical field, we have completed the enrollment of more than 1,000 subjects around the world. Specifically, the perspective is to prevent the onset of the disease by having people in various medical settings and those in close contact with the disease take the medication. The target number of patients is 2,200. This is also a very large-scale study, and we are continuing to enroll patients.

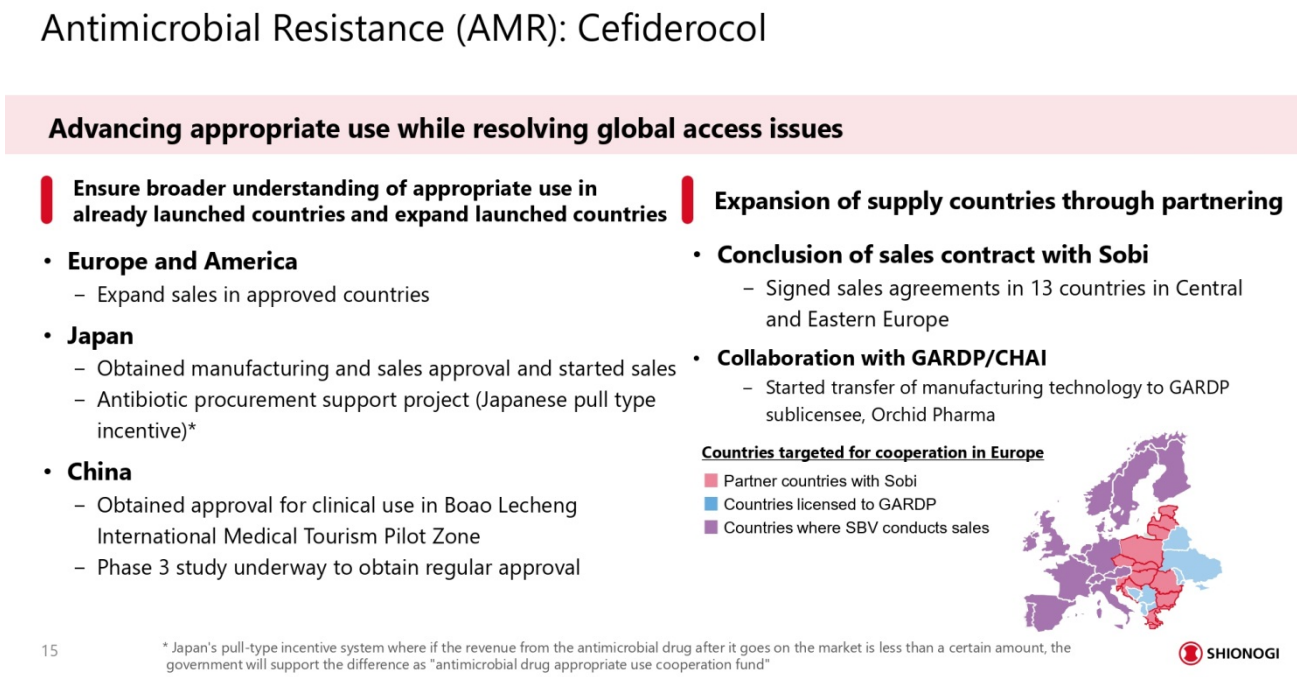
We are currently promoting the enrollment of pediatric patients in a study for domestic approval, in which a very small tablet is used to make it easier for patients to take the drug.

This is the situation in each country based on these clinical trials. Outside of Japan, in the United States, we are currently discussing with the FDA the detailed procedures to proceed with rolling submissions of data as soon as the SCORPIO-HR trial is completed.

In Japan, it is used in actual medical practice for a wide range of patients. In other countries, for example, in Singapore, we have already started prescribing the product for use in the medical field based on requests

from physicians under SAR system. The product is being used very favorably. The implementation of normal approval is being carried out by Juniper, with whom we have a partnership.

As for Korea, our partner, Ildong, has completed the technical transfer of manufacturing in Korea, as we have announced. We have submitted a new application to get the manufacturing approval for production and supply in South Korea, and we are currently in the process of its review.



Hanasaki: Now, I, Hanasaki, would like to explain the global expansion of cefiderocol as an initiative against drug resistance, or AMR.

During this fiscal term, we continued our efforts to promote appropriate use and improve access to medicines.

First, on the left side, I would like to explain further penetration in countries where the product is already on the market and the expansion of the number of countries where the product is launched on the market.

