

SHIONOGI & CO., LTD.

Financial Results Briefing for the Fiscal Year
Ended March 2020

Kyokawa: Good morning. This is Kyokawa of the Corporate Communications Department. Thank you for participating in the conference call for Shionogi's fiscal 2019 results presentation. Before I start the presentation, I would like to apologize that it will be done by conference call in consideration of the current state of emergency order due to the outbreak of the new coronavirus. Teshirogi will begin the presentation.

Teshirogi: Good morning. Thank you for participating in the conference call.

Let me start from page 2. I would first like to explain the impact of COVID-19 on our business. Our supply chain has not been hit significantly at present. A vast amount of our various raw ingredients is, as I hear is also the case at generic drug manufacturers, bulk materials from China or inactive ingredients. The situation in China seems to be recovering considerably. However, I do believe that we should be prepared for the possible impact of a second or third wave of infections.

Looking at the Japanese market, our promotions were basically carried out from home or at the office, and promotion to medical institutions was mainly done through e-detail. The sales of the influenza family, which received great expectations from you, turned out to be very disappointing for us too for FY2019 due to the small market and the limitations of promotion.

In terms of R&D, while we have hardly had any impact on research activities, we are gradually seeing an impact on global clinical trials. For items of particular importance, we are considering how to compensate them by communicating with the CROs of different countries on a daily basis.

With regard to business operations in FY2020, we expect to see both reversible and irreversible recovery in promotion. Concerning the latter, in particular, we think it will be necessary to review the promotion, including e-detail, or fundamentally reconsider marketing activities. Therefore, in FY2020 we are considering future new ways of promotion by having Sawada, who is here today, be in charge of the Integrated Disease Care Division.

Concerning internal activities, telework has been going on for quite a while now, which we view as an excellent opportunity to find out where unnecessary operations exist. We are thinking of reviewing our operations on a company-wide basis.

Our Efforts to Fight COVID-19



Discovery of novel therapeutic drugs

- Initiated a collaborative research effort to **identify drugs active against SARS-CoV-2** with the Hokkaido University Research Center for Zoonosis Control.
- Promising lead compounds have been selected in *in vitro* studies.
- Accelerating research activities with the goal of initiating clinical trials in FY2020 as one of our top priority projects.

Discovery of Prophylactic Vaccine

- UMN Pharma Inc., a subsidiary of Shionogi, is pursuing the **discovery and development of a recombinant protein vaccine for COVID-19**, using their unique technology, "BEVS*" with the National Institute of Infectious Diseases and the Kyushu University.
- Accelerating vaccine research with the goal of initiating clinical trials in 2020 as one of our top priority projects.
- Planning scale-up to provide the vaccine to c.a. 10 million people

Offering antibody test kit

- Agreed with Micro Blood Science Inc. to **in-license the IgG/IgM antibody test kit**.
- Undertaking performance testing to demonstrate its suitability for practical use in Japan.
- Clinical research is planned to obtain additional evidence

Contribute to early diagnosis and then treatment for COVID-19, to restore greater safety to society



* BEVS (Baculovirus Expression Vector System):
protein expression technologies employing insects cells and so on

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Please turn to page 3. As a specialized manufacturer of infectious disease drugs, we believe the current outbreak of COVID-19 is extremely important in terms of showing our presence. In the discovery of novel therapeutic drugs, we are still vigorously carrying out screening of compounds, or SAR, and intend to position the three months of April, May, and June as the three months in which we will identify the most promising compounds. We were working on this period without taking Golden Week holidays and believe that we have something quite interesting. At the moment, since the drug will not be used chronically, we are assuming that it will not require such a long period of toxicity testing and are aiming to start clinical trials within FY2020.

Prophylactic vaccines—a very large proportion of our efforts are currently allocated in developing this. We have completely reversed the influenza vaccine development plan at the Akita Plant owned by UMN Pharma and have assigned the plant to the development of a vaccine for COVID-19. We are currently expecting the start of clinical trials within 2020 but are allocating considerable resources of the company to accelerate the development.

With regard to SARS-CoV-2 antibody test kits, we have introduced an IgG/IgM antibody test kit from China and are currently conducting performance testing. We have started to obtain certain amount of data and hope to deliver to the market as soon as possible.

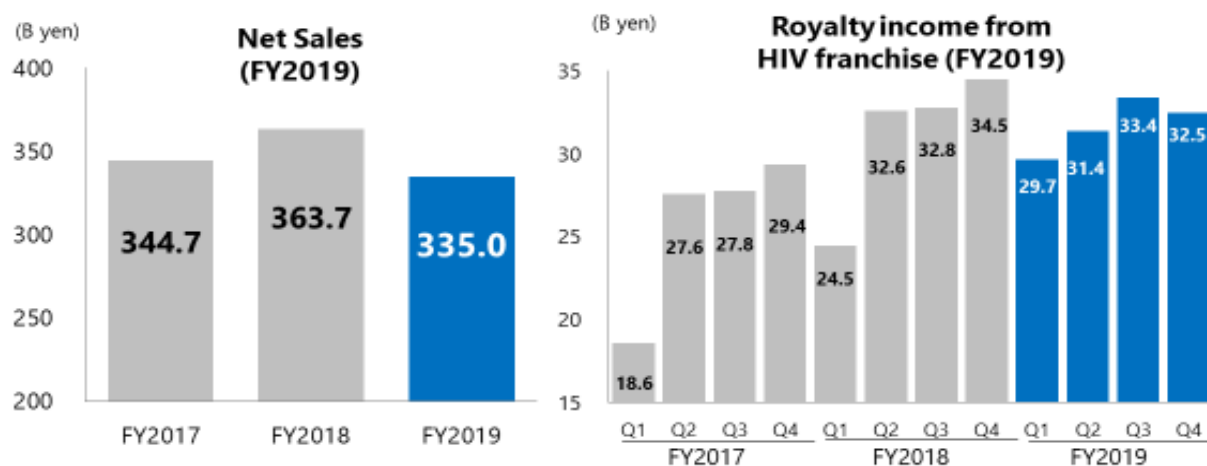
Highlight (1)

Japan Generally Accepted Accounting Principles (JGAAP)



◆ Net sales : **335.0 B yen** ^{vs prior FY} (-7.9%)

◆ Royalty income : **127.1 B yen** ^{vs prior FY} (+2.1%)
from HIV franchise



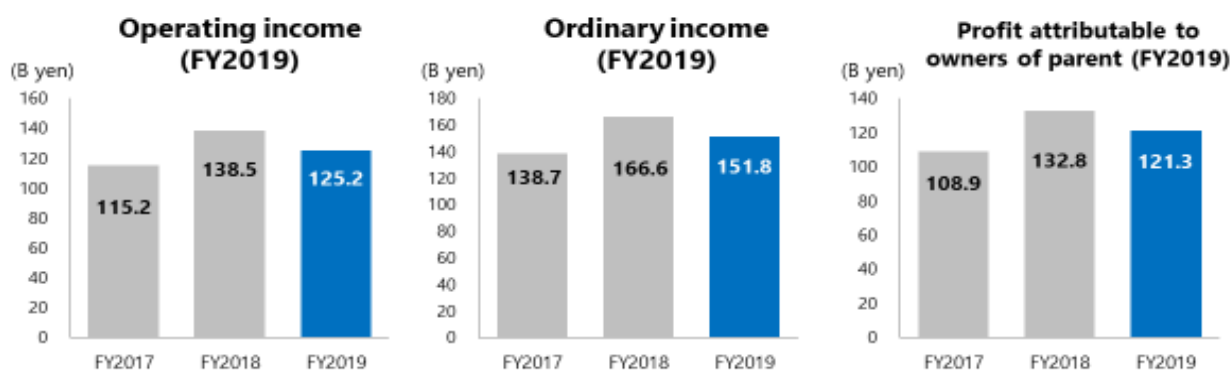
Let me move on to the overview of financial results for FY2019. Please turn to page 6. Net sales were 335 billion yen, down 7.9% year on year. Royalty income was 127.1 billion yen, up 2.1% from the previous year, as we succeeded in utilizing foreign exchange contracts against a considerably stronger yen in the latter half of the fiscal year.

