SHIONOGI & CO., LTD.

2nd Quarter of Fiscal 2022 Financial Results

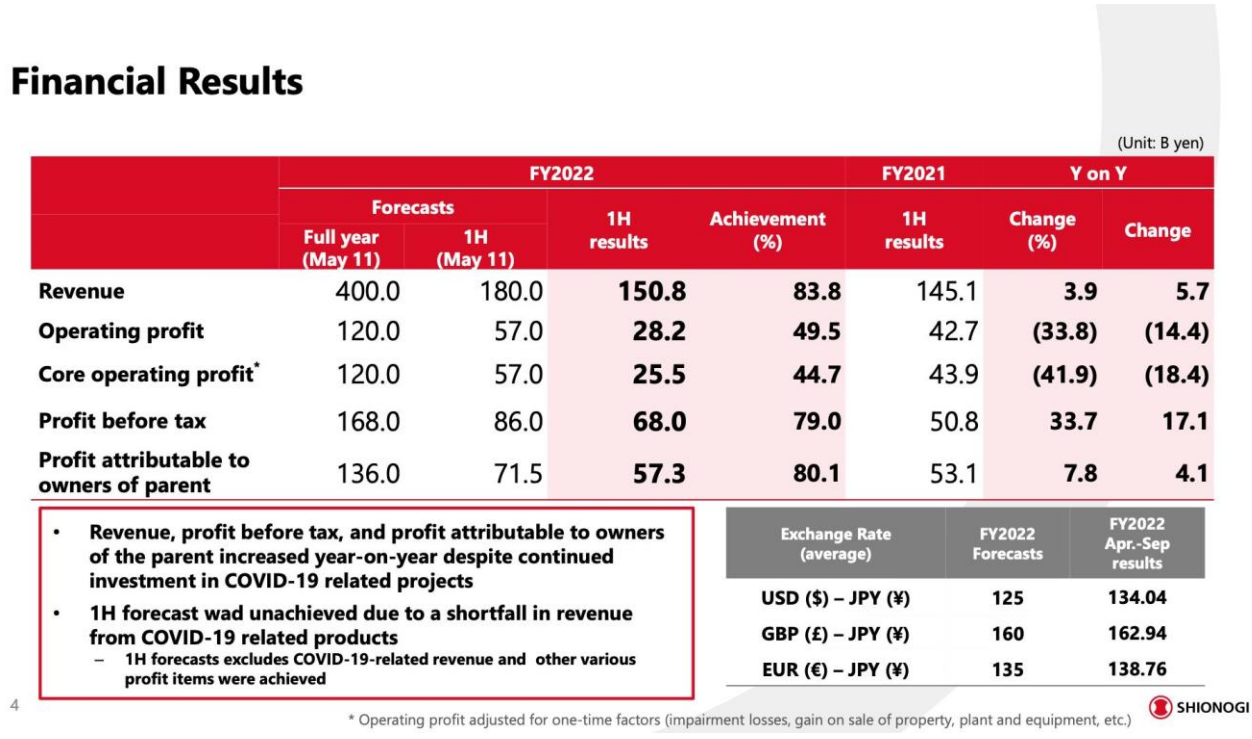
November 1, 2022

Kyokawa: Thank you very much for taking time out of your busy schedule to join us today. Now we would like to start a briefing of the financial results for Q2 of the fiscal year ending March 31, 2023.

First, let me introduce today's speakers. This is Isao Teshirogi, PhD, Chief Executive Officer. This is John Keller, PhD, Senior Executive Officer, Senior Vice President, R&D Supervisory Unit. Next, this is Toshinobu Iwasaki, Senior Executive Officer, Senior Vice President, Healthcare Business Supervisory Unit and Pharmaceutical Commercial Division. Next, this is Ryuichi Kiyama, PhD, Senior Executive Officer, Senior Vice President, Corporate Strategy Division and Corporate Planning Department. Finally, this is Susumu Mitsumori, PhD, Vice President, Finance & Accounting Department. These are the members who are attending today.

After giving an overview of today's financial results, I will take time for Question & Answer session. The event is scheduled to end at 12:00 PM. Please note that simultaneous interpretation capability will be available for today's briefing. Let us begin.

Teshirogi: Thank you very much. I am sure you have seen the downward revision for H1 and the slight upward revision for the full year that we disclosed last week. Today, I would like to spend much time on Q&A, hopefully touching on some key points about the contents of these revisions.



Financial Results

(Unit: B yen)

	FY2022				FY2021	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year (May 11)	1H (May 11)					
Revenue	400.0	180.0	**150.8**	**83.8**	145.1	**3.9**	**5.7**
Operating profit	120.0	57.0	**28.2**	**49.5**	42.7	**(33.8)**	**(14.4)**
Core operating profit*	120.0	57.0	**25.5**	**44.7**	43.9	**(41.9)**	**(18.4)**
Profit before tax	168.0	86.0	**68.0**	**79.0**	50.8	**33.7**	**17.1**
Profit attributable to owners of parent	136.0	71.5	**57.3**	**80.1**	53.1	**7.8**	**4.1**

- **Revenue, profit before tax, and profit attributable to owners of the parent increased year-on-year despite continued investment in COVID-19 related projects**
- **1H forecast wad unachieved due to a shortfall in revenue from COVID-19 related products**
  - **1H forecasts excludes COVID-19-related revenue and other various profit items were achieved**

Exchange Rate (average)	FY2022 Forecasts	FY2022 Apr.-Sep results
USD ($) – JPY (¥)	125	134.04
GBP (£) – JPY (¥)	160	162.94
EUR (€) – JPY (¥)	135	138.76

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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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Now, let's move on to page four. For the period under review, the Q2 results show sales revenue of JPY150.8 billion. As you are all aware, a certain amount of ensitrelvir's sales have been shifted to H2. As a result, the percentage of progress for H1 in terms of revenue and profit is in the 80% range for before income taxes. However, if you look at the right side of the graph, you will see an increase in revenue and an increase in final profit compared to the previous year.

As for operating income, we did not originally intend to spend so much, but we are making very much progress in R&D expenses. On the other hand, we cannot delay R&D of COVID-19, and we are also working on S-812217 as a post-COVID-19 pipeline, S-005151, S-309309, and so on at the same time.

Financial Results
(Excluding forecasts for COVID-19 related products)

Excludes the following items from 1H forecast
- Revenue of COVID-19 related products 45 billion yen
- Cost of sales associated with sales of COVID-19 related products

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts 1H (May 11)	1H Results	Achievement (%)	1H Results	Change (%)	Change
Revenue	135.0	**150.8**	**111.7**	145.1	3.9	5.7
Operating profit	17.5	**28.2**	**161.3**	42.7	(33.8)	(14.4)
Core operating profit	17.5	**25.5**	**145.6**	43.9	(41.9)	(18.4)
Profit before tax	46.5	**68.0**	**146.2**	50.8	33.7	17.1
Profit attributable to owners of parent	42.0	**57.3**	**136.3**	53.1	7.8	4.1

Base business achieved 1H forecast

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Page five. We separate COVID-19 related and non-related budget. As you can see, the progress rate for H1 is also very good in terms of items other than COVID-19. We believe that the base business in general is strong, especially in terms of operating income, which is 161.3%, as you can see how much resources were spent on COVID-19.

Statement of Profit or Loss

	FY2022				FY2021	Y on Y	
	Forecasts Full year (May 11)	Forecasts 1H (May 11)	1H results	Achievement (%)	1H results	Change (%)	Change
Revenue	400.0	180.0	**150.8**	**83.8**	145.1	**3.9**	**5.7**
Cost of Sales	88.0	31.5	**27.4**	**86.9**	27.0	**1.4**	**0.4**
	22.0	17.5	18.2		18.6		
Gross profit	312.0	148.5	**123.4**	**83.1**	118.1	**4.5**	**5.3**
Selling, general& administrative expenses, R&D expenses total	190.0	91.0	**97.2**	**106.8**	74.1	**31.2**	**23.1**
	47.5	50.6	64.5		51.0		
Selling, general& administrative expenses	120.0	59.0	**48.5**	**82.2**	45.9	**5.6**	**2.6**
	30.0	32.8	32.1		31.6		
R&D expenses	70.0	32.0	**48.7**	**152.3**	28.2	**72.9**	**20.6**
	17.5	17.8	32.3		19.4		
Other income & expenses	(2.0)	(0.5)	**2.0**	-	(1.4)	-	**3.4**
Operating profit	120.0	57.0	**28.2**	**49.5**	42.7	**(33.8)**	**(14.4)**
	30.0	31.7	18.7		29.4		
Core operating profit	120.0	57.0	**25.5**	**44.7**	43.9	**(41.9)**	**(18.4)**
	30.0	31.7	16.9		30.2		
Finance income & costs	48.0	29.0	**39.8**	**137.1**	8.2	**386.7**	**31.6**
Profit before tax	168.0	86.0	**68.0**	**79.0**	50.8	**33.7**	**17.1**
	42.0	47.8	45.1		35.0		
Profit attributable to owners of parent	136.0	71.5	**57.3**	**80.1**	53.1	**7.8**	**4.1**

(Unit: B yen)

Main Variation Factors (Y on Y)

- **Revenue**
  - Increase: Sales of Cefiderocol in the US and Europe
    : Royalty income (HIV franchise)
  - Decrease: Domestic sales of prescription drugs
- **R&D**
  - Increase: Investment in R&D activities related to COVID-19
- **Finance income & costs**
  - Increase in income
    : Increased dividend reflecting ViiV's strong business
    : Receipt of dividends from ViiV which was scheduled to be received in 4th quarter of FY2021
    : Increased dividends due to ViiV receipt of lump sum payment from the settlement with Gilead (Both are transient factors)
- **Profit attributable to owners of the parent**
  Received in 1Q of FY2021 refund regarding favorable Judgement on the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau

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Page six is a breakdown of this information. As indicated as main variation factors on the right side of the slide, the main drivers of the increase in sales revenue are royalties, the extremely strong ViiV business, and the

depreciation of the yen. However, overall overseas sales and domestic sales, excluding the light-off of Xofluza, which had been on the market, are expected to be strong both domestically and overseas.

Regarding R&D expenses, I understand that it is JPY48.7 billion. We are using about 1.5 times as much, and we are also running quite a variety of tests on COVID-19, especially vaccines. Also, encitrelvir is also progressing a very large advance in pediatric preparation or prophylaxis, and in US trials.

As for financial income, there are several points, but in general, the dividend from ViiV is solid. In particular, as you may remember, we received three dividends in H1 of this year alone, due to the April 1 delay of last year's March dividend.

In addition, as we have said before, it is impossible to predict exactly how much dividends will really come in, so we should hedge our bets here. The structure is almost completely naked, so the strong British pound is a driving factor. Naturally, the effective tax rate will also be lower if dividends are higher, so I believe that this is a very significant benefit to our company in this regard.

Quarterly income before income taxes was JPY68 billion, an increase of JPY17.1 billion from the previous year, but quarterly income increased by only JPY4.1 billion, which we believe is due to the tax refund of JPY13.3 billion last year.

