SHIONOGI & CO., LTD.

Fiscal2021 Financial Results Briefing

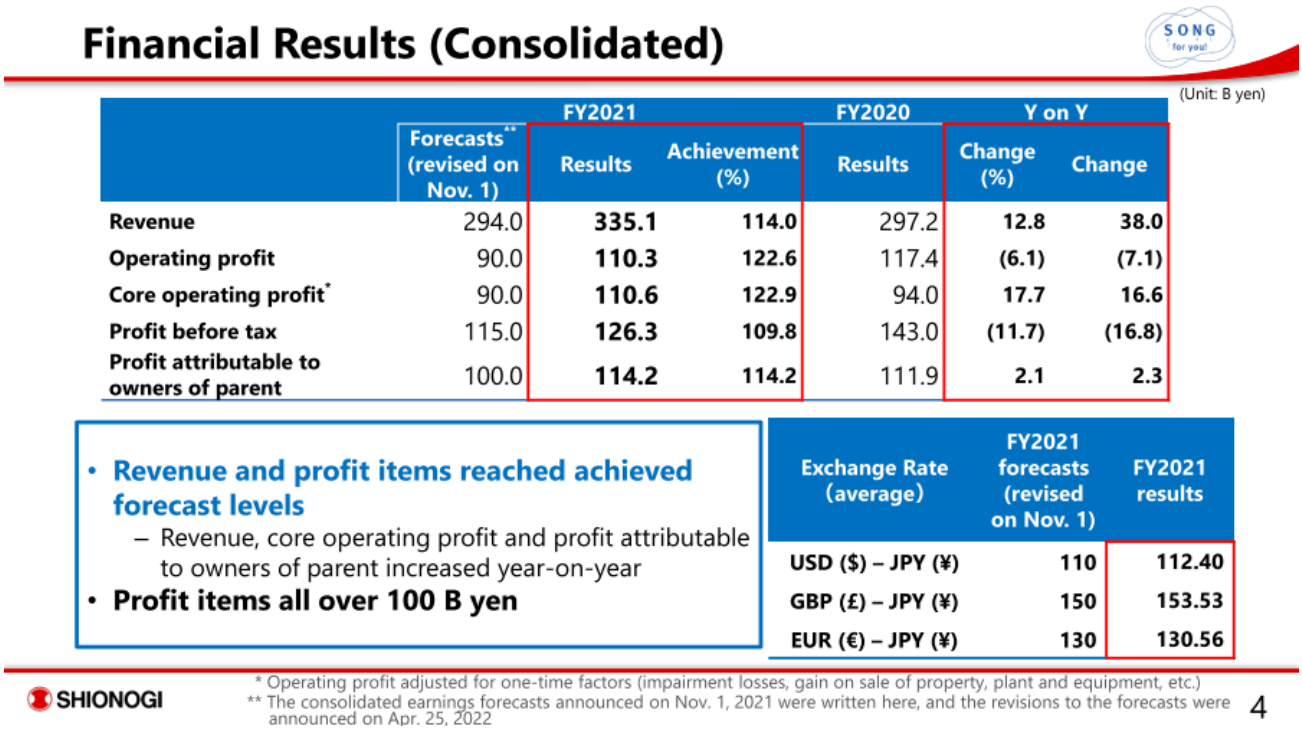
May 12, 2022

Presentation

Kyokawa: Let us start this briefing. My name's Kyokawa and I am the Vice President of the Corporation Communications Department. Thank you very much for attending this briefing of the Financial Results for FY2021.

Now, let's begin. Dr. Teshirogi.

Teshirogi: Good morning everyone.



Now let's get started. These are the financial results.

The revenue was JPY335.1 billion. That's up 12.8% from the previous year and the achievement ratio is 114%. The Operating profit was JPY110.3 billion, down 6.1% from the previous year, but the achievement ratio was 122%. The core operating profit, JPY110.6 billion; the achievement ratio of 122.9%. Last year, there was special profit from the real estate which is up 17.7% from the previous year.

Profit before tax is JPY126.3 billion and the reason for this decline is the ViiV dividend, which comes at the end of March. The dividend for the quarter is usually very big. But due to the schedule of ViiV, the Board meeting was held on April 1 and we had a discussion with the accounting company. April 1 of the other country is April 2 in Japan, which is the next fiscal year, and we are going to book a dividend of five times. That's why for the profit before tax, the achievement ratio was only 109.8%.

Profit attributable to owners of parent was JPY114.2 billion, the achievement ratio was 114% and there was a 2.1% change from the previous year. As you can see at the top and the bottom, we enjoyed an increase both in revenue and profits.

In January and February, including S-217622, when we will be able to get approval and when we will be able to launch, we've had a lot of discussion on that and we are saying that it might be difficult at the end of March.

There, we had to think about ViiV and Gilead, and in FY2021, onetime income from ViiV was booked so that we could have relevant revenue and profit. This took a lot for R&D and the harvesting, and the scene beyond 2022 is looking towards growth.

As for the exchange rate, 2021 was on track and as for 2022, the yen is expected to go down a bit from here.

Statement of Profit or Loss (Consolidated)

(Unit: B yen)

	FY2021			FY2020	Y on Y	
	Forecasts** (revised on Nov. 1)	Results	Achievement (%)	Results	Change (%)	Change
Revenue	294.0	**335.1**	**114.0**	297.2	**12.8**	**38.0**
Cost of sales	19.4 57.0	16.5 **55.4**	**97.2**	17.7 52.5	**5.5**	**2.9**
Gross profit	237.0	**279.7**	**118.0**	244.7	**14.3**	**35.1**
Selling, general & administrative expenses	30.3 89.0	28.4 **95.2**	**107.0**	32.0 95.1	**0.1**	**0.1**
R&D expenses	18.9 55.5	21.8 **73.0**	**131.5**	18.3 54.2	**34.6**	**18.7**
Other income & expenses	(2.5)	**(1.2)**	**46.7**	22.1	**(105.3)**	**(23.3)**
Operating profit	30.6 90.0	32.9 **110.3**	**122.6**	39.5 117.4	**(6.1)**	**(7.1)**
Core operating profit*	30.6 90.0	33.0 **110.6**	**122.9**	31.6 94.0	**17.7**	**16.6**
Finance income & costs	25.0	**16.0**	**63.8**	25.6	**(37.6)**	**(9.6)**
Profit before tax	39.1 115.0	37.7 **126.3**	**109.8**	48.1 143.0	**(11.7)**	**(16.8)**
Profit attributable to owners of parent	100.0	**114.2**	**114.2**	111.9	**2.1**	**2.3**

Main Variation Factors (Forecast Comparison*)**

- **Revenue**
  - Increase: Royalty income (HIV franchise)
  - Decrease: Prescription drugs
- **Selling, general & administrative expenses**
  - Increase: Launch and sales activity costs to support strong sales of Fetroja® and Fetcroja®, launch preparation costsd for S-217622
- **R&D**
  - Increase: Intensive investment in R&D activities related to COVID-19
- **Finance income & costs**
  - Decrease in income :Shift to FY2022 in receiving dividend from ViiV in the 4th quarter of FY2021

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* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)
** The consolidated earnings forecasts announced on Nov. 1, 2021 were written here, and the revisions to the forecasts were announced on Apr. 25, 2022
*** Appendix p.35: Year-on-Year Comparison

This is the statement of Profit or Loss, the consolidated version.

The cost of sales achievement ratio was 97.2%. For most of the sales, about JPY50 billion come from ViiV, the one-off payment. Concerning that, as to the cost of sales, it's almost on track I would say. But the achievement ratio was 97.2% and for the gross profit, the achievement ratio was 118%.

Selling, general & administrative expenses was higher than our forecast because of the cefiderocol in Europe and the US. We had to invest for that product, but it was almost the same as the previous year.

As for R&D, it was 131% and it grew 35% from the previous year, so the result was JPY73 billion. This was a record-high figure in Shionogi's history.

As I mentioned, we had onetime income from ViiV, we wanted to spend for R&D, so that we can have up-front investment in target-related products. Including that, the OP was JPY110 billion and by having this up-front investment, we'll be able to realize a good operating profit or income.

As I mentioned before, the growth of the profit before tax was lower, and that's because we achieved 63.8% of the financial income, we didn't receive the dividend from ViiV, but we received it on April 1. Next time, you will have the dividend for two times in 1Q. The profit attributable to owners of parent was JPY114.2 billion, and the achievement ratio was 114%.

Revenue by Segment

	FY2021			FY2020	Y on Y	
	Forecasts** (revised on Nov. 1)	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	94.4	**89.1**	**94.4**	94.7	**(5.9)**	**(5.6)**
Overseas subsidiaries/export	35.0	**34.4**	**98.3**	24.6	**39.5**	**9.7**
Shionogi Inc.	12.7	**13.8**	**108.5**	7.5	**84.5**	**6.3**
Fetroja®	-	**6.2**	-	1.7	**268.7**	**4.6**
Ping An-Shionogi* /C&O	12.3	**10.2**	**82.6**	10.1	**1.1**	**0.1**
SBV(Europe)	5.0	**5.0**	**99.8**	2.0	**153.7**	**3.0**
Contract manufacturing	17.8	**17.4**	**97.9**	19.7	**(11.7)**	**(2.3)**
OTC and quasi-drug	13.4	**11.2**	**83.0**	11.7	**(4.8)**	**(0.6)**
Royalty income	132.0	**181.3**	**137.4**	144.6	**25.3**	**36.6**
HIV franchise	125.2	**174.0**	**138.9**	123.4	**41.0**	**50.6**
Crestor®	-	**1.2**	-	16.6	**(93.1)**	**(15.4)**
Others	6.7	**6.1**	**91.5**	4.7	**30.8**	**1.4**
Others	1.4	**1.8**	**124.4**	1.8	**1.7**	**0.0**
Total	294.0	**335.1**	**114.0**	297.2	**12.8**	**38.0**

(Unit: B yen)

Main Variation Factors (Forecast Comparison*)**

- **Prescription drugs**
  - Decrease: Sales of Influenza franchise
- **Overseas subsidiaries/export**
  - US/EU: Increase: Sales of cefiderocol (Fetroja®)
  - China: Decrease: Sales on online medical platform lower than projections
- **OTC and quasi-drug**
  - Decrease: sales of ISODINE®
- **Royalty income**
  - HIV franchise

  : Increase: Royalty income from the conclusion of dolutegravir patent license agreement (transient factor)
  HIV royalties excluding the one-time payment increased year-on-year

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* OTC and quasi-drugs also include in revenue of joint venture
** The consolidated earnings forecasts announced on Nov. 1, 2021 were written here, and the revisions to the forecasts were announced on Apr. 25, 2022
*** Appendix p.36: Year-on-Year Comparison

As for the sales of domestic prescription drugs, the achievement ratio was 94.4%. We missed the target. It's down JPY5.6 billion from the previous year. For the influenza drug Xofluza, we were expecting to see JPY5 billion. However, it was actually almost zero. It was down JPY4.8 billion because of the influenza family products. And that's why we couldn't meet the forecast.