Highlight (2)

JGAAP



- ◆ Operating income: **125.2 B yen** ^{vs prior FY} (-9.6%)
- ◆ Ordinary income: **151.8 B yen** ^{vs prior FY} (-8.9%)
- ◆ Profit attributable to owners of parent: **121.3 B yen** ^{vs prior FY} (-8.6%)



Please turn to page 7. Operating income was 125.2 billion yen, down 9.6% year on year, ordinary income was 151.8 billion yen, down 8.9%, and profit attributable to owners of parent was 121.3 billion yen, down 8.6%. We consider these results to be very disappointing, as this was the first decrease in profits after a period of record profits. Meanwhile, when we think of what happened with the influenza family including Xofluza, we view this as a certain milestone, a phase during which to consider how to turn around the results.

Financial Results (Consolidated)



JGAAP (Unit: B yen)	FY2019				FY2018	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Feb. 3)	Results	Achievem ent	Results	Change (%)	Change (B yen)
Sales	365.5	355.0	335.0	94.4%	363.7	(7.9%)	(28.8)
Operating income	147.0	141.5	125.2	88.5%	138.5	(9.6%)	(13.3)
Ordinary income	170.5	167.0	151.8	90.9%	166.6	(8.9%)	(14.8)
Profit attributable to owners of parent	133.0	133.0	121.3	91.2%	132.8	(8.6%)	(11.5)

- The plan has fallen short of expectations due to the large decrease in domestic sales of Flu-F*.
- Sales progressed as planned in the revised forecasts excluding sales of Flu-F**

Exchange rate (average)	FY2019 forecasts (May 9)	FY2019 forecasts (Feb. 3)	FY2020 results
USD (\$) – JPY (¥)	110.0	107.0	108.72
GBP (£) – JPY (¥)	145.0	133.0	138.15
EUR (€) – JPY (¥)	130.0	120.0	120.82



* Flu-F: Influenza family
(Xofluza®, Rapiacta®, Brightpoc® Flu+Neo)

** Sales excluding Flu-F:
Revised forecast; 332.2 B yen, actual 332.5 B yen

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Please turn to page 8. In profit and loss, what we place great importance on is the fourth column: the achievement rate of the revised forecast. The achievement rate was 94.4% for sales, 88.5% for operating income, 90.9% for ordinary income, and 91.2% for profit attributable to owners of parent. According to my memory, this is the first time in eight years—since 2011—that we ended lower than what we disclosed. Although a major cause was the year-on-year decrease in sales of more than 27 billion yen in Xofluza, Brightpoc, and Rapiacta, we recognize that the fact that we failed to accurately estimate the drop and reflect it to the forecasts is a major issue for the future.

Considering that, as is written in small letters at the bottom, sales excluding the flu family were roughly on track at 332.5 billion yen against a forecast of 332.2 billion yen, we recognize that a major issue is how to make an estimate of this infectious disease area.

Statement of Income (Consolidated)



JGAAP (Unit: B yen)	FY2019		Results	Achievement (%)	FY2018	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Feb. 3)			Results	Change (%)	Change (B yen)
Sales	365.5	355.0	335.0	94.4	363.7	(7.9)	(28.8)
	14.6	16.2	16.9		15.1		
Cost of sales	53.5	57.5	56.7	98.6	54.9	3.3	1.8
Gross profit	312.0	297.5	278.3	93.5	308.8	(9.9)	(30.6)
	45.1	43.9	45.7		46.8		
SG&A expenses	165.0	156.0	153.0	98.1	170.3	(10.1)	(17.3)
Selling & administrative expenses	31.6	30.4	31.6	98.0	102.0	3.8	3.9
	13.5	13.5	14.1		18.8		
R&D expenses	49.5	48.0	47.2	98.3	68.3	(30.9)	(21.1)
Ordinary R&D expenses	49.5	48.0	47.2	98.3	51.4	(8.2)	(4.2)
Strategic investment	-	-	-	-	16.9	-	(16.9)
	40.2	39.9	37.4		38.1		
Operating income	147.0	141.5	125.2	88.5	138.5	(9.6)	(13.3)
Non-operating income & expenses	23.5	25.5	26.5	104.0	28.0	(5.4)	(1.5)
	46.6	47.0	45.3		45.8		
Ordinary income	170.5	167.0	151.8	90.9	166.6	(8.9)	(14.8)
Profit attributable to owners of parent	133.0	133.0	121.3	91.2	132.8	(8.6)	(11.5)



Please turn to page 9. Although we will not disclose everything, the achievement rate of cost was 98.6%, which is larger than the shortfall of sales against the revised forecast. The reason for this is that Xofluza is our own product and has a considerably low cost ratio, so if Xofluza's shortfall of sales is large, it has a major impact on sales.

For SG&A expenses and R&D expenses, the achievement rate was 98%, which means that the necessary costs were spent and costs that could be saved were saved. However, the achievement rate of gross profit, which combines sales and cost of sales, was low at 93.5%, leading to achievement rates of around 90% for operating income and remaining incomes.

In year-on-year terms, sales were less 28.8 billion yen. I will describe a little more in detail later, but there was a drop of more than 27 billion yen in the influenza family including Xofluza. We had forecast a mild increase in sales and income by making up for the drop of around 15 billion yen in milestone income from Roche this year with sales of proprietary products including Xofluza, but the plan did not work out and the year-on-year results ended at relatively large declines.

In R&D expenses, the lack of last year's 16.9 billion yen in strategic investment and the lack of costs for cefiderocol, which completed phase 3 studies, resulted in a drop of around 20 billion yen in total R&D expenses, but this failed to make up for the drop in sales.