Revenue by Segment

	FY2022 Forecasts Full year (May 11)	FY2022 Forecasts 1H (May 11)	FY2022 1H results	Achievement (%)	FY2021 1H results	Y on Y Change (%)	Y on Y Change
Prescription drugs	78.6	35.5	**33.4**	**93.9**	47.1	**(29.2)**	**(13.8)**
Overseas subsidiaries/export	41.6	18.1	**19.9**	**110.4**	17.4	**14.5**	**2.5**
Shionogi Inc.	13.0	6.0	**7.4**	**123.4**	7.9	**(6.2)**	**(0.5)**
Fetroja®	-	-	**4.7**	-	2.9	**65.0**	**1.9**
Ping An-Shionogi*/C&O	14.8	6.3	**5.6**	**88.9**	4.7	**19.0**	**0.9**
Shionogi BV(Europe)	8.4	3.4	**4.3**	**127.1**	2.3	**88.3**	**2.0**
Contract manufacturing	14.8	6.3	**7.4**	**117.4**	8.4	**(12.0)**	**(1.0)**
OTC and quasi-drug	13.4	6.3	**6.3**	**99.3**	6.0	**3.7**	**0.2**
Royalty income	140.4	68.2	**83.3**	**122.0**	65.4	**27.4**	**17.9**
HIV franchise	133.9	67.0	**80.4**	**119.9**	61.2	**31.2**	**19.1**
Others	6.5	1.2	**2.9**	**239.3**	4.1	**(29.6)**	**(1.2)**
COVID-19 related products**	110.0	45.0	-	-	-	-	-
Others	1.2	0.6	**0.6**	**98.9**	0.8	**(21.9)**	**(0.2)**
Total	400.0	180.0	**150.8**	**83.8**	145.1	**3.9**	**5.7**

(Unit: B yen)

Main Variation Factors (Y on Y)

- **Prescription drugs**
  - Increase: Sales of Intuniv® and Vyvanse®
  - Decrease: Sales of Cymbalta®
    : Returns of Xofluza® and Rapiacta®
- **Overseas subsidiaries/export**
  - US: Increase: Sales of cefiderocol (Fetroja®)
    : Decrease: Received in 1Q of FY2021 a one-time payment for the transfer of FORTAMET® sales rights, etc. (2.2 B yen)
  - EU: Increase: Sales of cefiderocol (Fetcroja®)
- **Royalty income**
  - HIV franchise
  : Increase: Strong sales of ViiV's HIV franchise

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

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Page seven. If I may speak a little bit about what I mentioned earlier, the background of the relatively strong domestic market is strong for Intuniv and Vyvanse.

Other products were also modest, but sales of anti-infective drugs and old antibiotics were relatively strong, although I think this was partly due to generic drugs shortage, etc. I think this trend will probably continue in H2 and beyond.

As for Cymbalta, I think we are doing relatively well, but we are still being hit pretty hard by generics.

I will explain the return of Xofluza and Rapiacta for influenza later.

Overseas, cefiderocol is doing well in both the US and Europe.

The reason Shionogi is JPY0.5 billion down or negative 6.2% is because JPY2.2 billion of FORTAMET was recorded last year, and we just don't have that, so you can see that even if you deduct that, we are still up JPY1.7 billion to JPY1.8 billion in revenue.

Royalties have risen considerably, but I would say that about one-third of the increase is from ViiV's strong business, which is growing, and about two-thirds is from the effect of foreign exchange rates. I would like to think that the contribution is about 40:60 or 35:65.

Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022				FY2021	Y on Y	
	Forecasts						
	Full year (May 11)	1H (May 11)	1H results	Achievement (%)	1H results	Change (%)	Change
Intuniv®	19.5	9.0	**9.5**	**104.8**	7.6	**24.3**	**1.8**
Vyvanse®	1.1	0.5	**0.6**	**138.5**	0.3	**97.6**	**0.3**
Infectious disease drugs	13.4	4.3	**(0.6)**	-	5.8	-	**(6.4)**
Influenza franchise	5.1	0.3	**(5.0)**	-	1.5	-	**(6.4)**
Cymbalta®	6.1	3.1	**3.0**	**98.7**	11.5	**(73.4)**	**(8.4)**
OxyContin® franchise	4.5	2.3	**2.3**	**100.2**	2.5	**(7.2)**	**(0.2)**
Symproic®	3.3	1.5	**1.6**	**106.8**	1.3	**29.3**	**0.4**
Actair®	0.6	0.3	**0.3**	**95.9**	0.2	**9.8**	**0.0**
Mulpleta®	0.1	0.1	**0.1**	**93.7**	0.1	**(7.9)**	**(0.0)**
Pirespa®	2.4	1.2	**1.4**	**114.3**	2.0	**(31.1)**	**(0.6)**
Others	27.6	13.3	**15.2**	**114.1**	15.9	**(4.6)**	**(0.7)**
Crestor®	3.3	1.7	**2.1**	**126.4**	3.1	**(30.3)**	**(0.9)**
Prescription drugs	78.6	35.5	**33.4**	**93.9**	47.1	**(29.2)**	**(13.8)**

<Products included in infectious disease drugs>

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

Influenza franchise

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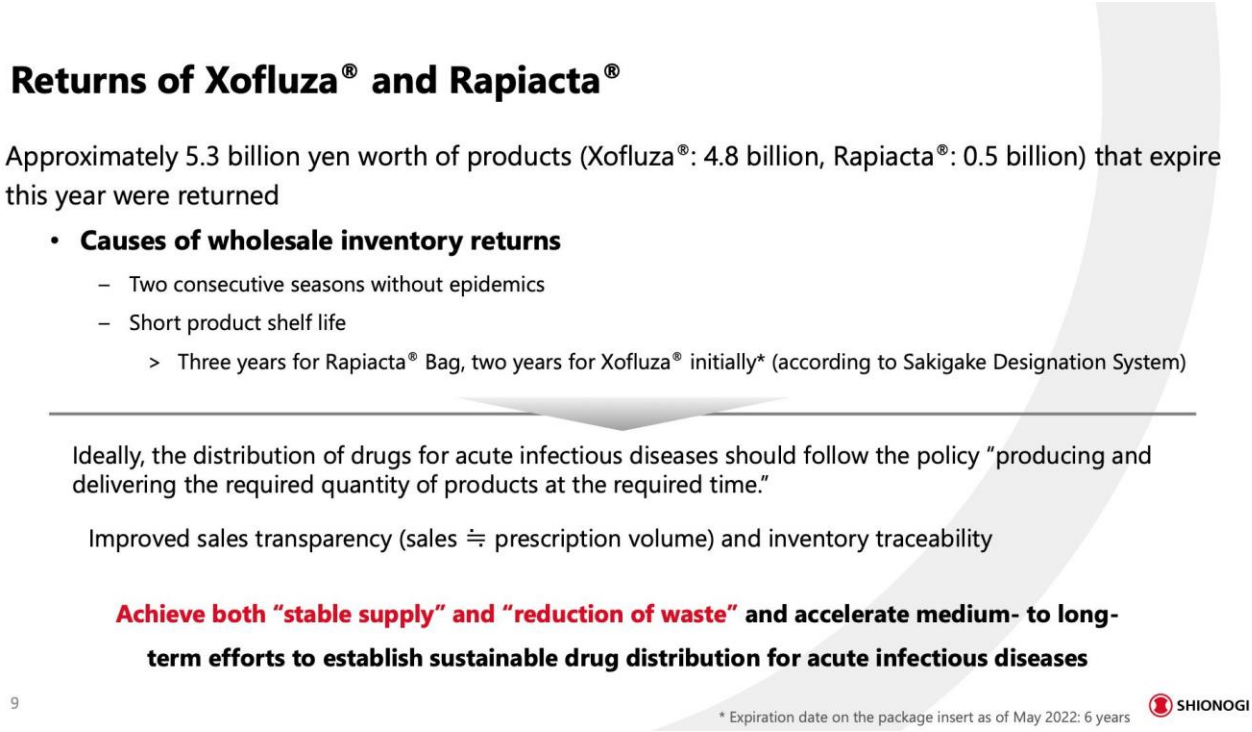
Page eight is a domestic breakdown. We believe that we have almost met our initial H1 forecasts for Intuniv and Vyvanse. For all other areas are generally in line with our forecasts, except for influenza.

As I mentioned earlier, the other areas are not so weak in terms of sales, even though Crestor is reasonably weak YoY, because the other items, especially antibiotic-related products, are strong.

We are also acting to sell OxyContin and Symproic again.



Page nine. Although there is a question as to how much impact a single company can have on the industry as a whole, this was a business in which the industry as a whole had this tendency in the influenza area. Since the epidemic of infectious diseases varies from year to year, if the influenza epidemic does not spread for two consecutive seasons like this time, the expiration date of the product stored in the wholesaler's inventory may expire.

Rapiacta, Xofluza in the future, but our antivirals are very stable. Now Xofluza has a shelf life of up to six years and will probably extend to about 10 years. Since they are basically stable, there is no waste if the unused ones are returned and repackaged after proper checking, but once they leave us, they are out of GMP, so it is not possible to return and repackage them.

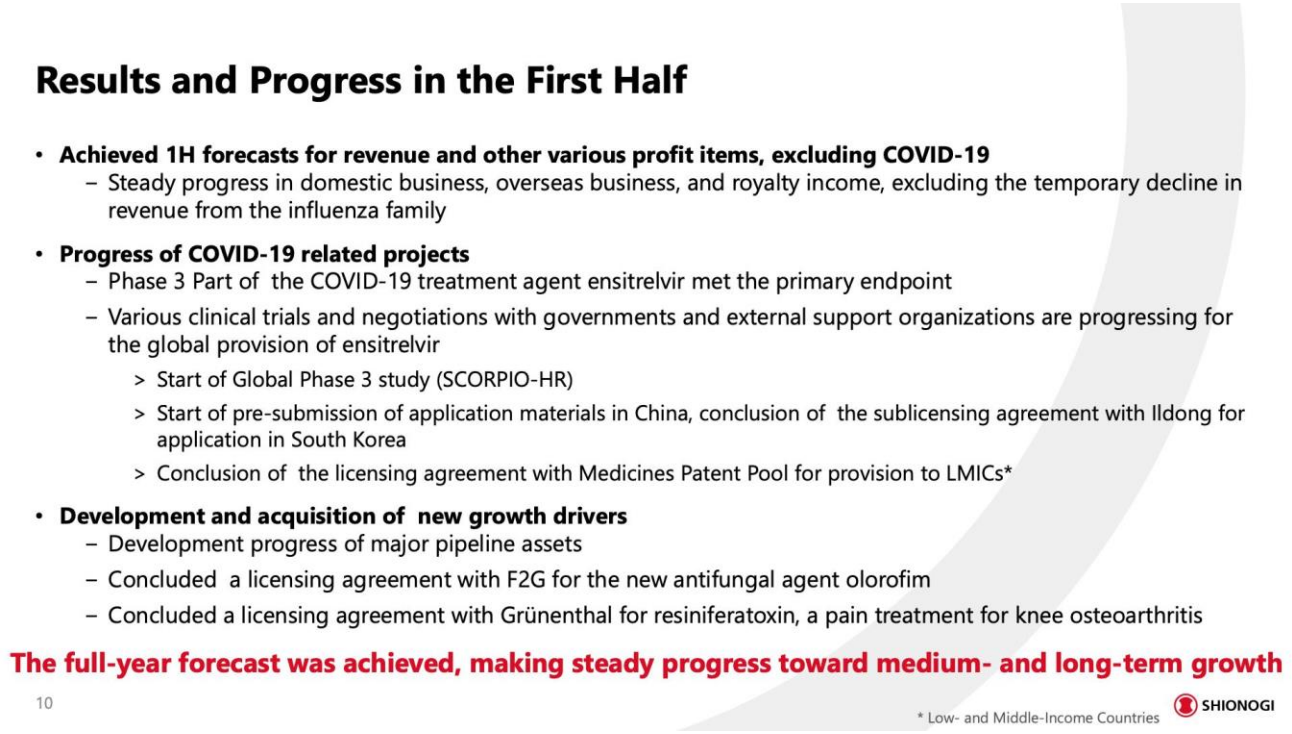
Therefore, it is possible to change the packaging for the ones placed under GMP. But we must throw them away anyway, and we are wondering if it is okay to dispose of large quantities of old items, even though we tell people not to emit CO2 or burn them.