As for overseas subsidiaries, there is FORTAMET, as I mentioned before, but excluding that, cefiderocol was very good. And Fetroja, JPY6.2 billion, it was 2.7 times more than last year, so it's going very well.

Ping An-Shionogi/C&O is the same as the previous year. We wanted to grow it more, but it's been delayed. The Ping An products using the Good Doctor, in February and March, they had some deals but they couldn't realize those deals. That's why it was down. And as to SBV, cefiderocol and Fetcroja is doing well.

As to OTC, we have seen growth in the past, but now, associated in cold medicines have struggled. As to Rinderon, it was very good, but the others didn't reach the forecast.

As to royalties, it's JPY50.6 billion. The base business as you can see at the lower right, the royalty, excluding the onetime income was a bit positive. The base business of ViiV is going very well. In addition to that, there was a big onetime income because of the settlements, and that made a huge contribution.

Revenue from Prescription Drugs in Japan

(Unit: B yen)

	FY2021		FY2020	Y on Y	
	Forecasts* (revised on Nov. 1)	Results	Results	Change (%)	Change
Cymbalta®	17.1	**15.9**	26.5	**(39.9)**	**(10.6)**
Intuniv®	16.6	**16.4**	13.1	**25.4**	**3.3**
Vyvanse®	1.0	**0.8**	0.3	**190.7**	**0.5**
Infectious disease drugs	16.6	**11.8**	9.8	**20.8**	**2.0**
Influenza franchise	7.9	**3.1**	0.3	-	**2.8**
OxyContin® franchise	5.0	**4.8**	5.3	**(10.0)**	**(0.5)**
Symproic®	3.1	**2.7**	2.3	**17.9**	**0.4**
Actair®	0.4	**0.5**	0.3	**45.1**	**0.2**
Mulpleta®	0.1	**0.1**	0.1	**8.9**	**0.0**
Pirespa®	3.5	**3.8**	5.1	**(25.3)**	**(1.3)**
Others	30.8	**32.4**	32.0	**1.2**	**0.4**
Crestor®	5.7	**5.9**	6.7	**(11.0)**	**(0.7)**
Irbetan® franchise	3.1	**3.2**	3.3	**(5.0)**	**(0.2)**
Prescription drugs	94.4	**89.1**	94.7	**(5.9)**	**(5.6)**

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc®Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- ISODINE®

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This is for domestic prescription drugs.

Cymbalta generic has come into the market and so there was minus JPY10.6 billion YoY. Intuniv and Vyvanse, we were able to grow to some extent. However, we have not been able to fully catch up. Regarding the influenza franchise, it achieved JPY7.9 billion, but it lagged by JPY5 billion.

Summary of FY2021 Results

- **Domestic business**
  - Domestic prescription drugs sales did not reach the forecast due to a very small epidemic of influenza
  - OTC and quasi-drugs did not achieve the forecast due to lower-than-expected sales of ISODINE® while new products are steadily progressing
- **Overseas business**
  - Sales of cefiderocol in the United States and Europe are steadily progressing
- **Selling, general & administrative expenses**
  - Launch and sales activity supporting strong sales of Fetroja® and Fetcroja®
- **R&D expenses**
  - Due to intensive investment in R&D activities related to COVID-19, 73 billion yen (up 18.7-billion-yen year-on-year comparison) which is the largest amount ever
- **Settlement of dolutegravir patent infringement litigation with Gilead**
  - Recognized royalty on upfront and on an agreed projection of future royalty payments as revenue following the conclusion of the patent license agreement

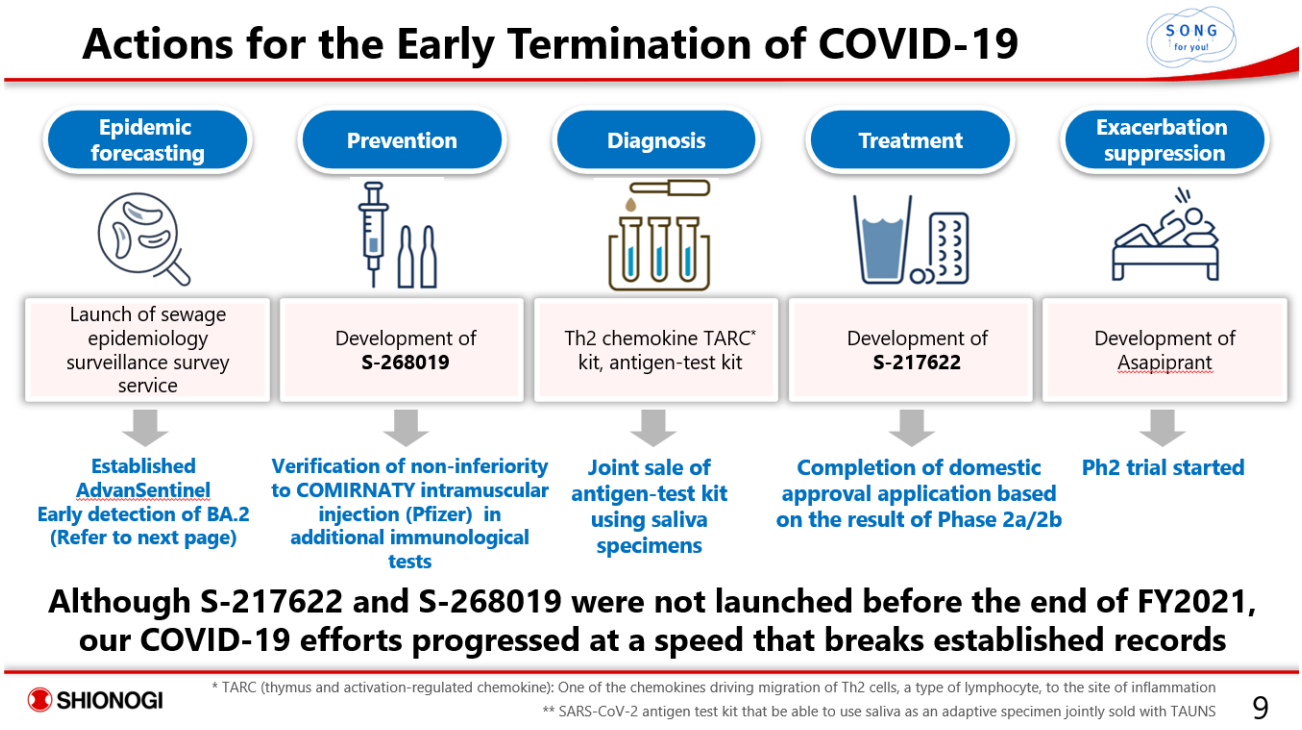
Achieved Initial and revised forecasts

And on page eight, as I have explained, this is the summary of our 2021 result.

Regarding the domestic business, there has been a patent expiration of Cymbalta and also the influenza family's sales were almost zero. Also, regarding OTC, for the team, I should say that they grew to some extent over a period of time. And in the last three years, we have been able to grow our position in the OTC market. However, we were not able to achieve our target.

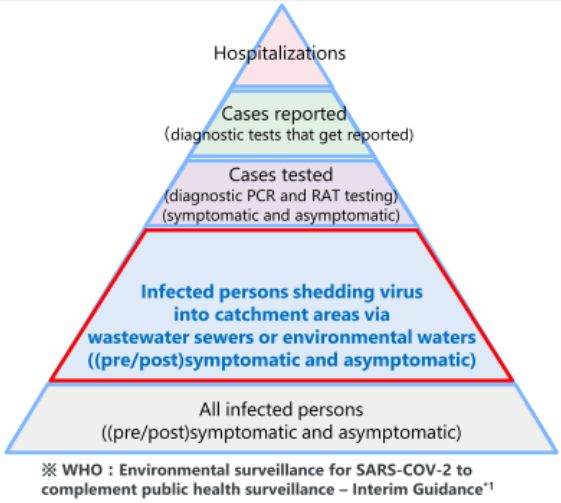
However, cefiderocol is growing smoothly for the overseas business. For S-217622 and S-268019, we are doing everything that we can. Of course, in the end, we will continue to pursue various things, such as subsidies from the government, but with regard to COVID-19, I decided to proceed as much as possible, including my determination.

Also, the settlement of the dolutegravir patent between Gilead and ViiV has made a huge profit.



Regarding COVID-19, we want to contribute throughout the various stages of the pandemic. And regarding diagnosis, we have collaborated with TAUNS to sale an antigen test kit using saliva specimens. We are considering a new diagnosis test. Also the exacerbation suppression S-555739, asapiprant, has started its Phase II trial.

Establishment of AdvanSentinel



※ WHO : Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance*1

AdvanSentinel

- **Early public health implementation of wastewater monitoring**
  - Partnering with SHIMADZU
  - **Wastewater monitoring is an indispensable method to more accurately assess the infection status of society as a whole, with less risk of selection bias seen with PCR or RAT tests**
  - **US and Europe were progressing this implementation during the COVID-19 pandemic**
    - > US: CDC has been leading wastewater monitoring in 46 states and published the results on a dashboard together with clinical tests*2
    - > Europe: All EU Member States have agreed with the European Commission recommendation and around 1370 wastewater treatment plants are under regular surveillance and the data are shared amongst countries*3
- **Actions for FY2022**
  - **Dissemination of wastewater epidemiological surveys and evidence building activities through supplementary budget and Ministry of Land, Infrastructure, Transport and Tourism projects**
  - **Launch of new method and kit with very high sensitivity and which can be automated**

By launching a new method with very high sensitivity and automation, we will contribute to the accurate understanding of infection epidemiology worldwide

*1 Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance (who.int)
*2 National Wastewater Surveillance System (NWSS) – a new public health tool to understand COVID-19 spread in a community | CDC
*3 Coronavirus response: monitoring of wastewater contributes to tracking coronavirus and variants across all EU countries (europa.eu)

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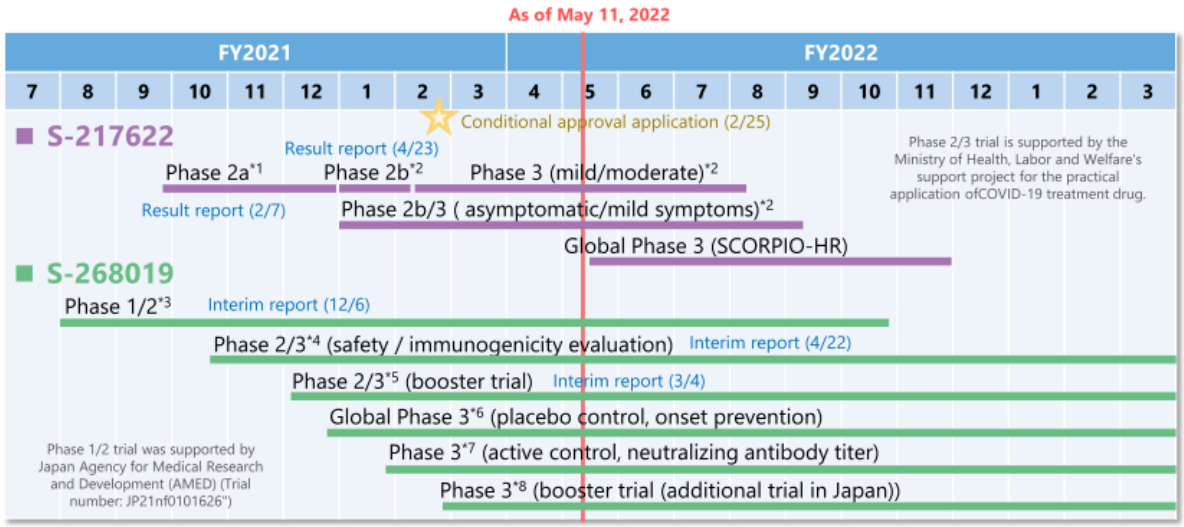
On page 10, regarding the epidemic forecast, we established the AdvanSentinel joint venture.