First of all, in Europe and the United States, the prescribing of cefiderocol has become widespread in the countries where it was launched due to activities to provide information on the proper use of the drug and the accumulation of real-world evidence, leading to an increase in sales YoY, as Kudou explained earlier.

In Japan, the product has been approved for production and marketing, and sales began in December. It is also the first drug to be selected for Japan's pull-type incentive program, the Support Project for Securing Antimicrobial Agents.

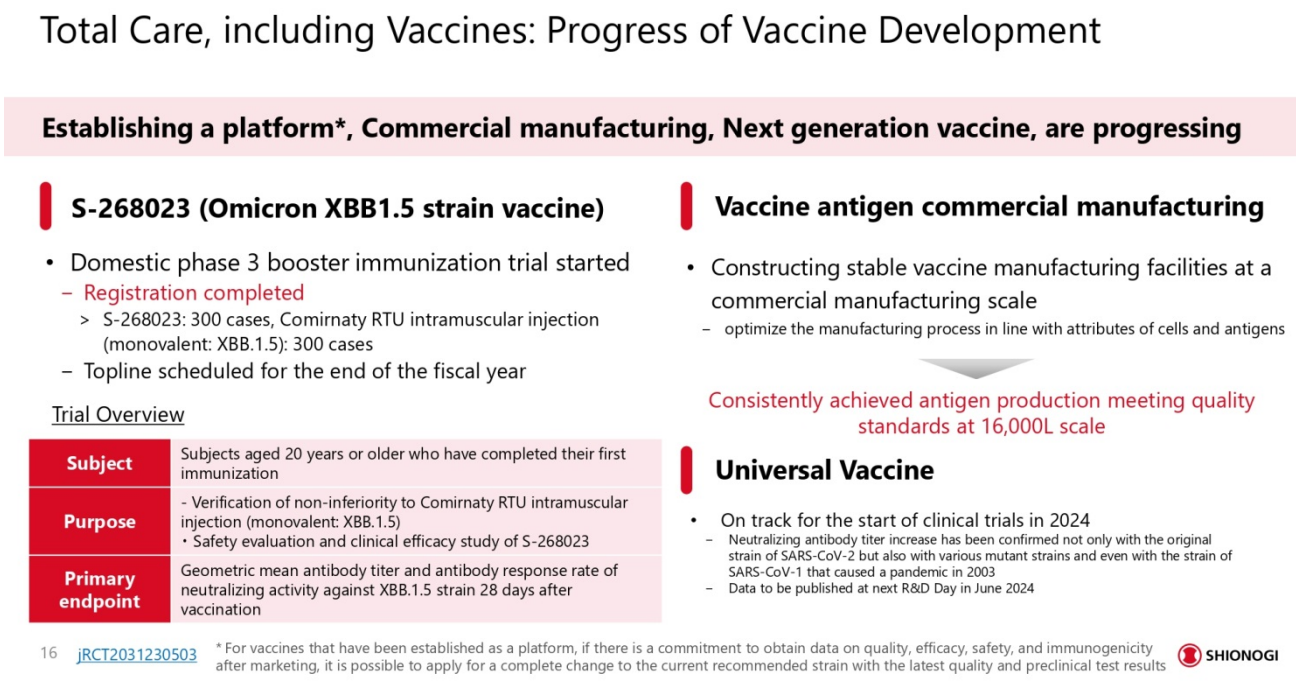
In China, as reported in the press release today, we were able to obtain approval in the Hainan Province Medical Special Zone. The Hainan Province Medical Special Zone is an advanced international medical tourism zone, which means that FDA-approved pharmaceutical products can be used within the zone through a relatively simple procedure. In addition, Phase III trials are progressing steadily toward the filing for regular approval.

Next, on the right side, as the expansion of supply countries through partnering, in December last year, we concluded a sales agreement with Sobi to sell our products in 13 countries in the Europe. This agreement will

allow Sobi to distribute the drug in areas where we do not have a sales network, and it enables us to deliver the drug to people who need it more efficiently. In terms of collaboration with GARDP and CHAI, GARDP has concluded a manufacturing license agreement with Orchid Pharma, a pharmaceutical company based in India, and we have started the transfer of technology.

The bottom right shows the overall picture of the supply structure in Europe. Purple is the countries where SHIONOGI Europe sells its products, and red is the 13 countries where we have partnered with Sobi, as mentioned earlier, and with GARDP, we are now ready to deliver cefiderocol throughout Europe.