With such advanced information technology, we are now in an era where doctors can read how many patients they have and how soon they can carry them from wholesalers as much as possible. So, again, we can tell for some extent from wastewater-based epidemiology, etc., that influenza or COVID-19 is likely to be prevalent here or there.

We have also been working for the past three years with Stream-I, which is a partnership with M3, to see if we can somehow predict the flow of patients and the possibility of influenza epidemics in this area or COVID-19 epidemics in that area about one week in advance. We have been doing this for the past three years. The accuracy is getting better and better so that we can find out something at least three days before the spread. Therefore, we would like to talk to wholesalers and ask them to let us take back the inventory and write off the inventory for one time only. We will sell on demand but would like to make it unreturnable no matter what.

We could not allow mass disposal of pharmaceuticals to continue, and we made a move to reduce the amount of waste. Some wholesalers and medical institutions have agreed with this, and some doctors have told us

that they bought them, returned them, and did not know we had to dispose of them. It is a challenge for us, but we are willing to take on this challenge.

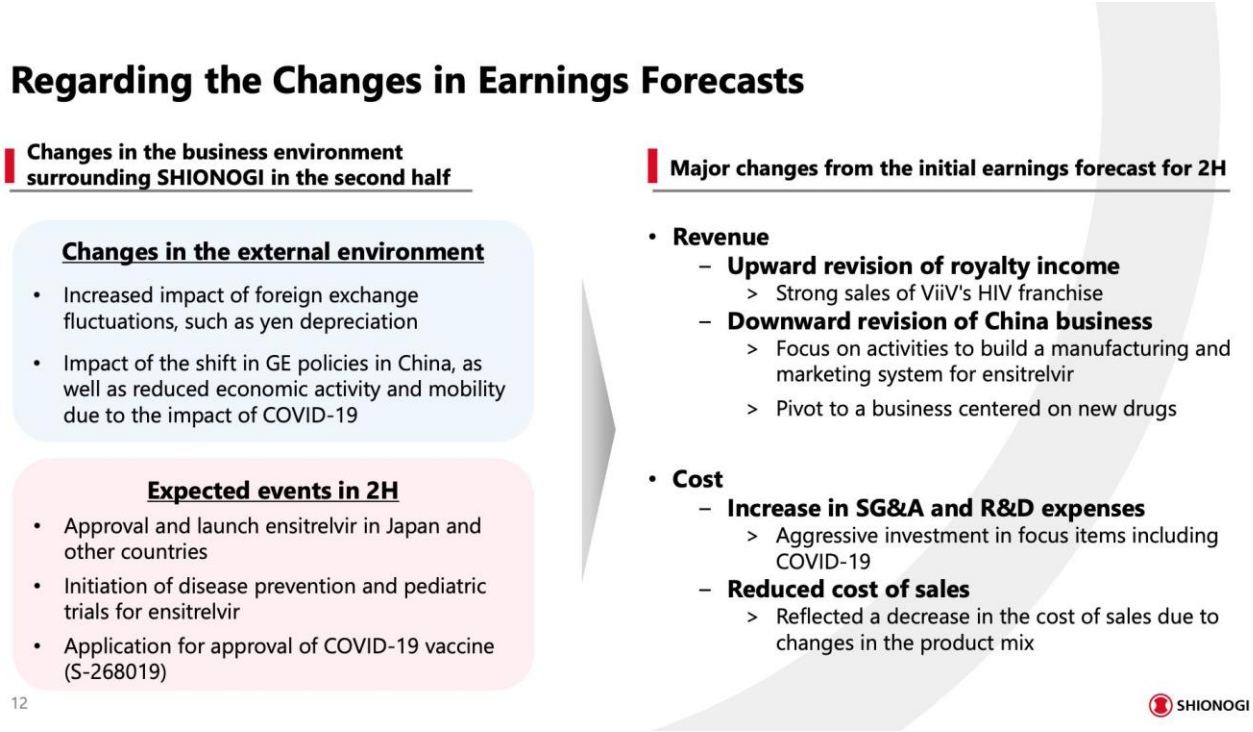


It takes a while to get here but now we look at page 10. As for H1, sales and profits are off the forecast due to the fact that the approval of Phase did not come in time for September. However, as you know, we had put in a reasonable amount of money in H1, but there was not that much of a gap, and the base business was relatively strong.

In addition, ensitrelvir has met its primary endpoint in Phase III part, so it is very difficult to say when, but we have been in close contact with the PMDA and the entire Ministry of Health, Labour and Welfare. For our part, we are working hard to provide it as soon as possible to deal with the eighth wave of COVID-19.

In addition to Japan, our interest is shifting to other Asian countries such as Korea, China, and Vietnam, as well as the US and Europe, with a focus on the area of John and Hanasaki. We are now working on what kind of trials are needed to conduct and how we will differentiate our products.

Two, it may not seem that big, but we would like to get licensed for the antifungal, olorofim, and then RTX for pain, which are relatively in the late stage, both are Phase III, and we hope to launch these as soon as possible.



The forecast for the full year, page 12. First, regarding ensitrelvir in the lower left corner, we expect it to move unobtrusively.

As we have received a question at the financial result announcement yesterday and questioned by many why submission were delayed so much. The main reason is that we have some issues in the manufacturing process but now we are finally on track. We are hoping to submit the application from the end of November to the end of this year.

In addition, as I mentioned to the analysts at the R&D Day, in the neutralizing antibody comparison trial, there were some cases where we had already clearly secured superiority, but, In terms of information disclosure,thiwe had to work a little harder than usual. I believe that the clinical work is almost complete as a package, so if we can put together the CMC relationship for this, we will be able to put it out. We are in very close contact with PMDA and the Ministry of Health, Labour and Welfare regarding this matter.

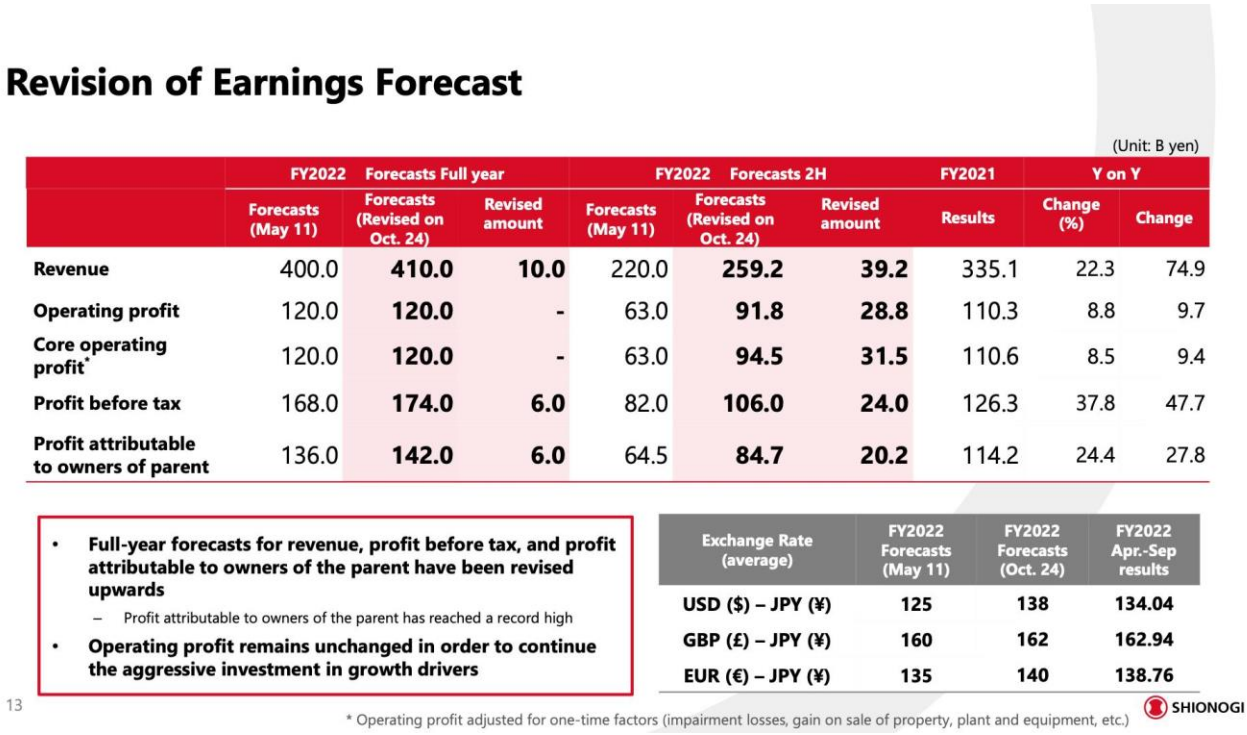
In my opinion we should not go under, so I put a conservative figure of JPY10 billion which is mainly for royalties on sales. I have not changed the figures of COVID-19 related since I announced in May.

As for the China business, when Ping An-Shionogi originally kicked off its operations, it said that it would transform into a pharmaceutical company with a new drug-centered model by around 2024, but they have to earn their own living in the meantime. We were planning to continue the business of generics or extensions of the generics that we had in C&O for at least two or three years to make the Company viable. Then we plan to sell the new drugs, especially cefiderocol and naldemedine, as soon as they were approved.

From the end of last year to this year, our Ping An-Shionogi team is already almost entirely working with ENSITRELVIR. In that sense, we don't have to do our best to develop generics, or we don't have to obtain only the sales rights to sell them, or we don't have to force ourselves to do things that are not so profitable to make ends meet. In a sense, we thought that we had neither time nor resources, so we decided to shift our business model to a new drug type all at once, and by obtaining approval for ensitrelvir as soon as possible. At the same time by filing and obtaining approval for cefiderocol and naldemedine in 2023 or 2024 as scheduled, we decided to make Ping An-Shionogi become a new drug centered pharmaceutical company not two years later but now.

In H2 of this fiscal year, we had planned to work with a large pharmacy chain and a large supermarket to build sales, but we decided to cancel that plan, including negotiations, and focus exclusively on new drugs. So we have revised downward our sales forecast for that portion. Since it does not make a large profit margin to begin with, the profit will not change that much just because the sale has been revised downward, but in terms of the sale, it has been revised downward.

As I mentioned earlier, we are planning to spend a little more on R&D this year because we need to finish COVID-19 or conduct LCM of COVID-19 and at the same time, we need to move forward with the next compound. Since you are all already experts on this, I will be straight with you. There is a clear difference in the cost ratio between vaccines and oral drugs. I am thinking that with the oral drugs coming forward, there will be a very preferable effect on the cost ratio, maybe a little better.



Revision of Earnings Forecast

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Revenue	400.0	**410.0**	**10.0**	220.0	**259.2**	**39.2**	335.1	22.3	74.9
Operating profit	120.0	**120.0**	**-**	63.0	**91.8**	**28.8**	110.3	8.8	9.7
Core operating profit*	120.0	**120.0**	**-**	63.0	**94.5**	**31.5**	110.6	8.5	9.4
Profit before tax	168.0	**174.0**	**6.0**	82.0	**106.0**	**24.0**	126.3	37.8	47.7
Profit attributable to owners of parent	136.0	**142.0**	**6.0**	64.5	**84.7**	**20.2**	114.2	24.4	27.8

- **Full-year forecasts for revenue, profit before tax, and profit attributable to owners of the parent have been revised upwards**
  - Profit attributable to owners of the parent has reached a record high
- **Operating profit remains unchanged in order to continue the aggressive investment in growth drivers**

Exchange Rate (average)	FY2022 Forecasts (May 11)	FY2022 Forecasts (Oct. 24)	FY2022 Apr.-Sep results
USD ($) – JPY (¥)	**125**	**138**	**134.04**
GBP (£) – JPY (¥)	**160**	**162**	**162.94**
EUR (€) – JPY (¥)	**135**	**140**	**138.76**

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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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Page 13. You may say why royalties on sales are only JPY10 billion, it should be more. Ensitrelvir Because of extremely tricky movement of Ensitrelvir or vaccines, we have left the operating income and other figures unchanged for the current fiscal year. But actually, when I unravel it, it seems that our highest sales have not been updated since 2002, which is JPY420 billion.