In the third bullet point, as it says, this implementation is ongoing in the United States and Europe already. However, the sensitivity and the speed are not enough to catch the new variant.

I think technically speaking, our system is better than in the US and Europe. We are considering overseas partners in US and Europe for this project. But first, we want to build the wastewater monitoring system in Japan.

Progress Summary of S-217622, S-268019



*1 jRCT2031210202, *2 jRCT2031210350, *3 jRCT2031210269, *4 jRCT2031210383, *5 jRCT2031210470, *6 NCT05212948, *7 jRCT2051210151, *8 jRCT2031210613

On page 11, this is the progress summary of S-217622 and S-268019.

The global Phase III for S-217622 is going under a final protocol agreement, but we have not been able to reach an agreement with the FDA about the finalized protocol for the global Phase III yet. The FDA, whether they are going to continue to provide approval for EUA is questionable. In the case of EUA, the death rate and exacerbation suppression is sought. I think this is the basic philosophy. To that, our compound is for a more general purpose. When you are infected, you should take the drug as soon as possible so that you will not spread the virus.

This is the positioning of S-217622. And therefore, from that perspective, we seem not to have an agreement with the FDA. Whether we should seek for EUA or whether we should seek for full NDA is the decision that we must be making.

For S-268019, as I will be explaining later, everything is going very smoothly. Also, the production data has to be taken as soon as possible to apply as a full package to the PMDA.

Actions for COVID-19

S-217622 (oral therapeutic drug)

- **Domestic manufacturing and marketing approval application**
  - Application based on the results and analysis from Phase 2b part (February 25, 2022)
- **Phase 2b result report**
  - Efficacy and safety results announced at 32nd ECCMID*
- **Continuation of Phase 2/3 trial**
  - Phase 3 part (mild/moderate) and Phase 2b/3 part (asymptomatic/mild symptoms) are underway
    - > Patient registration is proceeding smoothly including Vietnam and South Korea
- **Global Phase 3 trial started**
  - Preparing to Initiate ACTIV-2d (SCORPIO-HR trial) in collaboration with ACTG**
- **Supply**
  - Completed production for 1 million people
  - Since April 2022, production is expanding to supply more than 10 million people annually
  - Started preparations for building a global supply system

Preparations are progressing steadily for domestic and global provision

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* European Congress of Clinical Microbiology and Infectious Diseases ** The AIDS Clinical Trial Group: The world's largest HIV research network expanding its activities to evaluate outpatient treatment of COVID-19 in recent years ***Quality test completed

Presentation: https://www.shionogi.com/global/en/investors/ir-library/presentation-materials.html

We talked about Phase 2b at the 32nd ECCMID.

When a new pandemic emerges, the strain may mutate and the clinical manifestations may change. In such a situation, our idea is that we are trying to find out what kind of drug efficacy evaluation should be done on-time to correctly evaluate the drug, although it is difficult.

The number of cases is small, but in the Phase II Delta variant study, if we were able to increase the number of cases, we think we would be able to prove the efficacy. in the 12 symptoms. However, due to the replacement with the Omicron strain, while collecting Phase 2b data, about 6 out of 12 symptoms were almost nonexistent in the placebo group. Analysis including patients with Omicron strains is not statistically significant. I intend to pack this part a lot with PMDA. As for what to do with the primary endpoint, we had only Phase 2a data at that time, so we decided to set 12 symptoms.

However, Phase 2/3 is a clinical trial with strains that are fairly completed, including Omicron, BA.1 and BA.2. For this trial, we think we can get results by working according to the primary endpoint we originally set.

All in all, we think it is a high antiviral effect and probably the strongest in the world when viewed on an RNA basis. The challenge is how to utilize the antiviral effect in clinical practice and in the actual market.

With regarding to the global Phase III trial, as I said, we are finalizing the protocol with the FDA right now. And so we are seeking for EUA right now, but whether EUA is the right path or full NDA is another option is what we are considering right now.

With regards to the supply, we are working on one million people. And from June, the plant will be restarting. It has been shut down for a while now. we will be able to expand the supply to 10 million people, but we don't think that's enough. In addition, because we depend on China for all starting materials, we are quite energetically promoting the preparation and formulation of APIs from the beginning in India or the United States.

Actions for COVID-19

S-268019 (recombinant protein vaccine)

5 Pivotal clinical trials in progress

- **Phase 2/3 trial**
  - Safety/immunogenicity evaluation trial in 3,100 adults aged 20 and over and the elderly aged 65 and over
  - Top-Line results: Disclosed at the Infectious Diseases Society (April 22, 2022)
- **Active control, neutralizing antibody titer trial**
  - Superiority verification trial over VAXZEVRIA (AstraZeneca)
  - Top-Line results will be obtained in May (scheduled to be published in a paper)
- **Phase 2/3 booster trial**
  - Non-inferiority verification trial with COMIRNATY (Pfizer) by booster immunization after 2 doses of COMIRNATY
  - Achieved the primary endpoint in the interim analysis
- **Phase 3 booster trial (additional trial in Japan)**
  - For adults aged 20 to 64 years who received SPIKEVAX (Moderna) twice and elderly people aged 65 years or older who received COMIRNATY or SPIKEVAX twice
  - Top-Line results will be obtained in May
- **Placebo control, onset prevention trial**
  - Advance start in Vietnam from December 2021
  - Subject registration is progressing smoothly

Each trial is steadily progressing in support of both initial immunity and booster immunity indications

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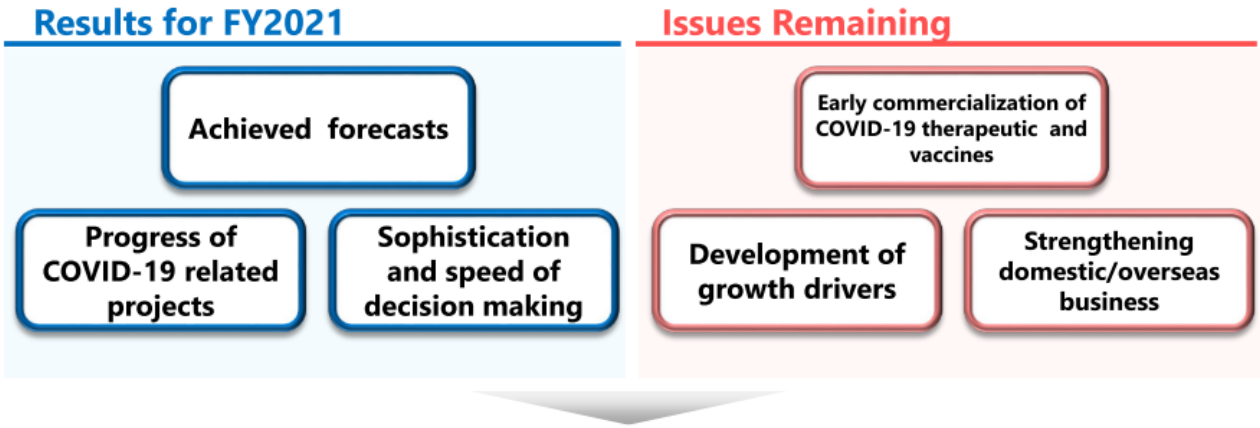
Supported by AMED issue number JP21nf0101626 in investigational drug manufacturing in each clinical trial

For vaccines with regarding to the neutralizing antibody titer trial, again VAXZEVRIA, we are working on a superiority verification. We are seeking for superiority verification over VAXZEVRIA , because we can get the samples right away domestically.

Top-line results will be obtained in May, and we have scheduled to publish the results in a paper. The neutralizing antibody generation and safety in Japanese patients over 3000 cases, and we have already pressed, non-inferiority in the comparative trial with the COMINATY, and comparison of safety. We believe that these trials meet all of the full packages that PMDA has suggested to consider packages in this way, in accordance with ICMRA's thinking, if we do not conduct placebo-controlled onset prevention trials. Lastly, this is about the prevention study trial. We have just exceeded 10,000 cases. Actually, Omicron's been very dominant, so Moderna or Pfizer's products, they give two shots for naive patients and the efficacy was 14% or 15%. For Omicron, the issue is how much difference they can show as compared to a placebo. We won't know until we open the trial result.

I think the first part, that included the Delta variant, but now almost all of them are Omicron so that may affect our results. In July or August, we'll have the result of the study of 10,000 cases. But this is not mandatory for NDA in Japan because conducting onset prevention trials is very difficult. We are conducting a comparative trial with a positive control based on the agreement of ICMRA. Therefore, this is just reference data.

