SHIONOGI & CO., LTD.

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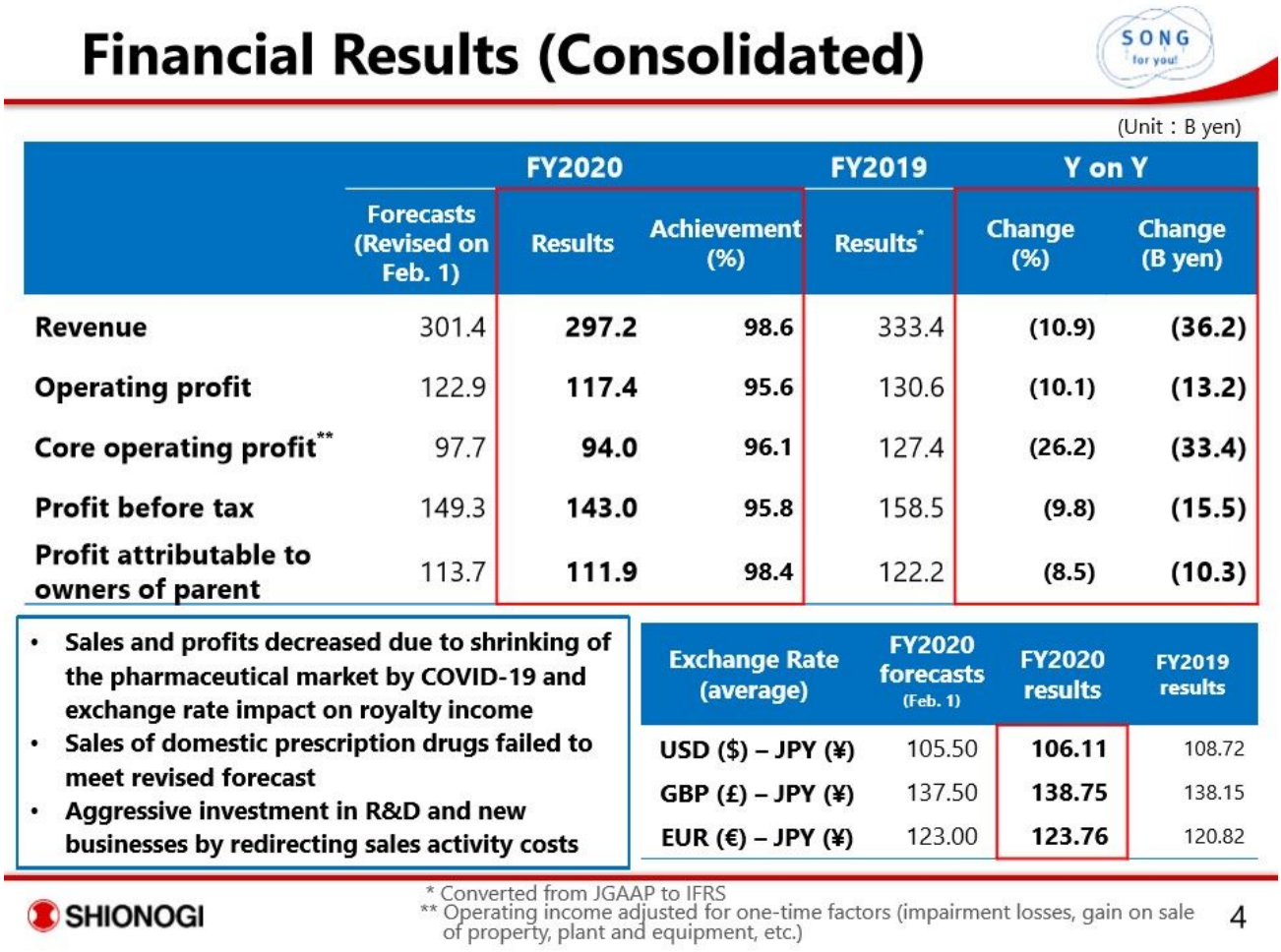
Fiscal 2020 Financial Results Briefing

May 11, 2021

Presentation

Teshirogi: Good morning . Thank you very much for your cooperation.

We announced our financial results yesterday, so I'm sure you've seen most of the figures, but I'd like to run through them a little bit and take some time to explain about our projects.



Financial Results (Consolidated)

(Unit : B yen)

	FY2020			FY2019	Y on Y	
	Forecasts (Revised on Feb. 1)	Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Revenue	301.4	**297.2**	**98.6**	333.4	**(10.9)**	**(36.2)**
Operating profit	122.9	**117.4**	**95.6**	130.6	**(10.1)**	**(13.2)**
Core operating profit**	97.7	**94.0**	**96.1**	127.4	**(26.2)**	**(33.4)**
Profit before tax	149.3	**143.0**	**95.8**	158.5	**(9.8)**	**(15.5)**
Profit attributable to owners of parent	113.7	**111.9**	**98.4**	122.2	**(8.5)**	**(10.3)**

- **Sales and profits decreased due to shrinking of the pharmaceutical market by COVID-19 and exchange rate impact on royalty income**
- **Sales of domestic prescription drugs failed to meet revised forecast**
- **Aggressive investment in R&D and new businesses by redirecting sales activity costs**

Exchange Rate (average)	FY2020 forecasts (Feb. 1)	FY2020 results	FY2019 results
USD ($) – JPY (¥)	105.50	**106.11**	108.72
GBP (£) – JPY (¥)	137.50	**138.75**	138.15
EUR (€) – JPY (¥)	123.00	**123.76**	120.82

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

4

This is page 4.

Operating income was JPY117.4 billion, down 10.1%. Income before income taxes was JPY143 billion, also down 9.8%. Net income was JPY111.9 billion, down 8.5%. These are extremely challenging results, with almost all sales and profits figures declining by around 10%.

The effect of COVID-19 on the drug market has been quite tricky, especially in the area of infectious diseases and influenza. The market was quite sluggish, and we hoped to make up for that in Japan with drugs such as Cymbalta and Intuniv. Although sales of these products increase, they could not cover the difference.

In particular, the number of new patients, especially in the areas of CNS and pain medications, has been lower than our expectation due to reduced new patient clinic appointments.

In addition, since the second half of last fiscal year, we have been aggressively increasing R&D expenses in relation to manufacturers specializing in infectious diseases. This is because we believe that now is not the

time to hesitate in conducting R&D, especially in the field of infectious diseases. This is the cause of the problem.

As for the exchange rate, it is almost exactly as we expected.

Statement of Profit or Loss (Consolidated)

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Forecasts (Revised on Feb. 1)	Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Revenue	301.4	297.2	98.6	333.4	(10.9)	(36.2)
Cost of sales	18.1 54.5	17.7 52.5	96.4	17.0 56.8	(7.5)	(4.3)
Gross profit	246.9	244.7	99.1	276.6	(11.5)	(31.9)
Selling general & administrative expenses	31.3 94.4	32.0 95.1	100.8	29.5 98.4	(3.3)	(3.2)
R&D expenses	17.3 52.0	18.3 54.2	104.3	14.4 47.9	13.1	6.3
Other income	25.5	26.4	103.5	4.3	515.3	22.1
Other expenses	3.1	4.3	137.3	4.0	7.7	0.3
Operating profit	40.8 122.9	39.5 117.4	95.6	39.2 130.6	(10.1)	(13.2)
Core operating profit**	32.4 97.7	31.6 94.0	96.1	38.2 127.4	(26.2)	(33.4)
Finance income	28.3	26.5	93.7	30.5	(13.1)	(4.0)
Finance costs	1.9	0.9	49.4	2.6	(64.0)	(1.7)
Profit before tax	49.5 149.3	48.1 143.0	95.8	47.5 158.5	(9.8)	(15.5)
Profit attributable to owners of parent	113.7	111.9	98.4	122.2	(8.5)	(10.3)

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

This is page 5.

The P&L statement shows a 7.5% decrease in cost of sales against sales revenue, corresponding to JPY4.3 billion. Although we made efforts to reduce costs to a certain extent, due to the large decrease in sales, gross profit decreased by 11.5%. This figure is a little larger than the reduction in sales revenue.

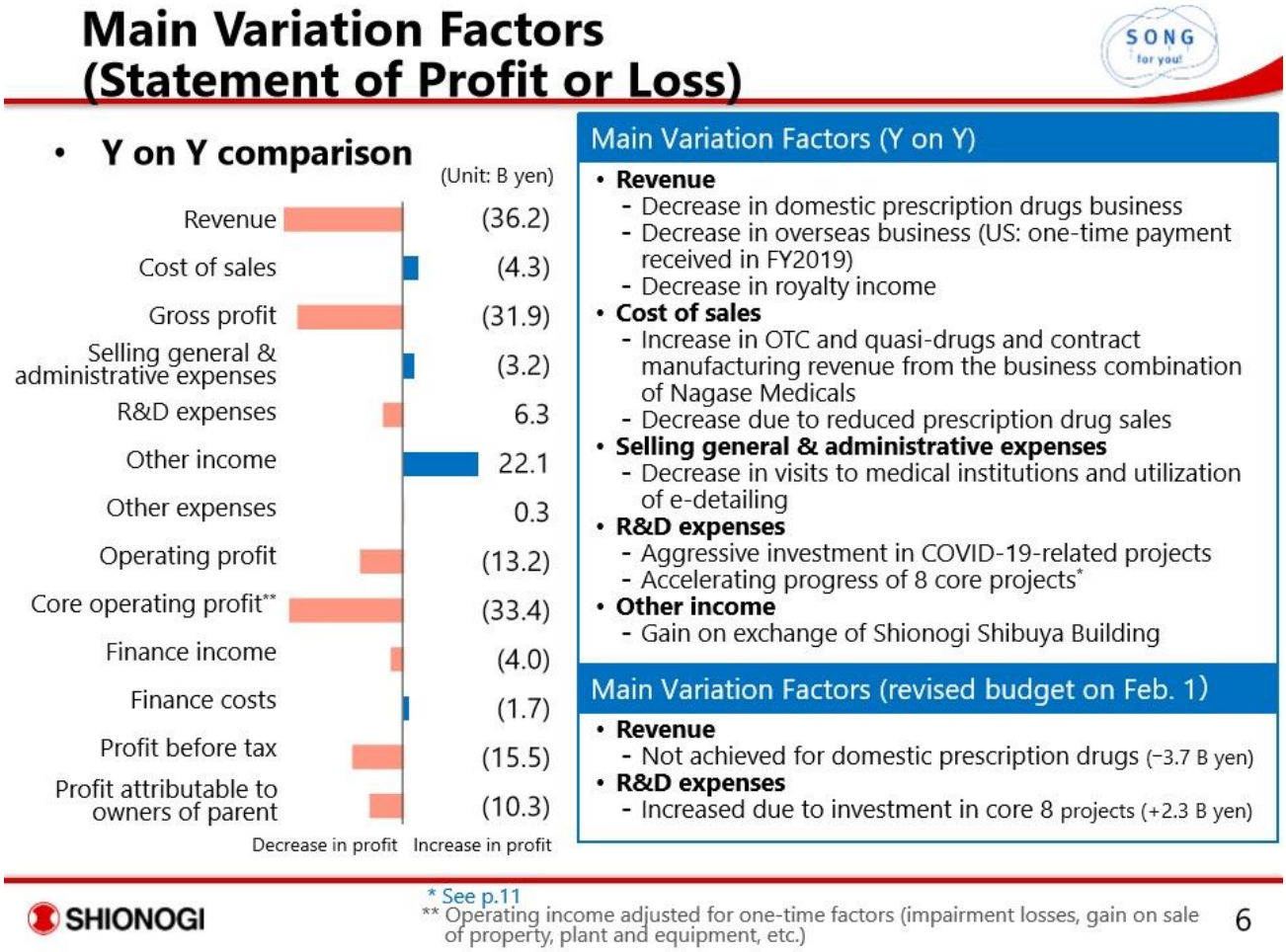
As for selling, general and administrative expenses, although further cutbacks would have been ideal, the savings we made resulted in a reduction of 3.3%. We have been working hard to improve the efficiency of our sales activities and IT, but we believe that further cuts are still possible.

Research and development expenses exceeded the initial plan and increased by more than 13% or JPY6.3 billion compared to the previous year. We invested quite aggressively in research and development related to COVID-19 in particular.

Operating income decreased by 10.1%, but if it were not for the gain on the exchange from redevelopment of Shionogi Shibuya Building, core operating income would have been even more negative.

As for the financial income, we received dividends from ViiV, which was a little less than we had expected, although it is difficult to read the dividends since they change from time to time.