Operating profit and core operating profit, profit before tax, profit attributable to owners of parent were the highest in FY2018, at JPY145 billion, JPY174 billion, and JPY137 billion respectively, and I am naturally aiming to break all of these in the current fiscal year. We believe that we will be able to achieve our goal, but rather than announce it in today, we have left the operating income figure at JPY120 billion unchanged, as we would like to keep it firm.

We have received various comments on this. We are recording that as an expense at this time, including the additional R&D expenses. We would like to ask your permission for us to present these figures at this time, of course, we believe that the next movements, including ensitrelvir, will be much easier to read in Q3. So we have decided to present this figure, while keeping in mind the possibility that we may have to announce it again, including revisions, as the case may be.

Revision of Earnings Forecast: Statement of Profit and Loss

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Revenue	400.0	**410.0**	**10.0**	220.0	**259.2**	**39.2**	335.1	22.3	74.9
Cost of Sales	22.0 88.0	19.5 **80.0**	**(8.0)**	25.7 56.5	20.3 **52.6**	**(3.9)**	16.5 55.4	44.4	24.6
Gross profit	312.0	**330.0**	**18.0**	163.5	**206.6**	**43.1**	279.7	18.0	50.3
Selling, general& administrative expenses, R&D expenses total	47.5 190.0	50.7 **208.0**	**18.0**	45.0 99.0	42.7 **110.8**	**11.8**	50.2 168.2	23.6	39.8
Selling, general& administrative expenses	30.0 120.0	27.6 **113.0**	**(7.0)**	27.7 61.0	24.9 **64.5**	**3.5**	28.4 95.2	18.6	17.8
R&D expenses	17.5 70.0	23.2 **95.0**	**25.0**	17.3 38.0	17.8 **46.3**	**8.3**	21.8 73.0	30.1	22.0
Other income & expenses	(2.0)	**(2.0)**	**-**	(1.5)	**(4.0)**	**(2.5)**	(1.2)	71.5	(0.8)
Operating profit	30.0 120.0	29.3 **120.0**	**-**	28.6 63.0	35.4 **91.8**	**28.8**	32.9 110.3	8.8	9.7
Core operating profit	30.0 120.0	29.3 **120.0**	**-**	28.6 63.0	36.5 **94.5**	**31.5**	33.0 110.6	8.5	9.4
Finance income & costs	48.0	**54.0**	**6.0**	19.0	**14.2**	**(4.8)**	16.0	238.4	38.0
Profit before tax	42.0 168.0	42.4 **174.0**	**6.0**	37.3 82.0	40.9 **106.0**	**24.0**	37.7 126.3	37.8	47.7
Profit attributable to owners of parent	136.0	**142.0**	**6.0**	64.5	**84.7**	**20.2**	114.2	24.4	27.8

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Page 14 is the figure that includes it. This is also a particularly difficult point, as the financial income and cost is also JPY54 billion, and if you only look at H2, it is negative JPY4.8 billion. ViiV's dividend is paid according to ViiV's remaining cash, so the cash at the end of the period will be driven by how much R&D progress is made. So it is possible to move that depends on how it will work.

However, since a pound is already at JPY170 today, if the exchange rate moves at the current level, the financial income and cost of JPY14.2 billion for H2 may be a little too firm. Including this area, this net income before taxes of JPY174 billion is precisely the highest ever. Also, the net income of JPY142 billion is also a record high, so I think the background is that we have let this area out as the lowest line.

Revision of Earnings Forecast: Revenue by Segment

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Prescription drugs	78.6	**76.4**	**(2.2)**	43.1	**43.1**	**-**	89.1	(14.3)	(12.7)
Overseas subsidiaries/export	41.6	**39.3**	**(2.3)**	23.6	**19.4**	**(4.2)**	34.4	14.4	5.0
Shionogi Inc.	13.0	**14.4**	**1.5**	7.0	**7.1**	**0.1**	13.8	4.8	0.7
Ping An-Shionogi* /C&O	14.8	**10.4**	**(4.4)**	8.4	**4.8**	**(3.7)**	10.2	2.1	0.2
Shionogi BV(Europe)	8.4	**8.6**	**0.2**	5.0	**4.3**	**(0.7)**	5.0	71.7	3.6
Contract manufacturing	14.8	**14.8**	**-**	8.5	**7.4**	**(1.1)**	17.4	(15.3)	(2.7)
OTC and quasi-drug	13.4	**13.2**	**(0.1)**	7.1	**7.0**	**(0.1)**	11.2	18.7	2.1
Royalty income	140.4	**155.0**	**14.6**	72.2	**71.8**	**(0.4)**	181.3	(14.5)	(26.2)
HIV franchise	133.9	**150.2**	**16.4**	66.9	**69.9**	**3.0**	174.0	(13.6)	(23.7)
Others	6.5	**4.8**	**(1.7)**	5.3	**1.9**	**(3.4)**	7.3	(34.5)	(2.5)
COVID-19 related products**	110.0	**110.0**	**-**	65.0	**110.0**	**45.0**	-	-	110.0
Others	1.2	**1.2**	**-**	0.6	**0.6**	**-**	1.8	(32.6)	(0.6)
Total	400.0	**410.0**	**10.0**	220.0	**259.2**	**39.2**	335.1	22.3	74.9

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

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Page 15 is a breakdown of the modifications. The negative JPY2.2 billion in Japan was due to the fact that we were not able to make up the difference between Xofluza and its returns in the full year. Regarding Ping An-Shionogi, I explained earlier.

One thing you may wonder is why there is such a negative figure, at the fifth or fourth from the bottom which says negative JPY26.2 billion and JPY23.7 billion, when the royalty is so strong. However, this is a comparison with the JPY50 billion we received in a lump sum last year, including the future portion, as a result of the settlement with Gilead. Therefore, if you subtract this amount, you can see that the actual royalty income for this fiscal year alone increased about JPY25 billion.

Revision of Earnings Forecast: Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Intuniv®	19.5	**20.0**	**0.4**	10.5	**10.5**	-	16.4	21.7	3.6
Vyvanse®	1.1	**1.3**	**0.2**	0.6	**0.6**	-	0.8	61.4	0.5
Infectious disease drugs	13.4	**8.8**	**(4.7)**	9.1	**9.3**	**0.2**	11.8	(25.8)	(3.0)
Influenza franchise	5.1	**0.1**	**(5.0)**	4.8	**5.1**	**0.3**	3.1	(95.3)	(2.9)
Cymbalta®	6.1	**6.1**	-	3.0	**3.0**	-	15.9	(61.7)	(9.8)
OxyContin® franchise	4.5	**4.5**	-	2.2	**2.2**	-	4.8	(6.5)	(0.3)
Symproic®	3.3	**3.4**	**0.1**	1.8	**1.8**	-	2.7	28.0	0.7
Actair®	0.6	**0.6**	-	0.3	**0.3**	-	0.5	16.4	0.1
Mulpleta®	0.1	**0.1**	-	0.1	**0.1**	-	0.1	2.4	0.0
Pirespa®	2.4	**2.4**	-	1.2	**1.0**	**(0.2)**	3.8	(37.8)	(1.4)
Others	27.6	**29.4**	**1.8**	14.3	**14.2**	**(0.1)**	32.4	(9.2)	(3.0)
Crestor®	3.3	**3.9**	**0.6**	1.6	**1.8**	**0.2**	5.9	(33.4)	(2.0)
Prescription drugs	78.6	**76.4**	**(2.2)**	43.1	**43.1**	-	89.1	(14.3)	(12.7)

<Products included in infectious disease drugs>

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

Influenza franchise

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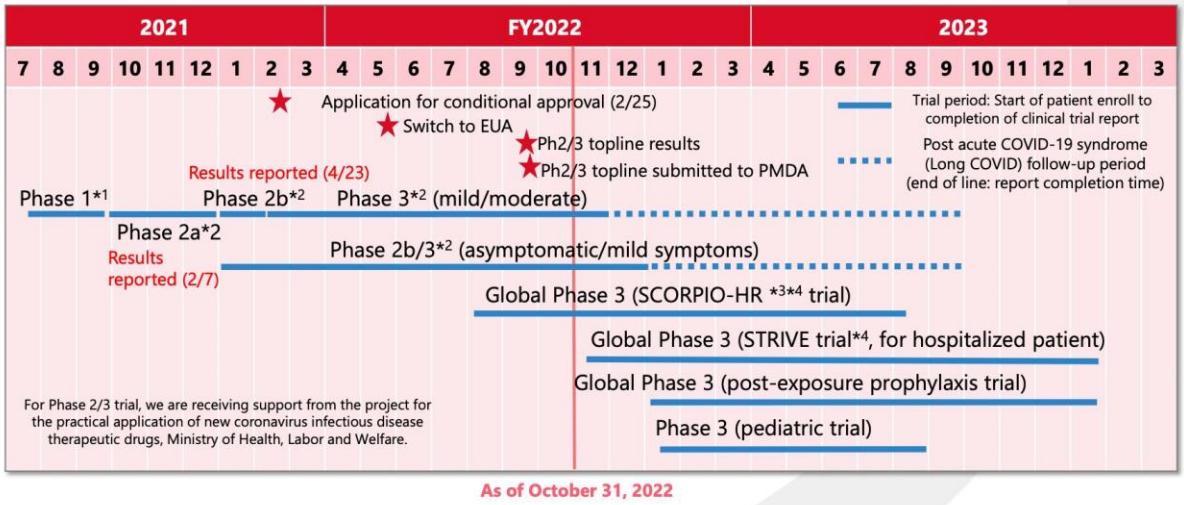
In Japan, we announced that Takeda has exercised the option right, originally granted to Shire (integrated with Takeda in 2019), to re-acquire full rights to the attention-deficit/hyperactivity disorder therapeutic agents Intuniv® Tablets 1mg/3mg (hereafter "Intuniv®") and Vyvanse® Capsules 20mg/30mg (hereafter "Vyvanse®"), as specified in the license agreement for co-development and co-commercialization in Japan between Shire (merged with Takeda in 2019) and Shionogi, concluded in November 2011.

We will receive the appropriate compensation when it moves to the other side in April, but I can't tell you how much we received and how we judged it because of the relationship with the Takeda.

Ensitrelvir: Progress Summary



18

*1 jRCT2031210202、*2 jRCT2031210350、*3 NCT05305547、*4 NIH sponsored trial

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Let us turn to page 18, ensitrelvir. There is no change from R&D Day, so there is no need to provide any additional explanation to the analysts.