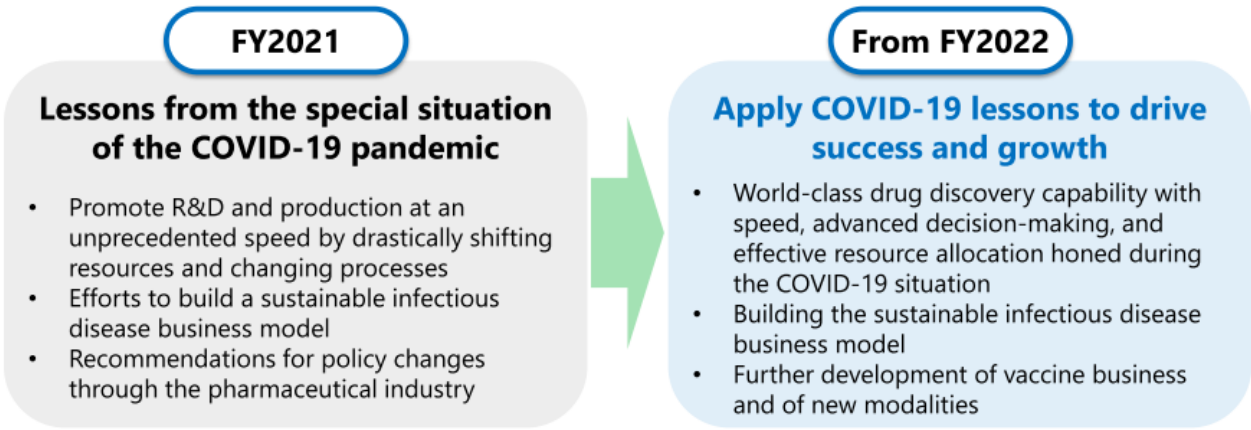
Results for FY2021 and Issues Remaining



Focus on efforts for medium- to long-term growth in parallel with aiming to provide solutions for COVID-19

I think we have successfully showed you the increase from the previous year and the speed of decision-making as to the allocation of the resources. I think we've been very good. But unfortunately, last year, we couldn't commercialize the COVID-19 Therapeutic drug and vaccine. We would like to achieve that this year. You may say that we now see the goal of COVID-19, but what's going to happen beyond that? I would like to continue talking about this.

What is Shionogi after FY2022

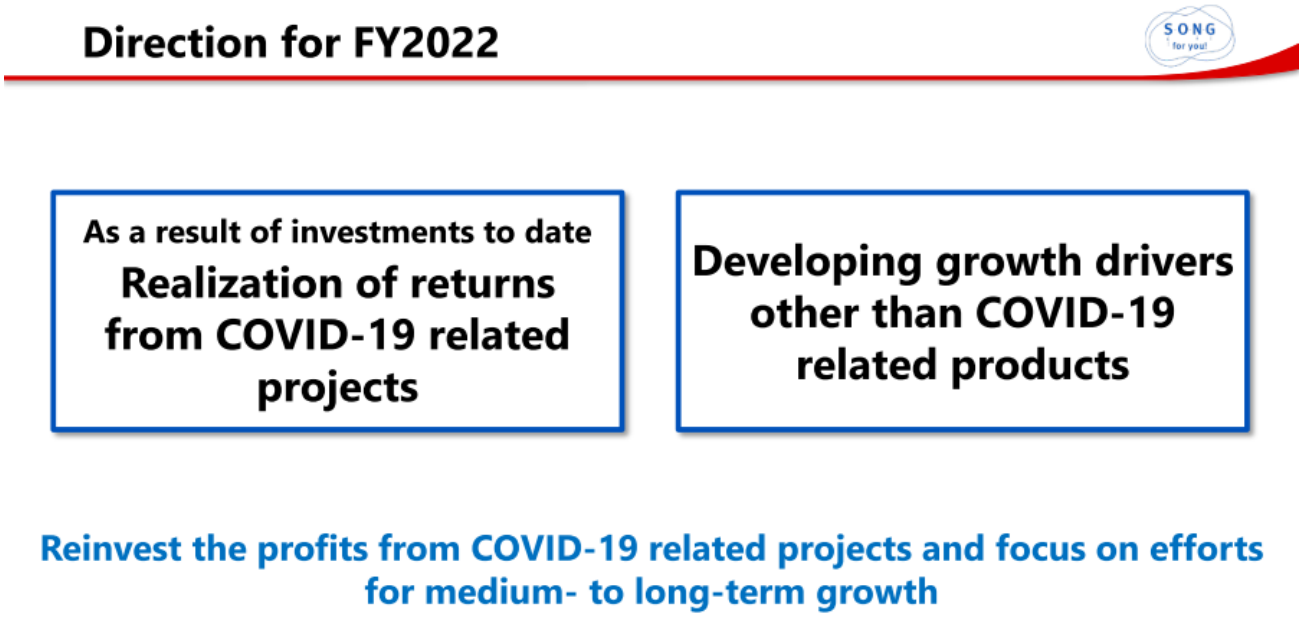


Taking the special situation of FY2021 as "the new normal", promote pandemic experience-based transformation without changing gears

One thing I'd like to say is that we spent a lot of profit for COVID-19 products. And now we have a new way of developing products. For example, in preclinical development from single toxicities to lead to multiple number

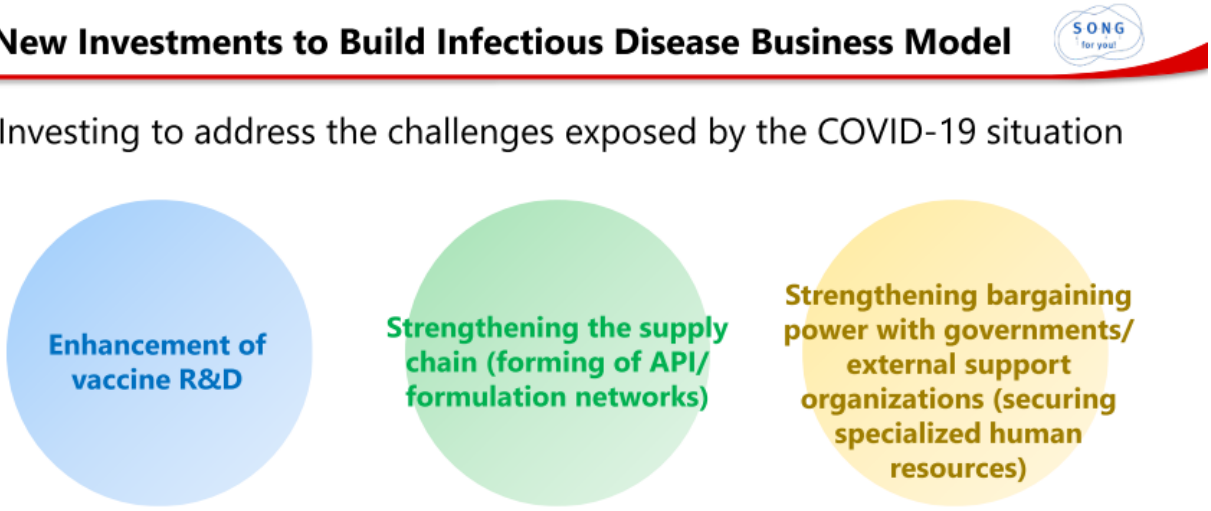
of toxicity trials, in the past, we were doing them chronologically, but now we are doing them at the same time. We can do that for strategic products, and that will enhance the speed of the development.

S-217622 in July of last year, we started Phase I trial. Even with conditional early approval, from an EUA perspective, you may take it for granted that we will complete certain clinical trials and apply for approval in February of this year. In Shionogi, CMC and preclinical and regulatory bodies, we revisited how things work in the company. It was such a huge experience for us. By applying the new method to other products, we can improve the speed and quality of product development. And that way, we can differentiate the Company from other companies after 2022.



First, vaccination and therapeutic agent, we spent a lot for R&D. And then in 2022 and beyond, we would like to harvest sales and profit. Also, at the same time, the question is how we can enrich our pipeline is the question.

New Investments to Build Infectious Disease Business Model



This slide may be confusing. Since last year, with John, we have been having discussion about how to partner with other companies, especially for S-217622. Overseas therapeutic drugs for COVID-19, antibodies, and injections and other products, it may be better to listen to companies. But many Companies are now thinking about how sustainable this business is.

Some companies are very confident about the sustainability of this business. But others are not that confident about the sustainability of these products. For us, by having down payment or each milestone, and also benefits we would get in the future, how we can take the right balance between the two is very important. How much physical help we can get from those potential companies, we are still discussing with 3 and 4 companies in parallel. When we look at the net present value base, the value is sometimes not good enough. The amount of money to go over there is large for our efforts.

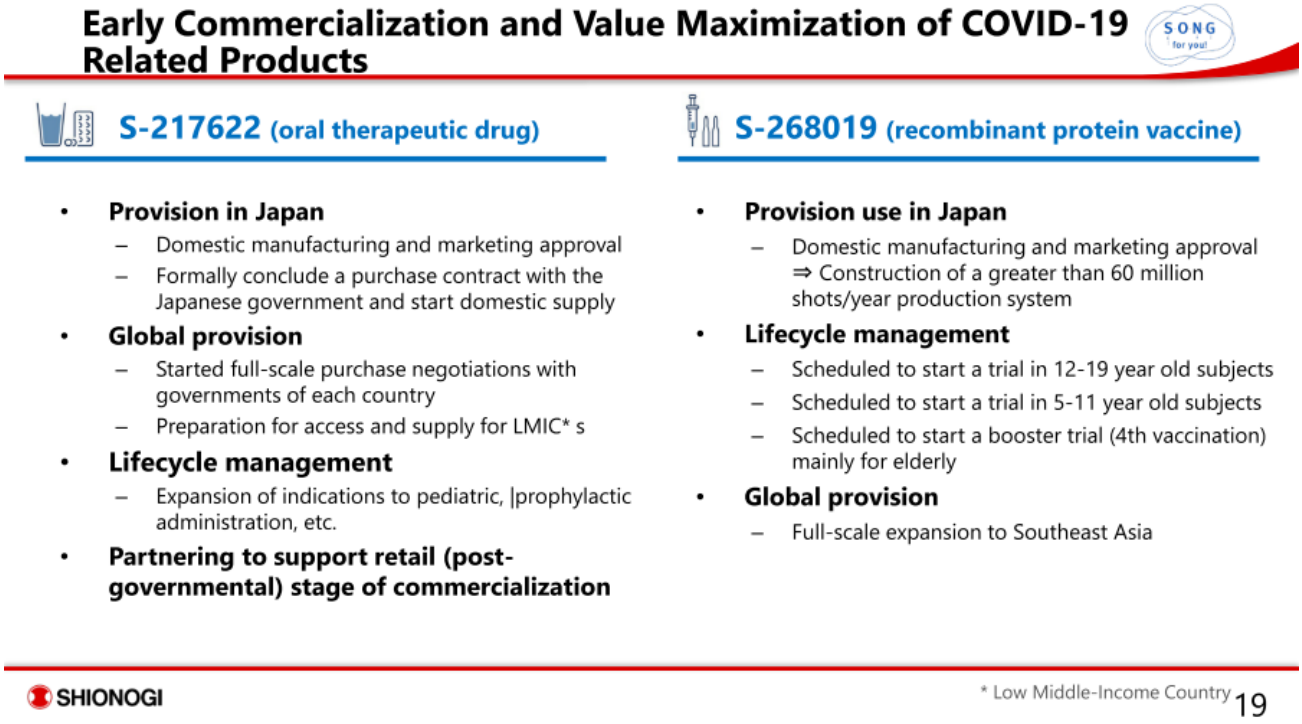
At the time talking about xofluza with Roche, there was the same kind of discussion. At that time, of course, it was primary care area, and we had to sell them in EU and the US. We cannot afford to sell in those areas. In the time, the clinical trial Phase III was done by us alone. And then, we had a partnership with Roche after that. Global and Asia Phase III are done by us this time as well. And we are talking to FDA and NIH, and we are conducting this trial on our own. We're making a lot of effort. I think we should have a bigger benefit out of this business. When the next pandemic comes, we also have to think about whether we should negotiate the same.