Y on Y Comparison and Main Variation Factors (Statements of Income)



• Y on Y comparison (Unit: B yen)

Sales	(28.8)
Cost of sales	+1.8
Gross profit	(30.6)
Selling & administrative expenses	+3.9
R&D expenses	(21.1)
Operating income	(13.3)
Non-operating income & expenses	(1.5)
Ordinary income	(14.8)
Extraordinary income or losses	+3.0
Profit attributable to owners of parent	(11.5)

Decrease in profit Increase in profit

Main Variation Factors (Y on Y)

- **Sales**
 - Decrease in domestic prescription drugs
 - Decrease in milestone income* from Roche for Xofluza®
- **Cost of sales**
 - Increased Xofluza® exports, impact of item mix
- **SG & A expenses**
 - **Selling & administrative expenses**
 - › Cost increase due to domestic strategic products and sales expansion in China
 - **R&D expenses**
 - › Strategic business investment in FY2018 (16.9 B yen)
 - › Completed Phase 3 studies of cefiderocol and Xofluza®
- **Non-operating income & expenses**
 - Received extraordinary dividend from ViiV in FY2018
- **Extraordinary income or loss**
 - Profit on sale of investment securities
- **Corporate tax**
 - Increase in deduction amount due to R&D investment in FY2018

Main Variation Factors (revised budget)

- **Sales**
 - Decrease of domestic prescription drugs

Page 10 explains this in a little more detail. To fill in what I had left out, in non-operating income & expenses, FY2019 saw no extraordinary dividend that was received in FY2018, which led to an ordinary level of non-operating income & expenses. In addition, since we do not hedge our dividends, we are extremely susceptible to the impact of a stronger yen. In corporate tax, the lack of 16.9 billion yen of strategic business investment and 4.2 billion yen for phase 3 Cefiderocol resulted in a drop in R&D expenses of more than 20 billion yen, which led to the elimination of tax deductions for R&D investment. This led to an increase in corporate tax, which in turn led to a small drop in income.

Sales by Segment



(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Oct. 29)	Results	Achieve- ment (%)	Results	Change (%)	Change (B yen)
Prescription drugs	144.1	129.1	108.6	84.1	128.7	(15.6)	(20.1)
Overseas subsidiaries/export	31.4	31.3	30.8	98.1	29.4	4.5	1.3
Shionogi Inc.	9.9	10.2	10.1	99.3	11.8	(14.4)	(1.7)
Mulpleta®	1.0	1.0	0.54	54.3	0.08*	-*	0.5
C&O	14.6	13.3	13.1	98.5	11.5	14.4	1.6
Contract manufacturing	14.3	16.9	17.6	104.2	14.8	19.0	2.8
OTC and quasi-drug	9.7	9.7	10.3	106.0	8.1	26.9	2.2
Royalty income	163.6	165.7	165.6	99.9	180.3	(8.2)	(14.7)
HIV franchise	126.5	127.1	127.1	100.0	124.4	2.1	2.6
Crestor®	22.0	22.0	22.0	100.0	22.0	0.3	0.1
Others	15.1	16.6	16.5	98.9	33.9	(51.4)	(17.4)
Others	2.4	2.2	2.2	96.2	2.5	(12.2)	(0.3)
Total	365.5	355.0	335.0	94.4	363.7	(7.9)	(28.8)



* The full-scale promotion was initiated in Dec. 2018.

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Please turn to page 11. I will explain about prescription drugs later in page 13, so here I will talk about the other items. Shionogi Inc. saw a drop in sales of 1.7 billion yen. This is because we failed to make up for the 4.8 billion yen of one-time income we received from Purdue in FY2018 with the 3.5 billion yen income from BDSI for Symproic in FY2019.

Contract manufacturing and the export of Xofluza formulations were extremely strong. However, the extremely high cost levels had a negative impact on the cost ratio. In OTC and quasi-drugs, cold medicine was very weak, with weakness seen in Pylon PL granule and Pylon PL tablets, but the sales volume of coronavirus-related products such as Isodine was strong, which resulted in an increase overall.

In terms of royalty income, there was a large milestone income from Roche in FY2018 due to the success of our phase 3 studies and a high-risk approval milestone income of around 11 billion yen in FY2019, as mentioned in the "others" section, but the latter was less than the former, resulting in a 28.8 billion yen decrease in total sales.

I will omit explanation here since this is explained in a little more detail on page 12.

Sales of Prescription Drugs in Japan



JGAAP (Unit: B yen)	FY2019		Results	Achievement (%)	FY2018	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Feb. 3)			Results	Change (%)	Change (B yen)
Cymbalta®	29.3	27.3	26.2	96.0	24.1	8.8	2.1
Intuniv®	13.6	10.6	10.6	100.0	5.3	100.7	5.3
Vyvanse®	0.38	0.05	0.01	19.9	-*	-*	0.01
Xofluza®	28.0	18.0	0.43	2.4	26.3	(98.4)	(25.9)
Rapiacta®	2.6	2.6	1.2	45.1	2.0	(42.4)	(0.9)
Brightpoc® Flu・Neo	1.8	2.2	0.85	39.6	1.2	(27.1)	(0.3)
Total of strategic products	75.7	60.7	39.3	64.7	58.9	(33.3)	(19.6)
OxyContin® franchise	6.7	6.4	6.1	94.4	7.3	(16.9)	(1.2)
Symproic®	2.3	2.3	2.2	96.8	1.6	39.2	0.6
Actair®	0.27	0.26	0.28	108.8	0.19	47.5	0.1
Mulpleta®	0.33	0.23	0.13	55.7	0.15	(16.3)	(0.0)
Pirespa®	6.9	7.0	6.8	97.0	5.7	19.3	1.1
Total of new products	92.2	76.9	54.7	71.2	73.8	(25.8)	(19.1)
Crestor®	10.0	9.5	8.9	93.9	9.9	(9.9)	(1.0)
Irbetan® franchise	4.9	4.6	4.4	94.3	5.4	(18.5)	(1.0)
Others	36.9	38.1	40.6	106.6	39.6	2.3	0.9
Prescription drugs	144.1	129.1	108.6	84.1	128.7	(15.6)	(20.1)

Prescription drugs excluding Flu-F almost achieved the revised target**



* Launched on Dec., 2019

** Prescription drug sales excluding Flu-F: Revised forecast; 106.3 B yen, actual 106.1 B yen

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Please turn to page 13. Cymbalta was a little short of the revised forecast but was relatively strong especially in February and March and has been strong in April and May so far. I think that Cymbalta may be gradually getting on track.

Sales of Intuniv doubled from last year. It saw robust sales due to application to adults. The achievement rate of the revised forecast was also roughly on track. This is also seeing strong sales in April and May so far. The Cymbalta and Intuniv product groups have been seeing relatively strong sales in February, March, April, and May.

I will explain later, but Xofluza, Rapiacta, and Brightpoc, the influenza family, are facing difficulties.

In other products, Pirespa saw a 20% year-on-year increase. This increase is due to the strong efforts we made in the respiratory disease area.