Ensitrelvir

Continuation of Phase 2/3 trial

- Obtained Top-Line results of Phase 3 part (September 28, 2022)
  - Demonstrating a significant reduction vs placebo in the time to resolution of five typical Omicron-related symptoms: **Achieved the Primary Endpoint**
  - Ensitrelvir also showed a significant reduction in viral RNA on day 4 (following the third dose) relative to placebo: Key Secondary Endpoint

Registration in Japan

- Discussions are underway with MHLW and PMDA regarding future approval reviews and deliberations

Global registration

- Korea : Execution of Sub-license Agreement for ILDONG
  - In consultation with authorities for approval process
- China : Ping An-Shionogi Co., Ltd. has initiated the submission of preparatory materials for an application
- US/EU : Under discussion with FDA,EMA and MHRA
- Low- and middle-income countries (LMICs): Execution of License Agreement with Medicines Patent Pool
  - Activities to provide access to 117 countries

Supply

- Building a global supply system
  - Since April 2022, production has been expanding to supply more than 10 million people annually
  - Plans to manufacture in China and the United States for further supply expansion

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SHIONOGI

So I would like to ask you to move on to page 19. As I mentioned a little bit yesterday, we understood that the authorities evaluated us above satisfactory with the fact that we have met the major evaluation items. The PMDA has said "let's keep up your best," and the Ministry of Health, Labour and Welfare has also taken this matter seriously.

Our ensitrelvir is a drug that always works as expected without fail. We are very confident that this is a compound with a very high degree of perfection as an antiviral agent, and that it will remain unchanged no matter which way we cut it after conducting so many different tests.

As for overseas, first of all, ILDONG has been talking really closely with the Ministry of Health, Labour and Welfare over there.

As for overseas, first of all, ILDONG has been talking really closely with the Ministry of Health, Labour and Welfare over there.

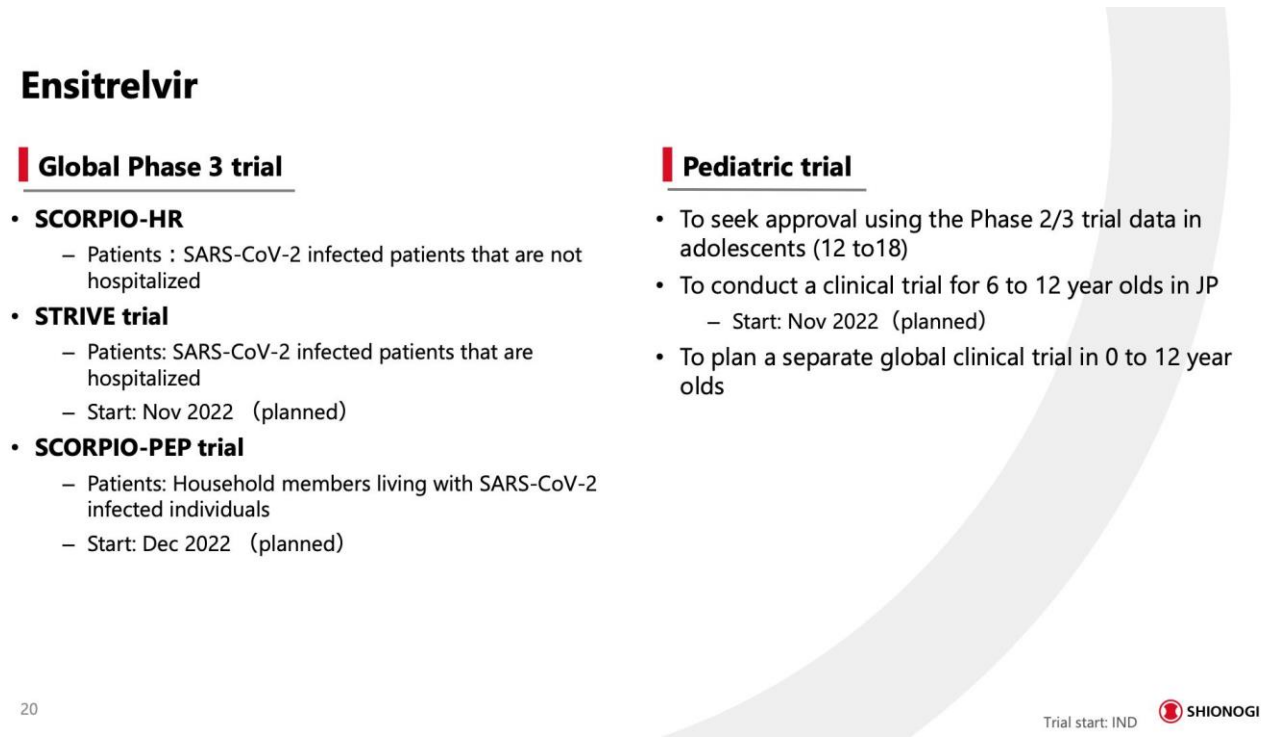
As for China, after we get our Japanese approval, would it be better to use it to take the form of exports from Japan, or would it be better to let everything be done locally? We will make a move after the authorities decide how and which category this drug will fall in, so-called category V or I issue. So we think it will be clearer in the end if we start making everything local in China at this moment.

By the end of the year, all two API plants, as well as our formulation plant, will have completed PV. So, with that, if we have everything set up by the end of the year, we will be able to provide you with our clinical data. We are talking with local companies about production, supply, distribution, and sales promotions.

So, in that sense, we are making APIs and formulations, and then we are really entering into partnerships with Chinese companies for distribution and sales promotion. We are thinking in that direction, as the name Ping An is also impressive, and if you could consider that we are doing things properly in China.

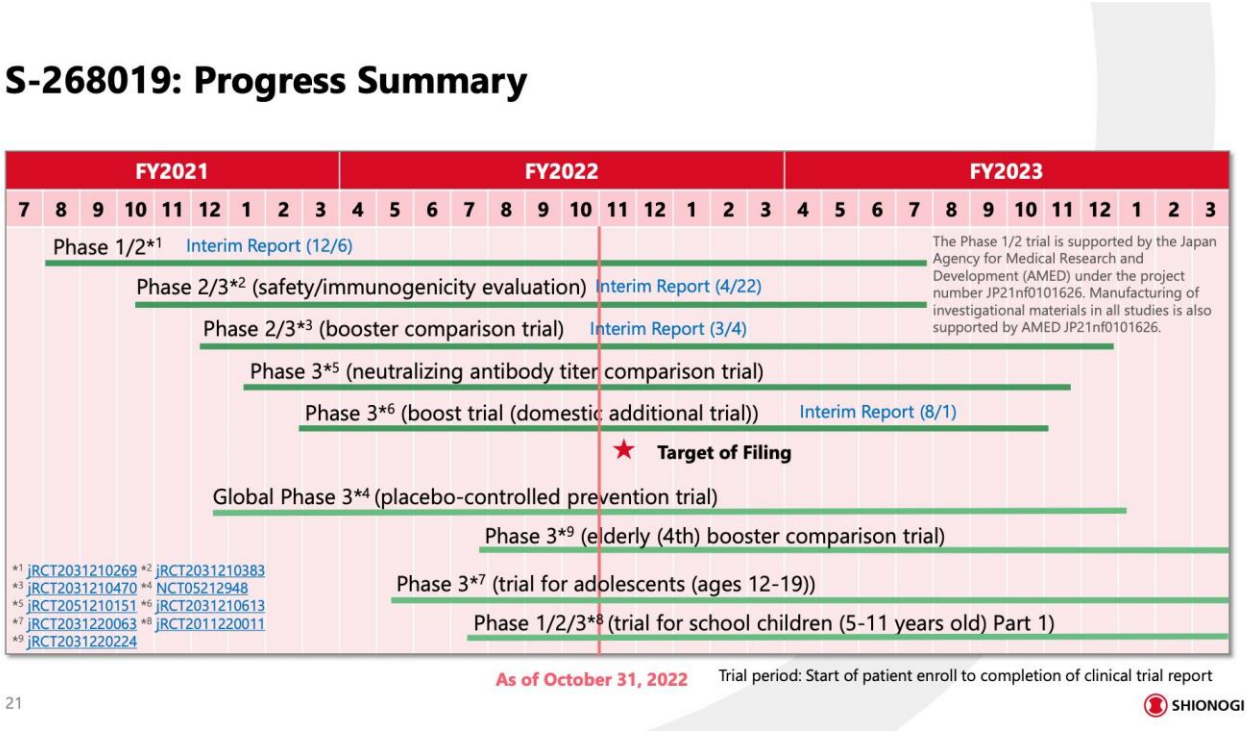
We are also continuing to talk with the FDA, EMA, and MHRA, and they are naturally concerned about whether the Japanese government will approve it or not. So if they do approve, our dialogue with them will change.

As for the MPP, I am planning to move it steadily. It is a small detail, but it is considerably more than the other two oral pills, and we have included all 117 countries in the sum set that contain both, which gives the MPP rights more widely than anyone else.

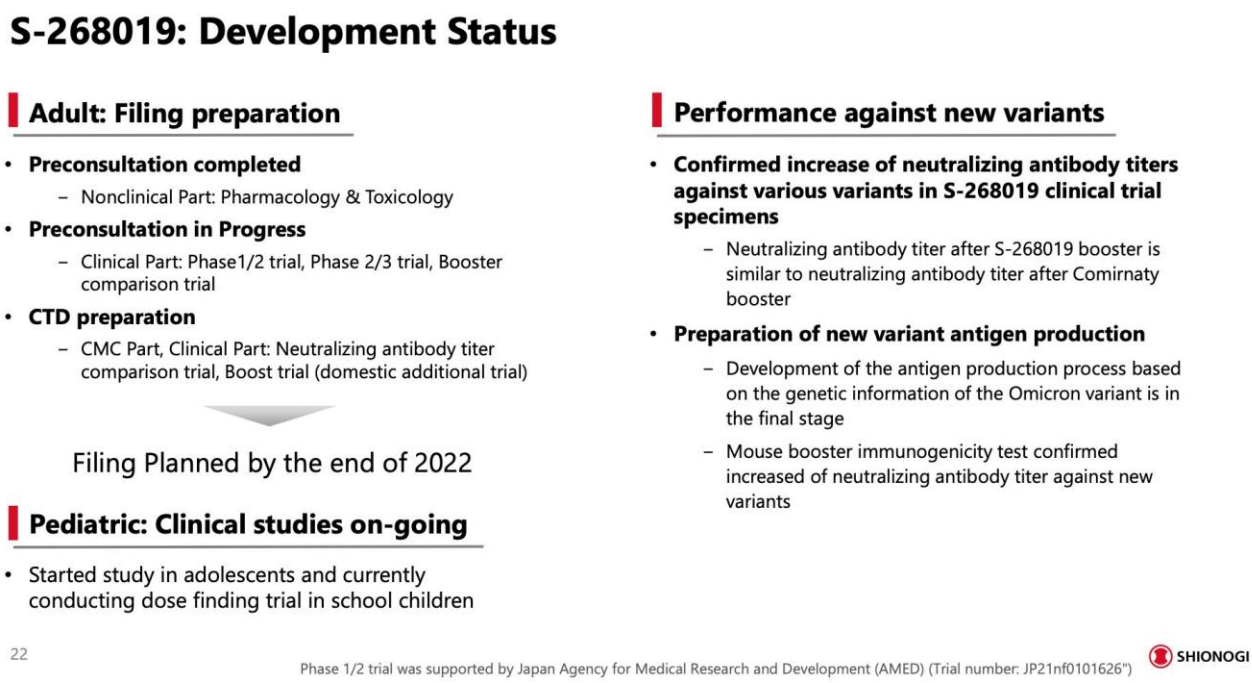


Page 20. This has also changed little, but one thing I would like to mention is that we said that the onset prevention trial was scheduled to begin in December, but I believe that the actual first patient-in will be in January.

Sorry to say this is another local story, but all of the agencies are reviewed by the same person, so I was told to wait because they are busy. We are putting our priority to have the original approval as soon as possible, so we would like the reviewers to spend their time on that. Including those factors, it will be January.