As a result, income before income taxes and minority interests decreased by 9.8% and net income decreased by 8.5%.



Moving on to page 6, I would like to discuss what I have just explained by project.

Regarding the decrease in sales in overseas business, this is due to the out-licensing of Symproic, for which BDSI provided us with approximately JPY3.5 to JPY3.6 billion. We believe that cefiderocol is on the right track.

As for the cost of sales, sales of OTC drugs are increasing. There are also the sales through Nagase Medicals Co. Ltd., the contract manufacturer that we acquired in the middle of the fiscal year. Sales of prescription drugs related to influenza have been almost non-existent. As you know, the cost of the raw materials for Zofluza is very low, so although we have made efforts to reduce costs in this area, we have not made much progress.

In terms of selling, general and administrative expenses, certain investments have been necessary to utilize digital technology, but we have been able to make reductions. I think we could have reduced the figure even more.

As for research and development, as I will explain later, the eight projects that we are focusing on are progressing smoothly.

As for the revised forecast announced on February 1, the company has already increased R&D, and domestic prescription drugs have not achieved the sales revenue forecast. I think we need to be a little more precise in our reading of this area.

Revenue by Segment

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Forecasts (Revised on Feb. 1)	Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Domestic Prescription drugs	98.3	**94.7**	**96.3**	106.3	**(10.9)**	**(11.6)**
Overseas subsidiaries/export	24.5	**24.6**	**100.5**	30.8	**(20.0)**	**(6.2)**
Shionogi Inc.	7.0	**7.5**	**107.0**	10.1	**(26.3)**	**(2.7)**
Fetroja®**	–	**1.7**	–	0.0	–	**1.6**
C&O	10.1	**10.1**	**99.8**	13.1	**(23.3)**	**(3.1)**
Contract manufacturing	19.0	**19.7**	**104.1**	17.6	**12.3**	**2.2**
OTC and quasi-drug	11.9	**11.7**	**98.7**	9.7	**20.7**	**2.0**
Royalty income	146.2	**144.6**	**98.9**	166.9	**(13.3)**	**(22.2)**
HIV franchise	124.3	**123.4**	**99.2**	128.1	**(3.7)**	**(4.7)**
Crestor®	16.9	**16.6**	**98.1**	22.3	**(25.7)**	**(5.7)**
Others	5.0	**4.7**	**94.4**	16.5	**(71.5)**	**(11.8)**
Others	1.5	**1.8**	**114.7**	2.2	**(18.5)**	**(0.4)**
Total	301.4	**297.2**	**98.6**	333.4	**(10.9)**	**(36.2)**

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* Converted from JGAAP to IFRS ** Launched in Feb. 2020 7

Page 7 shows sales by business area.

Fetroja had sales of JPY1.7 billion, which I think it is a relatively solid start.

In terms of C&O, the progress to forecast is 99.8%, which is almost on track. Compared to the previous year, sales of rabeprazole were a little negative. The alliance with Good Doctor will be in full swing this fiscal year, but the C&O period is from January to December. In terms of the previous year.

In the area of contract manufacturing and OTC drugs, as I mentioned earlier, we had some sales due to Nagase, and in OTC drugs, Isodine made a significant contribution, especially in the first half.

In terms of royalties, the HIV franchise has decreased by 3.7%, which is quite a large decrease. As I mentioned on February 1, the Pound's strength against the Dollar has reduced the amount of sales on a GBP basis. GBP/JPY was on-track.

As for Crestor, we have received the cash flow, but under IFRS, only three quarters are accounted for, so it is reduced by one quarter's worth, or JPY5.7 billion.

In the Other category, we received a milestone payment for the approval of Zofluza in the US in the previous year, which was of course absent this fiscal year.

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Forecasts (Revised on Feb. 1)	Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Cymbalta®	27.4	**26.5**	**96.4**	26.2	**0.9**	**0.2**
Intuniv®	14.0	**13.1**	**93.6**	10.6	**22.8**	**2.4**
Vyvanse®**	0.5	**0.3**	**59.7**	0.0	—	**0.3**
Infectious disease drugs	10.6	**9.8**	**91.8**	16.0	**(39.1)**	**(6.3)**
Influenza franchise	0.7	**0.3**	**35.7**	2.4	**(89.1)**	**(2.1)**
OxyContin® franchise	5.5	**5.3**	**96.3**	5.8	**(8.7)**	**(0.5)**
Symproic®	2.3	**2.3**	**98.3**	2.1	**6.8**	**0.1**
Actair®	0.3	**0.3**	**101.7**	0.3	**25.3**	**0.1**
Mulpleta®	0.1	**0.1**	**85.0**	0.1	**(23.4)**	**(0.0)**
Pirespa®	5.2	**5.1**	**97.7**	6.8	**(24.3)**	**(1.6)**
Others	32.3	**32.0**	**98.9**	38.3	**(16.4)**	**(6.3)**
Crestor®	6.9	**6.7**	**97.1**	8.6	**(22.4)**	**(1.9)**
Irbetan® franchise	3.4	**3.3**	**97.7**	4.2	**(21.2)**	**(0.9)**
Prescription drugs	98.3	**94.7**	**96.3**	106.3	**(10.9)**	**(11.6)**

<Products included in infectious disease drugs>

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

SHIONOGI Influenza franchise * Converted from JGAAP to IFRS ** Launched in Dec. 2019 8

This is page 8.

As I mentioned earlier, the sales of Cymbalta and Intuniv have increased YoY, but progress toward the full-year forecast has been less than we anticipated. We are working to remedy this, including in the way we conduct our sales activities.

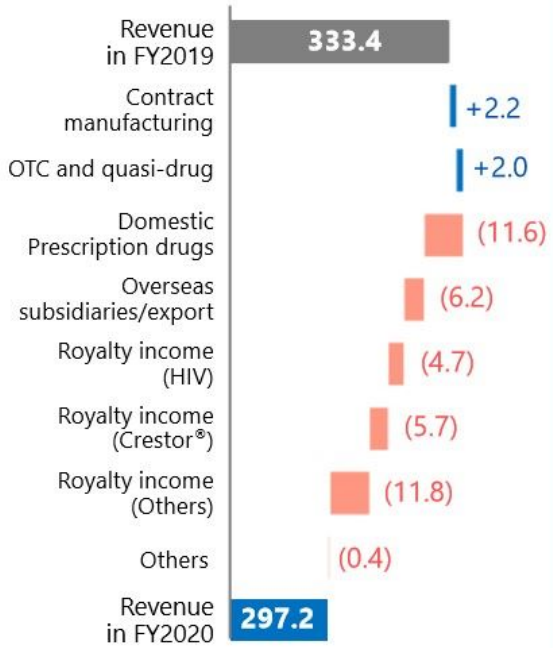
The results for infectious disease drugs, especially influenza medications, were down JPY2 billion from the previous year, and the results for other infectious disease drugs were also extremely weak.

In total, sales of prescription drugs domestically were down JPY11.6 billion.

Main Variation Factors (Revenue by Segment)

- **Y on Y comparison**

(Unit: B yen)



Main Variation Factors (Y on Y)

- **Domestic Prescription drugs**
  - Increase in sales of Intuniv®
  - Decrease in sales of infectious disease drugs and impact of price revision
- **Overseas subsidiaries/export**
  - US: Fetroja® sales more than projected
    : Decrease due to one-time payment received from BDSI* for Symproic® (Received in FY2019)
  - China: Decrease in sales of rabeprazole
- **Contract manufacturing**
  - Increase of contract manufacturing revenue of Nagase Medicals
- **OTC and quasi-drug**
  - Increase of infectious disease-related products and release of RINDERON®
- **Royalty income**
  - Exchange rate impact on royalty income from HIV franchise (£/$)
    > Temporary increase in demand at the start of COVID-19 in 4Q of FY2020
  - Decrease in royalty income of Crestor® from Jan. 2021 based on the contract
  - Decrease due to one-time payment received from Roche for Xofluza® (received in FY2019)

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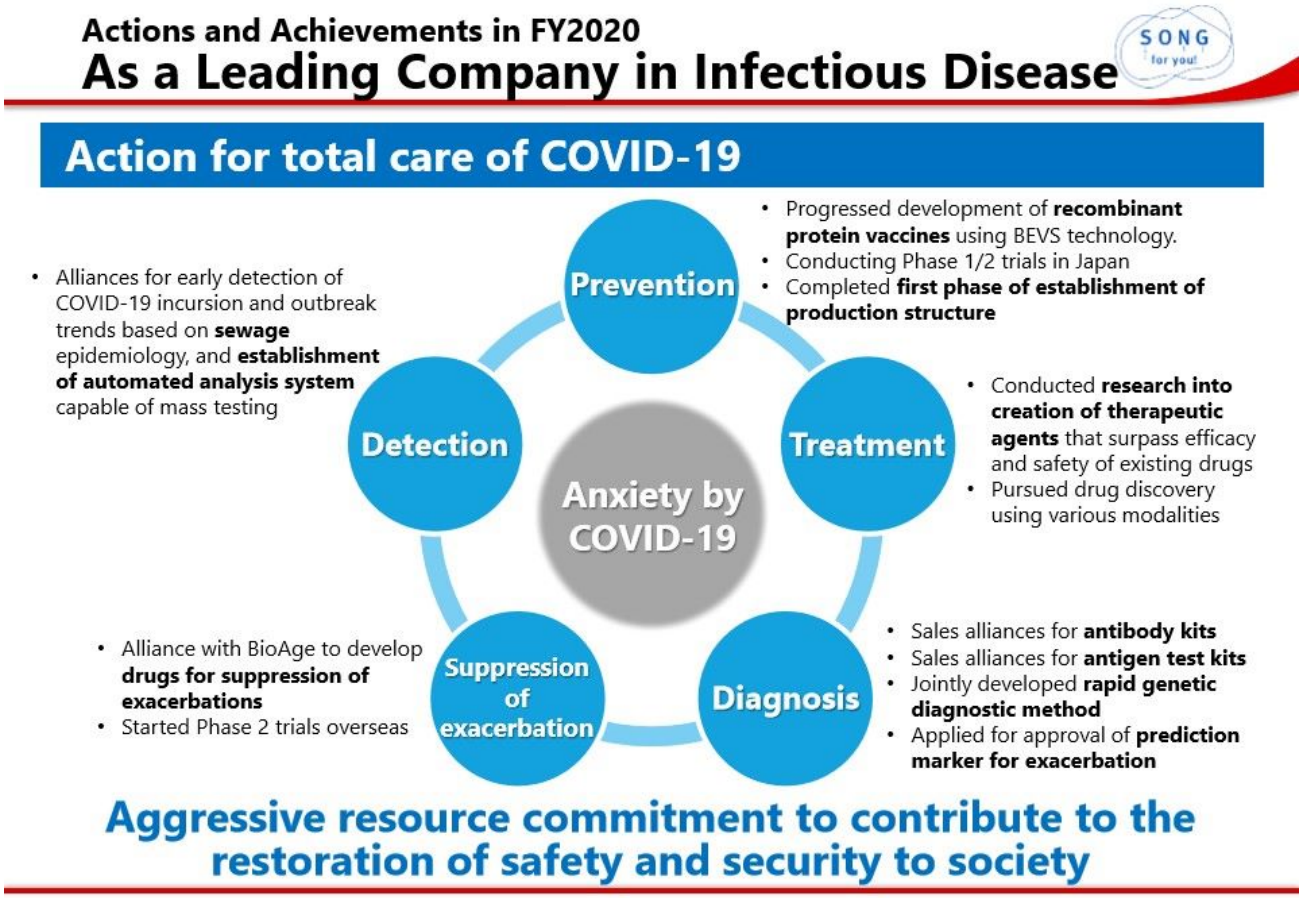
* BioDelivery Sciences International, Inc.

On page 9, you can see the plus and minus figures for the sales revenue.

As I mentioned earlier, contract manufacturing and quasi-drugs showed positive growth, but the negative was very large mainly in domestic prescription drugs, which resulted in a large negative change.



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From at least the second half of fiscal year 2020 onward, we have been battling a virus that has been much tougher than we initially thought.

As a manufacturer of infectious disease medications, we need to make a significant contribution to this area in a comprehensive manner, so we are shifting considerable resources, mainly in R&D, but also in production and CMC. Through this type of activity, we have managed to become a leading company in the field of infectious diseases, and in FY2021, we have been working to contribute in the form of results.

In the lower left corner of the pentagon, starting from detection, prevention, treatment, diagnosis, and suppression of exacerbation, these five areas are the core of the Healthcare as a Service HaaS value chain that we have introduced in our new mid-term management plan. We aim to join these parts. We are using infectious diseases as a model for this.