We have to be decisive here. Especially when it comes to negotiation in development with government, we have to do business on our own as much as possible. Of course, we are continuing the negotiations with potential partners, but the help we want is in sales. But otherwise, we want to do it on our own as much as possible so that we can get the benefit as much as possible.

In order to be a global company focusing on infectious diseases, that's a transformation for us. We've had a lot of discussions with Sawada-san and John, so we will have to acquire talent about these area so that we will be able to do this in US and EU, LMICs market as well. That way, by changing the paradigm from February to April, we will be able to further increase our presence when the next pandemic occurs.

Negotiation with other countries' authorities and increasing the capacity globally, we are now having a different mindset from in the past.

That's what's shown on page 18 - it means that we have completely taken the helm to create a business foundation for infectious diseases that allows us to expand infectious disease drugs globally ourselves.



As for S-217622, we would like to come to a conclusion about how to conduct global Phase III by this month. And how should we supply to LMIC. And in Vietnam and Kore We are conducting clinical trial. And we are now talking to China as well. We would like to decide how to provide S-217622 to these countries. Since the number of infected people has decreased a little, there are not many registered cases for Phase 3 in Asia, but we think it will end in June at the latest. After that, we would like to start LCM for children and prophylactic administration soon.

As for the vaccine, the active control, neutralizing antibody titter trial with Bakiszebria will be the last piece for approval application, so We would like to apply for approval sometime from June to July.

As the characteristic of S-268019 is rhabdovirus-free, we think it will definitely be an advantage for the future. And generally speaking, the third booster or the fourth booster, for multiple doses, the biggest issue is still safety. That's the assessment. The benefit of the recombinant protein vaccines, that's the safety. We will start the trial for 12 to 19 years old from this month in terms of further expanding the age group, which is the merit of recombinant protein. In addition, we plan to conduct a trial for 5 to 11 years old and a trial to verify the safety and neutralizing antibody when frequently administered mainly to the elderly.

Promotion of R&D

Promote R&D focusing on COVID-19 related projects, nasal vaccine, 8 core projects

Core pipeline (Blue: 8 core projects*)

	Project	Indication
Infectious disease	S-217622	COVID-19 treatment
	S-268019	COVID-19 vaccine
	S-875670	COVID-19 nasal vaccine
	S-872600	Influenza nasal vaccine
	S-540956	Infectious disease, cancer

	Project	Indication
Psycho-neurological diseases	S-600918 [sivopixant]	Refractory chronic cough
	S-812217 [zuranolone]	Depression
	BPN14770 [zatolmilast]	Fragile X syndrome
New growth areas	S-531011	Solid tumor
	S-005151 [redasemtide]	①Epidermolysis bullosa ②Acute ischemic stroke ③Knee osteoarthritis ④Chronic liver disease ⑤Cardiomyopathy

Accelerate the R&D of growth drivers by leveraging the speed gained from the COVID-19 experience

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*Appendix p.37

On page 20, on the left-hand side, these are some things that are remaining in relation to COVID-19 products. As for nasal vaccines, animal experiments including antigen adjuvants and bases are progressing to some extent, so we think that clinical trials will start within this year. Similarly, we would like to proceed with the nasal vaccine for influenza.

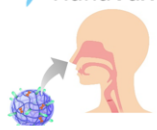
S-540956 adjuvant, with regarding to this, initially, about the OVID-19 vaccine I tried several TLRs when the adjuvant we used did not raise the neutralizing antibody. If it doesn't really work as an adjuvant, we think it's completely different. We think that TLR-based adjuvants also work for cancer and other viruses. For this reason, we would like to proceed with S-540956 as well.

On the right-hand side, these are the important ones for this year. And for psycho-neurological diseases, there are S-600918 and S-812217 and also BPN14770 Fragile X Syndrome. And S-531011 and S-005151, these are the new growth areas for us. Within this fiscal year, these will be a very big and important new step for us.

To Build the Foundation of the Vaccine Business

HanaVax

A drug discovery venture company originating at the University of Tokyo



Cationized nanogel delivery system

- Able to effectively induce immunity in respiratory mucosa, which is the area that becomes infected, as well as the entire body
- Simple administration with no pain caused by conventional needles

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UMN 株式会社UMNファーマ

- Vaccines using BEVS* are widely used, with established efficacy and safety
- Speedy, low cost, and suited to mass production

千葉大学 CHIBA UNIVERSITY

- Specializes in immunization studies
- Established a joint search department for human mucosal vaccines and opened in April 2022

- Utilizing our know-how in developing recombinant protein vaccines using BEVS* and adjuvants, we are considering expansion to other diseases (influenza, pneumococcal bacteria, RS virus, etc.) and development of combination vaccines
- Established the rhabdovirus free ** insect cell culture technology
- Plan to initiate clinical trials for Covid-19 nasal vaccine (S-875670) in FY2022

Strengthen and expand the vaccine business for medium- to long-term growth

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* BEVS：Baculovirus Expression Vector System

** Manufacturing method that does not contain rhabdovirus derived from insect cells contained in the manufacturing process

With Chiba University, we had a joint press conference in the past. For nasal vaccines, there is a need for the next option, including those who dislike injections in LMICs or developed countries. In addition, the rhabdovirus-free insect cell culture technology is the only technology we have in the world. Including these factors, we would like to fully promote the vaccine business.

Domestic and Overseas Business Initiatives

Domestic business

- **Infectious diseases**
  - Government stockpiling of xofluza and COVID-19 related products in preparation for future pandemics
- **Expansion of CNS projects**
  - **Insomnia treatment drug daridorexant**
    - > Concluded a memorandum of understanding with Mochida regarding a marketing rights license agreement (with certain conditions*) (March 31, 2022)
    - > Development status: Phase 3（JP）（US, EU: Approval）

・ADHD
- Intuniv®
- Vivanse®
- SDT-001

・Insomnia
- Insomnia treatment app
  - > Concluded a sales alliance agreement with SUSMED

・Depression
- S-812217

Create synergies with sales products and development compounds

Overseas business

- **COVID-19 related products**
  - Full-scale discussions with stakeholders in each country for commercialization
- **Western business**
  - Maximize the value of Cefiderocol
    - › High economic value evaluation by the National Institute for Health and Care Excellence (NICE)
    - › Collecting and publishing real world data (RWD) evidence in clinical practice
    - › Efforts to improve access
- **China business**
  - Strengthen sales and expand new sales channels after launching products on medical platforms
  - Progression of activities for early launch of new drugs (cefiderocol, naldemedine)
  - Expansion of research approaches utilizing AI technology

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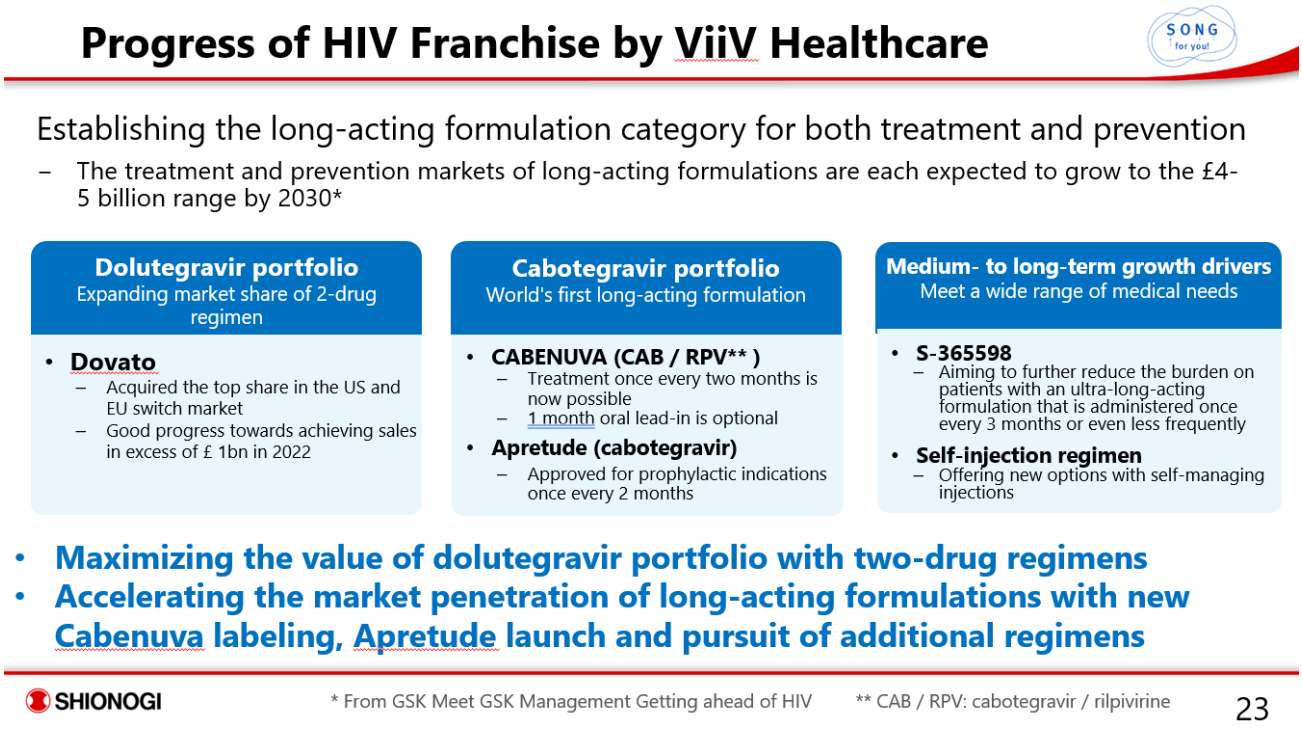
* Japanese Phase 3 trial results, etc.

This is something that we will have shown you for the first time. We have concluded a memorandum of understanding with Mochida regarding a marketing rights license of insomnia treatment drug daridorexant in Japan. It is drug of Idorsia approved in Europe on May 3rd. we have looked into that very deeply, and it has a

very good characteristic. As it is one of the pipelines in the field of psychiatric and neurological disorders, we would like to carry out Ph3 in Japan and then sell it as soon as possible.