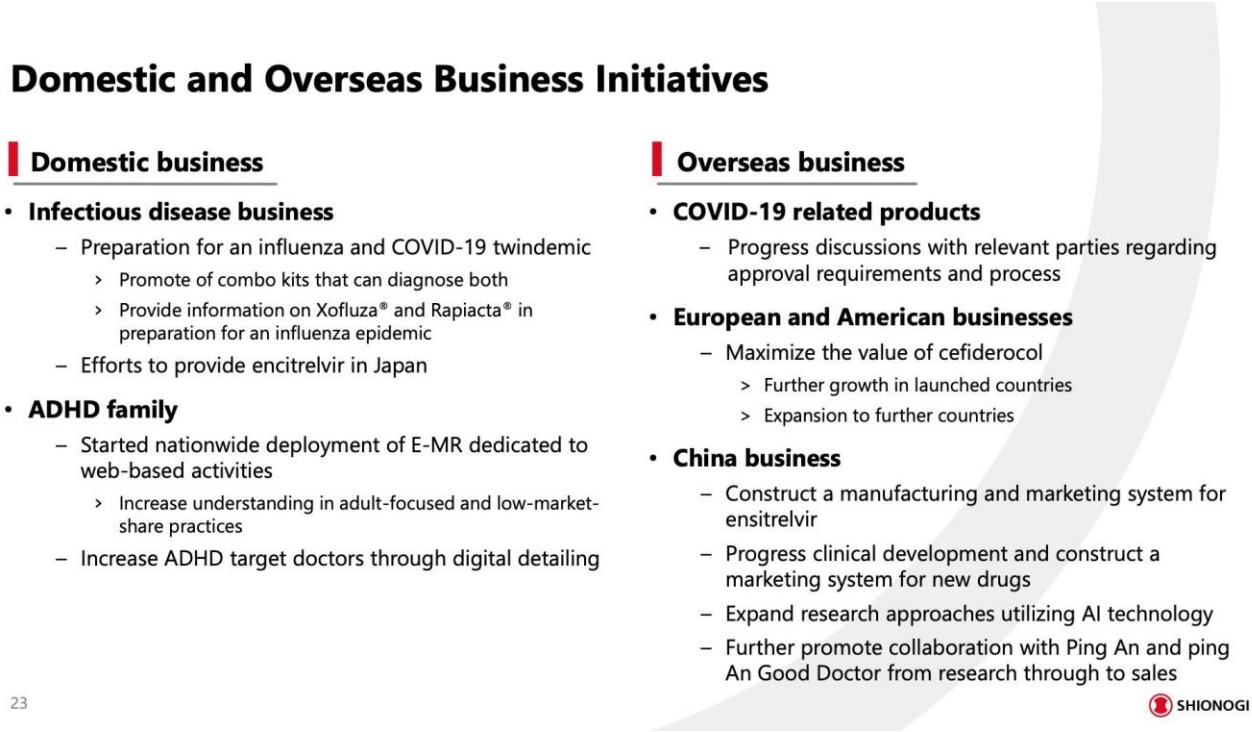
Page 21, vaccines. We are very confident that we will be able to apply for approval from the second half of November to mid-December, and I think this will probably go smoothly.



In addition, we have discussed the package with the PMDA and the Ministry of Health, Labour and Welfare in Japan, and clinical trials for children and adolescents are also proceeding properly.

Then, as for the Omicron mutant, we designed both BA.1-2 and BA.4-5, but I still think that BA.4-5 would be the main one from now on. If I were to add it as the bivalent for now, I think that BA.4-5 would be the main one.

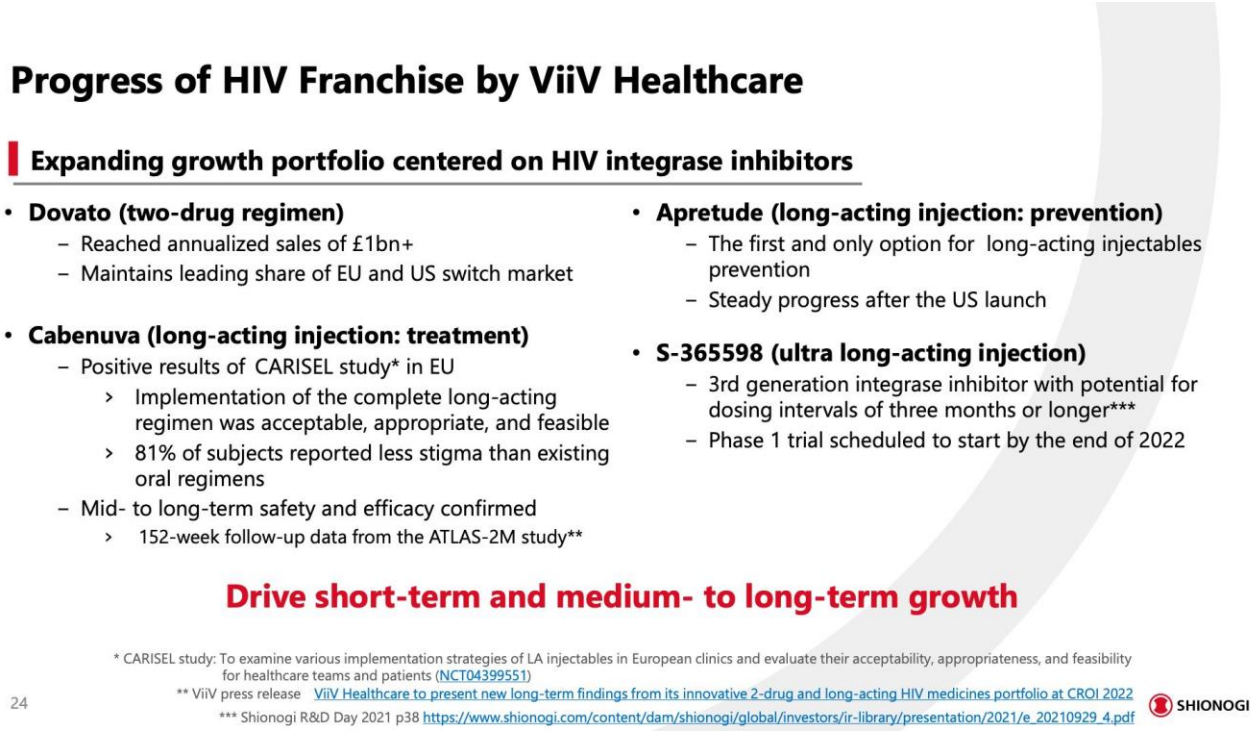
However, the way Japan is doing things now, we cannot immediately add bivalent and trivalent because the original vaccine has not been approved. So we will add antigens to the original vaccine after it is approved. We will consider the cue with a look at the balance of efficacy and safety of the recombinant protein especially, while showing clinical data in Japan. At the same time, we are continuing to study the possibility of bringing this to Southeast Asia, as we are currently conducting a disease prevention trial in Vietnam.



Page 23. As for the ADHD family, we would really like to keep it that way. Of course, we are also involved in digital medicine, and we have also been involved in the Children's Future Support Office, which is our overall commitment to children. Not only for doctors specialized in ADHD, but also we have ensitrelvir, and RSV. We would like to take care of the pediatric area as we are planning to expand our vaccines for them in the future as well.

For now, we are aiming for the highest sales until March 31, while we are working on how to fill the pipeline, which is of course our highest priority right now. Therefore, we would like to put together as much as possible during this six-month period, including the right to buy or sell products.

Though cefiderocol is strong in the overseas business, it is still an MR product, so there is still much work to be done, including subscriptions, in terms of changing the business model. We are now really struggling with how to sell cefiderocol in Japan, so I would like to think about how to push it up, including this, with a focus on overseas markets.



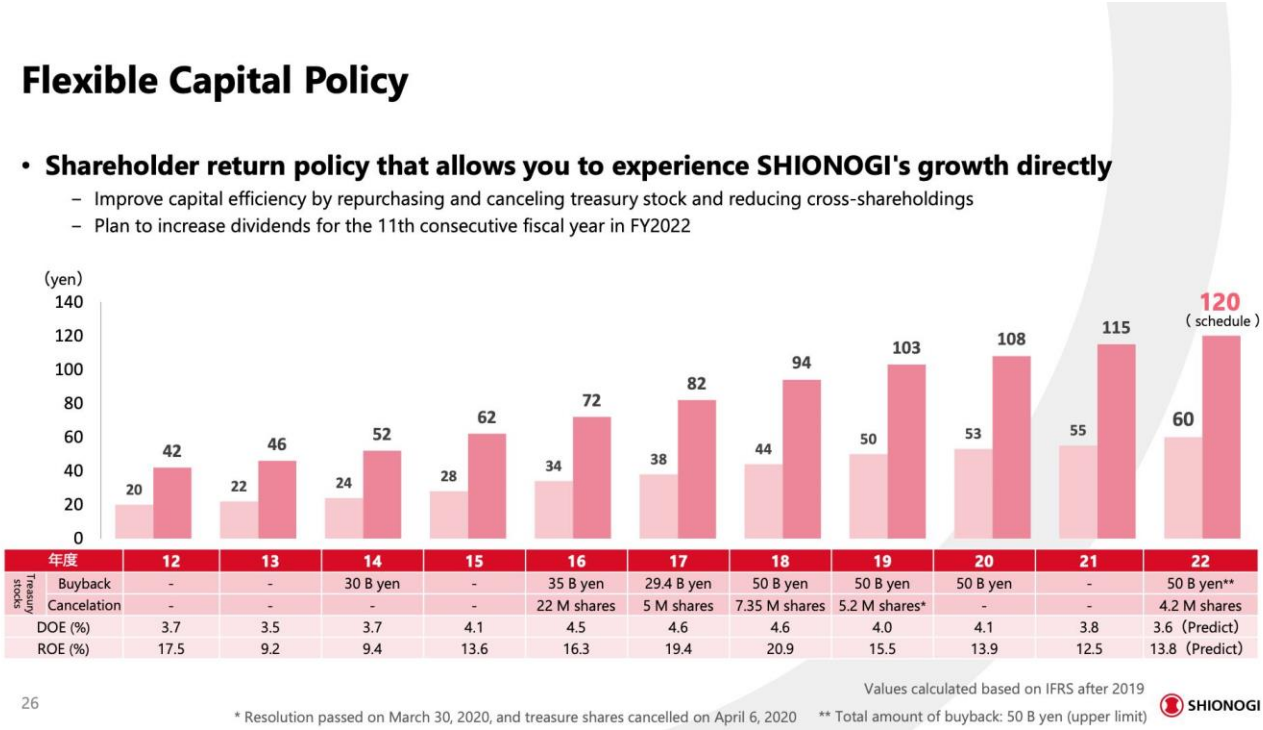
Page 24. As for HIV, John is here today and would like to take your inquiries, including the details. As I mentioned at the R&D day, we have had a very positive response to the launch of Cabenuva and Apretude. As for dolutegravir-cliffs, I think that it would be very difficult not only for us but also for our competitors in the area of once-a-day oral drugs market between 2027 and 2028.

If dolutegravir becomes generic as once-a-day oral drug, the generics companies can make all the various other combinations. So we have been saying for a long time that oral integrase market would be quite difficult, which we call dolutegravir-cliffs.

However, the base patent is 31 years old, and it's really not that easy to develop generics, including the fact that generics can get BE from injections that are once every two months. If you can take a fairly large seat in it, I think that the stability there will be much stronger than oral agents.

So we think it may be a very mild drop, or maybe even enough to avoid a drop, regarding royalties from the HIV family. Even though we offer a variety of products, the amount of revenue we receive from the HIV franchise is important for the stability of the Company, so we have become much more comfortable in this respect.

Naturally, in the meantime, we will continue to work vigorously on how to fill the gap with vaccines and other pipelines, and I believe that visibility in this area has improved considerably.