Failure to Meet Revised Target for Xofluza®



Assumptions for revised target (18.0 B yen)

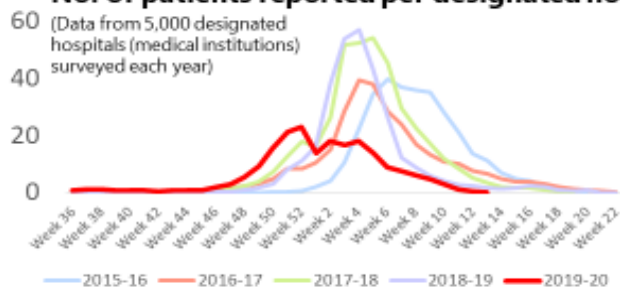
- Seasonal influenza epidemic from January in 2019/2020 season is similar as that of the previous season
- As in typical years, increase in proportion of adolescent and adult patients from January
- Restoration of market share to same level as the previous season in adolescent/adult market

Gaps to revised target

• Gap [1]: Seasonal epidemic of influenza

- This season, influenza spread very slowly even in and after January

No. of patients reported per designated hospital



Cumulative estimates of no. of patients treated*

(Cumulative total for 36th week to 13th week in each season)

2019/2020 season: Approx. 7.28 M persons

2018/2019 season: Approx. 11.7 M persons

38% Y on Y drop, lowest figure in past 10 years



Graph produced based on no. of patients reported per designated hospital used in the Ministry of Health, Labour and Welfare's influenza outbreak level maps (36th week: 2019/9/2-9/8, 13th week: 2020/3/23-3/29)

*Estimates of figures for all medical institutions nationwide based on the no. of patients reported by 5,000 designated hospitals

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Please turn to page 14. Let me explain a little about Xofluza's shortfall against the revised forecast. When we revised our forecast from 28 billion yen to 18 billion yen, it was based on an assumption that the seasonal influenza epidemic of roughly the same scale of the previous season would continue into February and March, and when sales grow in February and March it is usually in the adult patients' area, so that area would grow. The first difference from our assumption was that the influenza epidemic ended considerably earlier than forecast and at a smaller scale. I think it was a mixture of no influenza epidemic and that people who had noticed symptoms of coronavirus infection did not go to the hospital out of fear. In any case, the number of patients was the smallest in the past 10 years, which led to the extreme weakness of the market.

Please turn to page 15. Furthermore, the number of patients was smaller than our forecast, and those who went to the hospital were mostly children. As a result, the proportion of young people remained high this season. Due to the disadvantage in terms of guidelines, Xofluza does not reap benefits unless adult patients increase, for last year at least. Our market share was between 20% and 25%, and although progress was made in increasing understanding among medical professionals, we failed to carry out activities leading to prescription.

Variant Strains in 2019/2020 Season



- **Japan survey by NIID: Detection of antiviral drug-resistant viruses during 2019/2020 season (as of Apr. 30, 2020) – Results for Xofluza® shown below**

	A(H1N1)pdm09	A(H3N2)	B
Resistant (%)	1* (0.14%)	0 (0.0%)	0 (0.0%)
Number of samples tested	738	49	27

*In accordance with WHO's provisional standards, defined as a reduced susceptibility virus when three fold or more susceptibility reduction is confirmed, patient without treatment

- **Japan survey by Niigata university: Xofluza® use result survey result (as of Apr. 28, 2020)**
Frequency of influenza patients with PA mutations in pre-treatment samples during 2019/2020 season

	A(H1N1)pdm09	A(H3N2)	A(H1N1)pdm09 and A(H3N2)	B	A and B
Resistant (%)	0 (0.0%)	0	1*	0 (0.0%)	0
Number of samples tested	277	2	2	53	2

* A patient with mixed infection of A(H1N1)pdm09 and A(H3N2) harboring PA/I38T. The A(H1N1)pdm09 sequencing was unavailable.

- **Global survey reported by WHO (as of Feb. 28, 2020) – Results for Xofluza® shown below**

	A(H1N1)pdm09	A(H3N2)	B
Resistant (%)	1* (0.07%)	1** (0.1%)	0 (0.0%)
Number of samples tested	1,355	1,012	930

* pre-treatment sample, E23K variant ** pre/post-treatment is unclear, I38M variant

Only a few isolates with reduced susceptibility to Xofluza® were identified, and none of them were confirmed as being widespread



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Japan survey (NIID, Niigata univ.)
<https://www.niid.go.jp/niid/ja/influ-resist.html>
<http://www.med.niigata-u.ac.jp/pub/category/influenzasearch/>

WHO report
https://www.who.int/influenza/vaccines/virus/recommendations/202002_recommendation.pdf?ua=1

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Please turn to page 16. This is the data by NIID and the use results survey by Niigata University, which we have requested. And also, the global survey taken from the WHO report. In all surveys, the reduced susceptibility viruses have hardly been acknowledged. In FY2018, our product was used rather considerably in Japan, and although it depends on how we examine the various data, the percentage for H3N2, which had the highest probability, was around 8%.

And about how this would be in the winter of FY2019—since September, which is the start of the season, reduced susceptibility virus and I38 mutant virus have not been isolated. If you look at one winter only, as in the pandemic in 2009 for Tamiflu, you see extremely high Tamiflu resistance or neuraminidase resistance, but somehow that disappears the next winter and it is unlikely to see an effect of accumulation. We think the same can probably be said for Xofluza. With these data I explain about Japan's guidelines. I think that you are more aware, but high concerns toward these mutants are actually only seen in Japan, and the product has already been acknowledged as the first choice by the CDC of the United States. Therefore, we intend to provide physicians with more details, including the global situation, next winter.

1. Sales

- **Influenza family**
 - All three products were heavily impacted by low infection level of influenza partially constrained by reaction to spread of COVID-19
 - While progress was made in increasing understanding regarding viruses with reduced susceptibility to Xofluza® amongst medical professionals, this did not lead to an increase in prescriptions
- **Cymbalta®**
 - Sales exceeded that of the previous year by growth in the pain area
 - The revised forecasts was not reached because the positioning message "first choice for chronic back pain" was not fully communicated to physicians
- **Intuniv®**
 - Pediatric: Attained top share in the new-patient market, and the dynamic market
 - Adult: Met revised target as a result of obtaining approval for additional indications and increased the number of facilities adopting the drug (sales: double from the previous year)
- **Vyvanse®**
 - Established a distribution management structure and launched the product

A year that left unanswered questions about how to expand sales of new products

This is page 18. It concerns our actions in FY2019, and regarding the influenza family, the situation was as I have explained. Although sales of Cymbalta missed the revised target, looking at the results in April and May, I think that the direction we have taken seems not to be wrong. So we intend to continue with the current approach. As for Vyvanse, the distribution management structure still hasn't bedded in, so we would like to establish how to use stimulants including Concerta in this year.

Actions and Progress in FY2019 (2/2)



2. Investment (R&D)

- To overcome the HIV-product patent cliff, identified "key pipeline assets for transforming treatment paradigms*," and made an additional equity investment in Tetra
- Made advances in the development of next-gen growth drivers such as S-600918, zuranolone, redasemtide, S-648414, etc.
- Launched cefiderocol in US, and obtained approval in EU in Apr. 2020
- Progress of global development of Xofluza®

**Progressed smoothly advancing growth drivers
building a foundation for overseas business**

3. Business innovation

- Established Stream-I, a joint venture with M3
 - Began development of new information-delivery model
- Turned UMN Pharma into a wholly-owned subsidiary
 - Made a full-fledged entry into the vaccine business
- Formed capital and business alliance with Ping An Insurance Company of China, Ltd. (Basic agreement)
 - Transformed China business
- Developed app for domestic clinical studies of ADHD digital treatment product candidate SDT-001

 M3, Inc.