With regard to the overseas business, with cefiderocol at the center, we need to establish evidence in the real world and also establish how we can use this without resistance. And also, together with NICE, we would like to look at the economic value. Sales are increasing, but for us as a manufacturer specializing in infectious diseases, we would like to grow into products that can be used properly over a long span, including stewardship, rather than wishing for sales to increase in the short term.

Regarding the Chinese business, we think we can talk about the progress in the first half. The clinical trial of cefiderocol and naldemedine is a little late, but we have started development from the first half of this year. We are also starting a dialogue about S-217622. We haven't been able to disclose all of this yet, but once this starts to move, wet think we will have to invest people, money, and things.



With regard to ViiV Healthcare, everything is going smoothly. Especially in the United States and Europe, post-COVID-19, things are becoming more and more normalized. And regarding Cabenuva, in the past two years, the switching of the injection was not proceeding well. In the meantime, the good news is that we're getting a lot of citizenship about 2 drug regimens, including Dovato. From this year onward, we have great expectations for CAVENUVA and Apretude, as they are franchises centered on injections that we only have. And for S-365598, by the end of this year, Phase I will be conducted.

Medium- to Long-term Commitment as a Leading Company in Infectious Diseases

Material goal that Shionogi is committed to address: "Protect people worldwide from the threat of infectious diseases"

Participate in industry activities and R&D funds	Continue drug discovery research by making use of our strengths	Collaborate to generate innovation and maximize product value
• Provision of R&D investment and technical support through participation in AMR* Action Fund, GHIT Fund, etc. • Dialogue with national governments to develop sound markets • Lobbying for establishment of clinical trial networks and more responsive regulation on a global basis	• Initiatives in serious infectious diseases incl. viral infectious diseases, the three major infectious diseases and AMR • Initiatives in Neglected Tropical Diseases (NTDs) that are overlooked • Expansion into total care against infectious diseases	• Collaboration with academia, ventures and other industries that strive to tackle infectious diseases • Collaborations in overseas development and marketing • Partnering for expansion of LMICs access

Continuous production, support and development of researchers and research institutions are essential to sustain innovation that can meet unmet needs related to infectious diseases and prepare against unknown threats

Establish Shionogi's own, new foundation that supports and encourages research in Japan

* AMR: Antimicrobial Resistance

As we talked to the media in the announcement of financial results yesterday, it is a very difficult issue how to think about scholarship donations in Japan. For the past two years, we have been considering this in-house.

We think it is very important to continue research in case of an infectious disease pandemic in the future. In addition, since we are asking the government for the importance of infectious diseases from the perspective of national security, we would like to create a framework to support basic researchers in the medium to long term by substituting scholarship donations. From this background, we would like to create a foundation.

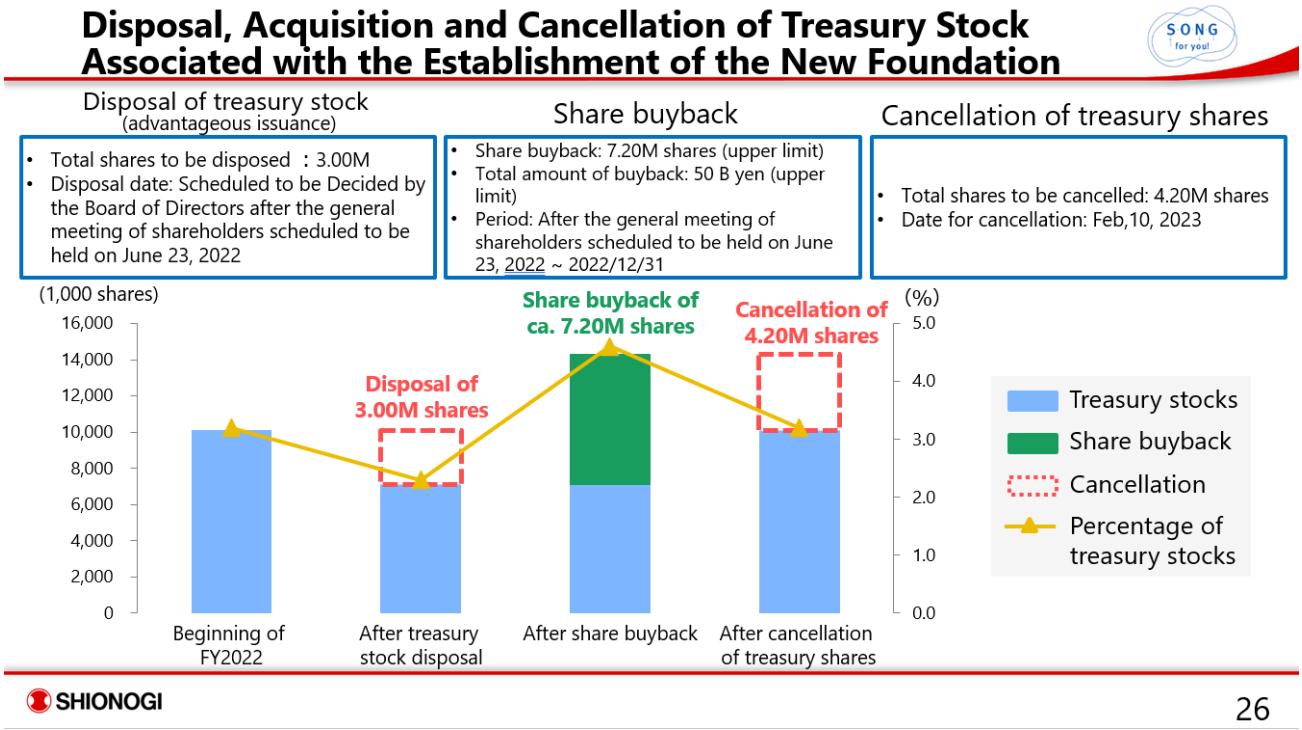
Establishment of SHIONOGI INFECTIOUS DISEASE RESEARCH PROMOTION FOUNDATION

- **Background of the foundation**
  - Society & Economy: The importance of infectious disease research was reaffirmed due to the once-in-a-lifetime COVID-19 pandemic
  - Pharmaceutical companies: Efforts against infectious diseases have tended to be reduced or withdrawn from a business feasibility perspective, leading to loss of employment opportunities for researchers
  - Academia: Lack of funds and employment irrespective of the disease area and the avoidance of infectious disease area where the market size is small have posed a problem for the fostering of young researchers
    ⇒ Considering a new academic research support scheme
- **Activity details (Annual budget: Around 300 million yen is planned)**
  - Granting subsidies for research on infectious diseases; awards for distinguished achievements
  - Hosting lectures and symposiums on infectious diseases ..and more
- **Interest bearing issuance of treasury shares with Sumitomo Mitsui Trust Bank as the trustee and the Foundation as the beneficiary (3 million shares)**
  - To be submitted as a matter for special resolution at the 157th Annual General Meeting of Shareholders to be held on June 23, 2022

Fulfill our corporate social responsibilities
by supporting and encouraging research in the infectious disease area,
thereby contributing to academic research progress and the welfare of mankind

In the mid and long-term period, we want to establish a foundation for this purpose. And so this will be a new foundation named Shionogi Infectious Disease Research Promotion Foundation. When thinking about how to obtain stable operating funds, we will constantly issue annual activity costs based on our stock, referring to the framework of other companies such as Toyota and Ajinomoto.

We would like to submitted matter that interest bearing issuance of treasury shares with Sumitomo Mitsui Trust Bank as the trustee and the Foundation as the beneficiary, in the 157th Annual general meeting of shareholders



When considering the return on shareholders this year, we wanted to buy back our own shares. Therefore, the proposal will be a combination of share buyback and this advantageous issuance.

Once approved at the general meeting of shareholders, we will issue 3 million shares in an advantageous manner, which will cause a temporary dilution, but after the same day, we will promptly acquire treasury stock, which is up to 50 billion yen or 7.2 million shares. Over 4.2 million shares will be amortized for a portion of them. We would like to ask for your consent at the General Meeting of Shareholders.

Financial Forecasts (Consolidated)

(Unit: B yen)

	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	400.0	180.0	335.1	19.4	64.9
Operating profit	120.0	57.0	110.3	8.8	9.7
Core operating profit*	120.0	57.0	110.6	8.5	9.4
Profit before tax	168.0	86.0	126.3	33.0	41.7
Profit attributable to owners of parent	136.0	71.5	114.2	19.1	21.8

A year to receive the return from COVID-19 related efforts and reinvest into future growth

Exchange Rate (average)	FY2022 Forecasts	FY2021 Results
USD ($) – JPY (¥)	125	112.40
GBP (£) – JPY (¥)	160	153.53
EUR (€) – JPY (¥)	135	130.56

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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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The Board of Directors also discussed the financial forecast yesterday, and some directors said that the sales of COVID-19 related products should be at zero. Then, of course, it looks like a decrease in the sales and profit. On the other hand, some directors said that they could maximize sales of COVID-19 related products. it was a difficult discussion because each idea is different.

We want to have the highest probability of revenue. And also, with regard to the operating profit, we wanted to be as conservative as possible. This was the discussion result of the meeting we had yesterday.

Normally, operating profit and core operating profit of JPY120 billion is quite conservative from my point of view. It is normal to plus JPY25 billion or JPY30 billion. However, as I have said, as a leading company of infectious diseases, we have to prepare our own infrastructure in US and Europe. Including this, we incorporated it into a part of SG&A.

This will be updated in detail at the end of first and second quarter each time it is decided how much profit will be made by selling with the contract with the government of each country. This is a discussion at our Board of Directors, and on the condition that we do it, we have provided this conservative figure, although there may be some criticism.

The operating profit ratio of 30% for revenue of JPY 400 billion is a very low level for us, so we are not satisfied with this figure. The message is that we would like to start with an increase in sales of about 20% and an increase in profit of 10%.

And the exchange rate is GBP1/JPY160, but we will obviously have a hedge based on discussion with Mr Hosogai. Unless extraordinary things happen, I think this is a reasonable figure.