Testing of wastewater is one area that we think could be applied in Japan, as has been done in the Netherlands and many other countries. This is something that Ms. Sawada will be able to take questions on. We are hoping to contribute to the early detection of COVID-19, especially of mutant strains. We are thinking of using this technology to detect influenza, norovirus, rotavirus, and other viruses, as well as antimicrobial-resistant bacteria. Our goal is to prevent further pandemics in the future.

It may seem like a small detail, but I think that this wastewater testing system could be a very useful tool. Just like other society-wide measures, there are no issues relating to personal information.

As for prevention, we are investing a lot in the area of vaccines, which I will explain later.

At the end of last year, in November, we decided that for the compounds we expected to be most effective in treating coronavirus, the extension of the current structure was not sufficient to separate the toxicity of the compounds. As a result, we stopped those particular projects. In order to develop a separate drug for coronavirus, we are working on small molecules, peptides, and antibodies of varying sizes, all of which are being developed in-house.

However, the more I looked, the more I realized that about 80% of patients were asymptomatic or had very mild disease. In addition, since these people are asymptomatic, they inevitably contribute to the spread of the disease, so we need to separate those with positive results by antigen and PCR tests at home or in hotels, et cetera, while they are still mildly ill, so that they can take antiviral drugs at home with peace of mind. If the PCR is negative, the patient can go back to his or her life. I believe that such needs are very high.

I am not saying that antibody drugs and proteins as injectable drugs are not useful, but in a situation like Japan where there is pressure on the healthcare system, there is a strong need for drugs that can be used outside of hospitals. This is why we have focused on oral drugs.

Therefore, we are planning to invest more resources in this fiscal year, as we have managed to produce a low-molecular-weight oral drug that has some potential.

In the area of diagnosis, we have invested a lot of resources in SATIC, but it is difficult to achieve reproducibility and there are issues surrounding mass production, so the Lumira antigen kit seems to be the option to answer peoples' needs at present. We believe that this is the antigen kit with the best quantitative performance, so we decided to go with it first.

A point I am very much looking forward to is TARC. In particular, if we can predict in the mild or asymptomatic stage whether a patient is more likely to become seriously ill or less likely to become seriously ill, the algorithm for patients in hospitals will become more accurate. Doctors of the NCGM have done a very good job with the research, and we have very high expectations for their work.

However, at this point in time, we have a very large workload in terms of vaccines, therapeutic drugs, and antivirals. Therefore, we have teamed up with BioAge to work on reducing the severity of the illness.

Actions and Achievements in FY2020
Promotion of R&D : Core 8 Projects

	Pipeline	Indication	Initial target for FY2020	Status
Infectious disease	**S-540956**	HIV infection, cancer	Initiation of Phase 1 study in 4Q FY2020	Changed to 1Q FY2021
Psycho-neurological diseases	**S-600918**	①Refractory chronic cough ②sleep apnea syndrome	①Phase 2b topline results are anticipated in 1Q FY2021 ②Phase 2a topline results (Japan) are anticipated in 1Q FY2021	①②On schedule
	S-637880	Neuropathic low back pain	Phase 2a topline results (Japan) are anticipated in 1Q FY2022	On schedule
	zuranolone [S-812217]	Depression	Phase 2 topline results (Japan) are anticipated in 3Q FY2021	**Topline results are anticipated in 2Q FY2021 (3M ahead of schedule)**
	BPN14770	①Alzheimer's disease ②Fragile X Syndrome	①Initiation of Phase 2 study (Japan) in 2Q FY2021 ②Initiation of Phase 3 study in FY2Q 2021	**①Phase 2 study started in 1Q FY2021 (3M ahead of schedule)** ②On schedule
	S-874713	Psycho-neurological diseases	Initiation of Phase I study in 4Q FY2020	Changed to 2Q FY2021
New growth areas	**S-531011**	Solid tumor	Initiation of Phase I study in 2Q FY2021	On schedule
	redasemtide [S-005151]	①Epidermolysis bullosa ②Acute stroke ③Osteoarthritis ④Chronic liver disease	①Preparing for application ②Phase 2 topline results (Japan) are anticipated in 3Q FY2021 ③④Phase 2 in progress (Japan) (Investigator initiated clinical trial)	①On schedule ②③④On schedule

Steady progress along with COVID-19-related projects, with some plans ahead of schedule*

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* See Appendix p.34-40

This is page 11.

This is a list of all the non corona-related items to provide an overall update. At this point, we are making good progress with the major compounds.

We will update the results as soon as we can, but certainly in July, at the R&D Day. Our development team is doing a good job in the development of COVID compounds and other compounds as well.

Actions and Achievements in FY2020

Progress in Overseas Business

US and Europe: Maximized value of cefiderocol

- **Promote both antimicrobial stewardship and infectious disease business growth**
  - US: Additional indication approval and designation for NTAP*
  - Europe: Sales growth in 5 countries (UK, Sweden, Germany, France, and Austria)
    - > Adopted for subscription-type reimbursement model in the UK of up to £10 million per year per product (payment contracts to begin in April 2022)
    - > Started supply as a delinked incentive model with guaranteed minimum payment in Sweden.

China: Ping An-Shionogi's business transformation

- **Completed establishment of Ping An-Shionogi** (Hong Kong: Aug.2020, Shanghai: Nov.2020)
  - Pharmaceutical sales: Started to supply products via Ping An Group's online treatment platform
  - New drug development: Advanced preparations for early approval of cefiderocol and naldemedine

Steady progress in Western and Chinese businesses

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*NTAP was designed to encourage the utilization of new medical technologies in the hospital inpatient setting for Medicare patients

This is page 12.

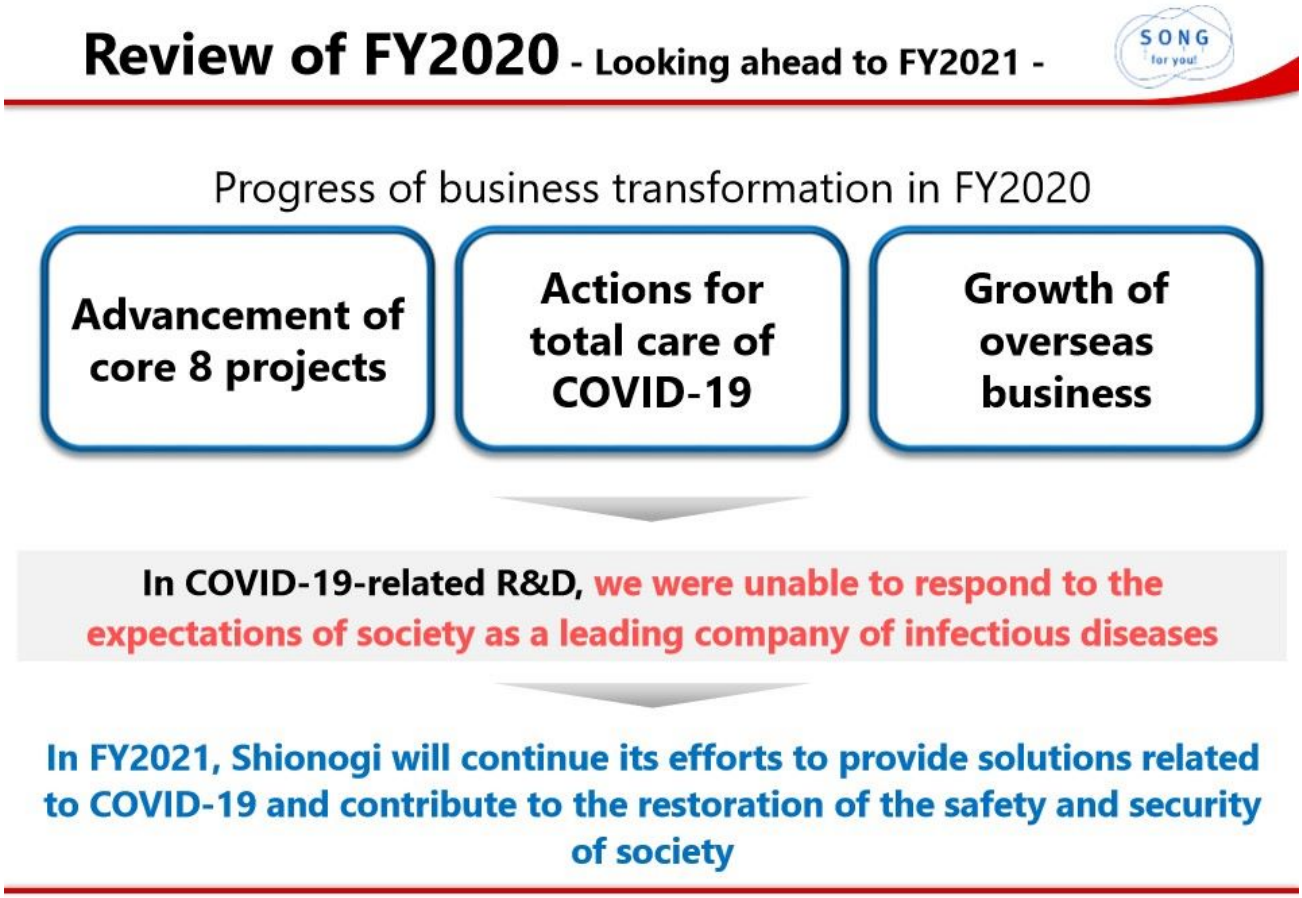
In particular, cefiderocol has been strong in Europe and the US, and this will be a key factor from FY2021 onward. However, it is important for us to fulfill our responsibility as a company in terms of stewardship, to prevent misuse. As a result, we will continue to promote the subscription model and stockpiling as much as possible, while at the same time, we will operate our plants properly and raise the utilization rate to a certain level.

In China, the new company has been in operation since around February, when it was officially established. The team members moved to Shanghai in December to start working.

Via Good Doctor, we intend to continue the C&O generic business. In addition, we have included Shionogi Healthcare as a group company under the umbrella of the Heian Shionogi Group, and we have started selling OTC drugs in China via that route.

In terms of new drugs, we would like to take the route of clinical exemption, if possible, for cefiderocol and naldemedine, which have been approved in the US and Europe. For naldemedine, in particular, even if we don't get 100% clinical exemption, we would like to conduct a small clinical trial to bring it to market as soon as possible.

With the flow of these two products, Heian Shionogi's business will shift from generics to new drugs. We believe that this is just the start.



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In that sense, the company really wants to deliver COVID treatments to patients as soon as possible. It has been unfortunate that we have not been able to provide vaccines or other treatments in this area in FY2020.

In FY2021, we will continue to focus on achieving results in the research and development of therapies and vaccines that will contribute as soon as possible, as this disease is expanding considerably on a global scale.