 中国平安
PING AN
金融 · 科技

Became more proactive about creating new value in healthcare



* See Appendix p.53

19

Let's move to page 19. Note that although such issues exist, regarding the areas we are going to be focusing on in FY2020 and thereafter, I feel that we've got off to a pretty good start. One factor is the pipeline. S-600918, as well as S-812217 and S-005151 redasemtide, and also S-648414. And as for Tetra's compound, we are currently already making preparations to start Phase 2 in Japan in the near future. We have a great relationship with Tetra, and when things settle down a little, I think we'll be able to make a more detailed announcement to you. Regarding BPN14770, we're making preparations to begin Phase 2 in Japan.

We've launched Cefiderocol in the US and obtained approval for it in the EU, so the task now is to figure out how to sell it. But in the Europe and the US, too, almost everyone is working from home, so we're just focusing on making solid preparations.

In the realm of new business innovation, this is the first fiscal year for Stream-I. Especially regarding how to take e-information and how to feedback, there were some parts that COVID-19 could not do, but I feel that Stream-I is starting to produce results.

We're also making a full-fledged entry into the vaccine business. We originally thought we'd go in with influenza, but this has suddenly changed to corona, and we're moving rapidly and aggressively. It's truly wonderful that we have been able to obtain a superb set of products through the deal with UMN Pharma.

As for the deal with China's Ping An, we're currently ironing out the details of the final contract, and we'll be telling you what sort of business it will be in initially in July, as originally planned, though I actually think we'll be able to do so a little earlier than that. In FY2019 we made fairly good preparations for businesses that we want to pursue in tandem with the launch of new drugs from 2020 onwards, including Phase 2 of digital medicine, so we intend to build on that further in FY2020.

Page 20 contains the information I presented at the R&D briefing in March, so I won't go over it again today.

Investment Outcome - to Establish Global Presence

Progress with global development of Cefiderocol (Product name in the US: Fetroja®, in the EU: Fetcroja®)

- **US**
 - Feb. 2020: Launched in US for "the treatment of cUTI, including pyelonephritis caused by susceptible Gram-negative microorganisms**"
 - Mar. 2020: sNDA for use as "the treatment for nosocomial pneumonia caused by susceptible Gram-negative microorganisms**"
 - Approval expected in FY2020 1H (PDUFA date: Sep. 27, 2020)
- **EU**
 - Apr. 2020: Approved by European Medicines Agency (EMA) for "the treatment of infections due to aerobic Gram-negative organisms**"

Progress with global development of Xofluza®

Taiwan

- Launched for treatment for patients aged 12 years or older (Nov. 2019)
- sNDA for prophylaxis use (Mar. 2020)

Japan

- sNDA for prophylactic use (Oct. 2019)

Approved in 21 countries
(of which 7 are for high-risk patients)

US

- Obtained supplemental approval for high-risk patients, the main subjects of treatment with antiviral drugs (Oct. 2019)
- Accepted sNDA for children aged one year or older, for prophylaxis use, and in granule form (Mar. 2020)

EU

- MAA for treatment and prophylaxis of patients aged 12 years or older (Nov. 2019)

This is page 21. Regarding Cefiderocol, which I touched on earlier, as well as Xofluza, things are progressing really well outside Japan, and with Roche, in particular, the general pace in the January-March quarter indicates that the pace has picked up to around 15 billion yen annually, so if it can maintain sales in the EU and capture other regions, I think that Roche's sales of Xofluza will see further growth.

Establishment of Stream-I

Establishment of an information delivery model for improving productivity and supporting proper use of drugs that fuses digital and real information delivery

- In FY2019, Stream-I focused on delivering information about Xofluza®
- Digital: Conducted online questionnaire surveys of physicians for obtaining timely information about prescription trends and concerns among physicians, utilized medical marketers, conducted online lectures
- Real: Prepared informative material to meet needs based on results of physician surveys



Full-fledged entry into vaccine business by making UMN Pharma a wholly-owned subsidiary

Integrate Shionogi strength in infectious disease with UMN's strengths, and expand business into the field of prophylaxis through vaccines

UMN Pharma's technology (BEVS*)

A vaccine manufacturing platform that makes it possible to produce homogeneous and stable antigens without the need to cultivate pathogenic viruses

<Action in FY2019>

- **Initiated development of recombinant-protein vaccine for COVID-19**
- ⇒ Accelerating vaccine research with the goal of initiating clinical trials in 2020
- **Discovered candidates for development as prophylactic vaccines for influenza**

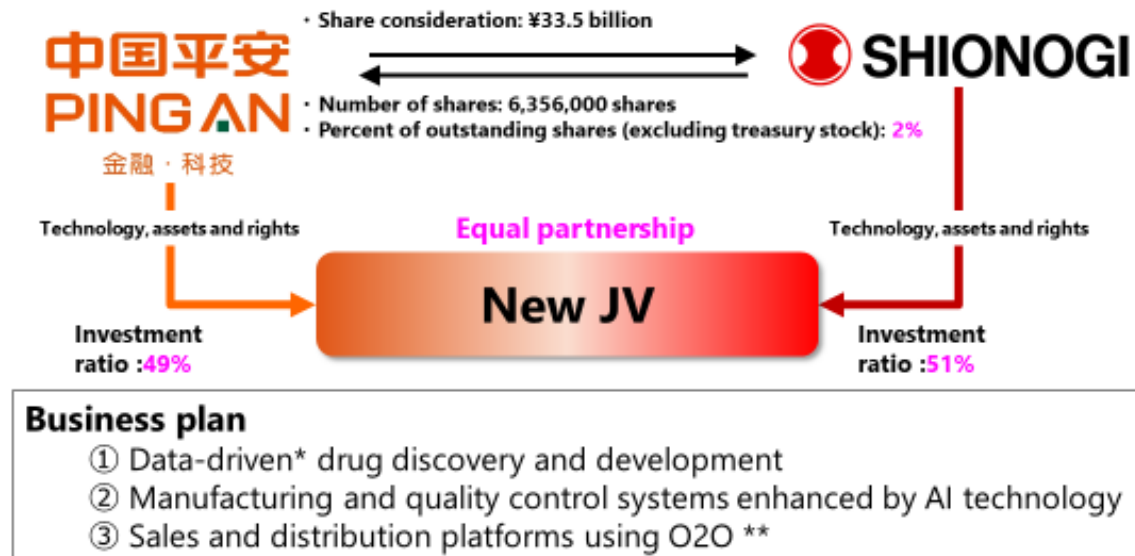
This is page 22. As I mentioned earlier, in FY2019 we laid much of the groundwork for conducting new businesses, including Stream-I and UMN Pharma.