Statement of Profit or Loss Forecast (Consolidated)

(Unit: B yen)

	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	400.0	180.0	335.1	19.4	64.9
Cost of Sales	22.0 88.0	17.5 31.5	16.5 55.4	58.8	32.6
Gross profit	312.0	148.5	279.7	11.5	32.3
Selling, general& administrative expenses	30.0 120.0	32.8 59.0	28.4 95.2	26.0	24.8
R&D expenses	17.5 70.0	17.8 32.0	21.8 73.0	(4.1)	(3.0)
Other income & expenses	(2.0)	(0.5)	(1.2)	71.5	(0.8)
Operating profit*	30.0 120.0	31.7 57.0	32.9 110.3	8.8	9.7
Core operating profit	30.0 120.0	31.7 57.0	33.0 110.6	8.5	9.4
Finance income & costs	48.0	29.0	16.0	200.8	32.0
Profit before tax	42.0 168.0	47.8 86.0	37.7 126.3	33.0	41.7
Profit attributable to owners of parent	136.0	71.5	114.2	19.1	21.8

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

This is the P&L. JPY70 billion for R&D expenses is such a big figure. As I mentioned, JPY73 billion for R&D expenses in FY2021 was a record high, but that included the advancement of the R&D expenses of COVID-19 related products. On the other hand, as I mentioned, we would like to conduct a pediatric or prevention trial of S-217622 and a certain degree of multiple doses trial of S-268019 in the lower-aged people or the elderly population. In addition, as the phases of S-600918, S-812217, S-531011, S-005151, etc. are advancing, we have entered a figure of JPY70 billion as for R&D expenses.

Revenue Forecast by Segment

(Unit: B yen)

	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Prescription drugs	78.6	35.5	89.1	(11.8)	(10.5)
Overseas subsidiaries/export	41.6	18.1	34.4	21.2	7.3
Shionogi Inc.	13.0	6.0	13.8	(6.0)	(0.8)
Ping An-Shionogi* /C&O	14.8	6.3	10.2	45.1	4.6
SBV(Europe)	8.4	3.4	5.0	67.9	3.4
Contract manufacturing	14.8	6.3	17.4	(15.3)	(2.7)
OTC and quasi-drug	13.4	6.3	11.2	20.0	2.2
Royalty income	140.4	68.2	181.3	(22.5)	(40.9)
HIV franchise	133.9	67.0	174.0	(23.0)	(40.1)
Crestor®	-	-	1.2	-	(1.2)
Others	6.5	1.2	6.1	5.9	0.4
COVID-19 related products**	110.0	45.0	-	-	-
Others	1.2	0.6	1.8	(65.3)	(0.6)
Total	400.0	180.0	335.1	19.4	64.9

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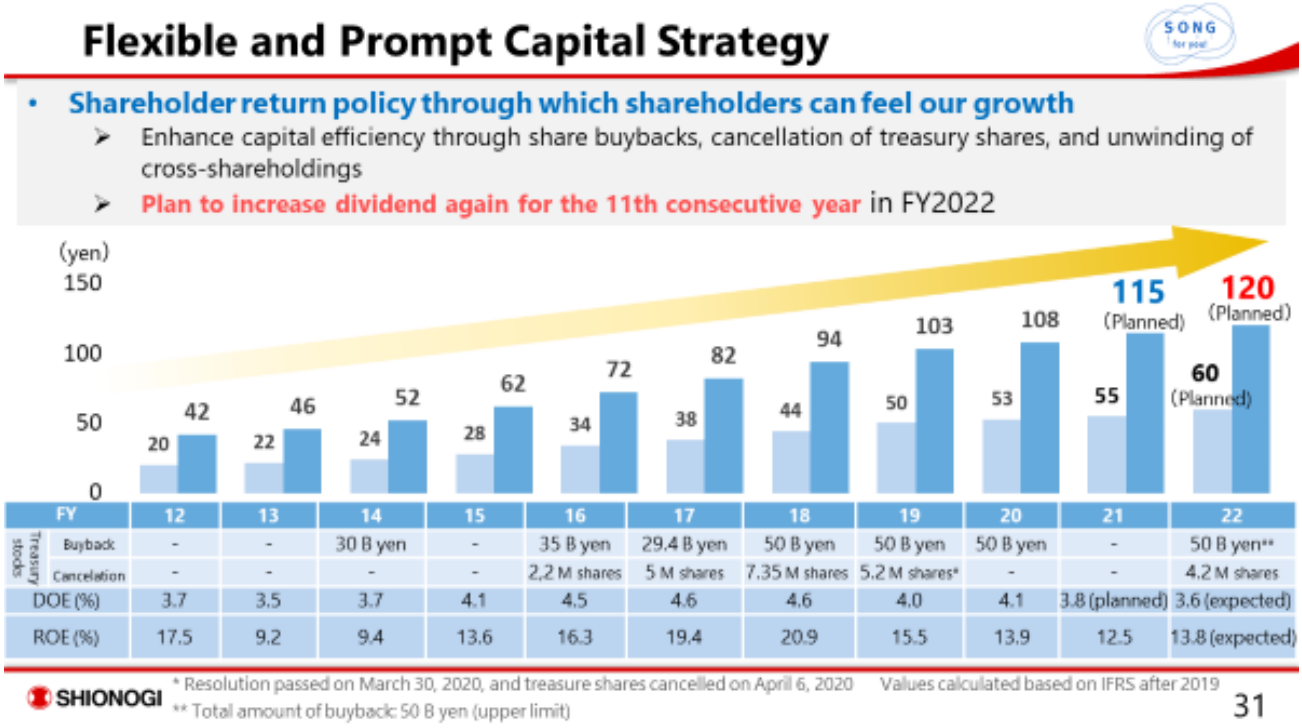
* OTC and quasi-drugs also include in revenue of joint venture
** Revenue from S-217622 and S-268019

Based on the sales, COVID-19 related products are JPY110 billion and JPY45 billion for the first half.

For us, I'm not going to talk about every single detail, but if we don't give the figure conservatively, we may create a big disappointment. After much consideration, we came up with these figures. As to cost of sales ratio, we've been very conservative so that we can cope with any unexpected events.

Those figures may be difficult to understand, and we apologize for this, but this is the minimum line. And then, after every three months or after every event, we are going to give you an update.



And now the shareholder return.

If we can get approval at the shareholders' meeting, we are considering a year-end dividend of JPY60, full-year dividend of JPY115, an increase dividend of JPY7, and a dividend increase for 11 consecutive years. For FY2022, of course, we will start from JPY60 for midterm and JPY120 at the end of the period. However, if our achievement are really successful, we would like to think about this again with the results of March and April as usual.

That's all from myself. Thank you very much.

Question & Answer

Kyokawa: Thank you very much. Now we will move on to the Q&A session.

Mr Yamaguchi from Citigroup Global Markets, please

Yamaguchi: I'm Yamaguchi from Citigroup. I would like to ask you two questions. First, as you explained, the SG&A expenses are considerably higher than the sales JPY110 of COVID-19 related products. It doesn't fit in the normal way. With regard to increase this increase in SG&A expenses, there is a possibility of the overseas infrastructure, but apart from that, it's difficult to understand why it will cost so much. There is a gap between the plan and fiscal year?

Teshirogi: Yes, I think so. Including Mr Hosogai, who has the hardest idea, let's start with the figure that can be achieved by whatever. For example, SG&A expenses have risen by about JPY25 billion, but we can't give you every detail. For us, the reality is that we should start with the operating profit that puts all of these together, but since JPY110 billion is also very conservative. This figure may change as well. I think those are the minimum figures.

Yamaguchi: I understand. The second question is about Phase III in the US. This trial hasn't started yet, but it was in talks with the FDA over protocol. You have talked about whether it is an EUA or NDA, but what I I want to understand is which one does your company prefer and which one does FDA prefer?

Teshirogi: Ms Sawada and Dr. John will explain it later in more detail, but from the perspective of wanting to get it out sooner, we would like to put it in the framework of the EUA. And if we offer protocol under EUA, the FDA would say that unvaccinated people with risk of exacerbation have to be compared. And, wherever there are good drugs available, they said that the person should be excluded because there is an available drug. In that case, is it possible to obtain EUA except for comparative studies in patients who are not vaccinated and are at risk of becoming severely ill outside the United States?

We will discuss internally whether such drugs are required in the world today. After taking the EUA, Pfizer has also been testing so-called normal patients. It seems that good results were not obtained in the interim analysis, but this is what the society is looking for. We are asking them to let us do that in Phase III, but FDA has been saying that it's different in EUA. They are talking about a very narrow protocol.

We are also telling them what we'll get from doing this. For us, if it weren't for EUA, it would be a different story. As to the product positioning, that might be a better option. Including NIH, we are now having a discussion. There is Ms Sawada, a protocol expert, so let her answer.

Sawada: In fact, the clinical trials conducted by Pfizer and Merck included high-risk patients who had not been vaccinated and had no history of infection. I wonder if there really are such patients all over the world nowadays, and even if such a trial is effective, there aren't many such patients anymore. Moreover, when the target is replaced by the Omicron variant and the severity rate or hospitalization rate is seen, does the percentage decrease really have an impact? ISAR had a fairly negative opinion at Molnupiravir.

We are proceeding with discussions on the idea that it would be beneficial to the world to discuss what kind of patients should actually be used in the future. I think the FDA has been very positive about that.

Yamaguchi : And then another question is about the funding for SCORPIO-HR. Regarding the funding, there is news such as there is the budget is running out and trouble in the parliament, you don't have any funding issue?

Sawada: We have secured the funds.

Yamaguchi : It means that protocol sharing is delayed, or that negotiations are underway, right? It seems that only that part is slightly behind.

Sawada: Yes, we are now having discussions to improve the protocol.

Kyokawa : Mr. Kohtani, please.

Kohtani : This is Kohtani from Nomura Securities Co., Ltd. I have two questions with regard to COVID-19. Since you believes that the possibility of approval is extremely high, you have included 110 billion yen in the FY2022 forecast. I think the premise is for you have to show the priority to VAXZEVRIA in Phase III. A Nature Medicine paper states that VAXZEVRIA has a 50% increase in neutralizing antibody titers against convalescent sera. To be honest, the hurdle seems to be low compared to 90% of the mRNA vaccine. However, as for the data in this paper, since only 5 people have taken convalescent serum, the numbers may actually fluctuate significantly, and I am a little worried when I think objectively.

S-268019 showed to have a positive conversion rate of about 99% in Phase 2/3, so I'm wondering if that's okay, but please tell us how confident you are.

Also, Takeda said that they can supply only 30 million bottles, even though they had initially said they would supply 150 million bottles of Nuvaxovid. They didn't say it clearly, but I think it's probably because of an adjuvant called Matrix-M. This is made by cutting down a Chilean soap tree, so it may not be so easy to make. Could you be sure to produce at least for 30 million people, including the adjuvant, in short for 60 million doses? This is the first point.

Sawada : With regard to the neutralizing antibody titer, the measurement terminology is different amongst different companies. Even if you look at the serum of the recovered patients, it's very difficult to do an apples-to-apples comparison. But when we did a company-wide vaccination, the neutralizing antibody titer was measured according to our methodology. And as a result of that, our 019 neutralizing antibody titer was measured quite accurately.