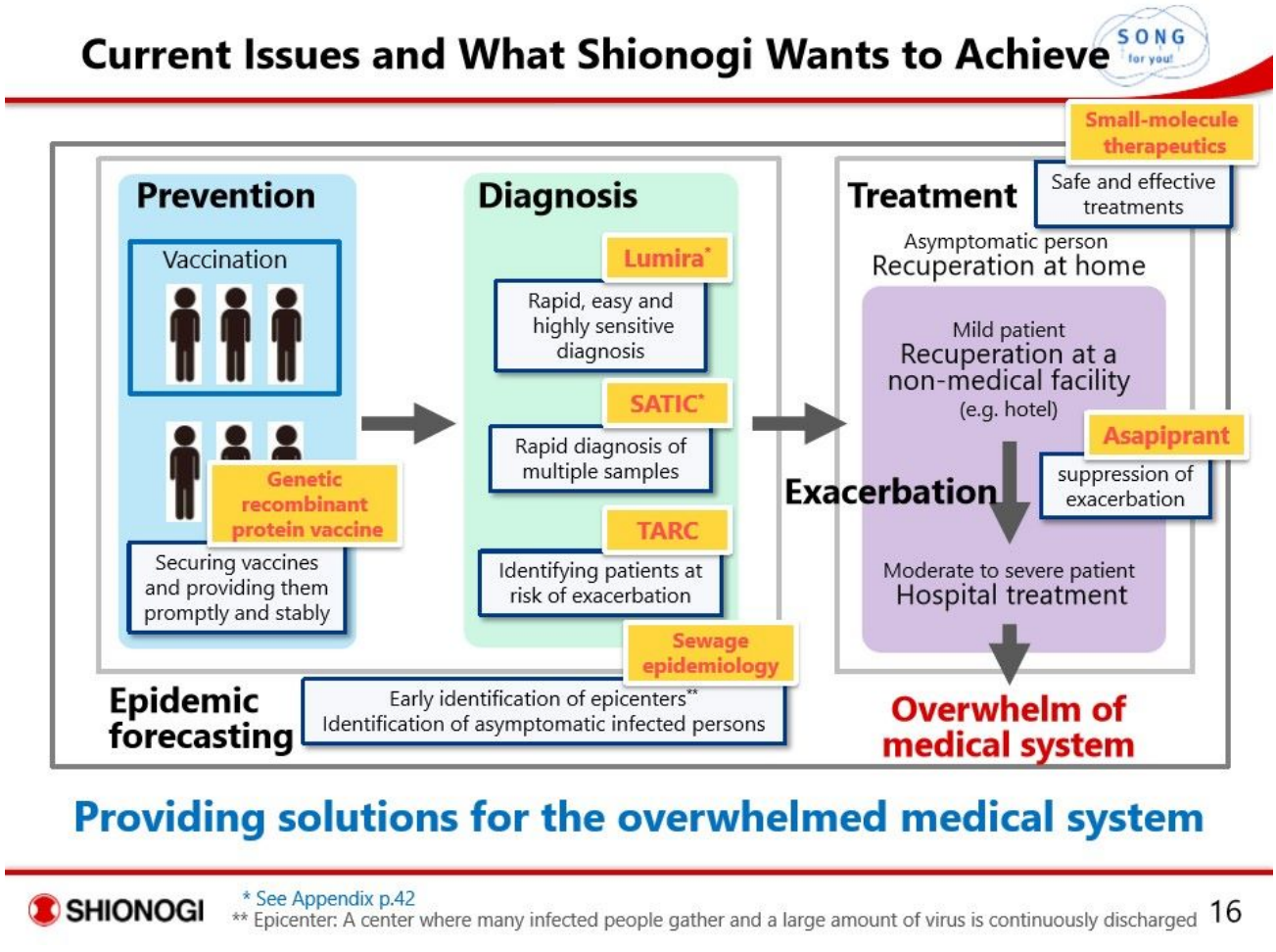
Shionogi's Commitment in FY2021

As a leading company in the infectious disease field

Shionogi will work intensively to counter the COVID-19 pandemic as our highest priority

This is page 15, the FY2021 forecast.

We have already invested more than 50% of our company's R&D allotment in COVID-19, so we will continue to focus on producing results.



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The yellow areas are our focus points. I would like to cover all aspects of epidemic forecasting and wastewater epidemiology, from the entry point to the exit point.

In terms of human, financial, and material resources, vaccines and small molecule therapeutics are particularly important for our company. In terms of expected value, I think that wastewater epidemiology, TARC, and LUMIRA or SATIC as diagnostic agents are absolutely necessary in the value chain, so we would like to proceed with these.

As for the prevention of severe disease, the results of Phase II of the BioAge trial will come out this year.

Business Environment Surrounding Shionogi
(COVID-19 related)

As society's need for an early end to the pandemic grows ever greater, the business environment is changing at an unprecedented speed

Vaccines
Hopes for a purely domestic vaccine
⇒ Expectations for domestic vaccines due to prolonged COVID-19 and widespread epidemic of mutant virus
⇒ Active discussions on reviewing the existing approval system in case of emergency response (EUA*-like system, etc.)

Therapeutic drugs
Hopes for new drugs that can end the pandemic
⇒ Signs of changes in current treatment indicators (symptom improvement ⇒ viral load reduction, etc.)
⇒ Possibility of using a conditional early approval system, etc.

Diagnosis
Diagnostic methods to reduce pressure on the medical system
⇒ Increasing need for diagnostics that allow patient triage, such as exacerbation markers
⇒ Expand to simultaneous diagnosis of flu and COVID-19

Epidemic detection and forecasting
Balancing infection control and economic activity
⇒ Increased focus on efforts to implement sewage epidemiology

* EUA: Emergency Use Authorization

On page 17, we have a list of all the things I mentioned earlier.

We are working hard to generate results via vaccines and therapeutic drugs.

Development and Stable Supply of Domestic Vaccines

Actions for the introduction of purely domestic vaccines

Development / production status

- **Conducting Ph1/2 trials in Japan**
  - Confirmed no major safety concerns
  - Preparing for Ph3 trials to start by end of year.
- **Production structure established**
  - Moving to second phase of construction to increase production

Vaccine production facility newly established at UNIGEN

Key factors influencing launch date

- Difficulty in conducting large-scale clinical trials worldwide

- Started discussion on **alternative methods to evaluate efficacy and safety**
- Increasing debate about **the flexible operation of the current approval system**

Continue to build evidence, increase production, and discuss with regulators and ministries to allow availability later in CY2021

This is page 18.

In terms of vaccines, we are now in Phase I and II, and we are preparing for Phase III, designing protocols, and discussing with CROs. In fact, there is a great global demand to move as soon as possible.

We have a telephone service for the general public, and normally, we would be answering questions and answers about our products, but so far, almost all of our calls, more than 99%, have been about our vaccines, which means that the world has high expectations of us.

The good news at least at this point is that there are no major safety concerns, and the production system is progressing extremely well. If approved, we will be able to produce it in units of 30 or 50 million.

Regarding effectiveness, today Takeda's Moderna Vaccine results in Japan are available, and it seems neutralizing antibodies were increased in all cases. However, we do not know the degree to which neutralizing antibodies were raised, how cellular immunity was affected, or how the memory B cells were affected.

We also have not been able to see much of Pfizer's products, which are in an advanced stage of development, and we have not been able to see other parameters other than large-scale clinical trials. I think we need to consider the trilogy of neutralizing antibodies, cellular immunity, and above all, safety, in order to meet the needs of the people in this country.

We have not cleared all the regulatory hurdles yet, but we are making preparations so that we can start offering the service by the end of this year.

Development of Therapeutic Drugs with Superior Efficacy and Safety

Drug discovery power for antiviral drugs + modalities

- **Changes in external environment surrounding COVID-19 drug development**
  - While the development of therapeutic drugs is progressing using various modalities, the number of discontinuations / EUA cancellations is also increasing
    > Antibody drugs, plasma fractionated drugs, etc.
  - The emergence of "a truly effective and safe drug" is still awaited
- **Shionogi's action**
  - Conducting drug discovery at top speed using various modalities
    > Selecting promising compounds from multiple approaches
  - **With a view to addressing mutant virus, promising oral compounds from small molecule drug discovery were selected**

A "therapeutic drug" is essential to ending the pandemic
Start clinical trials during the first half

This is page 19.

As I mentioned earlier, there are so-called antibody drugs, which is an injectable drug, it requires some level of contact with a hospital, and if we look at Lilly's example, the new virus mutations have large changes in the receptor-binding domain of the spike protein, so there remains the question of what kind of antibody should be designed.

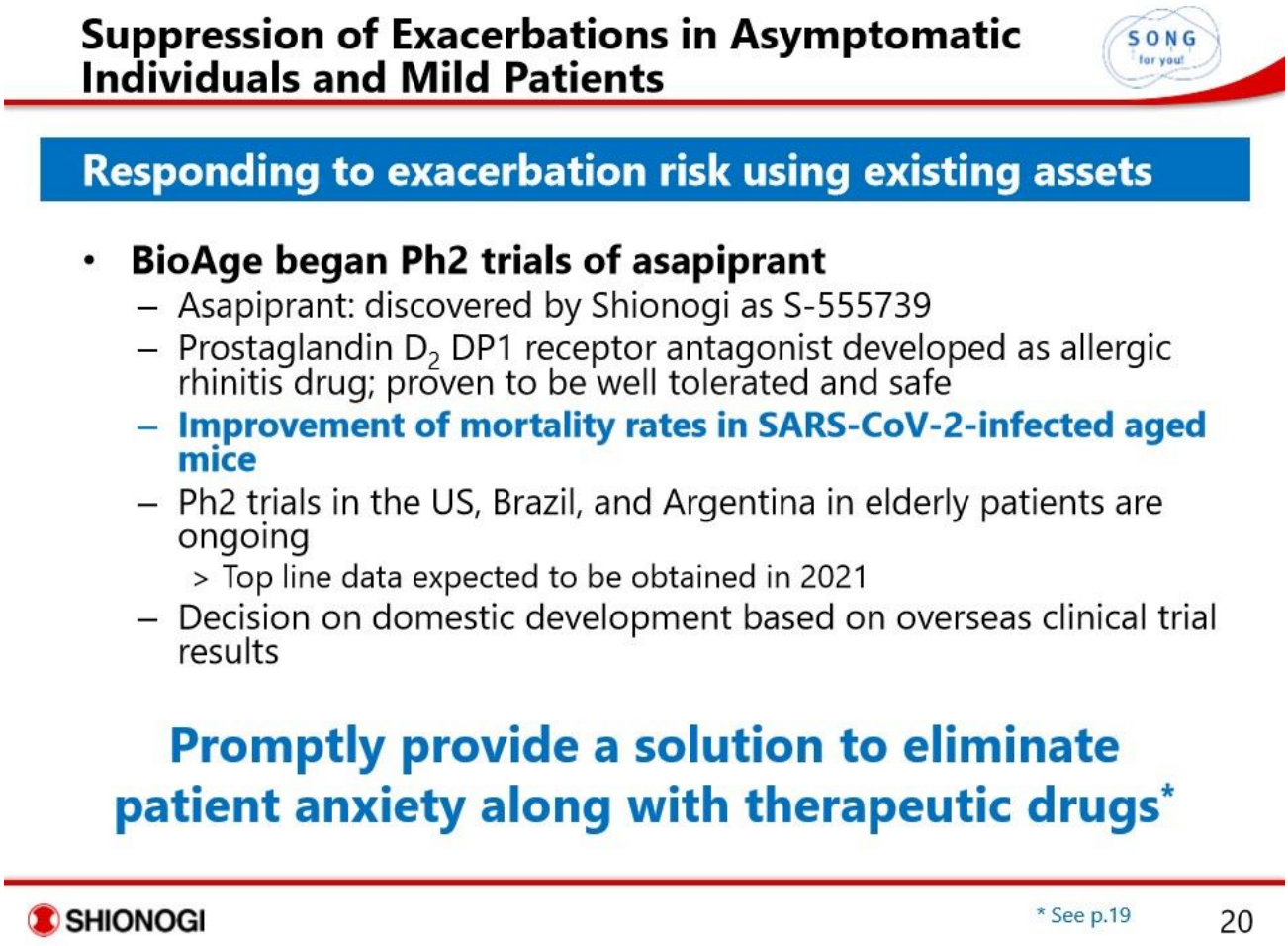
In addition, there are many things to consider, such as what kind of area to target, whether S1 or S2 is better, and we are working on that in our company.

For example, Merck's polymerase and Pfizer's protease are orally available, and they are effective against intracellular enzymes and have antiviral effects that are not related to the receptor binding domain as the outer body. In addition, it is an oral drug that can be taken at home or in a hotel, which I think is very important.

Today, there was a news report of a case where the infection has re-emerged despite two doses of vaccine. It is said that 70,000 or 80,000 people in the UK who have had two doses of vaccination have been infected.

Since it is a vaccine, the level of immunity after two doses of vaccination differs from individual to individual, and since it does not 100% prevent infection, we need an oral drug that can be taken safely in addition. On top of that, we need to build up strong immunity over a long period of time, over several years, by using vaccines, so that people are less likely to be infected, less likely to develop the disease, and less likely to become seriously ill. I think this is important.

In that sense, if we could quickly have two oral drugs such as Zofluza and Tamiflu, preferably with different mechanisms, the world would be extremely relieved.



This is page 20.

As for S-555739, it has shown very good results in animal models, and as you can see in the fourth and fifth lines, BioAge is currently conducting Phase II trials in the United States, Brazil, and Argentina, targeting elderly people. We will do our best to support them and look forward to the results.

Identify Patients at Risk of Exacerbation

Diagnostic markers that can predict exacerbation

- **HISCL® TARC* reagent**
  - It is difficult to ascertain patients who have the risk of exacerbation in the early stages of COVID-19, and **the risk of healthcare system collapse due to increased patient hospitalization and isolation is a concern for society**
    - > Measurement of serum TARC levels in COVID-19-positive patients **enables focus on patients who are at risk of exacerbation, thus optimizing use of medical resources**
    - > Highly specific markers that can be assessed even in patients with underlying disease

Filed application for approval for additional indication for use in prediction of risk of exacerbation (April 16, 2021)

Contributing to reduce the risk of collapse/overwhelming of medical system

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* TARC (thymus and activation-regulated chemokine)
One of the chemokines driving migration of Th2 cells, a type of lymphocyte, to the site of inflammation

This is page 21.