We will continue to develop a system to improve access to this drug and actively promote efforts, including the introduction of various incentives, with the aim of establishing a sustainable business model.



Uehara: Continuing on, I, Uehara would like to talk again about the current status of the COVID-19 vaccine.

As you are all aware, we have submitted all data up to Phase III for the vaccine corresponding to the S-268019 origin strain. In addition, we are proceeding with the development of a vaccine that has antigenicity against the currently prevalent XBB strain, and we would like to receive approval for our vaccine technology as a platform, including this data, so we are conducting a phase 3 trial.

We have completed the enrollment of patients for the Phase III study required by the end of the year. We are conducting a study of non-inferiority to Comirnaty, with 300 patients in each group. We expect to have the results available by the end of the fiscal year, in the spring, so we will have another opportunity to introduce you the results again.

In addition, we have conducted many studies on the future commercial production of the product, and we have studied the purification of the production process, the extraction conditions for each process, and the culture conditions for each process. We have reached the stage where we have generally optimized the manufacturing process, and we will continue to utilize this manufacturing process with XBB strains as well, and we are gradually reaching the stage where we will be able to manufacture the products on a large scale to meet quality standards.

Finally, the universal vaccine project Specifically, in light of the current situation where it is necessary to create different neutralizing antibodies for different strains of vaccine, such as the origin strain vaccine and the Omicron strain vaccine, we have succeeded in designing an antigen that can be expected to induce neutralizing antibodies against a wide range of strains in a universal manner.

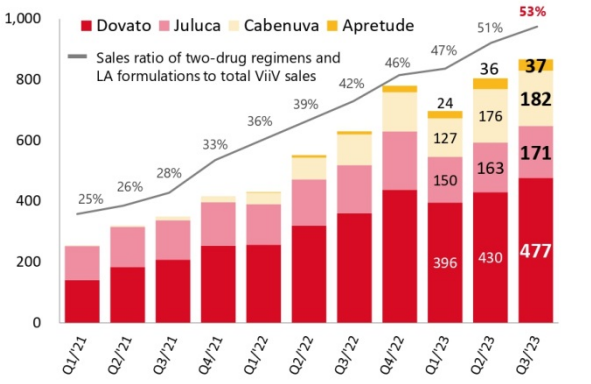
We are now preparing to use these new antigens to deliver a new vaccine to the world and to conduct clinical trials in the next fiscal year, 2024.

We are planning to hold an R&D Day in June and will disclose detailed data there.

Infectious Diseases Requiring a Long Period of Treatment(HIV) : Progress of HIV Business by ViiV

HIV business is strong due to growth in oral two-drug regimens*1 and LA formulations*2

ViiV sales trend of oral two-drug regimens and LA formulations*3



Growth in oral two-drug regimens and LA formulations

- Steady progress towards sales forecast of £7 billion in 2026
  - Sales ratio of two-drug regimens and LA formulations increased to 53%
  - Dovato drives sales
  - Cabenuva, Apretude market continues to expand

ULA*4 milestones for growth drivers

- Achieving sustainable growth by continuing to roll out new products beyond 2026

	2026年	2027年	2028-2030年
ULA (PrEP)	Q4M file・launch		Q6M file・launch
ULA (Treatment)		Q4M file・launch	Q6M file・launch
Self-injection (Treatment)			file・launch

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*1 Products name : Dovato, Juluca *2 Long Acting (Products name : Cabenuva, Apretude) *3 Source: GSK financial statement *4 Ultra Long Acting

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Keller: I'm John Keller. I would like to start by talking about the HIV franchise.

We are seeing very strong growth. We are seeing very strong growth based on the oral two-drug regimen primarily to Dovato and the growth of the long-acting formulations, especially the treatment formulation Cabenuva. Although these have just launched relatively recently, we are working on achieving sales projection of GBP7 billion for the HIV franchise in 2026.

We have a very exciting advancement in the next stage of the pipeline. Our current treatment is an injection once every two months. We are working on format that can achieve injection once every four months, only three times per year. This is a particularly important challenge. This is because it is very beneficial to the patient. We believe that patient convenience will be increased greatly. This is because there will be only three times per year, both for testing and for injection.

