SHIONOGI & CO., LTD.

Q2 Financial Results Briefing for the Fiscal Year Ending March 2021

November 2, 2020

Presentation

Kyokawa: Thank you very much for taking the time to gather today despite your busy schedule. I am Kyokawa, Vice President of Corporate Communications Department of SHIONOGI & CO., LTD.

We will now hold SHIONOGI & CO., LTD. Financial Results Briefing for Q2 of the Fiscal Year Ending March 2021.

First, let me introduce presenters. Mr. Isao Teshirogi, President and CEO.

Teshirogi: I am Teshirogi. Thank you.

Kyokawa: Ms. Takuko Sawada, Director and Executive Vice President and Senior Vice President of Integrated Disease Care Department.

Sawada: I am Sawada. Thank you.

Kyokawa: Mr. Koji Hanasaki, Senior Executive Officer, Senior Vice President, Corporate Strategy Division.

Hanasaki: I am Hanasaki. Thank you.

Kyokawa: Lastly, Mr. Yuji Hosogai, Vice President, Finance & Accounting Department Corporate Strategy Division.

Hosogai: I am Hosogai. Thank you.

Kyokawa: Today, Mr. Teshirogi will first explain the outline of the financial results, and then we receive your questions. Today, in addition to the venue, there are a large number of participants via telephone. We accept questions from both venue and telephone. The close time is scheduled to be 12:00 PM noon.

Now, we will start. President Teshirogi, please.

Teshirogi: I am Teyogi. Thank you. I apologize that we hold this briefing between holidays.

I would like to give an overview of H1 of the year's financial results. In addition, we have included some R&D data in the material, so I would like to explain them.

Business Impact of COVID-19

Impact of COVID-19 on 1st Half FY2020 and Our Response

- **Supply chain**
  - No impact on procurement of raw ingredients etc., production, or inventory – no hindrance to stable supply
  - Accelerated production of some products and secured inventory of materials imported from overseas
- **Promotion**
  - Patient visits for medical institutions in Japan are returning to approximately 70% of pre-COVID-19 levels, except for major hospitals.
  - Providing information virtually efficiently through web-conferences and e-details, in combination with face-to-face or online meetings, depending upon the needs of each medical institution
  - Continuing to train sales reps for comprehensive understanding of disease, in collaboration with the Integrated Disease Care Division
- **R&D**
  - Focus resources on COVID-19 related projects
  - No significant impact on the development timelines for 8 core projects* and other projects in the 2nd quarter**

* See Appendix p.39 ** See Appendix p.44, 45

Let's begin with impacts of COVID-19 on our business. At the present time no significant impact is seen. With regard to the supply chain, we have procured a variety of items far ahead of schedule, so I think we have no problem at this point.

Actually, around the vaccine we are currently doing as well, supply issues are seen. We have made quite a quick move for procurement of, for example, glass vials or rubber closures for vials. These products appear to be unimportant, but all over the world now has a lot of trouble with purchasing. It is not so easy, but as we have made quite a rapid move, I think it is possible to provide the vaccine for about 30 million people next year as we promised.

In addition, we are currently planning to distribute refrigerated vaccines as with normal vaccines. I will explain this again later. We think distribution of the nucleic acid type is quite difficult in our country because it needs minus 70 degrees or minus 80 degrees.

It depends on the manufacturer, but many seem to use one vial for 10 people, using a 20cc vial. If we think about Japan, one vial for one person would be simple to use. Therefore, we are procuring the smallest vials from early on. We should guarantee the efficacy and safety of vaccines, of course, but we have completed our preparation for such supplies to some extent.

Including above matters, our R&D activities are currently in good shape.

Financial Results (Consolidated)

(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Revenue	323.5	155.6	**148.5**	**95.4**	163.6	**(9.3)**	**(15.2)**
Operating profit	110.3	53.8	**55.3**	**102.7**	63.2	**(12.5)**	**(7.9)**
Core operating profit**	110.3	53.8	**55.8**	**103.6**	63.5	**(12.1)**	**(7.7)**
Profit before tax	136.3	61.6	**67.2**	**109.0**	70.7	**(4.9)**	**(3.5)**
Profit attributable to owners of parent	103.6	44.9	**49.4**	**110.0**	54.4	**(9.2)**	**(5.0)**

- **Revenue target was not achieved due to contraction of the pharmaceutical market, especially in the infectious disease areas, under the budget plan of decreased sales and profits**
- **Achieved all profit targets by managing costs in this changing business environment while maintaining investment in research and development**

Exchange Rate (average)	FY2020 Forecasts	FY2020 Apr.-Sep. Results
USD ($) – JPY (¥)	**107**	**106.93**
GBP (£) – JPY (¥)	**130**	**135.42**
EUR (€) – JPY (¥)	**120**	**121.34**

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* Converted from JGAAP to IFRS
** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

Now, let me explain the numbers. Let me discuss the H1 results on the fourth row from left, and the YoY change on the second row from right.

Please note that we reported the full-year results for FY2019 in accordance with IFRS, but we have not disclosed the results for H1 and H2 of the year until now. This is the first time that we disclose the IFRS figures for H1 and H2, as shown on the extreme right.

In the last fiscal year, we posted larger revenue and profit in H1 of the year compared with H2. Therefore, the decline in H1 of the year was a little larger than our forecasts.

On a full-year basis, this is as originally planned. But when looking at the results in H1 of the year, the decline appears to be slightly large, due to such a reason.

Revenue was JPY148.5 billion, 95.4% compared with H1 forecast, and down 9.3% from the previous year. We saw a largish decline.

Operating profit was JPY55.3 billion, 102.7% compared with H1 forecast. The YoY rate of decline in operating profit was 12.5%, showing a largish decline as our business performed very well in H1 of the previous year.

Core operating profit was a little more than 103% compared with H1 forecast. Profit before tax was JPY67.2 billion, 109% compared to H1 plan. Profit attributable to owners of parent was JPY49.4 billion, 110% compared with H1 plan. Dividends from ViiV were so large in H1 of the year. Therefore, the YoY declines in profit before tax and profit attributable to owners of parent were smaller than the decline in operating profit.

We have no longer paid a lump-sum payment of JPY35 billion for BDSI, particularly in Japan, but in the US as well. As a result, despite the YoY revenue decline and an increase in R&D expenses, we have managed to maintain our level of earnings.

Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H	Achievement	1H	Change	Change
	Full year	1H	Results	(%)	Results*	(%)	(B yen)
Revenue	323.5	155.6	**148.5**	95.4	163.6	(9.3)	(15.2)
Cost of sales	17.2 55.7	16.5 25.7	15.4 **22.9**	89.0	16.9 27.7	(17.5)	(4.8)
Gross profit	267.8	129.9	**125.6**	96.7	135.9	(7.6)	(10.3)
Selling general & administrative expenses	32.1 103.7	33.2 51.6	30.2 **44.8**	86.7	29.5 48.3	(7.2)	(3.5)
R&D expenses	15.5 50.2	14.8 23.0	16.7 **24.9**	107.8	14.3 23.3	6.5	1.5
Other income	0.5	0.3	**0.2**	93.3	0.2	0.2	0.0
Other expenses	4.0	1.6	**0.9**	55.5	1.4	(34.6)	(0.5)
Operating profit	34.1 110.3	34.6 53.8	37.3 **55.3**	102.7	38.6 63.2	(12.5)	(7.9)
Core operating profit	34.1 110.3	34.6 53.8	37.6 **55.8**	103.6	38.8 63.5	(12.1)	(7.7)
Finance income	27.5	8.4	**12.8**	152.3	9.7	31.8	3.1
Finance costs	1.6	0.6	**0.9**	151.3	2.3	(59.0)	(1.3)
Profit before tax	42.1 136.3	39.6 61.6	45.3 **67.2**	109.0	43.2 70.7	(4.9)	(3.5)
Profit attributable to owners of parent	103.6	44.9	**49.4**	110.0	54.4	(9.2)	(5.0)

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* Converted from JGAAP to IFRS

I will go into the detail. The achievement of cost of sales in H1 of the year was low. A considerable part of the decline in domestic sales is attributable to older products, which we call "other products," and many of these products have high costs. As sales of such products declined, the decline in the cost of sales ratio was large.

In addition, the cost of exporting dolutegravir and Xofluza is very high. This time, due in part to the shipping adjustments, sales of these products in H1 of the year was smaller, leading to the lower cost of sales.

As a result, the achievement rate of gross profit was slightly higher than the decrease in sales, with 96.7% compared to H1 forecast.

Achievement of R&D expenses was in the 107% range and of SG&A expenses was around 87%. As a result, the achievement of operating profit was a little more than planned for H1 of the year.

We posted a fairly large financial income of JPY12.8 billion due to dividends from ViiV. However, we expect that ViiV's dividends for the full year will not differ so much from the forecast. However, as ViiV's base businesses are very strong, we may receive a steady dividend in H2 of the year as well. So far, however, we have written this figure on the assumption that the dividend has been slightly biased toward H1 of the year and the dividend for the full fiscal year will be in line with the original forecast.

As a result, achievement of net profit was about 110%, and we were able to record a positive figure.

Revenue by Segment

(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts*		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Domestic Prescription drugs	123.9	53.1	**47.2**	88.8	51.5	(8.3)	(4.3)
Overseas subsidiaries/export	24.0	11.3	**11.0**	97.7	17.5	(37.3)	(6.5)
Shionogi Inc.	5.1	2.6	**3.3**	128.9	6.8	(50.9)	(3.5)
C&O	11.9	5.7	**4.2**	74.8	7.2	(40.6)	(2.9)
Contract manufacturing	15.4	7.9	**6.7**	84.6	10.1	(33.7)	(3.4)
OTC and quasi-drug	10.4	4.9	**5.5**	112.8	4.4	24.5	1.1
Royalty income	148.3	77.8	**77.3**	99.4	79.1	(2.2)	(1.7)
HIV franchise	126.3	64.2	**63.9**	99.6	64.9	(1.6)	(1.0)
Crestor®	16.9	11.1	**11.1**	100.0	11.3	(1.2)	(0.1)
Others	5.2	2.5	**2.3**	92.2	2.8	(20.7)	(0.6)
Others	1.3	0.7	**0.8**	121.6	1.1	(27.1)	(0.3)
Total	**323.5**	**155.6**	**148.5**	**95.4**	**163.6**	**(9.3)**	**(15.2)**

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* Converted from JGAAP to IFRS

Let me talk about revenue by segment. Domestic Prescription Drugs and Contract Manufacturing posted negative achievements. In addition, C&O has weakness in generics. Achievements of these three segments were low in H1 of the year.

On the other hand, with the exception of the lump-sum payment from BDSI in the previous year, Shionogi Inc. was almost on track or growing a little. In particular, we made a good start with cefiderocol (Fetroja) with JPY4 billion only in H1 of the year.

We will explain our domestic sales in the following section.

Royalty Income was almost on track. There were small decreases of JPY100 million or JPY200 million, but it was due to the exchange rate. We have almost reached the planned level.

What is worth noting is that OTC and Quasi-drug, which is shown in the middle, saw strong sales and profit due to the very strong pipeline for infectious diseases. The rate of increase was also 24% compared to the previous year, which represents a solid performance this time. Our forecast for OTC and Quasi-drug in H2 of the year is also fairly strong, with above JPY10 billion for the full year.

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta®	28.6	13.9	**13.5**	96.9	12.9	4.7	0.6
Intuniv®	16.7	6.8	**6.0**	88.3	4.5	35.1	1.6
Vyvanse®**	0.8	0.2	**0.1**	34.0	-	-	0.1
Infectious disease drugs	26.5	7.1	**4.9**	68.5	7.3	(33.5)	(2.5)
OxyContin® franchise	5.6	2.9	**2.8**	95.5	3.1	(10.0)	(0.3)
Symproic®	2.9	1.3	**1.1**	81.4	1.1	0.8	0.0
Actair®	0.4	0.2	**0.1**	90.6	0.1	22.4	0.0
Mulpleta®	0.1	0.1	**0.1**	90.7	0.1	(23.0)	(0.0)
Pirespa®	4.9	2.9	**2.8**	98.5	3.4	(17.6)	(0.6)
Others	37.5	17.7	**15.8**	89.4	19.0	(16.8)	(3.2)
Crestor®	8.3	4.2	**3.7**	88.4	4.4	(16.9)	(0.7)
Irbetan® franchise	3.7	1.8	**1.7**	94.2	2.2	(22.1)	(0.5)
Prescription drugs	**123.9**	**53.1**	**47.2**	**88.8**	**51.5**	**(8.3)**	**(4.3)**

<Products included in infectious disease drugs>

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

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* Converted from JGAAP to IFRS ** Launched in Dec. 2019

Please refer to page eight.

Achievements of Cymbalta and Intuniv have reached 96.9% and 88.3% of H1 forecast, respectively. In our analysis, we believe that we are not yet able to catch new patients with new ways of providing information.

Although it may be the same for other companies, while patients did not come to hospitals often and DO prescriptions were relatively easy, it was difficult particularly for Cymbalta to catch new patients or to promote a switch of drugs.

As for Intuniv, we have to grow the adult field. As patients should be adults, we have to talk with doctors, and doctors set up a patient and let the patient try the Intuniv for four weeks, or further two weeks. However, we are not making smooth progress in this process.

As for infectious disease drugs, revenue of Xofluza was not so large in H1 of the previous year as well. Therefore, this negative trend is due to the sluggish revenue of older infectious disease drugs, such as Flumarin, FINIVAX, and Flomox.

As for Others, as shown on the right edge, revenue decreased by JPY3.2 billion. In this case as well, sales of the products that were routinely sold have become so sluggish with the impact of restraints on medical examinations, et cetera. The negative figure around this point is large. In total, achievement of the forecast was 88.8%, and the decrease from the previous year was 8.3%. Although we have not completed the analysis of other companies in the same industry, I think that many companies posted declines in the range of 6% to 8%, so I think our decline is slightly larger. I think the cause is infectious disease drugs and others.