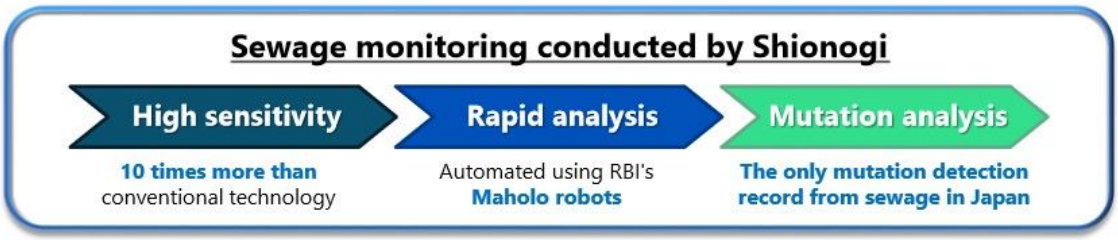
With regard to the HISCL TARC that I mentioned earlier, we have heard that it is very difficult for hospitals or medical facilities to create flow charts and algorithms for patients by predicting which patients are likely to have the risk of exacerbation.

We filed application for approval for additional indication for use to assist in predicting the exacerbation for HISCL TARC, which is the product that we originally sold. NCGM also says that they have high expectations. We believe that we will be able to cope with the situation, including a system to increase production, and We have very high expectations for this.

Early Prediction of Pandemic

Establishment of analysis system for SARS-CoV-2 in sewage

- Periodic monitoring of SARS-CoV-2 accumulation in sewage treatment plants and facility sewage makes it possible to obtain epidemiological information at the population level
- Collaboration with Hokkaido University, RBI*, and iLAC **to facilitate assessment of how COVID-19 is spreading and when an outbreak starts and will end, as well as early detection of trends in the proliferation and emergence of mutant virus**
- Started monitoring viral loads and genetic analysis in Osaka Prefecture since April
- **Service set to be launched in mid-June**



Expected to contribute to both infection control and resumption of economic activities

* Robotic Biology Institute Inc

On page 22, regarding the establishment of an analysis system for SARS-CoV-2 in sewage, we have made considerable progress in the past three months. The service will be available in June, and several manufacturers are thinking about providing similar service.

It's a new concept, and I think it would be confusing to have several manufacturers standing around saying different things. In this area, we are now actively working with other companies that have various capabilities in order to think about the best way to provide services in a nationwide manner, while having various dialogues with them.

To Avoid Continual Social Anxiety Caused by Infectious Diseases

Strengthen preparations for the next pandemic

- Accurate prediction of pandemics is difficult (COVID-19, flu, etc.)
- While the spread of COVID-19 has certainly raised public awareness of infectious diseases, crisis management for the next pandemic remains insufficient

Infectious disease control is an important issue closely related to national security

- Industry, government, and academia can work together to strengthen preparedness
- A framework is needed to prepare for emergencies arising from infectious diseases

Preparation of Shionogi	• Strengthening our actions in the infectious disease field as a core therapeutic area, and developing a business that offers total care • Policy recommendations and contributions to global health through industry activities • **Stable operation of infectious disease business**

This is page 23.

Our goal for FY2021 is for us to begin to establish, in dialogue with society, whether or not we can really continue to operate infectious diseases business in the current way.

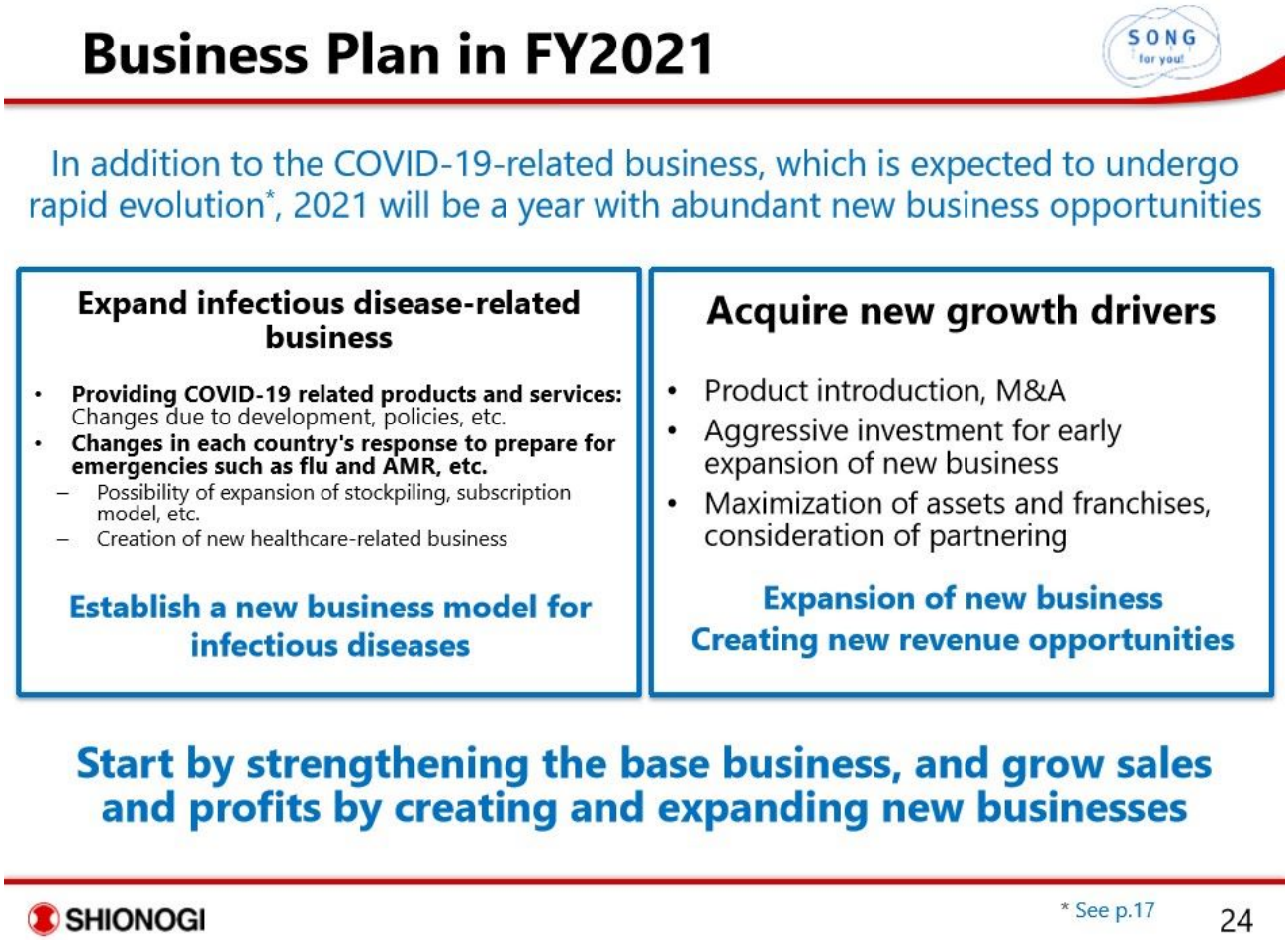
We believe that Xofluza is a really good drug, but if there is no influenza pandemic, we are looking at two consecutive years without sales. This makes the P&L very bumpy. This is the reason why companies all over the world are stepping back from infectious diseases business, as we have experienced firsthand.

On the other hand, we are working on infectious diseases business in the event of a pandemic and have a library of information about various viruses, for example influenza, and similar things for bacteria too, such as staphylococcus and pseudomonas aeruginosa.

If we do not continue to work on infectious diseases business, we will not be able to maintain this kind of library, and if we stop, it will be a big negative for the country. On the other hand, the fact that our business is so bumpy makes it very difficult for us and our shareholders, so in order to continue our business, whether it is vaccines or therapeutic drugs, we need to establish a new business model that will allow us to continue in this area.

All of you have experienced the extent to which societies can be destroyed when infectious diseases flare up into a pandemic. It is not only the Japanese government, but also the governments of other countries that will need to consider their stockpiles, and how to make international contributions in the form of ODA, and we have to research, develop, and continuously produce medicines for infectious diseases. We would like to establish a business model that will allow us to continue to do this by the end of this fiscal year.

If this is not acceptable to the governments and societies of each country, then we need to think about redirecting our capabilities to other therapeutic areas. As my personal responsibility, I think that thinking about and evolving this model is a very important theme for this fiscal year.



This is page 24.

In this context, I was wondering if there was any way that the vaccine could be delivered to the government, hopefully by the end of this fiscal year. As for the therapeutic drug, Pfizer started Phase II on March 23, and they said that they hope to achieve EUA-like status in September or October. Therefore, depending on the speed of the clinical trials that we start now, we may be able to deliver the product by the end of the fiscal year.

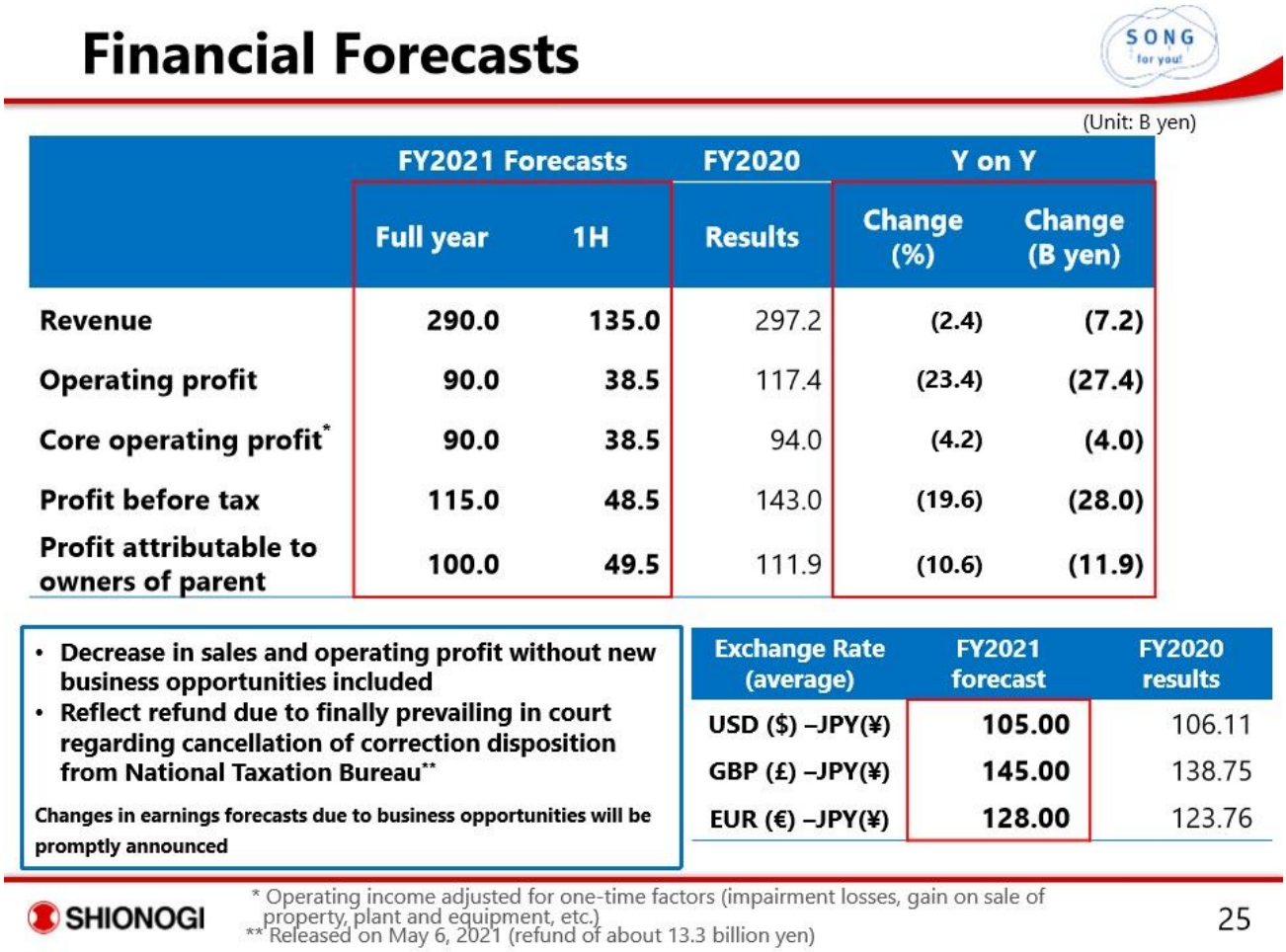
Our stockpile of Rapiacta was originally included in the stockpile schedule, so it is included in our business plan. As for Xofluza, this year is not the year to think about a new stockpile, so the government decided not to consider it this year, but we asked the government if that was really okay.