Next, regarding prevention, this does not require a partner drug and can be developed as a single drug, making development easier than treatment. We are first proceeding with development in the United States with the aim of filing an application in 2026. We are also aiming for ULA formulations, for example once every six months. We are also proceeding with the development of self-injections, with the aim of filing and launching each of these in the 2028-2030 timeframe.

Progress of Major Development Products

as of January 30, 2024

Disease area	Pipeline	Indication	Current stage	FY2023	FY2024	Note
COVID-19 Family	**S-268019**	**COVID-19 (Vaccine)**	**Submission**			
	Ensitrelvir	**COVID-19**	**Submission, Phase 3**			SCORPIO-HR registration completed
	S-268023	**COVID-19 (XBB 1.5, Vaccine)**	**Phase 3**	Phase 3 topline results (4Q)		Start Phase 3 (registration completed)
	S-892216	COVID-19	Phase 1	Phase 1 topline results		
	Universal Vaccine	**COVID-19 (Vaccine)**	**Preclinical**			
Infection diseases	**Olorofim**	**Invasive aspergillosis**	**Phase 3**	Completion of Phase 3 case registration (4Q)		Announced Phase2b results*
	S-337395	**RSV infections**	**Phase 2**			Start Phase 2
	S-743229	**AMR (Urinary tract infection)**	**Phase 1**	Phase 1 topline results		Start Phase 1 overseas
	S-649228	**AMR (Various infectious diseases)**	**Preclinical**			
QOL Diseases with High Social Impact	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 (FY24 3Q)	Submission (FY25 1Q)	
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2		Submission (3Q)	
	S-309309	**Obesity**	**Phase 2**	Obtain Phase 2 data (FY24 1Q)	Phase 3 start	Phase 2 registration completed
	S-531011	Solid tumor	Phase 1b/2		Phase 2 start (2Q)	
	S-151128	**Chronic pain**	**Phase 1**	Phase 1 topline results		Start of Phase 1b for OA patients

SHIONOGI R&D Day 2024 scheduled to be held on June 7 2024

topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately * Announced by F2G (October 30, 2023): F2G Press Releases

SHIONOGI

Now, let me turn to the overall pipeline.

We have already discussed the COVID-19 family, both treatment and vaccine, but to look at other infectious diseases.

First, we briefly mention RSV infection. As we mentioned, we are looking forward to a model of rapid testing and rapid treatment. We are testing for COVID-19, influenza, and RSV, can be rapidly achieve. And we SHIONOGI can offer solutions for each of those viruses when identified.

So that RSV oral agent we are progressing, has now move into a Phase II human challenge study. The two compounds on the graph below that, S-743229 and S-649228, are part of the Qpex acquisition and collaboration which are describing them in an upcoming slide.

The progress in other therapeutic areas; I'll be also talking about our S-309309 obesity drug in more detail shortly. But to mention others, S-151128, our chronic pain drug, will also be progressed Phase 1b study in osteoarthritis patient. And for Japan, we are progressing the preparation of the submissions for Zuranolone and for the digital therapeutic for ADHD SDT-001.

Also Zatolmilast is proceeding in Phase II/III. The top line results will be anticipated later this year.

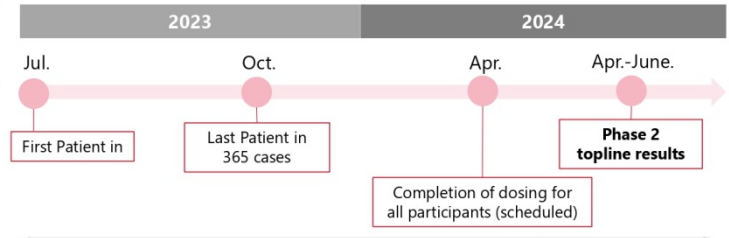
S-309309 (MGAT2* inhibitor) Development Progress

Phase 2 trial progressing as planned

Trial Overview**

Country	The U.S.
Subject	Adults with a BMI of 30 or higher
Trial design	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
Dosage number of cases	• Oral once daily for 24 weeks • S-309309: 3 doses, placebo, 80 in each group (320 in total)
Primary endpoint	Percent change in body weight from baseline (week 24)
Secondary endpoint	• Percentage of subjects achieving ≥5%/10%/15%/20% weight loss • Waist circumference, waist/hip ratio, BMI, abdominal fat/lean mass

Status of progress



- **Participant registration was completed in October, with a total of 365 cases registered**
- No adverse events that would affect the continuation of the trial have been reported
- After 24 weeks of treatment and follow-up period, we plan to provide topline results in April to June.