Summary of 1st Half -1-

Year-on-Year Comparison

- **Revenue (-15.2 B yen [-9.3%]** reference: -9.4 B yen at 1Q **)**
  - Japan
    - > **Sales growth of Cymbalta® and Intuniv®**
    - > Impact of price revision (long-listed products in "Infectious diseases drugs" and "Others")
  - Overseas :
    - > US: One-time payments received from BDSI for Symproic® in FY2019
    - > China: Decrease in sales of rabeprazole in the hospital market
  - Contract manufacturing
    - > Temporal reduction of dolutegravir API supply, due to manufacturing process improvements (already included in the original forecast)
    - > Decreased Xofluza® exports due to conservative epidemic forecast for this flu season
  - Royalty revenue
    - > Exchange rates impact on royalty income from HIV franchise
- **Selling general & administrative expenses (-3.5 B yen [-7.2%]** reference: -2.2 B yen at 1Q **)**
  - Decrease in costs due to less field activity in COVID-19 environment (reduced travel expenses, car expenses)
  - Investment for telework environment
- **R&D expenses (1.5 B yen [6.5%]** reference: 0.5 B yen at 1Q **)**
  - Ensuring and accelerating progress of 8 core projects including S-600918 and S-005151, and full-blown commitment to COVID-19 related projects

Pages 9 and 10 provide a summary of H1 of the year, including YoY comparisons and H1 forecast comparison.

In terms of the YoY comparison, revenue was weak in Japan, and there was absence of the portion of Chinese C&O and US BDSI. I think the Contract Manufacturing Business will be a little more on H2 of the year, but the reduction in H1 of the year was a major negative factor. Royalty revenue was on track. OTC drugs also have posted a positive figure to a certain extent.

As for selling, general and administrative (SG&A) expenses, although R&D expenses have been increased by about JPY1.5 billion, the SG&A expenses have been reduced by about JPY3.5 billion.

Summary of 1st Half -2-

1st Half forecast comparison

- **Revenue (-7.1 B yen)**
  - Japan:
    - > ADHD family: decreased market penetration opportunity due to slow recovery from COVID-19 reduction of physician visits by pediatric patients
    - > Infectious disease drugs: decreased prescriptions due to reduction in physician visits and in non-emergency surgery in many clinical departments
  - Overseas:
    - > U.S.: **Steady progress of cefiderocol (Fetroja®)**
  - Contract manufacturing：Adjustment of Xofluza® export to reflect low epidemic projections, while dolutegravir manufacturing exceeded expectations
  - OTC and quasi-drug: Sales increase of infectious disease-related products
  - Royalty revenue: **Achieved as forecasted**
- **Selling general & administrative expenses (-6.9 B yen)**
  - Cost reduction due to reduced sales activities and switching to virtual promotion with digital information
  - Decrease in cost due to reduced sales of rabeprazole in China
- **R&D expenses (1.8 B yen)**
  - Further acceleration of COVID-19-related projects
  - Investment to advance the development of core 8 projects at top speed under the COVID-19 expanding environment
    - > Addition of participation centers for clinical trials, flexible expansion of areas/countries for recruiting patients, etc.

Please go to page 10.

In terms of achievement of H1 forecast, domestic sales of new drugs have not grown sufficiently, but we believe that cefiderocol has made a very good start abroad. Also, royalty revenue was almost on track.

Selling, general and administrative (SG&A) expenses decreased by JPY6.9 billion compared to H1 forecast. In particular, as rabeprazole in China is under the two invoices system, if revenue declines, SG&A expenses will also decrease, which has an extremely large impact.

R&D expenses increased by JPY1.8 billion. This was due to the fact that we are spending a lot of money on COVID-19, including what we had not anticipated at the beginning of the year.

Summary of 1st Half

Market contraction and unachieved sales targets

- Although progress was made in implementing virtual detailing activities, especially for Cymbalta®, it was not possible to compensate for the contractions in the infectious diseases and pediatrics areas
- Steady progress of US and OTC businesses

Resource management

- Strict resource management reflecting current realities while still reliably supplying our products and product information, even in an unstable environment
- Active investment in R&D for medium to long term growth

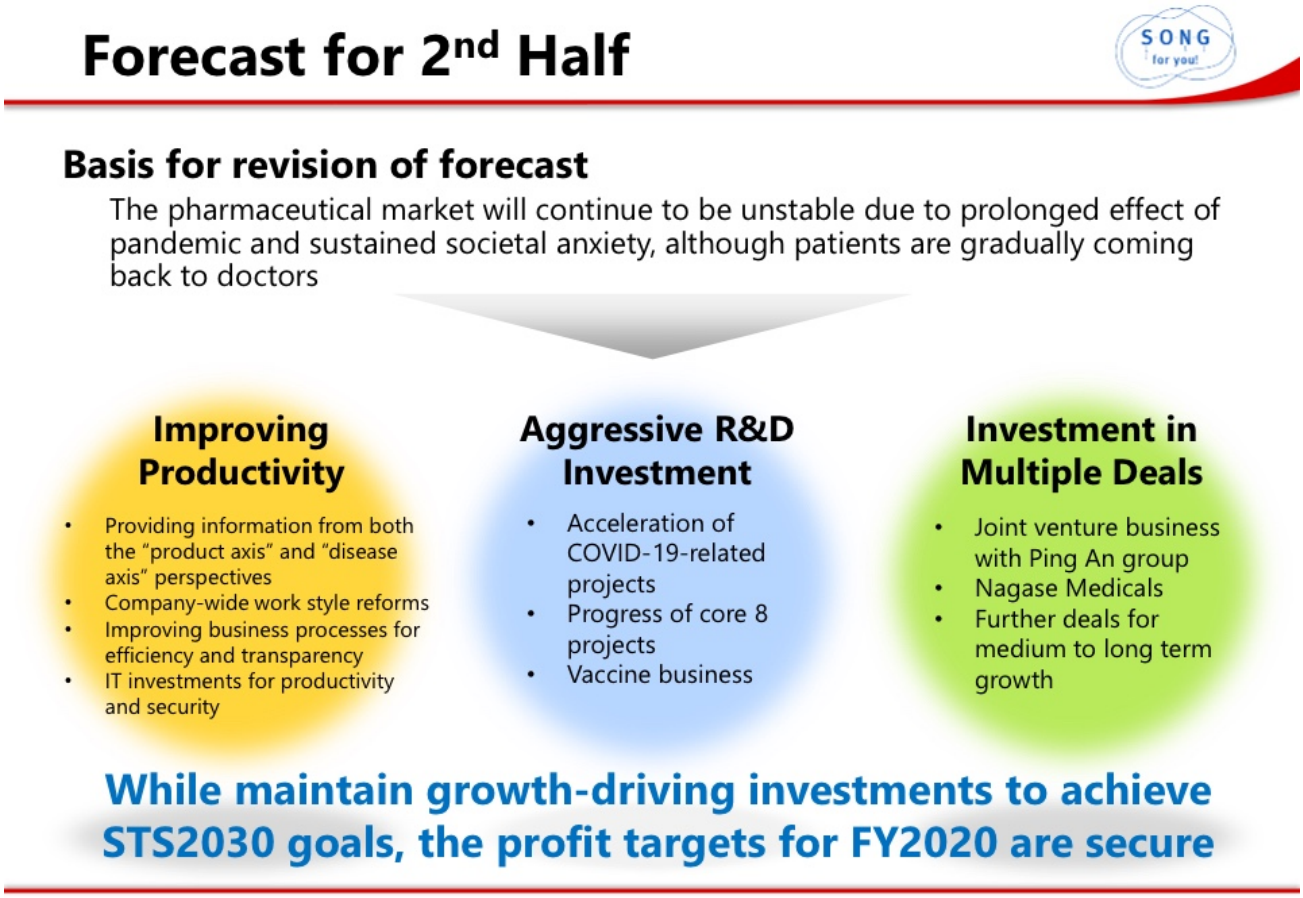
Achieved profit targets through cost management while actively investing in R&D even though revenue did not reach the target

Please go to the next page.

If H1 of the year is summarized, domestic revenue was weak, and how to improve this in H2 of the year is a major issue. The US, particularly Fetroja, and OTC businesses were robust. I would like to continue this solid performance in H2 of the year.

Regarding resource management, although I will not give you all the details, we have replaced all the methods of decision making in H1 of the year, and in October we have introduced an entirely new decision-making system. As a result, as we build our platform businesses "STS2030" other than pharmaceuticals, we will work to increase transparency and ensure traceability throughout the Company by speeding up our decision-making process.

In H1 of the year, we held manager training to instruct how to make decisions. We are spending a lot of money for people and things around the new system. From H2 of the year, its effectiveness will be put to the test.



Let me now discuss our forecasts for the full year and H2 of the year.

As for the improvement of productivity, as I just explained, we introduced a new system. It's not just the computer system. We will change the way we do things. We actually started it last year and we have almost completed it over a year, so it will be an important six-month period for us to have it take root.

In addition, although we are getting used to the situation, we should find the ways to improve efficiency of domestic sales. After that, as you know the problem in Taiwan, we must make investments for security of computer systems. We had offered considerably solid protection for domestic and other key group companies, mainly in the US and Europe in anticipation of such an attack, but had left Taiwan on a back burner.

We have to make substantial improvements to such IT security systems, so we must also invest in H2 of the year to protect them.

Regarding R&D, as I will discuss later, we would like to postpone the treatment of the drug for COVID-19 a little. However, we have not stopped it, and intend to continue with all of the vaccines, treatments, and diagnostics.

In particular, as I will explain later, 14770, which we received from Tetra, 918, and Redasemtide will be into a really crucial period in H2 of the year. We would like to provide more detailed information at the R&D Day in March.

We will also need a lot of money in this area, and in addition, CCR8 will enter the clinical phase around the beginning of next year. It is extremely important to manage R&D expenditures properly.

Then, in terms of multiple deals, our members will move to Ping An Shionogi in Shanghai from November 1, where they will start their work. As the collaboration between C&O and Good Doctor in particular is virtually now underway, so after completing the full setup, we will actually show you what the results will be in November and December.

Shionogi Pharma Co., Ltd. a manufacturing Group Company, has acquired Nagase Medicals, and its factory that manufactures products with particularly high physiological vitality, as well as human resources. In fact, UNIGEN will manufacture our vaccine with our facilities in it, but it's not a simple matter to secure human resources, so we're going to send our staff members. Looking at that comprehensively, the deal with Nagase has a great meaning.

As I will discuss later, our planned decrease in selling expenses including general and administrative expenses in H2 of the year is not large. Regarding this, we would like to conclude a number of deals in the next six months, so we factored in PMI fee or consultant fees in selling, general and administrative expenses in advance. I think the next six months will be a very important period for us as well.

Revision of earnings forecast
(excluding a gain on exchange of Shibuya Building (22.9 B yen))

(Unit: B yen)

	FY2020 Forecasts Full year			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	**318.1**	**(5.4)**	333.4	**(4.6)**	**(15.3)**
Operating profit	110.3	**110.3**	**-**	130.6	**(15.5)**	**(20.3)**
Core operating profit**	110.3	**108.5**	**(1.8)**	127.4	**(14.8)**	**(18.8)**
Profit before tax	136.3	**136.7**	**0.4**	158.5	**(13.8)**	**(21.8)**
Profit attributable to owners of parent	103.6	**103.6**	**-**	122.2	**(15.2)**	**(18.6)**

* Converted from JGAAP to IFRS ** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

In response to this, we have revised our earnings forecasts.

To put it straight, the buildings in Shibuya are hard to see, so we're excluding it. Actually, we wrote so in Appendix on page 37.

Since this design is the first year of "STS2030", we will raise or lower various things from the point that we will absolutely achieve the operating income and net income of the initial earnings forecast.

Maybe we can achieve a little more positive figure, but I think it is very bad news if we are below the figures made at the beginning of the year in the first year, so we made a revision.

Revision of earnings forecast (Announced on October 30, 2020)

(Unit: B yen)

	FY2020 Forecasts Full year			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	**318.1**	**(5.4)**	333.4	**(4.6)**	**(15.3)**
Operating profit	110.3	**133.2**	**22.9**	130.6	**2.0**	**2.6**
Core operating profit**	110.3	**108.5**	**(1.8)**	127.4	**(14.8)**	**(18.8)**
Profit before tax	136.3	**159.6**	**23.3**	158.5	**0.7**	**1.1**
Profit attributable to owners of parent	103.6	**119.7**	**16.1**	122.2	**(2.0)**	**(2.5)**

- **The revenue of initial forecast is expected not to be achieved, considering the 1st half result and the market environment**
- **A gain on exchange of Shibuya Building*** will give significant positive profit impact**
  - **Resulting in similar profit levels to previous year**
  - **No change in profit forecasts when this factor is removed *****

Exchange Rate (average)	FY2020 Forecasts (May 11)	FY2020 Forecasts (Oct. 30)	FY2020 Apr.-Sep. results
USD ($) – JPY (¥)	107	107	106.93
GBP (£) – JPY (¥)	130	135	135.42
EUR (€) – JPY (¥)	120	120	121.34

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* Converted from JGAAP to IFRS ** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)
*** Forecast excluding a gain on exchange of Shibuya Building (22.9 B yen) is in Appendix p.37

Please return to page 14, where we provide the revised forecast including it. Revenue is forecast to be JPY318.1 billion, a decrease of JPY5.4 billion. Operating profit is forecast to be JPY133.2 billion. The revised amount of JPY22.9 billion is for a gain on exchange of Shibuya Building. Profit before tax is forecast to be JPY159.6 billion, an upward revision of JPY23.3 billion, and net profit to be JPY119.7 billion, an increase of JPY16.1 billion. Taxes are not immediately incurred, but we have reserved them.

Compared with the previous year, revenue will decrease by 4.6%, and operating profit will increase by 2%. Core operating profit will be down 14.8%, as profit from Shibuya Building isn't naturally included in the core operating profit. Profit before tax will be up 0.7%, and net profit will be down 2%.

Again, our current design is based on the assumption that we achieve the figures we announced in May for operating profit and net profit.