From next year onward, when influenza, especially H5 and H7, for which the existing neuraminidase is not effective, comes out, we will not be able to produce it so easily even if we are asked to do so by the US and Japan. We told the government that effect, and they were convinced. Xofluza's five-year stability data is now available, and the government will consider stockpiling with this in mind. However we don't really know how much it will move, it is very difficult to know at what level to include it in the forecast.

In addition, as you can see in the box on the right, research and development other than COVID-19 is also progressing steadily. For example, in oncology and other fields where we do not have such strong expertise, we need to think about Maximization of assets and franchises, consideration of partnering.

In the beginning, it was difficult to disclose this information, but as we talked with the Board of Directors, especially with outside directors, we decided that it would be a good idea to give a minimum budget for the company and explain the positive factors that will come out of the project to some extent.

The business forecast that I am about to explain is really a base business, and we will start from here and see how much we can add from here in the context of COVID-19 or new growth drivers. If there are any changes, we will report them to you, and while we are aiming to increase sales and profits as a company, we have based our financial forecasts on the reality of what we can see now.



Financial Forecasts

(Unit: B yen)

	FY2021 Forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	**290.0**	**135.0**	297.2	**(2.4)**	**(7.2)**
Operating profit	**90.0**	**38.5**	117.4	**(23.4)**	**(27.4)**
Core operating profit*	**90.0**	**38.5**	94.0	**(4.2)**	**(4.0)**
Profit before tax	**115.0**	**48.5**	143.0	**(19.6)**	**(28.0)**
Profit attributable to owners of parent	**100.0**	**49.5**	111.9	**(10.6)**	**(11.9)**

- **Decrease in sales and operating profit without new business opportunities included**
- **Reflect refund due to finally prevailing in court regarding cancellation of correction disposition from National Taxation Bureau****

Changes in earnings forecasts due to business opportunities will be promptly announced

Exchange Rate (average)	FY2021 forecast	FY2020 results
USD ($) –JPY(¥)	**105.00**	106.11
GBP (£) –JPY(¥)	**145.00**	138.75
EUR (€) –JPY(¥)	**128.00**	123.76

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* Operating income adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)
** Released on May 6, 2021 (refund of about 13.3 billion yen)

25

This is page 25.

So, the full-year forecast for FY2021: revenue of JPY290 billion, down 2.4%; operating profit and core operating profit of JPY90 billion, down 23% and 4%, respectively; and profit before tax of JPY115 billion, down 19.6%. Profit attributable to owners of parent is JPY100 billion, a 10% decrease, which is a little smaller than profit before tax. This reflects the fact that over JPY13 billion will be returned due to the winning case for the Complaint for the Rescission of Tax Reassessment by the National Regional Taxation Bureau, as stated at the bottom of the box.

As for the exchange rate, I am not sure why the Pound is so high at the moment, but I think it will be around JPY150, and I would like to see it at around JPY145.

Statement of Profit or Loss Forecast

(Unit: B yen)

	FY2021 forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	290.0	135.0	297.2	(2.4)	(7.2)
Cost of sales	19.8 57.5	18.5 25.0	17.7 52.5	9.5	5.0
Gross profit	232.5	110.0	244.7	(5.0)	(12.2)
Selling general & administrative expenses	30.7 89.0	32.6 44.0	32.0 95.1	(6.4)	(6.1)
R&D expenses	17.9 52.0	18.5 25.0	18.3 54.2	(4.1)	(2.2)
Other income & expenses	(1.5)	(2.5)	22.1	–	(23.6)
Operating profit	31.0 90.0	28.5 38.5	39.5 117.4	(23.4)	(27.4)
Core operating profit*	31.0 90.0	28.5 38.5	31.6 94.0	(4.2)	(4.0)
Finance income & costs	25.0	10.0	25.6	(2.3)	(0.6)
Profit before tax	39.7 115.0	35.9 48.5	48.1 143.0	(19.6)	(28.0)
Profit attributable to owners of parent	100.0	49.5	111.9	(10.6)	(11.9)

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

Page 26, P&L.

The cost of sales is a little higher. To be straightforward, this business plan includes the fact that Cymbalta in Japan will probably lose a considerable amount of sales by the launch of generic drugs.

Cymbalta is a very low cost product, so this will be eliminated. In addition to that, the increase in sales in China, the increase in OTC sales, and the increase in sales from contract manufacturing, which includes Nagase, are also included in the additional sales. We will make efforts from here.

Selling general and administrative expenses are JPY89 billion, compared to JPY95 billion for this year. You may think that this is a small amount, but after taking a very detailed look at domestic and overseas business, we think we can achieve this level. Of course, we are considering how much we can achieve after working out the cost items in great detail at strategy meetings, et cetera, but I think we can manage to land on this level.

We would like to start with research and development costs of JPY52 billion. As I mentioned earlier, depending on COVID-19 or other growth drivers, we will not hesitate to increase R&D expenditures, but we are currently going to proceed from here.

In other income and expenses, the gain on the exchange of Shibuya Building will be eliminated.

Therefore, operating profit is JPY90 billion, but core operating profit is also JPY90 billion due to the absence of the gain on the exchange of Shibuya Building. We would like to manage to increase this core operating profit, and we would like to take advantage of the business opportunities as I explained on page 24.

Regarding financial income, dividends from ViiV are almost the same as the previous year. Profit before tax is expected to be JPY115 billion, and profit attributable to owners of parent is expected to be JPY100 billion.

Revenue Forecast by Segment

(Unit: B yen)

	FY2021 forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Domestic Prescription drugs*	**94.4**	**46.1**	94.7	**(0.3)**	**(0.3)**
Overseas subsidiaries/export	**31.1**	**12.2**	24.6	**26.2**	**6.5**
Shionogi Inc.	**8.4**	**4.2**	7.5	**12.5**	**0.9**
Ping An-Shionogi**/C&O	**14.3**	**3.9**	10.1	**42.0**	**4.2**
Contract manufacturing	**17.8**	**7.4**	19.7	**(9.7)**	**(1.9)**
OTC and quasi-drug	**15.4**	**6.9**	11.7	**31.8**	**3.7**
Royalty income	**129.8**	**61.7**	144.6	**(10.3)**	**(14.8)**
HIV franchise	**125.2**	**60.8**	123.4	**1.5**	**1.9**
Crestor®	**1.1**	**—**	16.6	**(93.7)**	**(15.5)**
Others	**3.5**	**0.9**	4.7	**(25.4)**	**(1.2)**
Others	**1.4**	**0.7**	1.8	**(18.2)**	**(0.3)**
Total	**290.0**	**135.0**	297.2	**(2.4)**	**(7.2)**

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* See Appendix p.41 for details
** OTC and quasi-drugs also include in revenue of joint venture

This is page 27.

Looking at the results by business segment, as is clear from the increase and decrease amounts, we believe that overseas and OTC drugs are the major factors for the increase in sales.

For Ping An-Shionogi, generics and OTC drugs through Good Doctor will make the largest contribution this fiscal year. Although we do not include cefiderocol and naldemedine in this list at this time, if we can win the so-called clinical study exemption, we would like to add the sales of these drugs later.

With regard to OTC drugs, sales of RINDERON as a switch OTC drug got off to an extremely strong start. On the other hand, last year, sales of cold medicine Pairon dropped from 60% to 50% of the previous year's level, as I am sure is the case with other manufacturers.

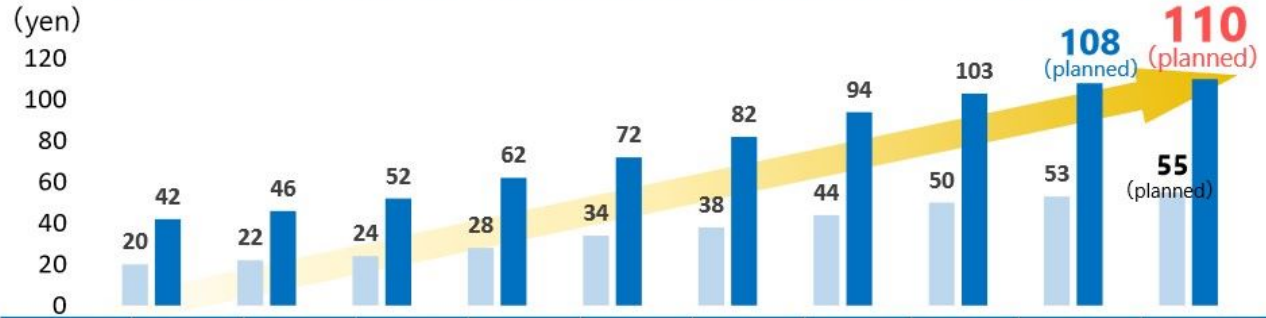
We expect a certain amount of sales of cold medicine and other products to return this year. And, due to the high level of concern about infection, the amount of increase in the ISODIN family is expected to be moderately strong.

As for royalties, HIV is business as usual, and we have not included the major contribution of cabotegravir in this at the moment, but if COVID-19 settles down and it becomes easier for patients to go to the hospital, especially in the US, turnover of once-monthly administration of cabotegravir will become larger. I would like to start with this area.

We believe that Crestor's JPY15.5 billion is effectively the end of the large royalties, and that only about JPY1 billion will remain.

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 FY2021 for the tenth consecutive year**



FY	12	13	14	15	16	17	18	19	20	21
Treasury stocks Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 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	4.1 (planned)	Over 4.0 (expected)
ROE (%)	17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	Over 11.5 (expected)

Converted from JGAAP to IFRS after FY2019

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

29

In addition, there is a section on shareholder returns on page 29.

As of April, the year-end dividend if the general meeting agrees, will be increased to JPY55. We are considering an increase from FY2020 of JPY5. The dividend for FY2020 is expected to be JPY108.

This is still a DOE of 4.1%, and a dividend payout ratio of 30%, so we would like to enhance our dividend payout ratio a little more.

Our basic policy is not to lower an increased dividend when viewed on a half-yearly basis, so JPY55 will be the starting point for this fiscal year. The dividend for FY2021 will be started at JPY110, an increase of JPY2. If our performance is good, I would like to ask the Board of Directors to further consider the year-end dividend.

As a Company Needed by Society

— Shionogi's commitment in FY2021 —

As a leading company in the infectious disease field

Shionogi will work intensively to counter the COVID-19 pandemic as our highest priority

Material issues to create new value for customers and society

Protect people worldwide from the threat of infectious diseases	• Develop infectious-disease-related products and accurately convey associated information • Address AMR/viral infectious diseases (influenza, corona, etc.) • Address three major infectious diseases (HIV, TB, malaria)

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See Appendix p.47 for the Shionogi Group's Materiality

Last but not least, I would like to make a company-wide contribution to bring back normal life from COVID-19 through vaccines, therapeutic drugs, sewage, antigen tests and HISCL TARC. We hope to contribute to the restoration of a normal life from COVID-19.

We look forward to working with you this year. That is all.

Question & Answer

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

Please follow the instructions of the operator.

Operator: Please state your company name and your name before you ask your question.

Our first question comes from Mr. Yamaguchi of Citigroup Global Markets Japan.

Yamaguchi: This is Yamaguchi from Citigroup. I have two questions.

The first is that you told us a lot of things in your full-year forecast, but you said that there were a few things that were not included. In terms of probability, there are two main areas: vaccines, which are relatively advanced, and new drugs related to China. In terms of the top line, I'm not sure about ViiV.

It may be difficult to give specific figures, but I think it would be great if you could give us something like a top three of things likely to be included.

Teshirogi: We have been making every effort since the end of last year to make some kind of sale of the vaccines and therapeutic drugs by the end of this fiscal year. If you had asked me six months ago what the probability was, I would have said it was quite low, but now I think the probability has risen to a very realistic figure, and we want to strongly promote these two issues.

Thirdly, we would like to actively negotiate with other companies for out-licensing and joint development of pipelines other than COVID-19, which we are currently working on.

In terms of certainty, I think the stockpile of Xofluza is a bit more probable.

Yamaguchi: That's not in there either.

Teshirogi: Correct.

Yamaguchi: I understand.