Business Innovation- Basic Agreement with Ping An Insurance Company for a Capital and Business Alliance



Establishment of Joint Venture (JV)

With a capital alliance supporting a strong, long-term strategic partnership

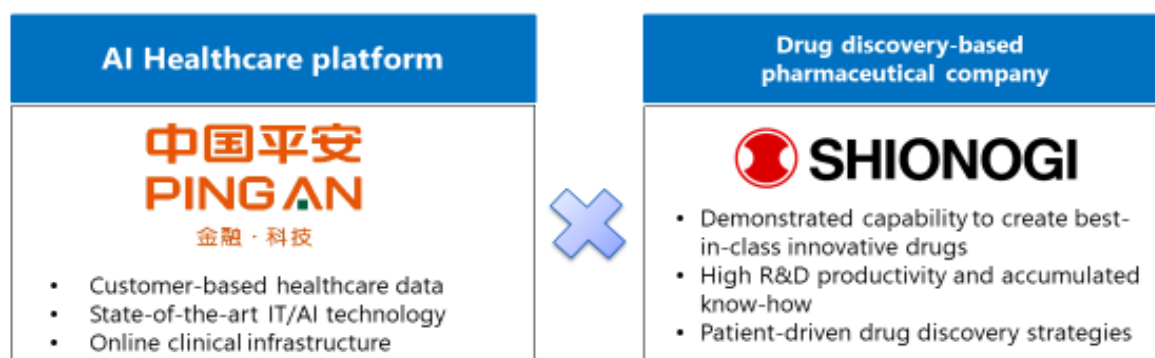


* Based on data such as real world data, market data, Web analysis data, etc.

** Online to Offline: Combine online Web and offline physical stores for maximally productive marketing and sales activities

This is page 23. It's a little hard to understand, so we've spread the information over pages 23 and 24, so regarding this, after we have signed the final contract, when we have put together the final deal with Ping An in June or July, I intend to tell you about how big a business we are going to pursue, how long we plan to conduct the business for, and how much sales revenue we intend to earn.

New Value Created by JV



To build the next evolution of a discovery-oriented healthcare company

**Providing healthcare solutions to patients and society,
contributing to the health of all and creating the future of healthcare
(Provide total healthcare service effective even in pandemic)**

From our point of view, over the next three to five years, we want this deal between Ping An and Shionogi to become our biggest contributor to global sales.

KPIs - Results in FY2019 -



		FY2020 target	FY2019 target*	FY2019 results	FY2018 results
Growth	Sales of new products**	200 B yen	100.6 B yen	62.9 B yen	83.1 B yen
	Ordinary Income	150 B yen	170.5 B yen	151.8 B yen	166.6 B yen
Efficiency	ROIC***	Over 13.5%	Over15.0%	13.8%	16.5%
	CCC****	7.0 months	7.6 months	7.7 months	8.9 months
	Original pipeline ratio	Over 50%	Over 50%	67%	69%
Shareholder return	ROE	Over 15.0%	Over18.0%	18.0%	20.9%
	DOE	Over 4.0%	4.3%	4.7% (planned)	4.6%



SHIONOGI

* Target set on May 9, 2019 ** New products: See the Appendix p.65
New Products were defined in Updates to SGS2020 issued on October 31, 2016

*** Return on invested capital
**** Cash conversion cycle

25

This is page 25. The results for FY2019 were disappointing, but because ordinary income was 151.8 billion yen, ROIC was 13.8%, ROE was 18%, and DOE was 4.7%, we've reached the point where we should somehow be able to move forward to the targets we initially presented for FY2020, even if conditions are considerably unfavorable.

Looking back on FY2019 and Looking Ahead to FY2020



FY2019 summary

Achieved

- Increased breadth of future business through business alliances
- Obtained approval for Cefiderocol, our core overseas project, in the US and EU
- Enrich PoC products and non-clinical pipeline

Tasks remaining

- Establish best practices for domestic business
- Expand new products domestically and overseas
- Enrich later-stage pipeline

FY2020 focal points for achieving sustainable growth

1. Domestic/overseas business: Achieve sales growth through new products

- Establish Integrated Disease Care Division and reorganize Pharmaceutical Commercial Division
 - Proposal of total care for diseases
 - Global consistent brand strategy
 - Firmly establish data-based strategy formulation and activities
- Transform overseas business, including through the establishment of a new business model in China

2. R&D: Accelerate R&D for discovery and progression of growth drivers

This is page 26, and it provides a summary. Although we achieved some things, there are still a lot of tasks remaining, so regarding this fiscal year in particular, I'd like you to ask lots of questions to Sawada, but by establishing the Integrated Disease Care Division, and reworking our strategy, including domestically, to base it on disease, from this fiscal year, we're going to be pressing ahead with a new approach to business. This fiscal year is going to be all about developing new businesses in China, and in the vaccine arena, and we're currently taking aggressive action.

Adoption of International Financial Reporting Standards (IFRS)



Changes in FY2019 performance due to application of IFRS

(Unit: B yen)

JGAAP		IFRS*		Difference**
Sales	335.0	Revenue	333.3	(1.6)
Cost of sales	56.7	Cost of sales	56.8	0.1
Gross profit	278.3	Gross profit	276.5	(1.8)
Selling & administrative expenses	105.8	Selling, general & administrative expenses	98.1	(7.8)
R&D expenses	47.2	R&D expenses	47.9	0.7
		Other income & expenses	0.8	0.8
Operating income	125.2	Operating profit	131.4	6.1
		Core operating profit	128.2	
Non-operating income & expenses	26.5			(26.5)
Extraordinary profit / loss	6.8			(6.8)
		Finance income & costs	28.2	28.2
Income taxes	37.3	Income taxes	37.2	(0.0)
Profit attributable to owners of parent	121.3	Profit attributable to owners of parent	122.3	1.0

Definition of core operating income following application of IFRS

Full operating income is adjusted for the following one-time factors:

- Impairment losses
- Gains on sale of tangible fixed assets
- Business restructuring expenses
- Losses due to disasters
- Litigation expenses, compensation, and out-of-court settlements
- Other factors that the company deems should be excluded



* IFRS reclassified values for FY2019 are provisional values that have not been audited

** For details of differences, See Appendix p.48

Now let's move on to this fiscal year's financial forecasts. This is page 28. From this fiscal year, though we have been somewhat late to do so, we have adopted IFRS. During the past year, we have been operating both systems in parallel, and from this fiscal year will be announcing our financial results based on IFRS. As you can see, there some slight variances in figures between JGAAP and IFRS, but we believe we can make the change without altering the big picture too much. Looking back on sales in FY2019, revenue is a little lower, while profit attributable to owners of parent is slightly higher. I think you will agree that the differences are minimal.

Financial Forecasts (IFRS)



(Unit: B yen)

	FY2020 forecasts		FY2019 Results*	Y on Y	
	Full year	1H		Change (%)	Change (B yen)
Revenue	323.5	155.6	333.3	(3.0)	(9.8)
Operating profit	110.3	53.8	131.4	(16.0)	(21.0)
Core operating profit	110.3	53.8	128.2	(13.9)	(17.8)
Profit before tax	136.3	61.6	159.5	(14.6)	(23.2)
Profit attributable to owners of parent	103.6	44.9	122.3	(15.3)	(18.7)

Decrease in revenue and profit because decrease one-time income in FY2019 related to alliances is not expected to be fully covered by the increase in revenue from the growth of new products.