Now, just one last comment on shareholder returns. Regarding dividends, the Board of Directors approved an increase to JPY60 for the interim period yesterday. At present, we are paying a year-end dividend of JPY60, the same as the previous fiscal year, which makes it JPY120.

However, as I mentioned earlier, we are aiming for the highest sales and operating income since the Company was listed, so we are considering the possibility of making a slight upward revision to the dividend as well. The Board of Directors also told us that we should consider this in the context of shareholder returns. We will continue to promote shareholder returns, including share buybacks.

This is a bit long, but I would like to end my presentation and take your questions. Thank you very much.

Question & Answer

Kyokawa : I will move on to the Question & Answer session. I, Kyokawa, would like to nominate you, so please state your affiliation and name, and then ask your question. Now, Mr. Yamaguchi.

Yamaguchi : My name is Yamaguchi from Citi. I would like to ask you a few questions. One is ADHD. It is treated on the P&L in a manner that there will be no sales in the next fiscal year, and some compensation will be included in the forecast. We don't know about that compensation now, of course, but if we look at the earnings forecast for the next fiscal year, we will see that it is in there somewhere, is my understanding is correct?

Teshirogi : That is correct. In addition, Patients and doctors are what we are, so we have clearly stated to Takeda that we will work together to ensure a smooth transition between manufacturing and distribution.

Especially for the manufacturing part, as you know, including the fact that Vyvanse is a raw materials for stimulants, it is not so easy to find them and make a move, well, actually, until this announcement was made, it was also difficult for them to make a move. So, if Takeda is in trouble in future, we would be happy to cooperate with them, and we may retain a portion of the distribution fee or help with manufacturing, although it may be really small.

However, as Mr. Yamaguchi said, What was the price of the compensation part, and how much of the sales of our Intuniv and Vivance, and how much of the rough operating profit in your model was considered from that? I would like to present it at the time of next year's business forecast.

Yamaguchi : Regarding the domestic sales, Intuniv used to be your biggest product. So I think that your main products are becoming fewer and fewer in the domestic sales. On the other hand, I think that your company is conducting efficient sales, but do you feel that the number of MRs and digitalization is accelerating?

Teshirogi : That is correct. We are just reading this on RISFAX, so we don't really know what is going on, but we are looking at Pfizer and we think it is very drastic. Whether or not we can be drastic enough to change things overnight, we have been moving in that direction for quite some time now, and this will be an extension of that.

However, ensitrelvir, assuming it will be approved, will take some time and effort on our part. So, we need to shift the number of people in the field of infectious diseases from the current number, including general practitioners. I think there is quite a lot thing that needs to be done, at least for this next year or so.

However, John and I are now vigorously trying to see if we can get things somehow.

Yamaguchi : Lastly, regarding the premise of the earnings forecast, I think you started the fiscal year with something like a buffer for ensitrelvir. This time it is still the same, so what you just said is that there will be a lag between the first half and the second half, but if ensitrelvir is approved and sales come in, we will remove the buffer part and include that part in Q3. It sounds like you're going to reconsider everything, but is that the way to think about it?

Teshirogi : That is correct. Of course, when we will receive an approval, or the government's purchase, for 1 million people, has been signed by the Minister of Health, Labour and Welfare. We are not sure what form the eighth wave will take. Additionally general distribution of Lagevrio has begun, and pros/cons of it are gradually coming out. So we are not sure what form is best for our country. They have both options, from distributing it on a restricted basis to general distribution.

We would like to talk about what would be the best form for us when the Q3 result is released, which will be around the end of January or beginning of February. We think we will have a clean picture by then.

Yamaguchi : What did you mean when you mentioned pros cons?

Teshirogi : There is quite a disparate opinion between general distribution and so-called distribution on a restricted basis bought by the government, with some doctors preferring one and others preferring another.

However, from our point of view, we need to consider how much we can make, how much we can deliver, how we should initially market the product. we would like to see the characteristics of the drug for a while after it is released, including its safety, so I don't think it is desirable to be in a situation where the drug becomes too uncontrollable. On the other hand, there is a possibility that we will have to move quite flexibly, as we really cannot read about what the so-called eighth wave or what will happen to the twindemic. We are talking about this with the authorities, which means that there are both good and bad points.

Yamaguchi : Thank you very much.

Kohtani : I am Kohtani from Nomura Securities. I have several questions. On the first point, vaccines. Why did it take so long?

The original problem was that, from a few hundred liters at the Akita plant, you were suddenly required to go with a culture tank with a working volume of 18,000 liters, which is probably unprecedented in the entire world, and that was a super-expanded. After all, the yield changes considerably when the protein changes, so is it correct to say that it took a surprisingly long time to optimize? Also, is it my understanding that the Omicron variant is probably the best from now on. Is it correct to understand that the prospects for the Omicron-compatible vaccine are roughly in sight?

Teshirogi : Both are as you say. That is correct. We also experienced how difficult it is to suddenly convert a 500 liter or 600 liter tank into a 20,000-liter tank, including the fact that we had no experience with vaccines. Protein Sciences was the first company to do this with SF-1 cells and is now doing a full block of Sanofi, but they only have 2,000 liters to begin with. They have 10 units of 2,000 liters or something like that, and that's how they manage that amount.

When UMN teamed up with Astellas Pharma and IHI to try to develop influenza flu block in Japan, so they suddenly put in 20,000 liters, 10 times the amount, and although they had quite a bit of trouble, they somehow managed to accomplish it. However, they are now making Sanofi's there, and Sanofi's 2,000 liters has all the various findings from Protein Sciences, and on top of that, they made the 20,000 liters by trial and error as to how it should be done.

We went from 500 or 600 to 20,000 without a cushion, so a lot of things happened. We made something, but the one we made in a smaller scale at Akita was more beautiful. It means that it was quite difficult to do the purification and continue to take process validation.

Kohtani : This is a bit in detail, but the cells of the spodoptera are probably very hard compared to the current CHO cells of Chugai Pharmaceutical and other antibodies, and when they did simulations in the past, only the oxygen concentration, and even if amino acids were added, nothing changed. In the end it did not work out that way. They were able to do that because they had the background knowledge. I understand.

I would like to ask about Gilead as they are closing this term. I wonder why they did it, because they were doing a long-term trial of bictegravir and of course it failed, and since it is a copy of dolutegravir, of course it wouldn't work. In short, what I want to ask is, after all, I was reminded that subcutaneous injection is apparently very difficult in terms of trainability and tolerability. So, probably S-648414 is gone that reason.

I would like to confirm that you have already confirmed this with regard to your S-365598, and I understand that there is no problem at all in the area of three or six months or thereabouts.

Keller : As a premise, it is necessary to obtain clinical trial data. And now, oral trials have started for S-365598. However, in the non-clinical stage, that part has been confirmed. They have higher subcutaneous doses for longer duration. I'm guessing that there was a safety issue due to the technical problem there. With ViiV, we have a contract with Halozyme technology that allows us to increase the subcutaneous injection dose in a technically non-problematic way.

Kohtani : I understand. Finally, I want to know about S-531011, to rephrase a little bit from what I heard last time, the reason why all the drugs targeting regulatory T cells failed is because, to be honest, they killed all the regulatory T cells, but they did not activate the normal T cells at all. If this is the common denominator of mogamulizumab and other drugs that have been done up to now, maybe this time or 2023, we can see that before we move on to Phase II, right?

Will there be any scientific presentation at that point by the activation of T-cells of regulatory T-cells, perhaps Osaka University is involved, and Dr. Sakaguchi? I would like to know what kind of way you are going to present it, and how Dr. Sakaguchi is going to put into this project. I think he was involved in the mogamulizumab project in the past, but now that his name is on the patent, I think he must have put in a different amount of effort. This is the last.

Keller : We will conduct verification using various biomarkers, but since this point is complicated, we cannot say at this time how and when we will disclose it.

Teshirogi : We are not able to comment how we announce it before we get into Phase II trial, as we are not the type to take a risk unless we have a very high degree of certainty, and we are not a specialized oncology company at least. However, from our point of view, we will proceed only after discussing the results with the doctors and making sure if we should proceed to the second step or not. I have met Dr. Sakaguchi twice in person at his classroom, and I believe he is really into this project.

Kohtani : Thank you very much.

Hashiguchi : I am Hashiguchi from Daiwa Securities. Thank you for taking my questions. In your explanation of the full-year sales forecast, you mentioned that the mix has changed. Just to confirm, is this COVID-19 related, out of JPY110 billion in sales, is it correct to say that you lowered the vaccine and raised the therapeutic drug?

Teshirogi : That is correct.

Hashiguchi : I would like to know why. I believe that originally the therapeutic drugs were roughly both domestic and foreign, but could you please indicate whether the domestic or foreign went up and why, if you are able to show us the reason for the increase?

Teshirogi : Conservatively speaking, if an application for approval of a vaccine is filed by the end of November, or by the end of the year at the latest, it would not be appropriate to include it in sales for the fiscal year.

On the other hand, ensitrelvir is the first drug in the world to show some results in primary endpoints as symptoms in standard-risk patients, whether vaccinated or not. So, in that sense, we have received good feedback from people at the standard risk especially for younger patients, of course there are DDI and pregnant women however, including the fact that it is much easier for them to take, as it requires to take only once a day and fewer tablets needed.

Including those factors, we put upward numbers for both domestic and oversea, however another problem is that we have slowed down to product in Japan after the July results, so it is now quite critical as to how much can be produced. We are doing a variety of things, such as increasing the factory capacity from two shifts to three shifts system, and we have managed to put in about 0.7 times the total amount of sales we can deliver by March in this time.

Hashiguchi : In other words, the remaining 30%, did you say it was multiplied by 0.7, or is that what you put in the plan? So the 30% parts means that there is hopefully a possibility of an upward swing.

Teshirogi : We think so.

Hashiguchi : I understand that for the domestic market, you originally included only the initial shipments that had already been contracted. I wonder if that part has not changed, but the repeat orders, whether for re-shipments, second orders, or general distribution, have been newly added to the forecast this time, is that correct? Or is it possible that the conditions have changed for the initial shipment as well?

Teshirogi : I would appreciate your understanding that we are not able to say as now is a really important time.

Hashiguchi : Thank you very much. It's okay.

Ueda : My name is Ueda from Goldman Sachs Securities. I would like to start by asking you about your project in China. You mentioned earlier that you are going directly into the new drug business. Since your disclosure of Ping An-Shionogi a few years ago, there have been various changes in the business environment, such as stricter regulations on generics on the Chinese side.

So, if there is no change in the current situation, or in the way of looking at things, I think the situation will probably be better, since this new drug business will be accompanied by the COVID-19 therapeutic drug. Could you explain how your company's view of the China business has changed, including the new drug business in this area and later development utilizing big data, etc.?

Teshirogi : Thank you. We rather believe that we have not changed or increased the positive aspects. For one thing, we have decided to use our former C&O's Nanjing plant as a factory to make ensitrelvir. If we move at full capacity, we will become a factory that can only produce that drug, so now, on the contrary, we have a plan to continue selling rabeprazole and other products that we are making unless we go out on the market. We are now trying to change our business to one where we can make and sell new drugs.

As you can see from the sales of generics in H1 of this fiscal year, which is positive YoY, we believe that we can continue to capture a certain amount of the market for distinctive generics and older products even under difficult circumstances. That said, we, would like to manage to sell JPY100 billion in China alone, so it is not easy to accumulate generics in that kind of framework, so we will stand on the new drug side.

Actually, we had a pretty good discussion with the authorities about cefiderocol and naldemedine before ensitrelvir came out. I think that if cefiderocol, and naldemedine are added to ensitrelvir, it would be a good idea to sell three products, since we are likely to utilize the global package we were using so far, although some part of clinical work in China may be necessary.