Revision of earnings forecast
Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020 Forecasts			FY2020 2H Forecasts			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	**318.1**	(5.4)	167.9	**169.6**	1.8	333.4	**(4.6)**	**(15.3)**
Cost of sales	17.2 55.7	17.3 **55.1**	(0.6)	17.9 30.0	19.0 **32.2**	2.2	17.0 56.8	**(3.0)**	**(1.7)**
Gross profit	267.8	**263.0**	(4.7)	137.9	**137.4**	(0.5)	276.6	**(4.9)**	**(13.6)**
Selling general & administrative expenses	32.1 103.7	31.5 **100.2**	(3.5)	31.0 52.1	32.7 **55.4**	3.4	29.5 98.4	**1.9**	**1.9**
R&D expenses	15.5 50.2	16.4 **52.0**	1.9	16.2 27.1	16.0 **27.2**	0.1	14.4 47.9	**8.5**	**4.1**
Other income	0.5	**25.5**	25.0	0.3	**25.3**	25.0	4.3	**494.5**	**21.2**
Other expenses	4.0	**3.1**	(1.0)	2.4	**2.2**	(0.2)	4.0	**(22.3)**	**(0.9)**
Operating profit	34.1 110.3	41.9 **133.2**	22.9	33.7 56.5	45.9 **77.9**	21.4	39.2 130.6	**2.0**	**2.6**
Core operating profit	34.1 110.3	34.1 **108.5**	(1.8)	33.7 56.5	31.1 **52.7**	(3.8)	38.2 127.4	**(14.8)**	**(18.8)**
Finance income	27.5	**28.3**	0.8	19.1	**15.5**	(3.6)	30.5	**(7.2)**	**(2,2)**
Finance costs	1.6	**1.9**	0.3	1.0	**1.0**	0.0	2.6	**(27.2)**	**(0.7)**
Profit before tax	42.1 136.3	50.2 **159.6**	23.3	44.5 74.7	54.5 **92.4**	17.7	47.5 158.5	**0.7**	**1.1**
Profit attributable to owners of parent	103.6	**119.7**	16.1	58.7	**70.3**	11.6	122.2	**(2.0)**	**(2.5)**

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* Converted from JGAAP to IFRS 15

Please go to page 15.

These are detailed figures. I don't think I need to explain them in detail. The revenue revision of JPY1.8 billion corresponds to sales of Nagase of JPY1.8 billion in H2 of the year. The increase in cost of sales more than the increase in revenue is due to the fact that we plan to ship dolutegravir and Xofluza a little more in H2 of the year in the Contract Manufacturing Segment. The costs of sales for those drugs are high.

We upwardly revised selling, general and administrative expenses by JPY3.4 billion. As I mentioned earlier, this does not mean that domestic sales and other activities will increase so much. We need to strengthen information systems and security in particular. Furthermore, we will need a certain amount of money in general and administrative expenses in order to conclude the deals.

R&D expenses forecast has increased by JPY100 million. The initial forecast of JPY27.1 billion was a YoY increase of about JPY2 billion in the first place. If you look at it for the whole year, as shown on the right-hand side, R&D expenditures will increase by JPY4.1 billion, or 8.5%. In H2 of the year, the increase of R&D expenses will be JPY100 million.

Other income is extremely large because it includes the exchange gain of the Shibuya building, et cetera. Operating profit has been revised by JPY21.4 billion. As I mentioned earlier, making operating profit excluding Shibuya flat, we calculated core-operating profit backward. Therefore, although core operating profit was revised downward by JPY3.8 billion, this is because we reconstructed our plan in order to achieve the JPY110.3 billion operating profit, rather than due to special factors.

As finance income in H1 of the year was large, as shown on the right side, we set our dividends forecast fairly conservatively with a decrease of 7.2%, or JPY2.2 billion.

Net profit is as I explained earlier.

Revision of earnings forecast
Sales by Segment

(Unit: B yen)

	FY2020 Forecasts Full year			FY2020 Forecasts 2H			FY2019	Y on Y	
	Forecasts (May 11)	Forecast (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Domestic Prescription drugs	123.9	**115.3**	(8.7)	70.8	**68.1**	(2.7)	106.3	**8.5**	**9.0**
Overseas subsidiaries/export	24.0	**24.0**	-	12.8	**13.0**	0.3	30.8	**(21.9)**	**(6.8)**
Shionogi Inc.	5.1	**6.2**	1.1	2.6	**2.9**	0.3	10.1	**(38.7)**	**(3.9)**
C&O	11.9	**10.5**	(1.4)	6.2	**6.2**	-	13.1	**(20.1)**	**(2.6)**
Contract manufacturing	15.4	**17.1**	1.6	7.6	**10.4**	2.8	17.6	**(2.9)**	**(0.5)**
OTC and quasi-drug	10.4	**11.9**	1.4	5.6	**6.4**	0.8	9.7	**22.3**	**2.2**
Royalty income	148.3	**148.3**	-	70.5	**71.0**	0.5	166.9	**(11.1)**	**(18.6)**
HIV franchise	126.3	**126.3**	-	62.1	**62.4**	0.3	128.1	**(1.4)**	**(1.8)**
Crestor®	16.9	**16.9**	-	5.7	**5.7**	-	22.3	**(24.4)**	**(5.4)**
Others	5.2	**5.2**	-	2.7	**2.9**	0.2	16.5	**(68.7)**	**(11.3)**
Others	1.3	**1.5**	0.2	0.6	**0.7**	0.1	2.2	**(28.5)**	**(0.6)**
Total	**323.5**	**318.1**	**(5.4)**	**167.9**	**169.6**	**1.8**	**333.4**	**(4.6)**	**(15.3)**

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The revised forecast includes Ping An-Shionogi's revenue forecast.
The impact will be minor due to short accounting recognition period.

* Converted from JGAAP to IFRS

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Please refer to page 16.

Looking at the breakdown by business segment, Nagase's JPY1.8 billion is included in JPY2.8 billion for Contract Manufacturing. Taking account of other factors, such as dolutegravir shipments or Xofluza shipments, as well as revenue increase from OTC, we downwardly revised sales from prescription drugs forecast by JPY2.7 billion. As a result, total revised amount corresponds to JPY1.8 billion of Nagase.

On a YoY basis, this is a very tight year, but we would like to keep the total down to 4.6%.

In terms of royalties, we believe that the figure in H2 of the year will be almost on track and slightly positive compared with the previous year.

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020 Forecasts Full year			FY2020 Forecasts 2H			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Cymbalta®	28.6	**28.2**	(0.4)	14.7	**14.7**	-	26.2	**7.5**	**2.0**
Intuniv®	16.7	**15.9**	(0.8)	9.8	**9.8**	-	10.6	**49.0**	**5.2**
Vyvanse®**	0.8	**0.7**	(0.2)	0.6	**0.6**	-	0.0	**-****	**0.6****
Infectious disease drugs	26.5	**22.8**	(3.7)	19.4	**17.9**	(1.4)	16.0	**42.3**	**6.8**
OxyContin® franchise	5.6	**5.4**	(0.1)	2.7	**2.7**	-	5.8	**(6.9)**	**(0.4)**
Symproic®	2.9	**2.7**	(0.2)	1.6	**1.6**	-	2.1	**26.7**	**0.6**
Actair®	0.3	**0.3**	(0.0)	0.2	**0.2**	-	0.3	**23.2**	**0.1**
Mulpleta®	0.1	**0.1**	(0.0)	0.1	**0.1**	-	0.1	**(9.9)**	**(0.0)**
Pirespa®	4.9	**4.8**	(0.0)	2.0	**2.0**	-	6.8	**(28.4)**	**(1.9)**
Others	37.5	**34.4**	(3.2)	19.8	**18.5**	(1.3)	38.3	**(10.2)**	**(3.9)**
Crestor®	8.3	**7.8**	(0.5)	4.1	**4.1**	-	8.6	**(9.2)**	**(0.8)**
Irbetan® franchise	3.7	**3.6**	(0.1)	1.9	**1.9**	-	4.2	**(14.4)**	**(0.6)**
Prescription drugs	**123.9**	**115.3**	**(8.7)**	**70.8**	**68.1**	**(2.7)**	**106.3**	**8.5**	**9.0**

<Products included in infectious disease drugs>

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

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* Converted from JGAAP to IFRS ** Launched in Dec. 2019

17

Page 17: Domestic prescription drugs.

I do not think that COVID-19 has not broken out in Japan as in the US and Europe. However, we still do not see how patients will be receiving treatment in the winter. Therefore, we downwardly revised the forecast for total infectious disease drugs by JPY1.4 billion, and for others by JPY1.3 billion. We expect that H1 trend will continue to some extent, and revised downwardly by JPY2.7 billion in total.

As for the Cymbalta and Intuniv, some people may say that it is a little stretched when compared with H1 of the year, but at least from the results in October, we think that they are getting on track to some extent.

Japan Business

ADHD-family: Intuniv®, Vyvanse®

- **Providing options for ADHD treatment that matches each patient's needs by offering 2 drugs with distinct mechanisms**
  - Intuniv®
    - > Focus on providing information about efficacy on Hyperactivity/Impulsivity and rapid onset
    - > Drive recognition as a new option for adult patients
  - Vyvanse®
    - > Cleary convey the efficacy and safety profile and deepen understanding of distribution management system

Influenza-family: Xofluza®, Rapiacta®, BRIGHTPOC® Flu・Neo

- **Fulfilling patient needs via appropriate diagnosis and treatment by timely provision of information to doctors**
  - Providing relief from the distress of influenza symptoms and the anxiety around (co-)infection with SARS-CoV-2 by aiding correct diagnosis is our focus as an infectious diseases company
  - Help decrease the healthcare burden associated with influenza in light of COVID-19 pandemic by contributing to the societal needs of fast diagnosis and treatment by providing appropriate information from influenza virus diagnosis to treatment options
    - > Advocating the value of rapid viral load reduction with Xofluza® and Rapiacta®

Now, I would like to move on to future growth. This is page 19.

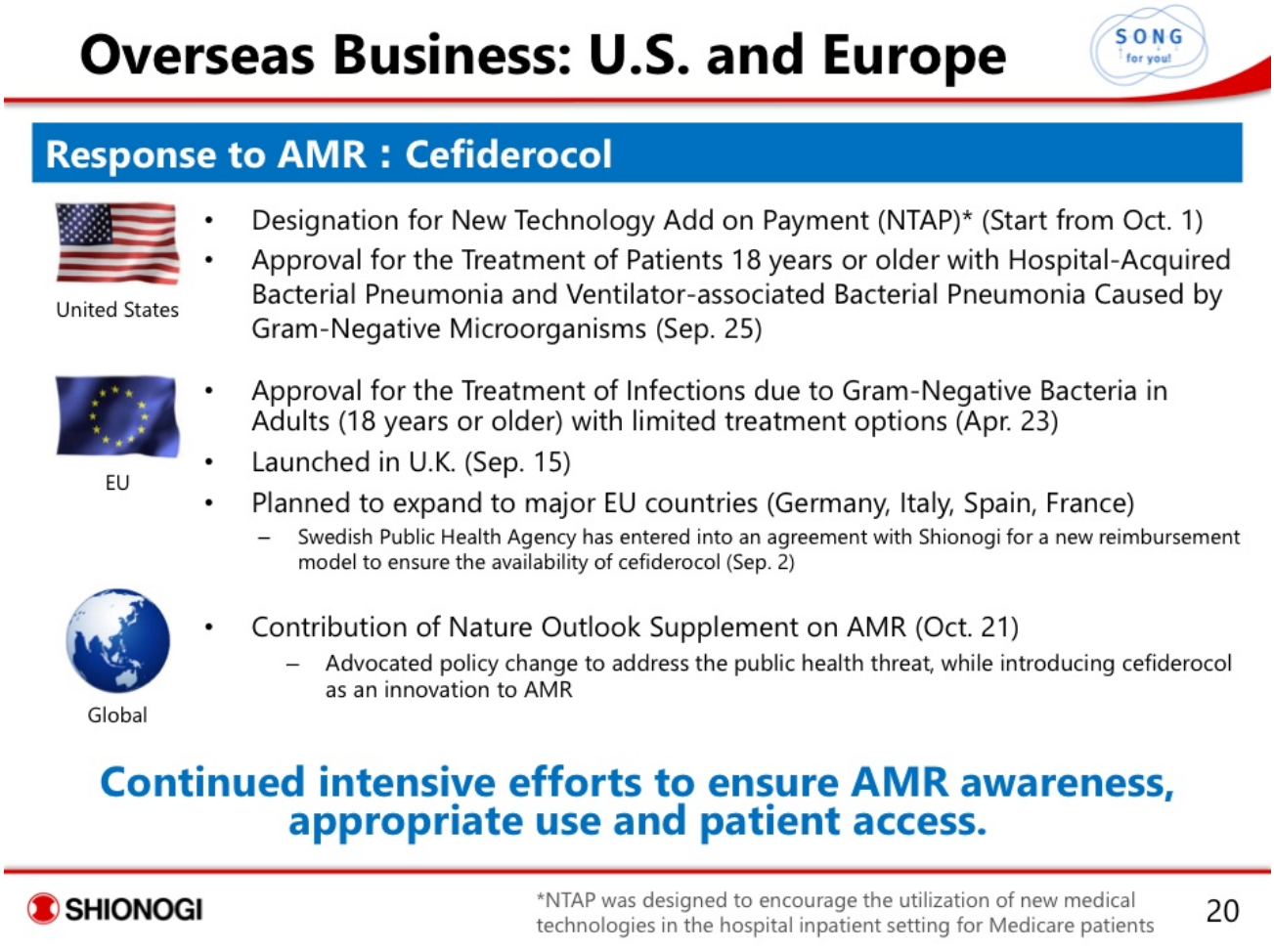
ADHD family. As for Cymbalta, in the middle of the next year, some generics will be launched, so we will sell them out for another year. However, in terms of strategic value, the ADHD family and the influenza family among tinfectious diseases are of great importance. So we listed them there To be honest, I haven't put the position of Vivance, especially the stimulant in the pediatric field, on the line well, even though I have both. Of course, the reduction of the examination in the childcare is very large. In addition, as this is a stimulant, in order to switch from Concerta, for example, fairly close examination of the patient is necessary. Therefore, there are few doctors who will try the new stimulant.