The second question is related to the first, but I think it might be difficult to answer because it relates to the regulatory authorities. Compared to a few months ago, or even half a year ago, the development of your company is progressing steadily, and the situation in the world is such that Pfizer had started vaccines, albeit belatedly, and Moderna and AstraZeneca were reportedly just ready. I think there is certainly a demand for domestic vaccines.

I think the political and regulatory part that actually drives change, but if you could, could you tell us about the authorities' thoughts here, including the EUA, has changed in the past six months and how it is likely to move, so we can prepare ourselves for further changes.

Teshirogi: We believe large-scale Phase III trial is vital. As I mentioned earlier, we are preparing for Phase III on a global basis, but as a matter of common sense in the vaccine industry, if a placebo-controlled trial is conducted, there will inevitably be an obligation to supply the vaccine to that country.

At the moment, the countries that are willing to take placebo-controlled trials, although we have to be careful about how we say this, are countries that do not have solid medical systems, or are mainly low and middle

income countries. Therefore, when we look at the efficacy of vaccines, there is a huge difference in the medical systems in developed countries, whether or not they are capable of reproducing the results.

We are trying to prepare for 30 or 50 million people with the government financial support. Considering the fact that a certain number of vaccines produced are supplied to other countries that participated in the clinical trials, I wondered if it was the best approach under giving government financial support. I think this goes back to the question of the degree to which neutralizing antibodies increased in the Takeda and Moderna result I mentioned.

In addition, other parameters, such as the Th1 shift, memory B cells, and safety, are not neatly presented in the database, which is somewhat of a frustration for us.

In a country where there is a little bit of hesitant about vaccines in general, there are a lot of people who are frustrated with the fact that the government is not providing any data on adverse reactions.

Politicians also have been asking for clearer data on all aspects of the drug, such as how much neutralizing antibody has been produced, how much cellular immunity has been induced, and how safe the drug is.

Also, regarding the Japanese mutant strains, if India, Brazil, and South Africa are also producing such a large number of mutant strains, are there really no mutant strains unique to Japan? When I talked with an official, he told me that it is very unfortunate if we do not have an environment where we can just make a phone call and say, make that.

It is true that we have to get a consensus from the PMDA on the extent to which the efficacy and safety of the drug should be assessed, but at the very least, if we manage to inoculate as many people as possible in June and July, in consideration of the Olympics prior to autumn, we will be able to do so with the help of Pfizer, Moderna, AstraZeneca, and other overseas representatives.

However, the second vaccination seems to be quite hard on the messenger RNA, so many medical professionals are beginning to ask whether it is really possible to give the vaccine three or four times. If it is going to last for a number of years, people want to use a safe, domestically produced product. If they can maintain and preserve immunity, we would like to create an environment where people can freely use such products from the beginning of the next fall.

On the other hand, I think that Phase IV is inadequate at the moment. I don't know how thorough it is possible to be with Phase IV, whether it's Pfizer's or Moderna's. In our case, it is one vial per person and can be refrigerated, so we are aware that the vaccine can be administered at a general practitioner in the same way as the influenza vaccine. If so, we will be able to do a very large Phase IV, almost a full case survey.

We think the government is starting to listen to us more and more about what kind of homework we should do and what we should offer.

Yamaguchi: Thank you very much. If there are any more updates, please let me know. That's all.

Teshirogi: Thank you very much.

Operator: Now I would like to move on to the next question.

The next question comes from Mr. Ueda of Goldman Sachs Japan. Please go ahead.

Ueda: Thank you. I would also like to ask you about the vaccine first.

I think your company has already obtained Phase I and II data to some extent, but you have already commented that you are close to launching the product, so I was wondering if you have gotten a promising response so far and when this data will be released. Also, could you please comment on the current status and outlook, including when the design of Phase III will be decided?

Teshirogi:

Of course, we are doing vaccine development based on science, so we have a lot of information already. To be honest, the reason why we are hesitant is that the way the data of the preceding vaccines was presented was not very clear, so it is difficult to understand how to present the data in a way that is most fair and comparable to what is being presented. If, for example, Pfizer's neutralizing antibodies in patients in Japan are measured not by the Pfizer method but by the Infectious Diseases Research Institute's method, we would like to know the data on how many neutralizing antibodies were raised and in what proportion. We are telling PMDA. That way, it is easier to compare.

Not only have they not come up with anything like that, but they probably didn't measure neutralizing antibodies using the Infection Research Institute method, which is very troubling because we can't compare from the same point of view.

So, based on our own science, we say that if we have all this data, we can proceed in this way, but how does that compare to other vaccines?

Mr. Ueda, what I am actually aware of is that when our vaccine come out, Pfizer, AstraZeneca, and possibly Sinovac of China may also come out, so all information is available for messenger RNA, viral vectors, inactivated, and recombinant protein vaccines. Then, the general public will naturally ask that which kind of vaccine should we take?

We feel that the government is not ready for this, and we are wondering how we should disclose the data. Dr. Morishita, who is working on the DNA vaccine, also said that he was concerned about how to present the data.

After all, there is no chance but to conduct large-scale Phase III, supply of our vaccine will be delayed again, so we are asking what we can do to make comparisons with other companies to some extent, but it is difficult to find out. So we are having a very difficult time with this.

However, in July or August, we have to say that we will proceed with the Phase III protocol if we have to pay a certain amount of money for it, so we would like to disclose as much information as possible about our achievements, what we are thinking about, and what we will do in the future by R&D Day.

At least, as I have been saying to the PMDA, the government should compare neutralizing antibodies of all vaccines by the Infection Research Institute method. So far, I have heard that Pfizer and Moderna have not responded favorably. We are measuring neutralizing antibodies based on the Infection Research Institute method, so we hope that this will somehow become a reality.

Ueda: Thank you very much. It was very easy to understand.

Secondly, on page 24, you introduced the expansion of infectious disease-related business, and I would like to know what changes have been made in the subscription model and stockpiling in each country.

Last year this model started in the UK and other countries, but I would like to know the current situation. And although you mention about the creation of new healthcare-related businesses, could you tell us what your company is thinking about in the future?

Sawada: I would like to respond to your question.

As for the situation overseas, the G7, hosted by the United Kingdom, is now moving forward, and AMR is on the agenda. we have the impression that the UK has a very strong will to present an action plan on pull incentives to the countries in the talks before the G7, and to agree on the phase of implementation.

As you already know about the UK and Sweden subscription model, or the minimum purchase guarantee system, Germany, France, and other countries have already started to introduce some AMR incentives in their drug price reimbursement systems.

In addition, three AMR-related bills have been drafted in the US, and one of them, the very recent SUPER BUGS act, has been introduced to encourage countries to work together. So we think that this year will be a very important year.

In Japan, the use of antimicrobial agents has been greatly reduced, but in other countries, the prescription of antimicrobial agents is actually more common than oxygen inhalation. There is a growing sense of crisis that this could lead to the further spread of multidrug-resistant bacterial infections.

Teshirogi: In terms of new healthcare-related business, within the framework of so-called Healthcare as a Service, HaaS, we are looking for ways to collaborate with other companies, especially in the areas of pre-disease and prevention, although vaccine is one of prevention. We are in talks with a number of companies.

We have not yet reached the concrete point, but at least this time, there is a great deal of interest in the sanitation environment, or something like that, and we have received several requests for partnerships because we are involved in infectious diseases. Therefore, we are currently working on a project to develop a business related to prevention and pre-disease.

Ueda: Thank you very much. That's all from me.

Teshirogi: Thank you very much.

Sawada: Thank you very much.

Operator: Now we will move on to the next question.

The next speaker is Mr. Kohtani from Nomura Securities. Please go ahead.

Kohtani: I'm Kohtani from Nomura Securities. There are several points I would like to ask, but first I would like to ask you to talk about the technical aspects of the coronavirus vaccine.

The reason I ask is that the mRNA vaccine appears to have won, and Pfizer is going to start testing a flu vaccine in the July-September period. They're also going to do a Phase III trial. Because of this, in conference calls of GSK and Sanofi, they were asked whether their long-term vaccine business is ok. The question is whether your cell-derived vaccine still has a chance to win.

In short, it would be great if you could also sort out the strengths and weaknesses of these insect cell-derived vaccines and mRNA vaccines. As far as I personally know, the biggest weakness of mRNA vaccines is pain, and the cause of the pain is probably the cationic lipids which compose liposome formulation, although I am not sure. Since the cationic lipids get into various cells, which naturally triggers the immune system, but I think it also triggers pain.

Then I'm thinking that maybe it is very difficult to remove the pain from the mRNA vaccine. About this, I wonder if it is correct to view pain as the biggest differentiator between genetic recombinant protein vaccine and mRNA vaccine. It would be helpful if you could sort out the good and the bad about it. This is the first point.

Teshirogi: Thank you very much.

I think I've already talked about that. Also, I think that long-term safety has not been established for messenger RNA vaccines. So, it may be that nothing will happen, but we don't know yet, so it will take some time.

At least when the parameter of efficacy is put on full display, the efficacy of messenger RNA vaccines, is the highest, and I think it is making viral vectors vaccne difficult to see.

On the other hand, if the messenger RNA vaccine is to be administered every year, although it depends on, for example, how long the antibodies last, as I mentioned earlier, the second administration is quite painful, and the fever is quite high in some people.

While some people may experience quite severe pain, our vaccine is extremely safe even with two shots, so I think this is the way to use our vaccine if we want to maintain immunity.

As you mentioned, if the fever or pain is caused by the mechanism, then our protein-derived vaccine will have an advantage in the maintenance of immunity.

The other thing is that the vaccine is based on intramuscular injection, which we think is a winning point for us. Originally, we were thinking of doing intranasal vaccines in earnest, and before COVID-19 was spread, we were thinking of starting with intranasal flu vaccines.

We believe this is one of the strengths of recombinant protein vaccine, and there are many emerging countries where intramuscular injection is not possible, especially where annual intramuscular injection is absolutely impossible. Intranasal devices can be self-administered, so although the price of the device may be an issue, I believe that having an application other than intramuscular injection will be very strong, at least in areas where the medical system is not well organized.

In this sense, inactivation vaccines may have similar applications, but it may also have different applications from messenger RNA or viral vector vaccines, such as nasal or transdermal applications. we think it would be good to have it in order to consider such applications.

On the other hand, the recombinant protein and inactivation vaccines were delayed because we had to analyze the spike protein, and it took some time to find the monkey VERO cells because of the problem of inactivation not increasing in eggs.

We still don't know whether or not all viruses will be able to function with messenger RNA or viral vector vaccines, so having four or five different vaccine methods is extremely important for pandemics.

Kohtani: I understand. Secondly, regarding coronavirus drugs, I think the competing drugs are mainly from Pfizer and Merck. Pfizer's PF-07321332, which is a 3CL protease inhibitor, has already started Phase I trials, and the Phase II and III trials for the oral version will start in July, Pfizer said on the earnings call.

Merck's molnupiravir, which is an RNA polymerase inhibitor, was originally a treatment for MERS. This is to start a global Phase 3 study in outpatients. To be honest, I have some doubts about the efficacy and speed with which it can compete with your therapeutic drug.

Also, in your March 2021 paper, recombined the gene to express ACE2in embryo-derived MRC-5 cells. Most of them are currently using monkey-derived VERO cells, but as I recall, only monkey-derived cells can be used to activate drugs, so there were some problems with that. This is the second point.

Teshirogi: Please excuse me for the latter question, but as you said, Pfizer started its trials in March, while Merck started around the end of last year, so I think there is a slight difference.

As a matter of course, if we look at the incidence and severity rates of the disease among patients in our country, and we should choose our words carefully, the incidence and severity rates are extremely low compared to other countries.

What is causing problems is that asymptomatic or mildly ill people are inevitably going out into the world and spreading the virus, so all activities are being suppressed. If a patient tests positive, the patient should stay at home for a week and take oral antivirals. If the PCR results are negative, the patient should be allowed to go out as usual.

If we can achieve a pattern just like the one, we are considering with Xofluza for influenza, I believe if we consider Japan, that the healthcare system will not collapse. In fact, if the number of beds is under control, the doctors have recently had experience in treating COVID-19, and if they can concentrate on patients we believe we can save a lot of lives.

Therefore, I think it would be different if we could remove the virus from the 80% or 90% of patients who are mildly ill or asymptomatic. The efficacy of the drug is based on viral reduction, and the safety of the drug is based on the safety of animal studies and clinical studies, such as 500 or 1,000 cases.

If that is the case, we think it will be possible for us to provide some kind of answer by the end of this fiscal year.