Exchange rate (average)	FY2020 forecasts	FY2019 results
USD (\$) – JPY (¥)	107	108.72
GBP (£) – JPY (¥)	130	138.15
EUR (€) – JPY (¥)	120	120.82



* Converted from JGAAP to IFRS
(IFRS reclassified values for FY2019 are provisional values that have not been audited)

29

This is page 29. It shows our financial forecasts under IFRS. Revenue is projected to be 323.5 billion yen, 3% down on the previous year. This is based on comparing IFRS with IFRS. Core operating profit, on the third line, is 110.3 billion yen, which is 13.9% lower. Profit before tax, at 136.3 billion yen, is down 14.6%. And at 103.6 billion yen, profit attributable to owners of parent, is down 15.3%. We're going to start with these targets.

Regarding sales, we think that domestic sales will increase slightly, but regarding so-called royalty income, we are receiving royalties from Roche, and as we are ultimately accepting a high level of risk, the 11.3 billion yen from Xofluz, and from Crestor, these generate 200 million dollars in cash flow, but there is a mismatch in recognition periods in conjunction with the switch to IFRS, so the income will be recognized by the end of December, and that will result in a reduction of 5.4 billion yen. And the derivation of Symproic, or Naldemedine, to BDSI, is worth 3.5 billion yen, and put together, this will reduce sales that contribute directly to profits by around 20 billion yen.

In addition, this slide also shows exchange rates, and financial institutions are predicting that the yen will appreciate substantially, and though we hope this prediction will prove false, the view from the outside is that the yen will move higher. The pound, in particular, dropped to the 120 yen range at the end of the fiscal year, and Hanasaki and Hosogai are taking this fairly seriously, and performing various royalty calculations, so in addition to that sort of milestone income disappearing to the tune of 20 billion yen, in

terms of profit, the changes will be -21.0 billion yen, -17.8 billion yen, -23.2 billion yen, and -18.7 billion yen, and this is the straight-up list of figures.

However, as I mentioned earlier, regarding what will happen this year with the joint venture with Ping An, and with the corona vaccine, we haven't factored these elements in at all as yet. And we're developing two or three other businesses, and they are not included, either. I think that some of these elements will contribute to profits this fiscal year, but because we haven't factored them in, as we continue with our core businesses, we have been fairly bold in taking into account adverse factors such as exchange rates, as well as the negative outlook for the domestic market.

This might just be my own personal view, but I think it's a real shame that the figures ended up lower than those we announced last year. For this fiscal year, we prepared our budget in such a way that we can discuss with you further how far we can go beyond the official figures. Incidentally, we're currently planning to announce our new medium-term plan on June 1, and you've put this in your schedules, but with this being the first fiscal year of the new medium-term plan, we cannot allow ourselves to miss our targets in the first fiscal year, so in light of that, we'd like to get off to a solid start.

Income Statement Forecast (IFRS)



(Unit: B yen)

	FY2020		FY2019	Y on Y	
	Full year	1H	Results*	Change (%)	Change (B yen)
Revenue	323.5	155.6	333.3	(3.0)	(9.8)
	17.2	16.5	17.0		
Cost of sales	55.7	25.7	56.8	(1.9)	(1.1)
Gross profit	267.8	129.9	276.5	(3.2)	(8.7)
	47.6	48.0	43.8		
SG&A expenses	153.9	74.7	145.9	5.5	8.0
	32.1	32.2	29.4		
Selling & administrative expenses	103.7	51.6	98.1	5.8	5.7
	15.5	14.8	14.4		
R&D expenses	50.2	23.0	47.9	4.8	2.3
Other income & expenses	(3.5)	(1.4)	0.8	(567.5)	(4.3)
	34.1	34.6	39.4		
Operating profit	110.3	53.8	131.4	(16.0)	(21.0)
	34.1	34.6	38.5		
Core operating profit	110.3	53.8	128.2	(13.9)	(17.8)
Finance income & costs	26.0	7.8	28.2	(7.8)	(2.2)
	42.1	39.6	47.9		
Profit before tax	136.3	61.6	159.5	(14.6)	(23.2)
Profit attributable to owners of parent	103.6	44.9	122.3	(15.3)	(18.7)



* Converted from JGAAP to IFRS
(IFRS reclassified values for FY2019 are provisional values that have not been audited)

30

Page 30 presents our income statement forecast, and regarding costs in relation to sales, we believe that sales of infectious disease drugs containing Xofluza will increase to some extent, and costs have been

expressed to match that. Regarding selling expenses and R&D expenses for products such as Cefiderocol overseas, though Phase 3 has finished, S-600918, BPN14770, which I mentioned earlier, and S-812217 from Sage are also moving domestically. And the second version of S-600918 for sleep apnea syndrome is also moving. Because progress will also be made with the corona vaccine and also other therapeutic drugs, we used an additional 2.3 billion yen, which means selling and administrative expenses are increasing. Therefore, operating income will decrease a little more substantially. However, I feel that in that sense FY2020 will be an extremely important year, so I hope we can be forgiven for being this aggressive.

Y on Y Comparison and Main Variation Factors (Statement of Income: IFRS)

• Y to Y comparison

(Unit: B yen)

Revenue	(9.8)
Cost of sales	(1.1)
Gross profit	(8.7)
Selling & administrative expenses	+5.7
R&D expenses	+2.3
Other income & expenses	(4.3)
Operating profit	(21.0)
Core operating profit	(17.8)
Finance income & costs	(2.2)
Profit before tax	(23.2)
Profit attributable to owners of parent	(18.7)

Decrease in profit

Increase in profit

Main Variation factors (Y on Y)

• Revenue (-9.8 B yen)

- Sales growth of prescription drugs in Japan
- Decrease of sales at overseas subsidiaries (Including one-time income)
- Decrease of royalty income (mainly due to one-time factors related to Xofluza® and Crestor®)
- Reduction of contract manufacturing

• SG & A expenses (+8.0 B yen)

- Selling & administrative expenses (+5.7 B yen)
 - › Japanese business: Increase in expenses due to sales increase of strategic products especially for Cymbalta® and Intuniv®
 - › Overseas business: Increase in expenses due to investment on pre/after-launch marketing activities for Fetcroja® in EU
 - › IT investment
- R&D expenses (+2.3 B yen)
 - › Advance R&D activities focused on core projects

This is page 31. The large decrease in revenue is due to the decrease in royalty income including Xofluza, Crestor, and BDSI. We also think that we will need to boost IT investment a little this year, so R&D expenses will rise.

Revenue Forecast by Segment (IFRS)



(Unit: B yen)

	FY2020		FY2019	Y on Y	
	Full year	1H	Results*	Change (%)	Change (B yen)
Prescription drugs	123.9	53.1	106.2	16.6	17.7
Oversea subsidiaries/export	24.0	11.3	30.8	(21.8)	(6.7)
Shionogi Inc.	5.1	2.6	10.1	(49.1)	(5.0)
C&O	11.9	5.7	13.1	(9.2)	(1.2)
Contract manufacturing	15.4	7.9	17.6	(12.2)	(2.1)
OTC and quasi-drug	10.4	4.9	9.7	7.5	0.7
Royalty income	148.3	77.8	166.9	(11.1)	(18.6)
HIV franchise	126.3	64.2	128.1	(1.4)	(1.8)
Crestor®	16.9	11.1	22.3	(24.4)	(5.4)
Others	5.2	2.5	16.5	(68.7)	(11.3)
Others	1.3	0.7	2.2	(39.0)	(0.8)
Total	323.5	155.6	333.3	(3.0)	(9.8)



* Converted from JGAAP to IFRS
(IFRS reclassified values for FY2019 are provisional values that have not been audited)

32

This is page 32. Regarding domestic sales, I will explain later. it's a question of how much we should expect from Regarding Fetroja in Shionogi Inc., we have very little idea of what to expect. We've been receiving various inquiries, and thinking about how to convert them into sales, but it's been extremely difficult to decide how much to factor in, so we hardly factored in anything in as we prepared this budget. We hope that these elements will serve to lift sales.