As a result of that, we have decided to do a noninferior booster trial against COMIRNATY. And also, we feel that we would be able to show a superiority against the VAXZEVRIA.

Teshirogi : With regard to the supply, we have to cover both antigen and adjuvant. Since our adjuvant is much easier to manufacture than Matrix-M, there is no problem so far including the antigen and the adjuvant. we are able to provide 60 million doses without any problems.

Kohtani : At the time of approval for Nuvaxovid, there was no problem with rhabdovirus, I wonder if it is OK because it is a imported product. When you launch, I think that you can say that it's a rhabdovirus-free. Are you going to come with the fact that it is a rhabdovirus-free with regards to your vaccine?

Teshirogi : Yes, we think so far.

Kohtani : And with regard to the treatment drug, according to Phase IIb, there was no significant difference in the recovery time of the symptoms. And looking at the changes that you have made, there was a subtle difference in the endpoint.

The endpoint changed from recovery to resolution. But do you think that the probability of success is higher with the changes in the endpoint? Six days of symptoms, how much it will change? And amongst the six symptoms, I think only a part of the symptoms are expressed. Therefore, the difference is almost zero. So, maybe the difference is very difficult to see.

The endpoint after the change is the time until the symptom disappears, but it is hard to imagine whether that really makes a difference. I would like to ask you your confidence with regards to showing the significant difference.

I think there is an importance of the public opinion for getting approval. There are some people who say that virus titers alone are not enough. Therefore, I think it will be difficult to be approved without showing that the primary endpoint has been achieved. I think you need to be able to show your confidence.

Sawada: Originally we have looked at the improvement. However, improvement is considered improvement when even one of all the symptoms becomes mild. If you have one moderate symptom and one of them becomes mild, that alone will actually improve it.

Then, as you can see, at an extremely early stage, even the placebo-administered group will improve. If only one symptom is improved a little, it will be OK, so it will be difficult to make a difference with this. I think this is clear even if you look at EPIC-SR for PAXLOVID.

During discussions with the FDA and others, there was an opinion that if we were to look at the duration of illness, it would be better to look at the period until complete recovery. When we consider this case, the difference becomes clear as our trial results.

In terms of resolution, the effect of the number of clinical symptoms targeted is actually almost eliminated. Therefore, if the variant changes in the future, we think we will be able to have an equal evaluation or a fair evaluation.

Kohtani: I see. Thank you very much.

Kyokawa: Next, Ueda-san.

Ueda: Ueda from Goldman Sachs Japan Co., Ltd. This question is about the plan for COVID-19 therapeutic drug, the current situation and future assessment. How is it going in terms of the review? The data you have submitted seems to be not sufficient. For approval, do we have to wait for the data with significant differences expected to be shown in Phase 3 etc. Could you tell us when your plan also incorporates approval?

Teshirogi: Considering the stage of questions from the Ministry of Health, Labor and Welfare and PMDA, we think it is near the final stage of the examination.

As I mentioned at the media meeting yesterday, when the EUA bill is passed due to the revision of the Pharmaceutical Machinery Law, the authorities need to confirm the safety, and can approve if it is presumed to be effective. It may be one of the approval options, at this point, but we're not talking at all whether it's applicable or not.

We think the data we submitted is sufficient for us to get conditional early approval. We think it depends on how the authorities think about it and how discuss they with us in the future.

On various occasions, the authorities say that they are now trying very hard to complete the review. In addition, one of the strengths of the EUA law is that it can be approved by estimating its effectiveness. Given these, authorities may also be considering using the EUA law for approval.

Ueda: Thank you very much. My second question is about the significance of S-217622 based on the data of S-217622 that was presented at the conference (ECCMID) in April.

Looking at the improvement of symptom score, I would like to know how clinically significant this data is.

Considering the previous story, I think that the infection prevention effect and antiviral effect of S-217622 are a benefit of this drug as well. Please tell us your thoughts on the post-launch positioning of this drug and its significance in society.

Sawada: At ECCMID, I have the impression that the discussion at ECCMID actually focused on the antiviral effect. In that sense, the impact on propagation itself, to be honest, is not yet available as data. However, there is also the possibility of reduction of the productivity of the people caused by the transmission and existence of a quarantine period. So, I think that the antiviral effect is very significant for society.

On the other hand, I think that the validity of clinical evaluation is still under discussion, and and it is naturally preferable that the time to symptom improvement or resolution is short. Therefore, by accumulating data on people who are currently considered to be the target of treatment, it will be possible to treat those who cannot, even if they want to, as soon as possible, and as a result, they will be able to return to society as soon as possible. I think that it is very important to create a healthy society.

In addition, I would like to take a look at Long COVID. as well. This will take some time to evaluate, so we will have to wait for the results of the follow-up exam for a while, but in parallel, we have already incorporated this into all Phase 3 exams.

Teshirogi: Long COVID is very important as well. But so far, we are doing a lot of research and development. However, since what sort of patient will suffer from long COVID is the question we have to follow-up all the cases. In the Phase III in Asia and global Phase III, we are going to follow them up for six months at least to see the incidence of long COVID.

Our hypothesis is that it seems that it is harder to become Long COVID if the virus is controlled and regulated at an early stage. Considering the antiviral data and convenience of taking medication, S-217622 has therefore an advantage. For the next phase, that will be a very important aspect and we are already thinking about incorporating it in global Phase 3.

Ueda: Thank you.

Kyokawa: Sakai-san, please.

Sakai: This is Sakai from Credit Suisse Securities (Japan) Limited. As a confirmation with regard to 622, is it okay to understand that onetime payment from overseas partnering is not included in your revenue of COVID-19 related products in this plan of your company this term?

Also, for the last one year, I think your company has made a big ripple in the way of thinking and how to formulate various protocols for infectious diseases, not just the COVID-19 as you mentioned, for example, PMD Act. However, how will this be taken over and discussed in the future? I think FDA and CDC will of course work on it but in case of Japan, where you do not know if the Central Social Insurance Medical Council is functioning, I think I think only Shionogi is going through this hardship.

So if you want to develop Shionogi as a global infectious disease company, at or where would you like to start this kind of discussion? If you have any prospects regarding the future.

Teshirogi: With regard to your first question, onetime payment is not included in the budget or the plan. However, I and John are always thinking about where and what to make. We haven't included it in our plan, so it will be a plus if it happens.

The second point is very difficult. we want to enhance the level of the medical care in Japan, and doctors who cooperate with us are passionate about it. Given that we are entrusted with management by our stakeholders,

we must think about getting approval and contributing as soon as possible. With that in mind, it may be a future practice to go abroad and get into full swing first.

Sakai: Thank you.

Kyokawa: Now let's go to the questions from the participants online.

Operator: Next, Hashiguchi-san from Daiwa Securities Co. Ltd. Please go ahead.

Hashiguchi: My first question is about the overseas revenue of S-217622. could you please tell us what you think about the timing of overseas sales of S-217622 at this point? As to Phase III structure, I felt that you were leaning toward getting normal approval instead of EUA. But In the case, when will you get enough results to apply?

Then, you used to say that you would like to use the help of your partner for overseas production. However, if you build your own production sites, when do you think you can prepare the setup for that?

Teshirogi: Thank you for your question. When we think about the global markets, EU and the US, we will refer Asia nation's a bit different. Korea, Vietnam, Indonesia, and China, those countries, once we have EUA in Japan or once we get the approval in Japan, they will move ahead as their positions. Approval in Japan, including EUA, once we get the approval, the time clock will start. That will be booked within the fiscal year.

As for the EU and the US, Asian Phase 3 trial is pivotal. We are thinking about if we can use that trial for the approval application. But FDA, if they want us to have the local trial results, the timing will change slightly depending on the scale of the trial we conduct. The expected total number of patients for this Asia Phase 3 trial is about1,800～2,000. I think that this data will be sufficient to look at the efficacy and safety. That's the basis of our negotiations with them. However, the EU and the US are not included in the JPY110 billion.

As for production, there are two issues. The first issue is that we have to increase capacity. And the second issue is that starting materials are all from China, so we have to provide hedge for this risk. Therefore, we are currently starting discussions centered on the CMO in India and the US.

We have been doing production domestically since last December. We have accumulated a great deal of know-how on API and formulations. Therefore, I think that technology transfer can be carried out smoothly as it is. We aim to start production around December of the year.

Hashiguchi: Production within the year will be more about raw materials and API, and will it be a while before we secure the distribution of the final products?

Teshirogi: Production within this year, I think that's about API. The final products will be later. As for the formulations, it's not very difficult. If there are API, it is not a long time to make a formulation.We would like to produce as much as possible within this year.

And the other thing is that one thing we can't really have a clear view is about China. The condition of the paxlovid's approval was to manufacture them in China. But the question is how much, to what level we'll have to manufacture in China? If China starts to move, the more quantities will be needed. If that's the case, we will have to accelerate our schedule. Otherwise, we won't be able to meet the needs.

At this point, we are considering production in India and the US, but we don't include supplies for China.

Operator: The next question will be our last question. JPMorgan Securities Japan Co., Ltd., Wakao-san, please.

Wakao: Wakao from JPMorgan. Regarding partnering, I have a question. I understand that you are considering a partnership to support the retail phase of commercialization. In that case, it was mentioned that the timing of the conclusion of partnering was the end of February or the end of March, but I realized that it was not necessary to hurry. At this point, when do you think the best timing for partnering is?

Keller: As we mentioned, our strategy for what a partner contributes has changed. We have made so much progress on our own with development and manufactured supply, we don't urgently need a partner for the first phase of offering the product in the US and EU.

Remember, with COVID products, the first phase is typically government purchase. And since we now have direct relationships ourselves with the relevant governments, we don't need a partner for that phase.

Then typically, after one year or so, the market moves to a retail commercial market. At that point, it can be quite broad, involving, depending, for example, if the Biden administration initiative of Test-to-Treat succeeds, that could quite broadly spread across pharmacies across the country. That kind of activity, a partner may be useful for.

I think over the course of this year, we will continue discussions. But really, for us, we're focused on getting the study and the approval, and the initial supply ourselves. And then a partner can come in later to support the broader commercialization.

Wakao: Thank you very much. And with regard to your operating profit, you have a conservative operating profit for the coming fiscal year. Even if there is a delay in the development of COVID-19-related products, I think you will be able to secure an operating profit of 120 billion yen by reducing SG & A expenses. So, I think about how much upside would come out from here. Is my understanding correct?

Teshirogi: Yes, at the Board of Directors meeting, that is the kind of discussion that we have had. That is our recognition, yes.

Wakao : Thank you very much.

Kyokawa: Thank you very much. I'm sorry that we have exceeded the allocated time, but we would like to conclude now with regard to the FY2021 Financial Results Meeting.

Teshirogi: Thank you very much.

[END]