Nevertheless, as we have both, we would like to emphasize that there are examples of insufficient effects of Intuniv, or that there are examples poor control for Concerta in the field of childcare.

Our important challenge is Intuniv for adults. As such, we have indications for antidepressants, and in fact, Lilly is now handling Cymbalta for the psychiatry and we are for the general internal medicine. As it is entering the terminal phase, we are currently in discussions with Lilly about handling Cymbalta in the psychology. By doing so, we intend to expand the Intuniv of the adult field.

Last year, we had a very challenging year with regard to Xofluza, but we have steadily conducted sales activities to doctors, particularly using CAPSTONE data. Of course, while flu is not prevalent, it is difficult to accurately see what the shares of Xofluza are at this point in time. As far as our barometer, our share is approximately 30% to 40%, which is a little larger than our target. And then, it will depend on the extent of prevalence.

As announced in RIS FAX today, it is likely that we will receive a go sign for the preventive administration, so we would like to leverage this area and proceed with the Xofluza.



Please refer to page 20.

With regard to Cefiderocol, we are doing our business more favorably than expected in the US or Europe. The Nature Outlook's AMR contribution is also very positive. Proper use is the basis, so we do not intend to expand sales of Cefiderocol anywhere, but our efforts have begun to be evaluated constantly, so we will continue to do so.

Incidentally, this is the first drug to be brought to the JV with Ping An in China. The more experienced we have in the US and Europe, the lower the hurdle to apply for approval in China. Therefore, we will recognize this as a crucial topic.

Overseas business: China, Asia

China/Asia business transformation by Ping An-Shionogi, a joint venture company with Ping An group

Shape the future of healthcare

Largest Big Data and health-tech platform

中国平安 PING AN
金融・科技

- **2nd** in the world in health-tech patent applications
- Strong healthcare big data access (including RWD) and AI analytics for maximizing the value and application of data
- Developing AI-based new production & quality management systems(QMS)

Strong distribution platform Supply of Shionogi products

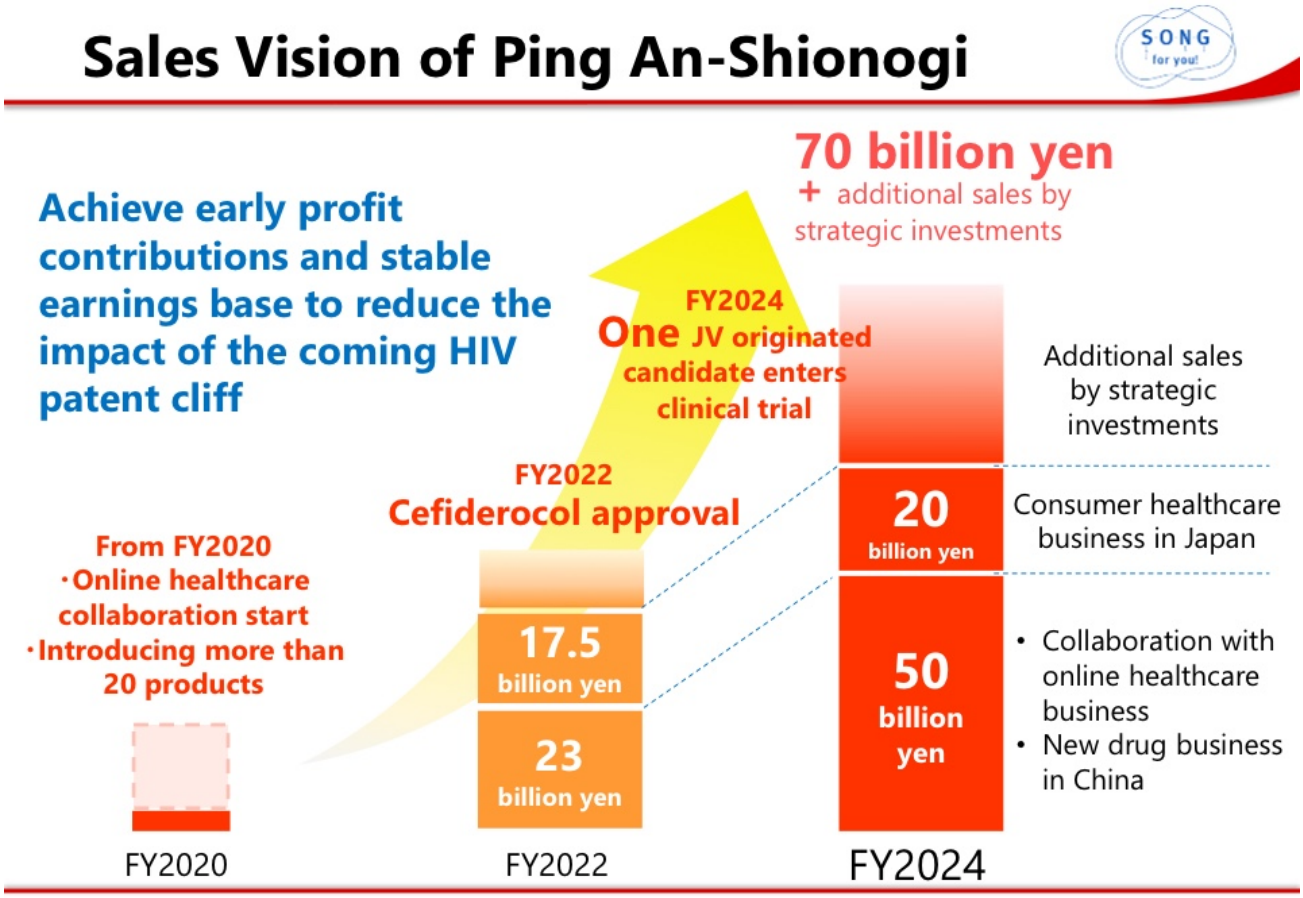
SHIONOGI

- Close collaboration with China's largest online healthcare platform, enabling an efficient sales model without brokers
- Extensive Partnership with **110,000** pharmacies and over **100,000** in-house medical team(1# in China)
- High quality medicinal drugs, generic drug, OTC

Professional expertise in pharmaceutical business

- More than 100 years of R&D experience
- Expertise in Pharmaceutical R&D, manufacturing and distribution
- High proportion of internally-generated pipelines and drug development success

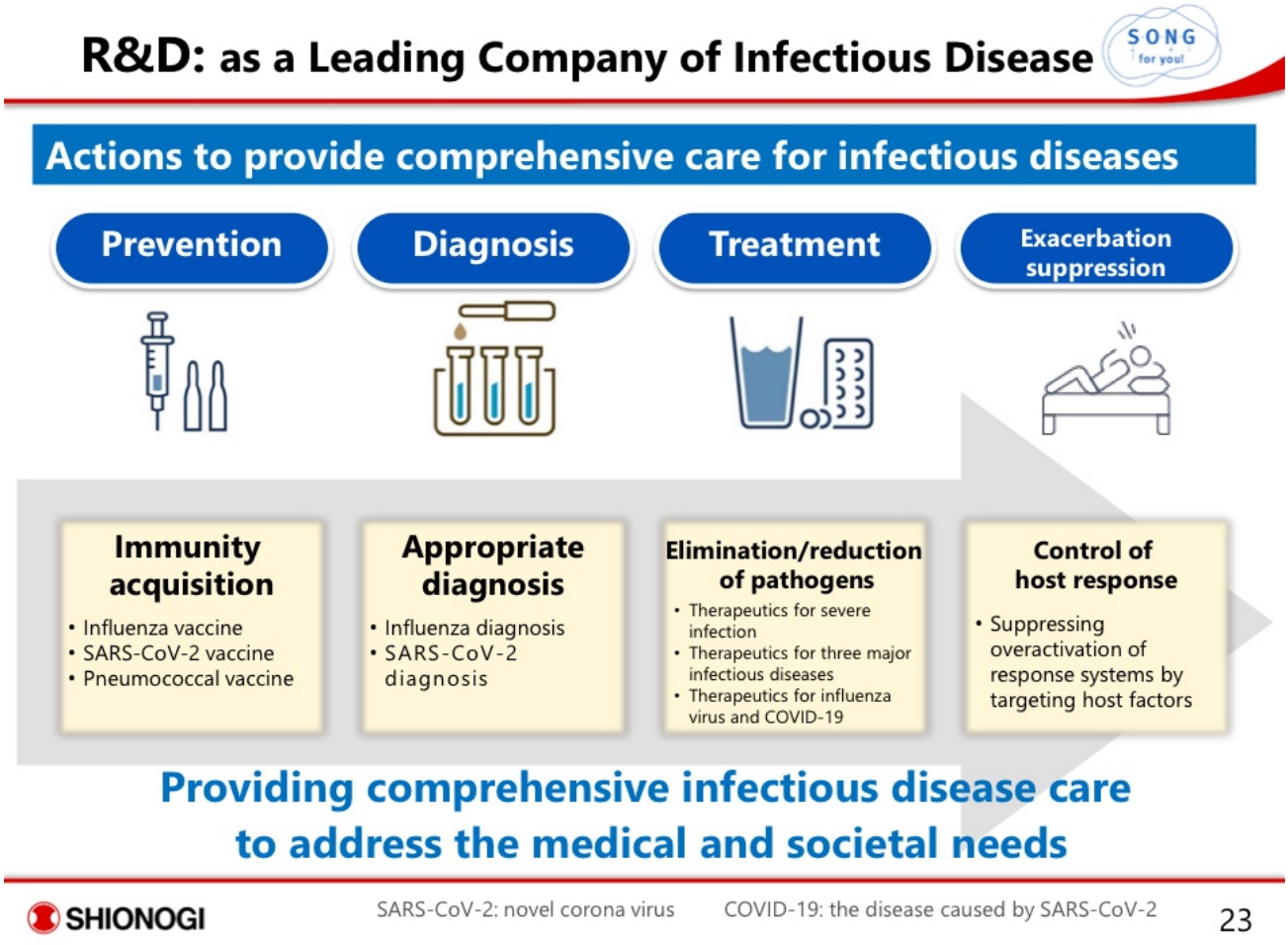
Regarding Ping An- Shionogi, I provided the explanation last time, so I will not explain the details this time.



Profit structures are shown on page 22. I heard that Mr. Yoshida was very humble last time.

Originally, the starting point was operating profit of at least 15% as a pharmaceutical Company. Our challenge is how much we can increase it. An operating profit of at least 15% is our theme through FY2024. As long as there is not much change, I think it will probably be possible.

Including royalties, we are well over 30% of operating profit for pharmaceutical businesses, as a whole. I think that it is still challenging how the Chinese business will grow, but at the present time, we are thinking of increasing operating profit rate by targeting a minimum line of 15% or, if possible, around 25%.



This is page 23.

We have changed the picture in "STS2030", andthis slide includes the detailed names of the products that were developed.

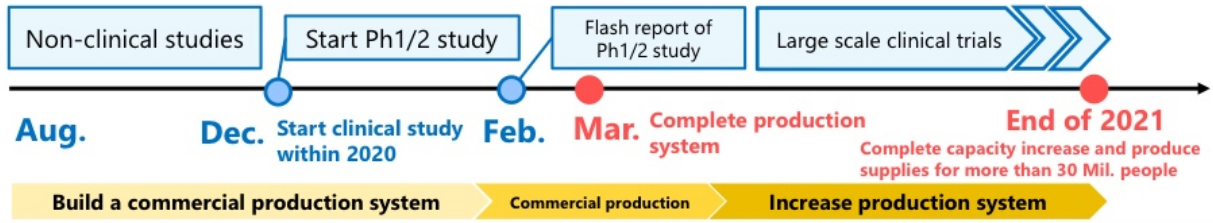
In particular, as for immunity acquisition, the so-called COVID-19 vaccine is naturally moving at priority No, one. The data of flu vaccine was founded last year. However, we have shifted all of our activity of flu vaccines to COVID-19. So we have halted our activity of flu vaccines slightly. We are finally seeing the end for COVID-19 investigational drugs at the plant in Akita, so we intend to roll out an intranasal flu vaccine at the earliest possible stage.

We have contracted with a venture company called HanaVax for a nasal pneumococcal vaccine. Although we don't have much data for COVID-19 vaccine yet, we see that the vaccine may involve pain from the results of our existing clinical trials. We must think of subcutaneous delivery or any other administration method. Considering whether it really will become widespread, we should consider about the next way, and we believe that the intranasal application will be one major option.

Our Efforts to Fight COVID-19

Development of Prophylactic Vaccine -1-

- **Developing a recombinant protein vaccine** based on established technology
- Selection of the antigen and the adjuvant completed in collaboration with National Institute of Infectious Diseases and Kyushu University
  - In non-clinical studies, the increase of antigen specific IgG titer and induction of virus neutralizing activity were confirmed
  - **Confirmed aggravation preventive efficacy of vaccination in an animal study (next page)**
- Non-clinical studies are progressing towards clinical trials, planned to **start by the end of 2020**
  - In discussions with regulatory authorities for the design and conduct of large scale clinical trials
- **Complete the 1st phase production system** in collaboration with UNIGEN (API production) and API (Pharmaceutical manufacturing) **within FY2020**
  - Utilizing the grant "Program for Promoting Investment in Japan to Strengthen Supply Chains" by the Ministry of Economy, Trade and Industry
  - Planning to further increase capacity by utilizing the subsidy from the Ministry of Health, Labor and Welfare



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Please look at page 24.

First, regarding the vaccine, it seems to have been delayed for about two weeks, but it has largely caught up, and it is almost on schedule. Since the middle of December, we will enter the Phase I study in Japan, and around the middle of January the Phase II study, and we are now preparing to enter a large-scale Phase III study from March or April.