Also, we were shocked in a good way when we heard the news of ensitrelvir. As I mentioned earlier, all of the big four local Chinese companies came to our company and offered various conditions for us to sell the product, and they are very strong. When I talked with these people, it was clear that the market in one part of China is already moving strongly, especially for area of new drugs. I am planning to sign contracts with at

least two of these companies after having discussed with how much they sell and how far they do by themselves.

By properly providing products and distributing and co-promoting good products with such partners, we have realized that China looks very interesting as a market for new drugs, and that is what we will do in the short term.

Also, we are now using AI and positioning CNS area, which I think we can already start clinical trials next year, and by doing these new initiatives in parallel, which is also a new drug, we want to make Ping An-Shionogi a very big seller and profit value driver for us by moving forward with this.

On the other hand, there are always risks in China. We are currently 51:49, but since we are partnering with Ping An, which is one of China's most prestigious companies, and we don't want to think too much about it, but in case worse comes to worst between the two countries, we would like to have an option to exit. If things go smoothly, we would like to aim the growth in there to contribute to Shionogi's growth as a whole.

By the way, many of the people who are coming for our interviews have high skilled backgrounds. I was surprised to see how different people coming from those who came to interview at the time of the C&O. We are surprised talented Chinese local people came to our interview since we have good products and going to do new drug development. We have an impression that it is progressing in that area.

Ueda : Thank you very much. The second is about a successor to the COVID-19 treatment. I understand that S-892216 is the successor, and I would like to know the details of S-892216, and what kind of problems ensitrelvir has had, and what kind of characteristics this compound has. Also, what is the timeline for this project? Could you share this as much as you are willing to disclose?

Teshirogi : I can say that the weak points of this compound, ensitrelvir, are DDI and pregnant women. If these can be improved, ensitrelvir can be used more broadly. As for antivirus effect and clinical efficacy, the more the results of the trials come out, the more confident we are becoming, since ensitrelvir has a great capability comparing to other drugs. So I don't think there will be any problem there. However, it is still very important to be able to lift DDI and Pregnancy.

The pregnancy part is especially important for young people who can use the drug without any limitation, while older people take various medications for hypertension, hyperlipidemia, etc., so I think it is difficult for doctors as they will need to take the time and precaution for elderly people. We are working on it now with John to see if it can be eliminated to produce better product.

Ueda : Thank you. That is all.

Sakai : My name is Sakai from Credit Suisse. Haven't you ever thought about improving the formulation of rilpivirine? I am asking about pain, but at least the life cycle is 30 years and beyond, so I think that improving this would be quite meaningful in terms of dissemination, as well as for patients, but is there anything at all in this area?

Keller : Now we have two injections. It may be reduced in volume to make it a simpler formulation, or possibly all in one injection. However, the latter is more difficult. We are also considering the development of a self-administered subcutaneous injection once a month. These are being implemented as joint projects by J&J and ViiV, and so far both are making good progress.

Teshirogi : J&J said at one time that it would be impossible to do something like this for more than two months, but after that, we are working as a joint project to see if subcutaneous injection can be done, if the volume can be lowered, and in some cases, if one-injection can be done. But the one-injection part is a two-separate

injection, because originally, I heard that formulations of rilpivirine are already well devised, and we can't mix it with other things, but it's definitely a pain. And the volume, too, because it's either 1 cc/1 cc or 2 cc/2 cc, which is quite a lot.

Keller : If the development of self-administered formulations is successful, we think it will become one of the preferred options for patients.

Sakai : Thank you very much. I think we have had a very turbulent year up until this year, but things will start to normalize a little from next year, both for the general public and for your company. I am getting variety of information now but when you share your thoughts about the shareholders or investors from a president point of view, I think a topic about shareholder returns will inevitably come up.

Why is that, after all, it will take a little more time for the pipeline to come out, and I'm not asking you to tell me at this point how to connect that part of the pipeline, but in the end, if you do that, then does it come down to where it is share buybacks and dividend increases? Or, as you have said before, you have cash, so you can spend about JPY500 billion. However if you ask me whether your company's M&A track record was good or bad, I think many of the results have not yet been very good.

But on the other hand, the stocks in that area, including biotech and others, are down quite a bit right now, in value. Do you see it as an opportunity? This may not be a question, but I wonder if you could summarize that and give us some current thoughts.

Teshirogi : We will continue to enhance shareholder returns, including dividend increases and share buybacks. Frankly speaking, I am very dissatisfied with the current stock price, and I also wonder what they are doing with such a stock price. I believe we can at least aim pretty high. Including that, after all, I haven't met directly with our shareholders in the US or Europe in the last three years, and in that sense, I'm also going to start activities again in terms of getting them to understand from scratch what we are trying to do.

However, even so, the balance sheet is now JPY1.2 trillion, and cash equivalents alone are probably JPY200 billion, so if the balance sheet remains as it is, ROE will not rise, and we will be left wondering what we are doing. So, at the same time, we need to think about how to expand our business, including M&A.

We have been thinking of M&A targets because of CMS or because of infectious diseases, but what John and I have been doing now is to think about where the unmet needs really are. We are thinking that it is appropriate to take an approach to find a company that can meet the unmet needs, regardless the therapeutic area. We would like to conduct M&As that originate from such patients in need in developed countries or in LMIC, for example, and we are working quite aggressively in this area.

So, it is not one or the other, and we believe that ensitrelvir will work in a positive direction at least for the time being, so cash flow will increase again, and we will have enough capacity to both return profits and invest in growth.

Sakai : Thank you very much.

Wakao : My name is Wakao from JPMorgan, thank you for taking my questions. I have two questions. As for COVID-19-related issues, there is an idea of JPY110 billion for COVID-19 related products. I think you mentioned earlier in Q&A that you do not include the vaccine in this figure. I believe that JPY45 billion worth was originally purchased by the Japanese government, JPY45 billion for ensitrelvir in Vietnam and Korea, and the remaining JPY20 billion was for the vaccines. Since the vaccine is not expected this time, you said that the JPY20 billion and the other 30% are excluded, but is it correct to think that the remaining ensitrelvir sales JPY20 billion will be purchased by Japan, Korea, and Vietnam? Or may I assume that other countries are becoming a possibility?

Teshirogi : If I were to answer your question directly now, it would be the first one. It means that we think that the demand in each country has a very big potential to be a little bit larger.

Wakao : I understand. Second, I would like to know about ensitrelvir's sales and the manufacturing system in China and its final form. First of all, I wonder if you expect for both government purchase and general distribution? I understand that you are planning to establish a manufacturing base in China, but what is the scale of the manufacturing base and what is the production volume?

Also, since you mentioned that Ping An-Shionogi and distributors will be involved, how much profit will your company get from the sales of ensitrelvir in China? Since there will be more players involved in various ways, how should we think about the profit that your company can ultimately take? That is all.

Teshirogi : Regarding your first question, I can only ask you to understand we are not able to comment. Even paxlovid is in an unclear situation. It is difficult to know how much oral antivirals they intend to use at this point in time with the zero-COVID-19 continuing, so I would like to ask you to understand that we refrain from disclosing what we are doing right now regarding the first question.

Secondly, we will have two API plants and a formulation plant, as I mentioned earlier, under our Ping An-Shionogi in Nanjing. If Ping An-Shionogi manufacture a full tablet, this may require the addition of a little tabletting machine, one that is not so big, but we think we can manage to produce 700 million tablets per year, enough for 100 million people. In addition, we are now in the process of completing the PV for the APIs based on receiving the corresponding amount of APIs from both plants, not ours but the CMO. I am hoping that everything will be ready by the end of the year.

Wakao : How much profit do you expect your company to make?

Teshirogi : Of course, we cannot disclose this as well, but in the Ping An-Shionogi framework, the value split is determined according to the contribution level.

So, for example, investment ratio in Ping An-Shionogi is 49 to 51, so what goes into Ping An-Shionogi is not Shionogi 51 and Ping An 49, but we are going by who made the greater contribution to this item. So at least with ensitrelvir, I and John are thinking that the contribution between Shionogi and Ping An is I think it is 95 to 5 or something like that. So, almost all of ensitrelvir's sales will stand, and the profit remaining after SG&A expenses are deducted from the sales will be Ping An-Shionogi's profit, but at the stage of how to divide it, we are now thinking that it will mostly come to Shionogi, dividing it according to the contribution level.

Wakao : Very well, thank you very much, that's all.

Muraoka : Hello, this is Morgan Stanley, Muraoka. I would like to confirm about the story of China for 700 million tablets a year now, or 100 million people. I believe that around May or June, when the possibility of China came up, there was talk that you might be able to secure CMOs for local manufacturing for about 20 million people, and from that point on, I think the numbers have grown in many ways. I'm not sure if 100 million is a pretty good reading, even as an actual end-demand, or if reading is an exaggeration, but I'm not sure with what degree of certainty we can multiply 100 million by us, so could you give us some tips on that?

Teshirogi : I'm sorry about this, but this is something Beijing knows only too well. It depends on how the policy will be implemented, so I am not sure how the zero-COVID-19 policy will be normalized, even I ask the local, say, head of Ping An-Shionogi. We don’t know what kind of timing and trigger will be used. It depends on the political direction.

However, I have heard that about 85% of vaccinations are inactivated vaccines, Sinovac, and Sinopharm. I think the whole thing will depend on whether a vaccine that is thought to be effective in preventing the

disease becomes widely available, or whether a simple antiviral agent like ours becomes widely available, or some combination of the two, but I honestly do not know who will pull the trigger at what time or in what way.

I was talking about capacity. If you are asking me if we intend to produce enough for 100 million people at the Nanjing plant, I am saying that we have a capacity to do so if we work that hard. However, it will be a different story how the operation would be.

Muraoka : I understand. Thank you very much. As for the capacity, you have a capacity for 10 million people for Japan as written in the page 19 of your slide. I honestly don't know what demand is in Japan but if it goes with general distribution, not government purchase, do you think it will be used for 10 million people? What do you feel about that?

Teshirogi : We have published figures on how much Lagevrio and Paxlovid are being used, so it is up to each individual to decide whether this is the case in the market or whether it is due to restrictions in various ways, such as difficulty in use, etc., but even here in Japan at this time, I do not think that oral agents are used to that extent in Japan at this point. So I am sure that there is no demand for the current extension, but that does not mean that we are very sure how much.

On the other hand, in Japan, we are initially planning to produce from Japan for the time being, except for China and the US, where we have received clear requests to manufacture locally, as I mentioned earlier, so this number includes those countries. Of course, each government are also asking us to let Korea make it locally in Korea and Vietnam in Vietnam, so at some stage we may have to think about the next pandemic and technology transfer or local manufacturing.

However, considering the fact that it is not that easy to do it in one or two years, I think that we will have enough capacity for the next three or four years, except for the local areas that I mentioned earlier, where we are told to local manufacture is mandatory. We think we will be able to start from Japan, including Europe. However, since we are talking about capacity, so if you ask we have the capacity. I would like you to understand that it will be a different story if we need to in accordance with the capacity, or not.

Muraoka : Thank you very much. Just one more thing, you are talking about the one-time payment from Takeda coming in next April, is this only going to be recorded for one year next year and that's it, or is there some kind of way to do it well and defer it to multiple years?

Teshirogi : That and other things are being considered by John and Kiyama, since we just put them out yesterday.

Muraoka : I understand. That is all, thank you.

Teshirogi : Thank you very much.

Kyokawa : This concludes the presentation of the financial results for Q2 of the fiscal year ending March 31, 2023, of SHIONOGI. Thank you very much for taking time out of your busy schedule to join us today.

[END]