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* Monoacylglycerol acyltransferase 2 ** ClinicalTrials.gov: NCT05925114

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Then, I will explain about obesity. Our MGAT2, which inhibits the enzyme necessary for the resynthesis of triglycerides in small intestinal epithelial cells, its Phase 2 study recruitment have already finished.

We are looking at a six-month treatment period. After completion of that six-month treatment period, and we have three doses and placebo being studied with 80 patients in each group. Then we have a follow-up period, and then we anticipate being able to provide the top-line results from this study in the April to June timeframe. We will be confirming body weight and tolerability.

The study is blinded yet, but so far, we are not seeing the sort of high-level GI side effects. The tolerability profile looks as good as we expected.

Further Strengthening R&D Capabilities in the Infectious Disease Field

Through Qpex, a wholly owned subsidiary, we have expanded our capabilities

Evolution of infectious disease R&D

- **Enhanced global R&D capabilities**
  - Smooth collaboration with Qpex Inc.
    - > Robust R&D activity including xeruborbactam*
  - Progress in strengthening external networks
    - > Enhancing collaboration with external organizations, including regulatory authorities and government agencies like BARDA
- **Maximizing antibacterial research**
  - Commenced research and development of novel infectious disease therapeutics with Qpex Inc.
  - Strengthen research in the field of infectious disease therapeutics to address remaining unmet needs

Progress of two development products

S-649228: xeruborbactam＋cefiderocol

- Injection in combination with cefiderocol
- Progress is being made in non-clinical trials, and transition to the clinical stage is scheduled for 1Q FY2024

S-743229: xeruborbactam＋ceftibuten

- Oral formulation in combination with the cephem antibiotic, ceftibuten
- Phase 1 trial ongoing

Funded in whole or in part with federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA) under OTA number HHSO100201600026C.

* β-lactamase inhibitor

SHIONOGI

Next, with respect to Qpex.

This is the company we acquired in the middle of last year, but the organization is deeply passionate about addressing infectious diseases. The company has been operating in this area for over a decade and has been involved in similar initiatives to ours.

With their specialized skills, they have xeruborbactam, which was part of the focus of the license. The acquisition with Qpex is now being progressed in collaboration effects in two formats. First, S-649228. This is injection in combination with cefiderocol. Cefiderocol has very strong coverage, but we are progressing to develop a new product in order to prepare for the continuing evolution of AMR bacteria.

Furthermore, in S-743229, it is currently in Phase I study and is also progressing well.

Equally important, regarding Qpex, we have very strong experience in the infectious disease area, and we will continue to work together to grow SHIONOGI's overall infectious disease area and pipeline.

As for the new projects, we will also continue to use their expertise and go forward to fulfill unmet needs.

Thank you very much.

Kyokawa: Thank you very much.

Question & Answer

Kyokawa: We will now start with a question-and-answer session.

If you have any questions, please click the “raise your hand” button. Also, after speaking, please press the “raise your hand” button again to lower your hand. I will make a nomination, and those who have been nominated are asked to state their affiliation and name, and then ask their questions.

Now, the first one, Mr. Yamaguchi from Citi, please.

Yamaguchi: This is Yamaguchi from Citigroup Global Markets. Thank you.

I would like first to confirm a few things about Xocova. First of all, I understand very well that you are rounding up the overall sales of infectious diseases, but in this Q3 sales of JPY20 billion, I think Xofluza has increased and Xocova has decreased, but if you could tell us how much the sales have decreased due to increased co-payments and epidemic, please.

Looking at IQVIA, it looks like the ratio is roughly 10 to 3 for Xofluza and Xocova, can you tell me what the ratio is?

Iwasaki: Iwasaki will answer the question. In many cases, as you mentioned, but we will refrain from giving specific figures today.

On the other hand, the treatment rate of COVID-19 with oral antiviral drug has decreased from 20% to 12-13% once since October. However, the ratio of Xocova increased significantly compared to the ratio of Xofluza within our sales in December and January due to Long COVID, data on sequelae, the need for treatment for the elderly, and is now expanding the wave of COVID-19.

However, the majority of Q3 sales were Xofluza. So, I hope you will agree with my answer.