Even with a figure of about 1% of the occurrence rate of COVID-19, Clinical trial needs about 20,000 patients. Naturally, the occurrence rate in our country is lower, so it will be extremely difficult to make a large-scale Phase III study in Japan, and we are now preparing to conduct the study abroad.

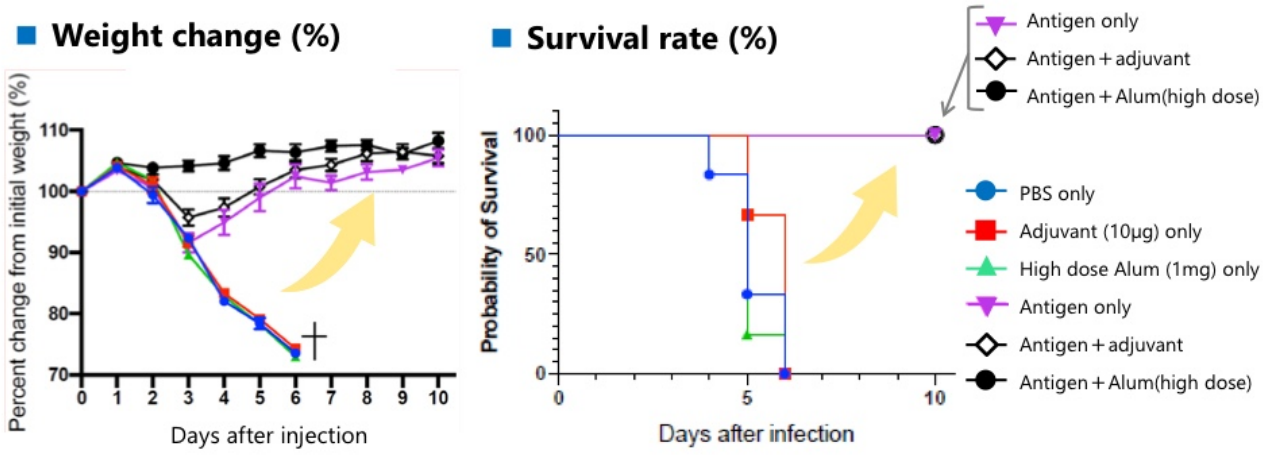
As I mentioned earlier, the manufacturing of investigational drugs at UMN's plant in Akita is proceeding smoothly, although it is a little old plant. On the other hand, the construction of facilities at UNIGEN with a grant from the Ministry of Economy, Trade and Industry and the Ministry of Health, Labour and Welfare is also proceeding extremely smoothly. We plan to take around January, February, and March to produce on a commercial scale, because the commercial facilities will start up by the end of the year.

Our Efforts to Fight COVID-19

Development of Prophylactic Vaccine -2-

Vaccinated animal → SARS-CoV-2 infection → 10days follow-up

Confirmed clear aggravation preventive efficacy (from death) in an animal study after vaccination including the selected antigen protein



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PBS: Phosphate buffered saline
Alum: a widely used, historical adjuvant composed of aluminum salts

Page 25 provides the data of National Institute of Infectious diseases. Other vaccines often use Alum s adjuvant. At the time of SARS, the fact that BD is seen with Alum, although is not a 100% causality. This suggests that it would be more reasonable scientifically to consider adjuvants other than Alum.

We are using a considerably high volume of Alum for the animal experiments. Combining our antigen, the adjuvants we are trying to use, and the very high volumes of Alum, we have seen enough preventive efficacy in respect of weight changes, survival rates, and so on. We are accumulating such data, including from monkeys.

This is why we are confident that we will enter the clinical trials of our COVID-19 vaccines, although we cannot know their efficacy, safety, and side-reaction.

Our Efforts to Fight COVID-19

Discovery of Novel Therapeutic Drugs

- Advancing collaborative research with Hokkaido Univ. and National Institutes of Biomedical Innovation, Health and Nutrition
- The efficacy and safety studies for the best candidate compound for SARS-CoV-2 were conducted
  - **Abandoned the target of entering clinical study within FY2020** as more efficacy and safety studies are needed
- We **continue efforts of drug discovery** which is active not only for SARS-CoV-2 but for other corona viruses broadly from the standpoint of potential future corona virus pandemic
  - Realizing more effective and safe drug than current repositioned drugs by taking advantage of various modalities

Offering Test/Diagnosis Kit

- Launched IgG/IgM Antibody-test Kit as a research reagent
  - For more convenience, the 20 tests/kit product was produced in exchange for 50 tests/kit.
- License agreement regarding developing a new rapid diagnostic method (SATIC*method) with 3 Univ.**
  - To address the needs of medical settings with this technology***, the initial delivery amount has to be secured.
    - > **The release target of the initial product was changed to December 2020** to focus more on supply system development
  - Acceleration of development and production scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples

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* SATIC ：Signal Amplification by Ternary Initiation Complexes
** Nihon Univ., Gunma Univ., Tokyo Medical Univ.
*** No special instrument, saliva sample, 25 minutes, visual detection diagnosis

This is page 26.

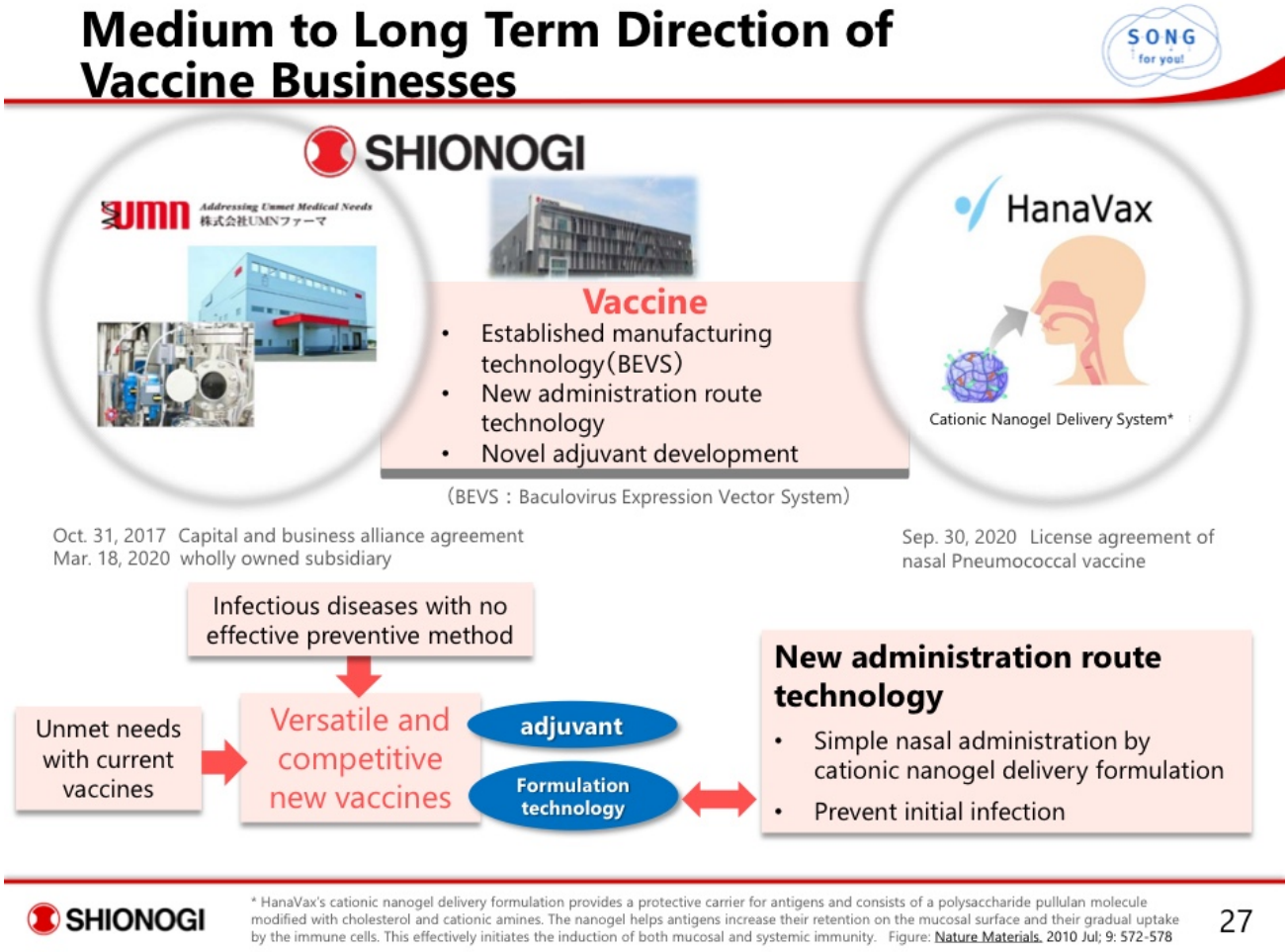
Regarding the therapeutic drugs, at the time of the R&D Day in March 2020, we said that we have originally a lead compound and we would like to proceed with it. It's not a repositioned drug, so we had to restart the toxicity test, so we've done it quite vigorously.

The safety margin of our candidate was less than 10 times. Even if we conduct the Phase II, Phase III and large-scale toxicity study with animals, and the compound is approved after three or four years, compared with Remdesivir or Avigan, for example, in respect to the profile, i.e. the balance between safety and efficacy, I don't think the world wants this new drug.

There was a desire to continue it and enter the clinical study as a research team, but if Shionogi developed it, then everyone expects such good products like Xofluza. I think that it is our stakeholders' expectations that we made products with placebo-like side effects and considerable sharp effect. Therefore, we have abandoned the entry of leading compounds into the clinical stage in March FY2020 and are considering continuing research.

Regarding the test/diagnostic kit, SATIC, I think it is an excellent conceptual idea of universities centered on Nihon University. How will this be commercialized to provide sufficient quantities to the world? We are having a hard time about how we will commercialize and provide enough quantities including the so-called scale-up. We are currently considering the application for approval at the end of December FY2020 and the improved kits in the winter of 2021 and beyond.

Including the SATIC diagnostic kit and COVID-19 vaccine, we are investing a considerable amount of our resources. We would like to respond to the expectations of the world.



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At this point in time, most of the injectable vaccines for COVID-19 are muscle injection. While nasal administration has begun in Hong Kong, I think it is still at an early stage.

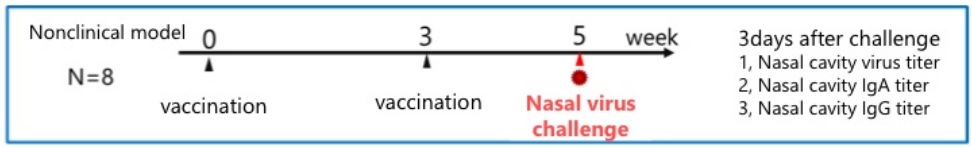
However, it is quite painful than flu vaccines, et cetera, at this point. In that sense, it would be better to develop a new administration.

We didn't present it at the R&D Day last fiscal year, because we had no room for it due to COVID-19.

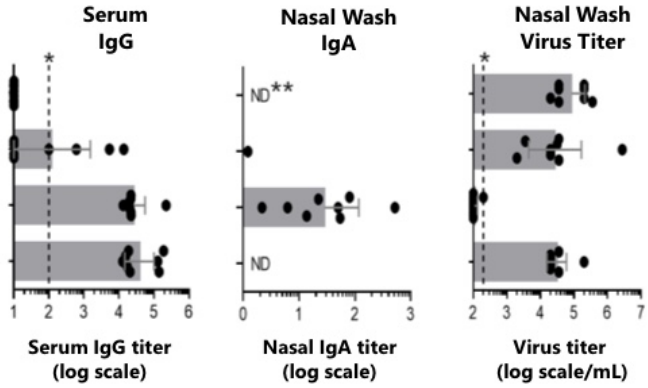
As I mentioned earlier, the Akita Plant is becoming available for flu as well, so clinical trials will be possible from next year. Therefore, we have announced this for the first time this time.