Kohtani: I'm sorry, this is a very long question, but for the 400 mg formulation of cabotegravir, the Phase I study of which started last year, part 1 calls for subcutaneous and intramuscular injections once a month, and part 2 calls for intramuscular injections once every three months. Can't you do a subcutaneous injection once every three months?

Also, regarding the others coming after, from Gilead and Merck, lenacapavir and islatravir, one is a subcutaneous injection once every six months, and the other is an implant once a year. The idea is that even once every three months is a good time to check up on HIV patients, so I'm wondering if this will provide some protection for the most part.

Also regarding S-648414, although this requires partner medication this is useless unless it can be administered once every three months, so can you tell us about all of that, too?

Teshirogi: You are right about S-648414. We don't think it makes sense without every three-month formulation.

We are also conducting market research withViiV, and we believe that there is no market for implants. It seems that even if you touch it from the outside, you can still feel it, so HIV patients are very reluctant to use it. we believe that implants will not be marketable, because avoiding simple detection is a patient need.

As for the capsaicin inhibitor every 6 months, of course, we think it poses a certain issue in terms of proceeding subcutaneously, but at least the resistance barrier is low. In addition, given that there is no partner drug, I'm not sure the results will be much different unless there is a subcutaneous partner drug every 6 months.

From this point of view, if we can provide intramuscular injections every three months, we can meet the needs of the majority of HIV patients.

Kohtani: Thank you very much for your very clear answer. That's all.

Operator: Now we will move on to the next question.

The next speaker is Mr. Sakai from Credit Suisse Securities Japan. Thank you.

Sakai: This is Sakai, Credit Suisse.

This question is a little bit different from the others about vaccines and HIV. But the monitoring system for sewage that you introduced this time has not been included in the financial results for this fiscal year. Since it is shown on page 17, can we expect it to contribute to the financial results to some extent? Is it at a level where some contribution to business performance can be expected?

In that case, how do you plan to monetize it? Could you please explain more about that? I have two questions, and this is the first question.

Sawada: Thank you very much.

In terms of monetization, we would like to proceed with this as a business, as a contracted business, so it will be similar to what Shimadzu Corporation's subsidiary has already started.

In the end, I think it will be a battle for the technical level of what we can provide through this sewage monitoring.

Sakai: If that's the case, what kind of time frame do you think we should be looking at for commercialization? It says that the service is scheduled to be launched in June, but will we see some kind of profitability from this point on, or will it be like a test run for the time being? What do you think about that?

Sawada: We would like to start commissioning relatively early, but how much it will spread depends on how much data we can accumulate, including the status of infection, as I mentioned earlier. As a result, I think it depends on how it is received by academics and the government as well.

In that sense, we would like to release the data as soon as possible. The researchers and staff in charge of this project are already working very hard, so we hope to release the news as soon as possible.

Sakai: I understand.

I am sorry to say that I have asked this question many times before, but I think unnecessaritys trend of MRs will accelerate especially as the environment becomes more and more conducive to the use of digital, but looking at it this time, I see that domestic sales are still very difficult.

This is why I think a bold restructuring of domestic business may be necessary. The reason for this is that I understand that there are various opportunities, but in the case of COVID-19, HIV, and this sewage testing, I think it is necessary to consider risk management from a management perspective in case things do not go well. Even based on the information that I can get from the outside from the current situation.

I would like to know if you are thinking of making any drastic changes in the system, including in this area. I wonder if it is something that is in the hands and in the minds of the Teshirogi-san before the next mid-term plan or so. Can you tell us about that?

Teshirogi: It's as if you are reading my mind.

Naturally, we have envisioned what will happen if these trigger points are achieved during the current fiscal year, and what will happen if they are not. In that case, I think we will have to consider some pretty big moves.

I don't think it's a matter of a next medium-term business plan anymore, but I think it could happen this year or next year.

Sakai: I understand. Keep at it. Thank you.

Teshirogi: Thank you very much.

Operator: Now we will move on to the next question.

The next speaker is Mr. Hashiguchi from Daiwa Securities. Thank you.

Hashiguchi: This is Hashiguchi from Daiwa Securities. Thank you.

First, regarding the COVID-19 treatment, how complete is the formulation that is about to enter clinical trials in the first half of this year? I think it's okay if the product is not 100% perfect at the first stage, but I would like to know how much possibility there is for future improvements, and if you could explain the stability, storage, and convenience of taking the medication.

Teshirogi: Since this is an oral small molecule drug, we are naturally specialized in this field, so we are considering an oral drug that can be distributed and taken normally with a high degree of certainty.

To be honest, the biggest challenge is mass production, and depending on the dose and how many days the drug will be administered, how many people we need to produce it for, and to what extent we need to build a production system that can handle the capacity between now and December is the biggest concerns. I have no concerns about the provision of formulations, including convenience.

Hashiguchi: Thank you very much.

Secondly, regarding SG&A expenses, you have given us a rough estimate for this fiscal year, but what should we think about for the next fiscal year and beyond? In relation to that, on slide 46, you introduce the recent cost structure reforms, but I couldn't understand it just by reading this very well, so could you give us some specific examples of what you are doing?

Teshirogi: I will pass this to Mr. Hosogai.

Hosogai: Hello.

We have been working on the reform of the cost structure since FY2020, and although we have received support from outside consultants, we identified each and every cost item and identified the room for reduction by the end of FY2020.

For FY2021, on a budgetary basis, this will be roughly in the range of JPY22 billion to JPY23 billion on a quarterly basis, but we will start implementing measures under the agreement of all the executive officer to keep it within this range. This is why we are making company-wide efforts to stop the decline in productivity associated with the decrease in sales.

Teshirogi: Specifically, Mr. Hashiguchi, if you look at the cost items, there are still a lot of To Do items from the previous year. As if they were not aware of this, even if all the executive officer and heads of organizations could see them, when they asked why we were doing this, there were still quite a few items that they said, well, we did it last year, so Mr. Hanasaaki and Mr. Hosogai identified all the cost items, and then asked why we needed to do this this year.

In terms of response, we have been able to see a lot of results in the third and fourth quarters, so we would like to try to achieve this this year. I will not be saving new items, but I will be cutting all the old items that are still in use.

Hashiguchi: Thank you very much.

Lastly, you mentioned that you would like to consider out-licensing or co-development of pipelines other than COVID-19, but what specific products do you have in mind?

Are these words assumed to further maximize the value of the pipeline, which is very important for your company? Or, on the other hand, is it possible that in order to devote more resources to such important items, you are asking for help from other companies for items that are not so important?

Teshirogi: I think that's a very good point. It's both. As I specifically mentioned, we believe that anticancer drugs have a huge potential, and we have been accumulating data this year.

We are not saying that we won't be involved at all, but we will consider collaboration in this area.

For example, for the S-600918 and BPN14770, we would like to pull in as much as we can on our own, but depending on the geography, there may be places where it is better to work in partnership. We are considering this.

As for the areas that are a little out of our reach, such as S-555739, the suppression of exacerbation is originally related to COVID-19, so you may say that it should be in-house. However, I think it would be better to do it outside rather than with our resources. We're going to go look into partnerships for these things. It is a combination of such things.

Hashiguchi: Thank you very much. That's all.

Teshirogi: Thank you very much.

Operator: Now we will move on to the next question.

The next speaker is Mr. Wakao from JP Morgan Securities Japan. Thank you.

Wakao: Hello. Thank you.

Today, I'd like to ask you about something that I haven't heard about today. What are your plans for the China business this fiscal year? If we look at the top and bottom of the chart, I think the second half of the year is larger, and I think this is in line with the progress of the business, but could you give us some background on this joint venture, how net profit is doing, and what your plans are for this fiscal year?

Teshirogi: As I mentioned earlier, the collaboration with Good Doctor is finally in full swing, and the so-called C&O has taken a concordance test and received approval for the generic, which was originally planned. This will gradually start to appear in the first half of the fiscal year, and we expect it to generate a certain amount of sales in the second half.

Originally, C&O was in a situation where it was either almost breakeven or slightly profitable, but we have been able to cut down on SG&A expenses by using Good Doctor, et cetera, so the profit environment has become much more profitable than when we were doing the C&O generic business.

On the other hand, looking at Ping An- Shionogi as a whole, as I mentioned earlier, SG&A expenses and R&D expenses will be incurred in how we promote new drugs, such as cefiderocol and naldemedine. For the time being, our goal is to achieve at least break even with using the money from the C&O generic business to cover R&D expenses. This is the basic idea.

However, according to Yoshida, Chairman & CEO of Ping An-Shionogi, who has been transferred to China, if you look carefully at China, there are quite a few interesting projects, and there seems to be an opportunity to introduce them. However, if we can expect significant growth in the future, we are suggesting that we do it within the framework agreed upon by the board of directors of Ping An-Shionogi.

Except for such ad hoc introduction projects, I basically told them to proceed with a breakeven P&L approach.

Wakao: Thank you very much.

Another point that I would like to know is the outlook for domestic prescription drugs for this fiscal year. Since the plan is minimum on the current fiscal year's plan, there is not much downside risk, but on the other hand, there was some weakness in the domestic market in the last fiscal year.

Therefore, I would like to know how you have factored in the impact by COVID-19 in your plan for the current fiscal year. In particular, the 40% increase in the sales of Intuniv appears to be somewhat strong.

Teshirogi: Thank you very much.

As you said, the area that we thought we would probably get the most questions in that sense is the area of Intuniv, and this is straightforwardly the area where most of the growth this time has come from, where there was almost no growth in the adult area last year.

In the pediatric field, our market share has risen to the point where we are in between the No. 1 and No. 2 positions, so we have made some progress in this area. The challenge is, how do we move to expand the market? In the adult field, we did not proceed shares for new patients very much. This is where, at least, the S-812217 anti-depressant seems to be working well, so we have to include this and see how we can take it in the adult field of neuropsychiatry.

Including the IT-based detailing that Mr. Sakai mentioned, I think the most important point is the expansion of the adult market for Intuniv.

However, considering the amount of prescriptions for Strattera and its generics, I believe we can achieve this because the adult market share for Intuniv is not that high yet.

Wakao: Thank you very much. Understood. That's all.

Teshirogi: Thank you very much.

Operator: Last question.

The next speaker is Muraoka from Morgan Stanley MUFG Securities.

Muraoka: This is Morgan Stanley, Muraoka. Thank you.

Regarding the coronavirus vaccine, the unit price is probably expected to be around 2 thousand yen for one dose, 4 thousand yen for two doses, each this fiscal year, and you hope to be able to deliver it by the end of this fiscal year. Of course, there are many unknowns about what will happen after that, but I wonder if considering the supply and demand situation, the unit price will drop considerably after that.

Teshirogi: It is difficult to say how far the goal will be in the future, but according to the doctors, the influenza vaccine is given every year, and they don't want to have to give it twice a year at different places. If possible, we would like to have only one vaccine, and I think that recombinant proteins will make that easier.

In that sense, our basic approach is to receive the same amount for COVID-19 as for influenza. In other words, I think it is realistic to say that the price will double of price of influenzavaccine when it comes to Influenza plus COVID-19. I think it's important to think in terms of the fact that this will always be a routine.

Muraoka: Thank you very much.

Also, in the mid-term plan that you released last year, I think the target was JPY120 billion in core operating income for FY2022. Although the level for this fiscal year may be higher, is it correct to say that you do not need to change your goal of JPY120 billion for FY2022 at this point?

Teshirogi: Depending on how far we can go with COVID segments in FY2021, we may need to make some changes in FY2022, but according to our plan, we believe that we will be able to achieve a certain level of progress in FY2021, including therapeutic drugs and the vaccine. So far, we believe that we will be able to achieve this goal in FY2022.

Muraoka: I understand.

Lastly, I would like to talk briefly about the NHI price revision. I think there was a miscalculation in the revised NHI prices at the end of the last year because we didn't expect such a devaluation.

As the chairman of the Japan Pharmaceutical Manufacturers Association, I was wondering if this has given you any cause to consider reviewing the future lobbying strategy with respect to Ministry of Finance or Council on Economic and Fiscal Policy.

Teshirogi: I think the official views of the Pharmaceutical Manufacturers Association of Japan is necessary here, but personally, I agree with you. Since the industry as a whole has been extremely naïve in this area, we have to focus on other stakeholders, especially those mentioned by yourself, or the industry will face serious problems.

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

Teshirogi: Thank you very much.

Kyokawa: Thank you very much.

This concludes the conference call for Shionogi & Co. to discuss the financial results for the fiscal year ending March 31, 2021.

Thank you very much for taking time out of your busy schedules to join us today.

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