Yamaguchi: Thank you very much. Also, there was a paper by a French team, I think, that analyzed the strains that are prevalent in Japan and found that the number of resistant strains to Xocova, ML49 or something, may be increasing quite a bit. How do you think about this? I think it has been mentioned that the number of resistant strains may be increasing quite a bit. Thank you.

Uehara: Thank you for your question. Uehara would like to answer.

Iin a non-clinical setting, some of these mutations can be taken into consideration. In terms of reduced susceptibility to Xocova, the mutations are not so wrong in terms of activity, and the data we have confirmed in the paper are the same as the data we have reported.

As for whether this would actually be a problem in actual clinical practice, the most worrisome scenario would be if a mutant strain emerges and is replaced by another strain that has higher proliferative activity than the current existing strain and in the end it was replaced by strains without susceptibility. In fact, we have not seen such an epidemic so far, and as you know, the spike protein is changing rapidly, and the so-called mutation is a situation of resistance, but we do not currently see any risk of clinical resistance to this extent.

Yamaguchi: I understand. There was no specific update on the situation in China, can you comment on this as well?

Uehara: The situation here is the same as before. We have submitted the data so far, so there is a possibility that we may move forward if the situation in China suddenly changes and we decide to move forward. We are also waiting for the HR study of SCORPIO to come out, so once such data is available, we will continue to submit the data to China, and it is up to the authorities as to when it will be officially approved.

Yamaguchi: I understand. Finally, a brief comment is fine, but was it your comment that HR will eventually be out in April?

Uehara: Yes. You are quite right about that.

Yamaguchi: It's April, right? I understand. Thank you. That's all.

Kyokawa: Thank you very much. Mr. Ueda from Goldman Sachs, please go ahead.

Ueda: This is Ueda from Goldman Sachs.

I would also like to confirm one point first about Xocova. Can you tell us about the trends in the prescription rate in Japan and what the trends are like on a monthly basis?

I would like to know what the treatment rate is and what the prescription rate of Xocova is among them, and also how the drug is positioned in terms of the outlook for the next fiscal year and beyond. I would like to know more about the qualitative aspects of the drug, including whether it is gradually becoming a widely prescribed drug just like a medicine for influenza in clinical practice.

Iwasaki: Thank you. Iwasaki will reply to you.

At this point, the overall treatment rate, which is 12-13%, they are often classified as with risk, and without risk, and the share of Xocova is 40-50% in without risk patient. And in with risk patient, it is a half of Lagevrio, according to our current analysis.

As for those with risk, we are now scrutinizing the data again. We believe that we have a dominant market in a risk-free area.

In the next fiscal year, the question is what will happen to NHI drug prices. If the current JPY9,000 fee is eliminated, the usual cost is 30%, 10%, or 20%, depending on age. In this case, I believe that this will have a positive effect on our company in terms of NHI prices.

Also, since Xocova can be used regardless of whether patients are at risk or not, such data are also collected in the real world. We hope to target the elderly in particular, who have a lower drug burden, and of course children still have medical assistance, so we wonder if they could use that as well.

Even though the drug burden has increased since October, the treatment rate for the elderly has not changed at all, remaining at around 40%. We recognize that there is still a high need for treatment for those at risk, and we would like to expand the market with new evidence and other means. That is all.

Ueda: Thank you very much. Second, I would like to know if you could tell me about how to consider expectations for the CAB 400 data that you will be presenting at the next conference, CROI 2024.

Now, if the CAB 400 PK data shows that the results are tolerable for dosing every 52 weeks or every 16 weeks, I wonder if we can see ViiV's presence in the market for this long-acting form as increasing further. Could you please explain what expectations we should have for this data?

Keller: As for CAB 400, the most important thing is of course the progress of CAB 400, but the selection of partner drugs is also very important. These two pieces together will produce this result this year. And so with those two pieces together, the progression into preparation for the pivotal studies starting in 2025 for the treatment combination will progress I think on the basis of CAB 400 PK alone, we can progress into the prep. everything is going very well now.

Ueda: I understand. That's all from me. Thank you.

Kyokawa: Thank you very much. Next, Ms. Haruta from UBS, please continue.

Haruta: This is Haruta form UBS Securities.

The first point is about S-309309. Phase II data will be available from April to June. I'm sorry to be hypothetical, but if you get good data, I would like to ask if you plan to enter Phase III on your own, while also doing partnering activities.

If the data were not good, is it likely that there would be a back-up program for this S-309309 that would proceed? Please tell us a little bit about what you can disclose in the area of strategy, as we have quite a bit more attention in the future.