S-872600 : Nasal Influenza Vaccine

Prevention from influenza virus challenge by nasal vaccination



Antigen	Adjuvant	Route of Administration
(-)	(-)	Nasal
(+)	(-)	Nasal
(+)	(+)	Nasal
(+)	(+)	subcutaneous



Contribute to global health and pandemic containment by providing effective preventive vaccines as a part of comprehensive care for infectious diseases

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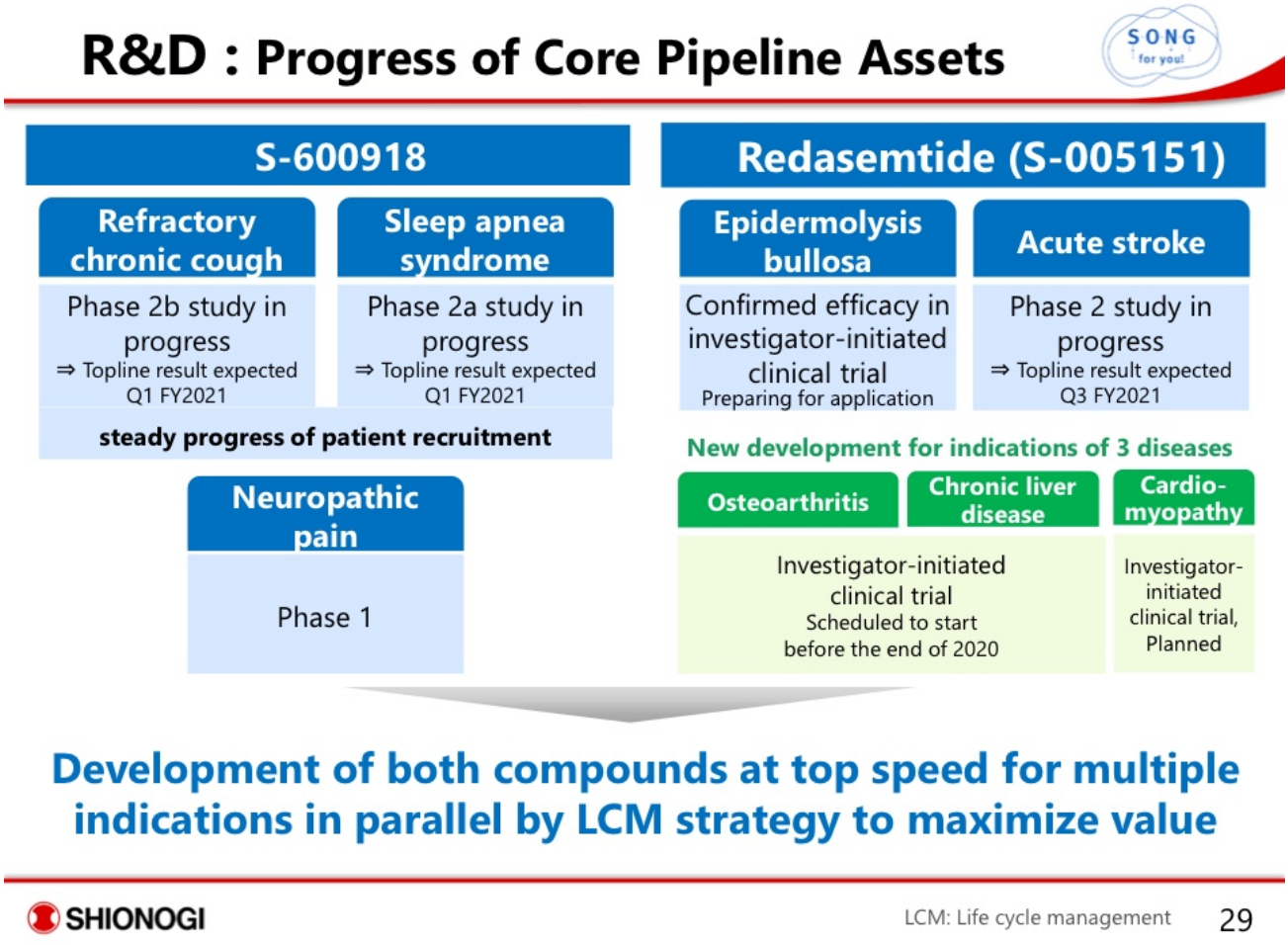
* Lower Limit of Quantification ** ND: not detected

As for the animal experiment of nasal influenza vaccine, as described above, we begin with the vaccination at the zero point, then vaccination three weeks later, and take on a challenge two weeks later.

The right-hand side is the result. When we look at the following nasal cavity virus titer, nasal with adjuvant is almost perfect effect. However, in the case of subcutaneous injection with adjuvant, IgG goes up very high, but IgA does not go up, which is perhaps important. In the case of nasal administration, virus titer is almost the same as others. As for influenza, nasal route is an especially important theme, so we believe our nasal vaccine is extremely promising.

Now, we have just begun trying same model of animal experiment for COVID-19 nasally. Although we have not had enough knowledge, COVID-19 vaccine are basically working with an injection. We think nuclear acid vaccine or viral vector vaccine are not really effective as a vaccine using the intranasal method. I think inactivation and recombinant protein tend to be effective nasally. Therefore, we may be able to promote this area, including for differentiation.

This is a comprehensive approach, including equipment and devices. We have been talking with equipment manufacturers from two years ago. The nasal vaccine of HanaVax using cation nanogel would be effective without any pain and with long stay in the nose. We intend to vigorously promote this area.



Please go to page 29.

I think we are making steady progress in the areas of S-600918, sleep apnea, and refractory chronic cough. We're conducting the domestic trials for the sleep apnea syndrome in the hospital. As some hospitals cannot receive admitted patients, we're increasing the number of hospitals. We're not seeing any particular delays.

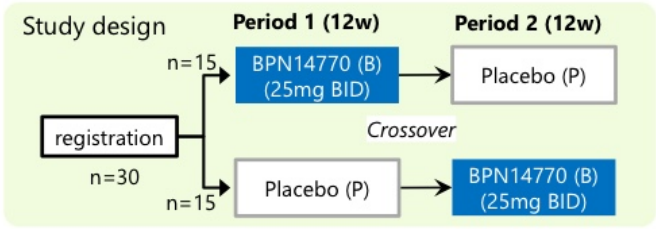
As for S-005151, Redasemtide, we are in the final negotiation with PMDA about epidermolysis bullosa. As for acute stroke, as I have mentioned, we have been making steady progress even in the COVID-19 pandemic. We have great hopes in this area, due partly to the lack of a very good drug.

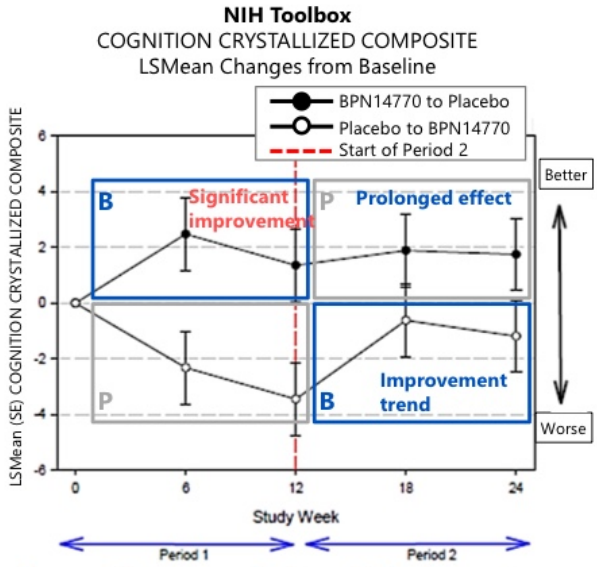
R&D : Progress of Core Pipeline Assets

BPN14770 : Positive results in Phase II study for FXS patients

Topline results of U.S. Phase 2 study for the treatment of Fragile X Syndrome (FXS)

- Safety: **No problematic side effects, including no vomiting**
- Efficacy: **Trend toward improvement in cognitive function**
  - Statistically significant improvement of cognitive functions, especially in language-related domain
  - Clinically significant improvement in overall daily function





Cognitive improvement trend was confirmed not only in Alzheimer's disease patients, but also in Fragile X Syndrome patients, with BPN14770

SHIONOGI

* ClinicalTrials.gov Identifier: NCT03569631
Primary endpoint：Safety and tolerability of BPN14770, 25 mg twice a day dosing for FXS patients

Please refer to page 30.

This is the first time we report about the BPN14770 for Fragile X. Because there is not a very large number of patients, we are conducting a crossover. So the design of the trial is a little difficult to understand.

In the left-hand side of the picture on the right-hand side of page 30, with the active drug on the top and placebo on the bottom, you see there is clearly an improvement. After the crossover, the above is placebo. We see that the effect continues because it has not fallen. On the other hand, there is a tendency to improve when the placebo group is switched to active drug.

While the actual number of cases is not so large, very good signs are coming out. Phase I study for Alzheimer has begun in Japan. We are considering incorporating Japanese patients into global tests for Fragile X. At the moment, we are thinking of entering the final phase after negotiations with the FDA at the beginning of the next year.

R&D : Progress of Core Pipeline Assets

Zuranolone（S-812217、SAGE-217）

- **Japan**
  - Phase 2 study is in progress for Major Depressive Disorder (MDD)
    - > Steady progress of patient recruitment, topline result expected 3rd quarter FY2021
- **Overseas**
  - Positive interim results of Phase 3 study (SHORELINE study) for adult MDD patients in U.S. conducted by Sage therapeutics

【SHORELINE study】

Study design : 1 year open label study, 1 course regimen* was set as zuranolone 30 mg or 50 mg was administered daily for 14 days
*The need for another treatment course was determined by the assessment of depressive symptoms at the end of each course

Safety, tolerability : No major concern was seen in either the 50 mg group or the 30 mg group

Efficacy : High efficacy was confirmed in both the 30 and 50 mg groups at 15 day point

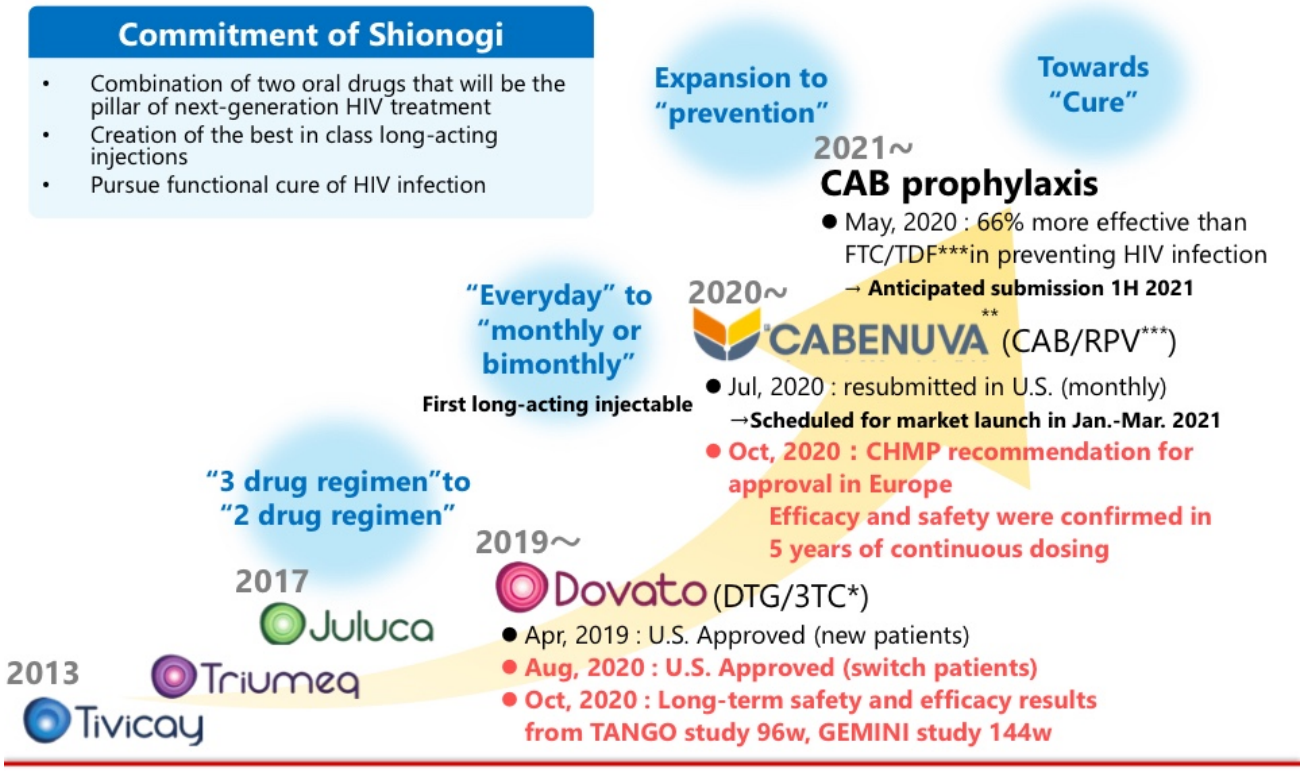
- 50 mg : response (39 patients, 75.0%), remission (25 patients, 48.1%)
- 30 mg : response (458 patients, 71.6%), remission (255 patients, 39.8%)

Next, regarding S-812217 and SAGE-217.

This is proceeding steadily in Japan. But SAGE has recently released a new SHORELINE study interim data, which shows that a sharp remission occurs within about two weeks. We have been talking with the FDA about how it will be maintained, whether we continue S-812217 or conventional antidepressants, or how many times a year S-812217 can be administered.

Basically, this trial is at least suggestive that the symptom can be controlled with three or four times a year. After a remission, some people can continue the remission, and some people are able to return to the remission with the drug when the condition becomes worse. How can we prove it in relation to the administration schedule? We are now seeing a more positive data. Using them as a reference, we will proceed with development in Japan, as well as research of the indications, effects, and how to use.

Progress of HIV Franchise by ViiV



SHIONOGI

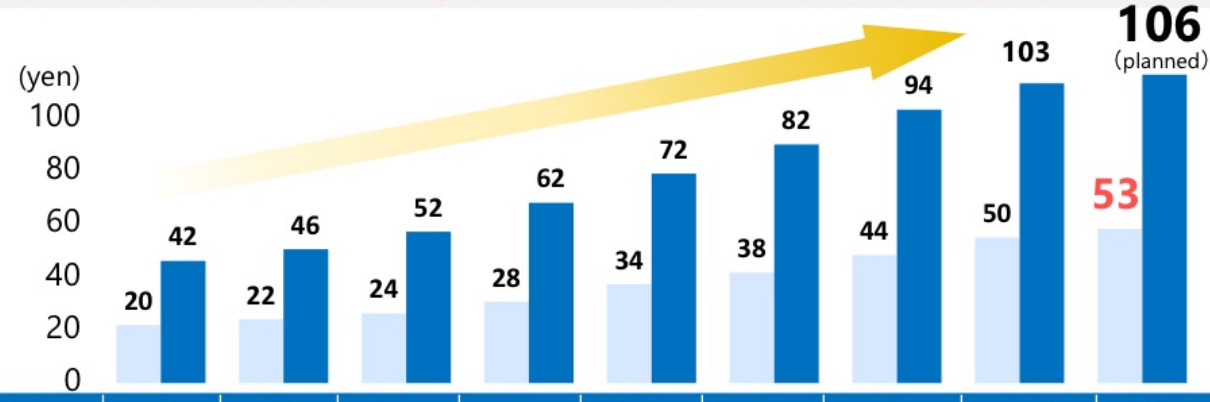
*DTG/3TC: dolutegravir/lamivudine ** CABENUVA: Product name in Canada
*** CAB/RPV: cabotegravir/rilpivirine **** FTC/TDF: emtricitabine/tenofovir disoproxil fumarate

Page 32, HIV.

The progress is well so far. In particular, we are also making steady progress with preventive administration of cabotegravir. So far, sales at ViiV have grown by a few percentage as a whole this fiscal year, but it is moving smoothly.

Flexible and Prompt Capital Strategy

- **Shareholder return policy through which shareholders can feel our growth**
  - Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
  - **Plan to increase dividend again** in FY2020 **for the ninth consecutive year**



FY	12	13	14	15	16	17	18	19**	20**
Treasury stocks: Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	
Treasury stocks: Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	
DOE (%)	3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	Over 4.0**
ROE (%)	17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	Over 12.5**

SHIONOGI

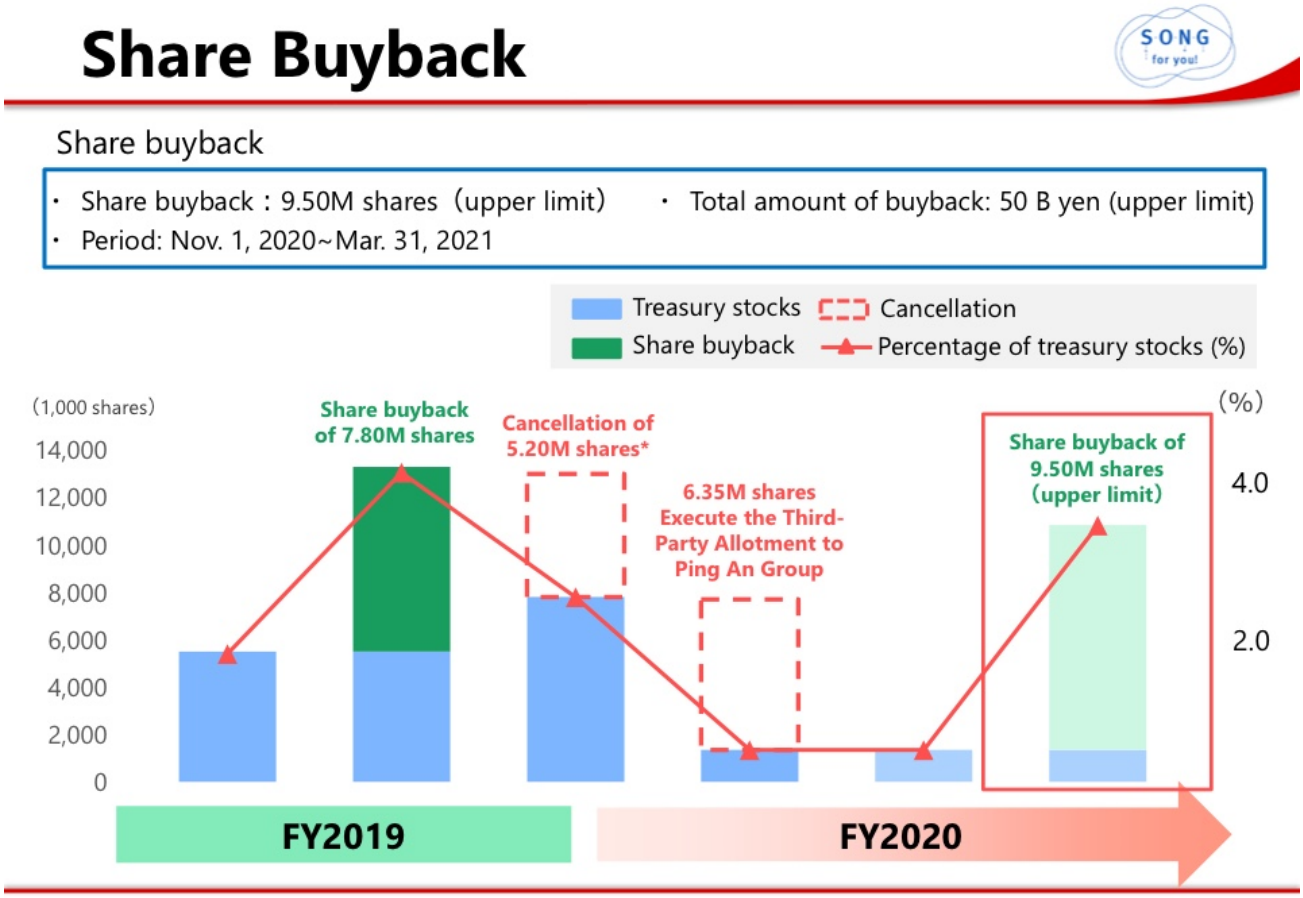
* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020
** Converted from JGAAP to IFRS

Finally, as for the profit return to shareholders.

As I have been expressing, we would like to consistently increase the dividend. As it was JPY53 at the end of the previous fiscal year, we would like to start with an interim dividend of JPY53, a YoY increase of JPY3.

Regarding the payment of dividends in H2 of the year, the Board of Directors will review the Company's operating results and make a decision.

Share Buyback



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

Please go to the next page.

We will conduct a share buyback of JPY50 billion in the current fiscal year, beginning in November. We plan to end it around the end of March 2021.

We intend to aggressively move forward with our "STS2030" plan, which is to invest around JPY500 billion. This has not changed. As I mentioned earlier, we are thinking of good deals in H2 of the year.

Anyway, although it is now on an IFRS basis, our balance sheet became considerably large. The Board of Directors has discussed whether it is appropriate to repurchase shares at this stage this fiscal year, including our message about the low stock price.

This concludes my explanation. Thank you very much.

Kyokawa: Thank you.

Question & Answer

Kyokawa: Now, we'll move to the question and answer session.

Mr. Hashiguchi, please.

Hashiguchi: I am Hashiguchi of Daiwa Securities. Thank you for your explanation. I have a few.

First of all, in the results for the full fiscal year, it appears you did not change Xofluza sales much. Amid the situation where the flu epidemic is now quite small, please tell us your thinking.

You have repeatedly said that you would like to achieve this plan. If revenue from Xofluza is lower, will you aim to secure profitability by cutting costs? Or, if the Xofluza revenue goes down, do you think you have no choice, as last year?

If you cut costs, what do you think of the risk of losing the investment you need in the future?

Teshirogi: We don't forecast the Xofluza revenue to be so strong, and we still have room for some cost cutting. I do not think that we have to cut the necessary investments in the future. We believe that we are able to do so as planned at this point in time.

Hashiguchi: Thank you very much. Next, about COVID-19 vaccine. The preparation of investigational drugs has progressed to a great extent, but in the past, the figure of 30 million people was an approximate guideline when the amount to be administered per person has not yet been decided. In terms of the latest information, do you see the figure?

Also, you said that products of other companies involve quite strong pain. Is it correct to understand that this is also the case of your Company's products?

Teshirogi: We have not conducted all the tests in human beings, so I think it is a little hubris to tell you at this point how much the dosage will be. We will conduct the Phase I and Phase II with low-volume, medium-volume, and high-volume, so if the volume is around the middle of that, I think the figure of 30 million people I mentioned will not be strange. Currently, we are considering administrating the drug twice with medium-volume.

Although there are too few data on how the formulation of the vaccine is related to the type and occurrence of adverse reactions, it is not possible to say anything. As Novavax are proceeding with recombinant protein vaccines, according to a paper published by Novavax, there is little side-reaction when injecting antibodies alone, however, because neutralized antibodies do not come out much as well. With adjuvants, the side reaction is actually fewer than the RNA, but almost same as virus vector and neutralizing antibodies also come out.

Regarding antibacterial protein, I think there will not be such a major change, although there may be a minor difference, of course, in the production method using vacuoro. The adjuvants they put in are quite unique, so we don't know at the moment what happens in humans in combination with the adjuvants we're trying to use.

Hashiguchi: Understood. Finally, you presented data on influenza, but please tell us its timeline. In addition, it seems that you are looking at the future application for the COVID-19 vaccine. If so, what image do you have at this point in time as to the scale of your business or the development schedule?

Teshirogi: As for the tetravalent influenza vaccine, I am sorry. I will present the details including the timeline at the time of R&D Day. We would like to commence the clinical trial from next fiscal year.

In the meantime, Dr. Hasegawa of the National Institute of Infectious Diseases said on a program of NHK that he could that COVID-19 vaccine can be applied nasally as well. In that case, at least because it is a single virus, Mr. Hasegawa commented that a pentavalent vaccine might not be possible in addition to the tetravalent for flu, and we think that is the case.

Therefore, as we don't yet have all of the data on nasal IgG and IgM for COVID-19, this is a phase in which we accumulate data and show a science potential.

By the way, with coronavirus is becoming the common sense in the world. Looking at the European outbreaks, it is true that the coronavirus is increasing in the winter. Generally speaking, when the humidity is low and the temperature is low, the viruses of respiratory infections become more active and capable of spreading.

In this sense, if we come to an age in which it is considered to be safe to get COVID-19 vaccine like the flu vaccine every year, it would be better for children to be administered thorough nose than injection. We would like to do this by collaborating with global partners.

Hashiguchi: Thank you very much. This is all.

Kyokawa: Mr. Kohtani, please.

Kohtani: I am Kohtani from Nomura Securities. Thank you for your continued support. I have a few questions.

First of all, I heard at the Gilead's conference call someone asked why the BIKTARVY prescription is flat, and the reason is that in this environment, patients will not switch to new drugs.

Your Company's cabotegravir, I think, will be launched for new patients, so it is not a switch. Nevertheless, I think it is quite difficult to launch new drugs in this environment. With regard to that, it may be difficult to talk about this because this is ViiV's medicine, but could you tell us how it is being prepared?

Teshirogi: This is really as you say. It may be self-abusive, but it would have been quite disastrous if CABENUVA's drug for once a month had been launched at the beginning of this year. Nobody would have probably switched to it if we had launched this injectable in situations where the patient cannot meet doctors face to face. While COVID-19 is stabilizing, we should launch a drug. Otherwise, as you say, if patients start by oral treatment, and then do it by injection, first once per month and then twice, we don't have a contact with doctors, then our drugs will not take root.

In fact, as with BIKTARVY, our Dovato is not selling that much. In the market for HIV as a whole, almost no switches are happening.

As new patients have not been actively identified, the number of new patients has not increased so much, so there are only currently prescribed patients. The prescription period is also becoming longer, from two months to four months, for example.

Although CABENUVA launch has not yet been announced by ViiV, we should talk with doctors about the circumstances in which patients are able to use CABENUVA properly. We do not want to mishandle, for example, generating CABENUVA resistance. We are requesting ViiV to launch the product in a well-controlled condition.

Kohtani: Thank you. The second point is about the cefiderocol. This is a question of whether or not you can resolve the contradictory situation in which it is difficult to sell drugs that are needed by humankind so much.

NTAP in the US made three reforms, and as a result you don't need to demonstrate the benefits, you have raised the cost paid to hospital from 50% to 75%, and you have raised the medical fees. Are there any impacts of these changes?

In addition, in UK, you said you started a subscription. Could you tell us its global progress?

Sawada: As for the impact of NTAP, it is difficult. However, even if people were aware that Colistin has clearly kidney toxicity, they have shifted to the cheaper drugs in the past. Now they are shifting a little more toward drugs for AMR. I think this is an impact of NTAP. But I think it is difficult to predict a specific number.

Regarding UK, by the end of this year we had originally planned to finish the selection of drugs subject to the subscription model, which we are trying to do as a trial. However, considering that even Brexit negotiations cannot be completed successfully, I believe that it is quite difficult to end it by the end of the year.

However, I believe that we are in a relatively good position, and we intend to continue negotiations with the Government of UK in the future as well, and we will see how the decision will be made.

Before that, Sweden had started a trial because the number of patients with AMR infection was low and it needs lower budgets. Five drugs were chosen for that purpose, and our cefiderocol was also selected.

In the US as well, Pasteur bill was issued, and there have also been moves in the domestic market to make recommendations. It is difficult to move drastically, but the move is certainly coming up.

I believe that the impact of COVID-19 is in some ways a tailwind, given that EMA Secretary clearly suggests that AMR responses should be included in the agenda.

Kohtani: Understood. The third point is the nasal flu vaccine. As you have said, looking at the data from other companies so far, mRNA vaccine involves severe fiber and pain. So far as I'm looking at Novavax's data, it didn't seem like that.

However, there is a nasal flu vaccine called FluMist. This doesn't have much good data, and the recommendation has been repeatedly withdrawn and coming back. This certainly does not apply to the elderly. In short, it is probably not very immunogenic.

Is there any technology that will work better than FluMist? Although the story is quite different, as FluMist is a live vaccine.

Teshirogi: As I mentioned earlier, it depends on what kind of device will be used, and what kind of equipment will be used to extend the staying time. We think that product profiles can be changed by the combination of what kind of adjuvant to use.

We are working with Mr. Hasegawa of National Institute of Infectious Diseases. He said on an NHK program that they have been working for 20 years and are finally finding a good one. The combination is important.

At the moment the vaccine is put in, it drips off, doesn't stay nasal for a certain time, or the introduction varies depending on the adjuvant. There are very many combinations, but I think we can find it.

We have been hearing from emerging countries that the injection is difficult, or even from various governments. Of course, there are scientific questions. In this COVID-19 pandemic, for example, it is impossible to come to the hospital for muscle injection every two weeks. There is not such an environment, and the medical care system is not in place.

In that sense, we will proceed with vaccines that need to be injected in the future, as there are a lot of such inquiries. This may be a very well-made microneedle patch, for example. We believe that vaccines only for use with muscle injection or subcutaneous injection may change in the next era.

Kohtani: Thank you very much.

Kyokawa: Mr. Ueda, please.

Ueda: I am Ueda of Goldman Sachs Securities. I would first like to ask about COVID-19 treatments.

This time, you are delaying the clinical entry from the initial schedule a little, and I think that you have considered both the efficacy and safety as the factors behind this. First, please tell us how the criteria of efficacy changed. I think that at the R&D Day in March, you mentioned that the first data were favorable than Remdesivir or Avigan. After that, development of Merck products have progressed, so has the criteria of efficacy changed? Alternatively, did you find that the efficacy was inadequate as you made a progress?