Keller: There are two points. If we have positive results, we will both be making certainly preparations not to slow down, but we will be aggressively looking for an appropriate partnership. Rather than out-licensing, we are considering joint development and joint sales.

S-309309 program will probably be very broad. It is likely to involve a wide range of treatments, including not just monotherapy but also maintenance therapy with various concomitant drugs. By continuing to look at various outcome studies and other parameters, we hope to obtain the appropriate positioning to survive this challenging competition. There is a possibility that we will partner with a company that is strongly willing to do this, but we have not seen any results for Phase 2 study yet, so we are not seriously partnering with them. Of course, we would like to thoroughly consider cases where the results are not positive, but there is a number of early initiatives on the discovery side that we have not made public yet.

Haruta: I understand. If this is good, can we naturally assume that Phase III will be entered in the sense that we will proceed aggressively in our own company?

Keller: Yes, we are preparing for that, but we are also trying to find partners aggressively. It is a bit complicated, but basically we are trying to start a very broad program as soon as possible, and we have no intention of slowing down. We are rapidly advancing this program, as we intend to make preparations in a way that is meaningful to us by incorporating our partners in parallel with our own efforts, of course.

Haruta: I understand very well. Thank you. The second point is just to confirm. The top-line data for SCORPIO-HR for COVID-19 will come out in April, is there a press release schedule for this, and the rolling submission is scheduled in the United States, and I would to know if you consider completion means to complete within this year.

Uehara: Thank you very much for the question. First, we are planning a press release. However, since the active team of the NIH in the United States is in charge of publicity for this study, there will probably be some restrictions on whether we can introduce all the data and figures as soon as the top line is released, but we are preparing for press releases of important information.

As for the U.S. application for approval, we are currently in discussions with the FDA on a Pre-NDA for a rolling submission as soon as it is completed, so the detailed timing has not been determined at this time. The current

assumption is Q1 FY2024, so as soon as we get a top line, we hope to submit the data within a few months and proceed with discussions for approval.

As for how long it will take for the FDA to approve the product, we have received a Priority Review so far, so it will be surely within a firm nine months, but we are still discussing how much flexibility we will have to accelerate the approval process.

Haruta: I understand. Thank you.

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

Wakao: Thank you very much. This is Wakao from JPMorgan Securities. Thank you.

Please also tell us about your future outlook of next fiscal term. I think your performance this fiscal year was good because you were able to sell Xocova without any out-of-pocket expenses in H1 of the year, in addition to the temporary income of transferring the ADHD license.

On the other hand, this part will disappear next term. You mentioned earlier that you will aggressively sell Xocova, but looking at the situation in H1 of this fiscal year, I think that the next fiscal year will be difficult for the full year. Is there anything you can tell us at this point about the outlook for the next fiscal year?

Kudou: Regarding the outlook for the next fiscal year, as I explained earlier, in the area of infectious disease drugs, we are building a stable revenue base in Japan with two drugs for acute respiratory tract infections. In the next fiscal year, we will continue to focus on these two domestic businesses while building up earnings, we believe that we are making positive progress toward achieving the mid-term plan by expanding Xocova globally and launching the COVID-19 vaccine in Japan, while continuing to generate earnings mainly from these two domestic businesses.

Wakao: Do you have the impression that the hurdles are quite high in terms of creating increased profits?

Kudou: Yes. That is the impression I have. We would like to work toward increasing revenues, including global expansion as I mentioned earlier.

Wakao: I understand. Can you provide some information about S-309309? I have been informed by your company that the weight loss rate for S-309309 is between 8% and 10%. Do you think that this range can be achieved within 24 weeks? Or are you anticipating a longer duration, 8% to 10% being the peak?

Keller: According to the preclinical data, we believe that the 8% to 10% weight loss range can be achieve within 24 weeks. I hope to put this into practice in our clinical practice in the future.

Wakao: I understand. Thank you. Since you mentioned finding partners, what would be the most important point in partnering activities? As for efficacy, I think it is lower than GLP-1, so I think the key point is safety or combination. On the other hand, I think that combination data is not yet human data, so I am not sure how smooth the actual partnering process will be. Could you please let me know?