Regarding safety, I understand that in the past, there were comments on the use of the drug for a relatively short period of time, and that if the minimum criteria could be cleared, you would emphasize its effectiveness. As it is about the same level as a placebo this time, can you tell us first whether there was any change in your thinking?

Teshirogi: Ms. Sawada will explain the mechanism later. SARS-CoV-2's *in vitro* and *in vivo* evaluation system has evolved globally than it had been since that time. Originally, infections in animal diseases were extremely difficult to establish, and at present, only hamsters seem to be used in Japan.

However, although hamster shows some signs of pneumonia in autopsy, it does not die from flu, for example, with weight loss in two or three days. So, no animal models that truly represent human pneumonia may be established worldwide. This is so difficult to evaluate.

in vitro evaluation system will be completely different, depending on human cells, the conditions and the type of culture medium used, for example. In March, we were able to give the best score in the *in vivo* and *in vitro* evaluation system, which we had accumulated over many years with flu research.

Even with Remdesivir or Favipiravir, we can see where the system works or not. It is certain that since around six months, we feel we may have to rebuild our animal model of, or even the vitro valuation system.

Therefore, if we use the evaluation system at that stage, there will be no change in our compound compared to Remdescivir or Favipiravir.

At that stage, for example, our compound has not shown the efficacy at single nM. It reaches a few 100 nM, and even the highest efficacy, it's as much as 100 nM. Not 0.5 nM just like Xofluza.

If it is oral treatment, the volume will be as much as Avigan. That's the amount you cannot keep drinking, isn't it? I think around 100 mg would be comfortable. When we try to get to such a point, we have to boost the activity, so we are struggling.

Also, as I mentioned earlier, the balance between efficacy and safety is important. While data of Dexamethasone or antibody drugs are accumulated, even limited amount, the compound we want most is what can eventually be taken at home. We have long thought of Xofluza and other drugs, but there will be a great advantage if there is a safe drug to be taken at home. We will proceed with such a drug.

At the time of SARS and MERS, no companies in the world have done so seriously. In the next era, including the variation of COVID-19 viruses themselves, such anti-coronavirus drug will be desirable. So if we do it, we should do our best.

Sawada: As of March, Remdesivir and other drugs were used as a control compound in order to evaluate the efficacy in reducing severity. Nonetheless, given that there are a variety of drugs, including Dexamethasone, the most important thing now is to reduce the amount of viruses when an infectious disease is discovered and to make people live as normal. More than 80 percent have no symptoms. If these people take the drug, naturally it is required to have extremely high levels of safety. I think the greatest change is the change in the risk-benefit balance.

Ueda: Thank you very much. Second, I would like to ask about COVID-19 vaccine. Does it use a new adjuvant? If so, please tell us whether you need time to check safety or other risks.

In addition, considering the impact on earnings forecasts, if you assume that you sell for 30 million people, can you assume, for example, JPY4,000 to JPY5,000 per person, with some reference of the US?

Regarding profitability, you mentioned earlier that operating profit rate is at least 15% for a pharmaceutical Company. Can you tell us about whether or not the business will be so profitable?

Teshirogi: Regarding the adjuvant, I would like to refrain from disclosing at this time. However, we intend to use the products that have been used in clinical use and we have experienced, so in terms of safety, we believe that the hurdles are quite low.

In terms of profitability of our recombinant protein, throughput is slightly lower. We know how much it will yield because we have experience with flu since the time of UMN. I honestly say this. However, it is only a little, not half or a third. The throughput is different among flu strains. It is the lowest throughput among them. Although it is within the range of expectations, but it's difficult to make it.

However, Flublok which is a tetravalent flu vaccine is the same price globally, so in terms of COVID-19, as it is monovalent, we think that this will naturally be able to be supplied at a price for Flublok.

I certainly do not think that profitability at that time will be lower than the numbers I have said. Although it is a public good, we are taking a certain amount of risk, so I think we can achieve a profit level that will allow us to continue our business. In fact, most companies made a factory with JPY110 billion at the time of flu, but since most factories are not in operation, many manufacturers say that they discard JPY1 billion in maintenance alone.

Regarding COVID-19 , we're talking that the situation is different. If profit will not be positive, no one will join the business. Since no technological foundation for such vaccines will be established in Japan, the same situation will happen. Therefore, based on the assumption that we will be able to establish a fairly good business, we have entered the business.

Ueda: Thank you very much. Finally, I would like to ask about Ping An-Shionogi. I think you are planning to grow revenue in FY2022 and beyond. But in the near term, when what kind of milestones are achieved, for example, in the current fiscal year, is it going well? Until FY2022, could you tell us what we should look at as a checkpoint from the outside?

Teshirogi: We have only two months. In that sense, revenue from C&O's generics two months after we put them on Good Doctor line of Ping An will be a starting point for us.

Then, we will immediately begin development of cefiderocol and Naldemedine through the next fiscal year, so how heavy clinical trials we will receive from negotiation with the authorities will be the next major milestone.

When considering COVID-19, we would like to receive an approval for cefiderocol from the government as close as possible to clinical-exemption, as it may be a product that the government should possess. Naturally, we conduct Phase IV or with Chinese patients, but logically, it has been approved in the US and Europe, so we would like to negotiate for the approval in China with clinical exemption.

As for Naldemedine, I heard that there has been little progress in recognizing, but in fact, the amount of opioid used have grown significantly in China. I saw a newspaper article that it would make a second opioid storm as in the US. The number of opioids is such growing in China.

On the other hand, since the side effects of opioid aren't improved in that sense, our data on Naldemedine are very favorable. I believe that how smoothly they will be developed will be a milestone in terms of how well Ping An- Shionogi works.

Ueda: Thank you very much. That is all.

Kyokawa: Mr. Sakai, please.

Sakai: Sakai from Credit Suisse. I would like to ask two questions regarding ViiV and HIV.

I think I asked the same questions last year. I think that the decline of Tivicay and Triumeq has not come to a halt. I think they are very important products for your company. I think that you probably wanted to extend the sales of Triumeq when launched. How are you now communicating with ViiV in that area?

You said that Dovato is not growing than you expected before. But figure was not so small, and if looking at the performance of ViiV alone, if there was not Dovato, the result would have been miserable. Next year, if cabotegravir does not come and sell, I think it will be more problematic. Could you tell us how you are currently thinking about this matter?

As for PrEP, prevention, Gilead is also switching to DESCOVY, because Truvada is going generic. So, I think that the launch of cabotegravir will become very crucial. GSK didn't update anything about that, so there's a question about what's going on. I'd like to take this opportunity to ask you a little.

Teshirogi: I think that we hold Triumeq in the US more than we think. As Mr. Kohtani asked earlier, the switch does not occur, so perhaps they are not making effort so much, but revenue did not decrease, at least during the last six months. At the present time, I believe that it is very beneficial for us.

Regarding Dovato, about half of them were already used for switching, which was originally approved for Naive alone, but this time we received approval for switching, so the noise is rising.

In addition, in fact, they hired MRs for CABENUVA for once a month, so all of them are stuck on Dovato right now, so I think the noise there is rising a certain amount.

But we thought it would grow faster, so that's what I just said before. However, as I said before, when it comes to the US, net sales from Triumeq or Dovato are not so much different for us.

This is because Dovato is a new product, but Triumeq has repeated price hikes for a long time, so it is necessary to subtract the portion from net sales. Dovato and Triumeq do not differ at least in terms of the wholesale value. If Dovato grows, we receive almost the same loyalty as Triumeq.

However, although actually we should replace orders for Biktarvy with Dovato, sales activities are a bit troublesome. We have been strongly saying that they should not be changed from Triumeq. I think that they are keeping it very strictly, particularly in Japan. I think that the trend is growing a little.

As for PrEP, they are expecting so much. Sorry, I don't know what GSK is not saying. Gilead says that Russian special virus will become resistant through injection, or so. However, while we will change PrEP to once every two to three months. This is extremely beneficial compared to having to continue drinking oral drugs every day. So we have a great expectation.

Indeed, we believe that DESCOVY is not free from side effects, and in particular renal or bone is not zero. It is conceptually correct to say that PrEP should be an integrase-centric regimen because, logically speaking, the patient has not suffered HIV yet, and they should not be exposed to the risk of long-term side effects.

So maybe they'll move to capsid. At least, as for PrEP, their resistance hurdle is lower than integrase. They seem to be trying things such as once every six months with capsid, so perhaps they're moving to PrEP, and they're thinking about DESCOVY tentatively, we think.

Sakai: Understood. Thank you very much.

Kyokawa: Mr. Hyogo, please.

Hyogo: I am Hyogo of Mitsubishi UFJ Trust. I have two questions about Ping An-Shionogi.

You plan JPY50 billion in FY2024 from collaboration with on-line medical services. I would like ask you about the likelihood of reaching this figure. How this figure was estimated?

Second, what business value did you find in this business when you decided from a longer term perspective? In short, it may depend on discount rates or so, but on what assumptions do you see the value of this business?

Teshirogi: Regarding the first question, we have answered at the time of the previous public announcement of Ping An-Shionogi. I think you see the number of new products such as 5, 4, and 7. We have considerably refined C&O's ability to assess consistency over the past three years or so. Currently, while talking with Ping An, we estimate from what kind of generics and when they are approved will result in how many prescriptions through Good Doctor. Then, we have considered the sales and profits figures.

As a basis, it is expected that Cefiderocol and Naldemedine will contribute to sales by 2024, and both will be sold for over JPY10 billion in total. We will make three or four new products a year what Good Doctors think are good to increase prescriptions. This is not the figure just in order to expand the sales, but we have a formula to estimate the figures.

As for the second question, Mr. Hyogo, it is very difficult. What I am most committed to is if the way of drug discovery in 2024 in Japan, the US, and Europe can remain as before. At the present time, we have only a research division and research institute in Japan in order to develop new drug discovery and healthcare services by combining personal information and AI. I haves a sense of urgency about whether there is really the next drug discovery in the extension of its combination with academia or venture companies.

So, in terms of the business structure, the risks of doing nothing are very large. We should have different approaches like this for drug discovery and the creation of healthcare products. I think that Japanese and other pharmaceutical companies in the world, like Novartis, which is doing medical systems like CAR-T or making a great commitment to something like a gene therapy, have a very great sense of crisis. Although we do not expect to do gene therapy.

However, if we will not create a model for how to enter the new healthcare system, we cannot ring in 2024. This is the biggest reason why we would like to form an alliance this time.

Hyogo: Thank you very much.

Kyokawa: Well then, we would like to receive your questions from the telephone. Please, then, the operator.

Operator: Mr. Yamaguchi of Citigroup, please.

Yamaguchi: Yamaguchi. I have two, please.

First. You have been talking about deals for second half of the year. What kind is expected?

The second issue concerns the approval or tentative approval of the influenza vaccine domestically. When foreign products have finished Phase III, or entered into Japan, is it possible for your vaccine tantatively approved with only neutralizing antibody data or a small number of subjects in Japan?

Teshirogi: Thank you. Is the second question about the COVID-19 vaccine?

Yamaguchi: That's right.

Teshirogi: As for the second point, it is correct to say that I don't know. However, I do not think that there is no chance that we have to conduct the Phase III separately after receiving a tentative approval, through comparing the size and strengths of neutralizing antibodies with other vaccines that have completed Phase III. But if anything, I think that it is related to safety.

The extent of safety information until about Phase II is crucial. Particularly induration at the injection site, fever, and considerable fulminant gastrointestinal symptoms, are seen by about 70% to 100% for medium-to high-volume vaccines of other companies. Compared with this, Asia in particular has a low mortality rate and a low incidence rate. In this situation, whether people will really immunize a vaccine with a substantial degree of side reaction, or whether they give a tentative approval for our vaccine. We have not talked with PMDA yet, so I hope you understand.

As for deals, I can't naturally say anything. We will secure JPY500 billion for the deals, as I said at the time of "STS." I can say that it is not a range of JPY10 billion or JPY20 billion.

In terms of direction, we are able to demonstrate our greatest strengths in infectious diseases, as well as in pain and CNS-related fields. Therefore, in principle, these are the first screening processes.

Yamaguchi: Thank you very much. This is all.

Operator: Mr. Muraoka from Morgan Stanley MUFG Securities.

Muraoka: Hello. Morgan Stanley, Muraoka. Thank you very much.

As for COVID-19 vaccine, although you cannot tell adjuvant, you said it was already in clinical use. In detail, is it an existing adjuvant on an aluminum basis? After all, is your COVID-19 vaccine a subcutaneous injection? Or, is it a so-called muscular injection as overseas?

One more thing, regarding the patent infringement lawsuit of Biktarvy of Gilead, I think the trial will be in March. I understand that when your company's assertion goes smoothly, if compensation of such as JPY3 billion comes in, this will contribute to your company's revenue through ViiV, for 10% of your share. Is that correct? This is all.

Teshirogi: As Mr. Muraoka understands, regarding the last question. This is not our direct issue, but we receive a dividend through ViiV.

As for the vaccine, I'm sorry, I may have said when answering the question of Mr. Kohtani. There was a talk at the time of SARS that one of the reasons of VDE and ADE can be aluminum adjuvant, so we would like to try different things in principle.

However, since it is the so-called standard, we always include aluminum adjuvants in the experimental system, but we think another thing in our clinical studies.

So far, it seems to be the consensus among people who are making vaccines that muscle injection is better to induce strong immunity, so we start from there.

Muraoka: As it's a muscle injection and involves pain, you try nasal vaccines?

Teshirogi: I don't think we can avoid the pain of intramuscular injection itself. However, data on the inactive vaccine in China, based on published papers, it is said to be painful on the injection site for roughly 30% of subjects. Although there's a large difference between 70% to 80% and about 30%, so we could also see the similar number to our vaccine. We would like to take a cautious look at the level of pain and degree compared with such products.

Muraoka: Understood. This is all. Thank you very much.

Kyokawa: I apologize for the slight extension.

Now, we would like to conclude SHIONOGI & CO., LTD.'s Financial Results Announcement Meeting for H1 of the Year Ending March 31, 2021. Thank you for today.

Teshirogi: Thank you very much.

[END]