Keller: I believe there are still other needs besides GLP-1, and the market for obesity is continuing to expand. Firstly, in the case of GLP-1, being an injectable formulation and causing gastrointestinal symptoms may render it unsuitable for some patients. Additionally, not all patients require rapid weight loss, and there may be cases where a high effectiveness from GLP-1 is not necessary. For instance, rapid weight loss can lead to noticeable changes in facial appearance and body, which could be perceived as negative by patients. It can also result in significant reduction of muscle mass, which may weaken the patients. Some doctors even refrain from prescribing GLP-1 to elderly patients due to concerns about muscle loss and potential frailty.

Moreover, companies like Pfizer and Eli Lilly are developing oral formulations of GLP-1. However, even with the best results, the oral formulations have not shown equivalent efficacy to injectable ones, achieving only around 10% effectiveness. This opens up the possibility of combining oral GLP-1 with S-309309 or even completely replacing injections with oral administration. This could potentially bring down the cost and allow for significant weight reduction when necessary for these patients.

Considering all these factors, I believe there is a positioning for S-309309 as an option for patients who are intolerant to GLP-1. There are numerous other potential positioning strategies to explore.

In terms of partnering, we are seeking partners who complement our capabilities and enable us to maximize the potential of S-309309 in various positioning scenarios. Therefore, we are looking for organizations that align well with us in this regard.

Wakao: I understand. Thank you. That's all.

Kyokawa: Thank you very much. Next, Mr. Mamegano of BofA Securities. Please go ahead.

Mamegano: Thank you very much. This is Mamegano from BofA Securities. Thank you.

I would like to inquire about the landing of this fiscal year's results. Looking at the progress up to Q3, it seems that sales are mostly in line with the Company's plan, but there appears to be slower progress in expenses. The operating income has also reached about 93%, I understand that there was an increase in R&D expenses in 2Q, can you provide us with details on your plans for these expenses? Will you utilize the remaining amount, and if so, in which areas? Thank you.

Kudou: I will answer the question. First of all, regarding sales expenses, when we revised our forecast, we reduced the China-related expenses for Xocova sales and allocated the remaining portion to preparations for the globalization of infectious disease drugs such as Xocova and cefiderocol.

We anticipate continued growth in the future, relying on the top line, and we are also considering further acceleration of investments for medium- to long-term growth, depending on the prevalence of influenza, COVID-19, and other diseases in Q4.

Specifically, we are considering pre-launch expenses for Xocova’s overseas operations and DX-related investments.

As for R&D expenses, although there has been an increase in R&D expenses as you mentioned, we expect that they will be in line with our forecast and be realized by the end of the fiscal year, as large-scale global trials for several major products are progressing smoothly.

Mamegano: Thank you very much.

Kyokawa: Okay, next, Mr. Matsubara from Nomura Securities, please go ahead.

Matsubara: My name is Matsubara from Nomura Securities. Thank you. I have two questions about Redasemtide. In the previous financial statement, it was mentioned that enrolling patients with dystrophic epidermolysis bullosa was challenging. Can you provide an update on the current status of patient enrollment?

Additionally, there has been no change in the application period compared to previous data from Q3 of FY2024.Can you provide us with an estimate of the probability of achieving this?

Uehara: Thank you for your question. Regarding Redasemtide, we are still in the process of enrolling patients. This Phase IIb trial aims to assess the effectiveness of Redasemtide in closing difficult-to-heal ulcers, making it challenging to find patients with such conditions. We are continuously recruiting patients.

Once we can demonstrate even one case of successful wound closure, we will proceed to the next step in the process. Currently, we are making progress and continuing to accumulate cases, but the target remains unchanged.

Matsubara: Thank you. That is all from me.

Kyokawa: Then, the next question will be the final one. Mr. Tsuzuki from Mizuho Securities, please go ahead.

Tsuzuki: I'm Tsuzuki, Mizuho Securities.

I believe I've covered most of the points, but I have one more question regarding your development products. I understand that the RS virus infection part is in Phase II this time. Can you provide any information on the potential acceleration of Phase II of COVID-19's S-892216, the next generation of Xocova, which is more effective and less likely to produce resistant strains for COVID-19?

Uehara: Thank you very much for the question. We are already proceeding full speed with S-892216. Phase I trials are going smoothly, and we are soon planning to Phase II.

Tsuzuki: I understand. Thank you very much.

Kyokawa: We would like to conclude SHIONOGI & CO., LTD.'s financial results briefing for Q3 of FY2023. Thank you very much for taking the time to join us today despite your busy schedules.