As for contract manufacturing, we produced a lot of Xofluza at the end of last FY2019. And regarding dolutegravir, it just happens to be the time that we are switching the manufacturing method to a new method. We are transitioning from a first-generation manufacturing method to a second-generation method, and exports of products manufactured using the new method will begin this fiscal year, so there will be a slight gap and the figure will be down a little. As for royalty income, as I've already explained, the figures for HIV franchise can be interpreted as being due to forex factors.

Revenue Forecast of Prescription Drugs in Japan (IFRS)



	FY2020		FY2019	Y on Y		(Unit: B yen)
	Full year	1H	Results*	Change (%)	Change (B yen)	
Cymbalta®	28.6	13.9	26.2	9.1	2.4	
Intuniv®	16.7	6.8	10.3	61.1	6.3	
Vyvanse®	0.8	0.2	0.0	-**	0.8	
Infectious disease drugs	26.5	7.1	16.1	65.0	10.4	
OxyContin® franchise	5.6	2.9	5.9	(5.4)	(0.3)	
Symproic®	2.9	1.3	2.1	37.1	0.8	
Actair®	0.3	0.2	0.3	27.6	0.1	
Mulpleta®	0.1	0.1	0.1	(3.0)	(0.0)	
Pirespa®	4.9	2.9	6.6	(25.6)	(1.7)	
Others	37.5	17.7	38.7	(2.9)	(1.1)	
Crestor®	8.3	4.2	8.6	(4.4)	(0.4)	
Irbetan® franchise	3.7	1.8	4.3	(12.5)	(0.5)	
Prescription drugs	123.9	53.1	106.2	16.6	17.7	

➤ Due to the epidemic of COVID-19, it is difficult to accurately estimate each infectious disease drug, forecasts of infectious disease drugs include the total amount of the following products

- Xofluza®
- Rapiacta®
- Brightpoc®Flu•Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Seftem®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole®
- ISODINE®
- SARS-CoV-2 antibody test kit***



SHIONOGI

* Converted from JGAAP to IFRS (IFRS reclassified values for FY2019 are provisional values that have not been audited)
 ** Launched in Dec., 2019 *** Pre-launch, collecting clinical data

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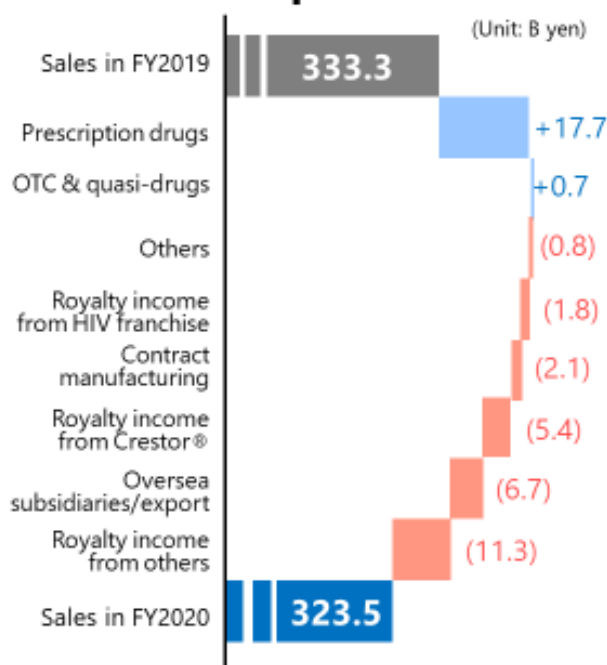
This is page 33. We cannot afford to book lower sales of Cymbalta and Intuniv, so we've initially set fairly aggressive targets. As for Xofluza, I talked with Sawada a lot about this. If this corona situation continues for a long time, what will happen to the patient treatment algorithm? For example, to what extent will things like so-called online medical examinations remain? How will influenza patients be identified? It's really difficult to see what will happen. One of our most important tasks is producing results not for each product, but for drugs for infectious diseases as a whole, and particularly in the area of disease strategy. Of course, our most important products are Xofluza and Rapiacta, and of course, Flumarin and Finibax. Our sales force are going to be able to sell products like this, so we've put them in one box called infectious-disease drugs, and arrived at a full-year forecast of 26.5 billion yen.

As for other products, sales are obviously going to drop bit by bit. Generic versions of Pirespa are now available, so we've incorporated that into the forecast.

Y on Y Comparison and Main Variation Factors (Revenue by Segments)



• Y on Y comparison



Main Variation factors (Y on Y)

- **Prescription drugs (+17.7 B yen)**
 - Sales growth of infectious disease drugs, ADHD family, Cymbalta®
- **Oversea subsidiaries/export (-6.7 B yen)**
 - Shionogi Inc.: One-time payment from alliance partners in FY2019
 - C&O: Decrease in sales due to unlisted flagship products for national insurance
- **Contract manufacturing (-2.1 B yen)**
 - Temporary reduction in supply amount while implementing planned improvements in manufacturing methods
- **Royalty income (-18.6 B yen)**
 - Milestone payment from Roche for Xofluza® in FY2019
 - Change in the timing of recording royalty income from AstraZeneca for Crestor® due to conversion from JGAAP to IFRS (Elimination of 1Q delay)
 - Decrease in royalty on HIV franchise due to exchange rate impact

This is page 34. Regarding C&O's flagship product, rabeprazole, it states here that it was affected by being unlisted for national insurance. In fact, in July C&O will be placed under the wing of Ping An-Shionogi, so the planning for how it will be sold has not been included here at all. Therefore, when the Ping An-Shionogi deal is done, we intend to present our forecasts for sales and profits in China as a whole, including C&O, once again.

Financial Forecasts (IFRS)



(Unit: B yen)

	FY2020 forecasts		FY2019 Results*	Y on Y	
	Full year	1H		Change (%)	Change (B yen)
Revenue	323.5	155.6	333.3	(3.0)	(9.8)
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Profit before tax	136.3	61.6	159.5	(14.6)	(23.2)
Profit attributable to owners of parent	103.6	44.9	122.3	(15.3)	(18.7)

Decrease in revenue and profit because decrease one-time income in FY2019 related to alliances is not expected to be fully covered by the increase in revenue from the growth of new products.

Exchange rate (average)	FY2020 forecasts	FY2019 results
USD (\$) – JPY (¥)	107	108.72
GBP (£) – JPY (¥)	130	138.15
EUR (€) – JPY (¥)	120	120.82

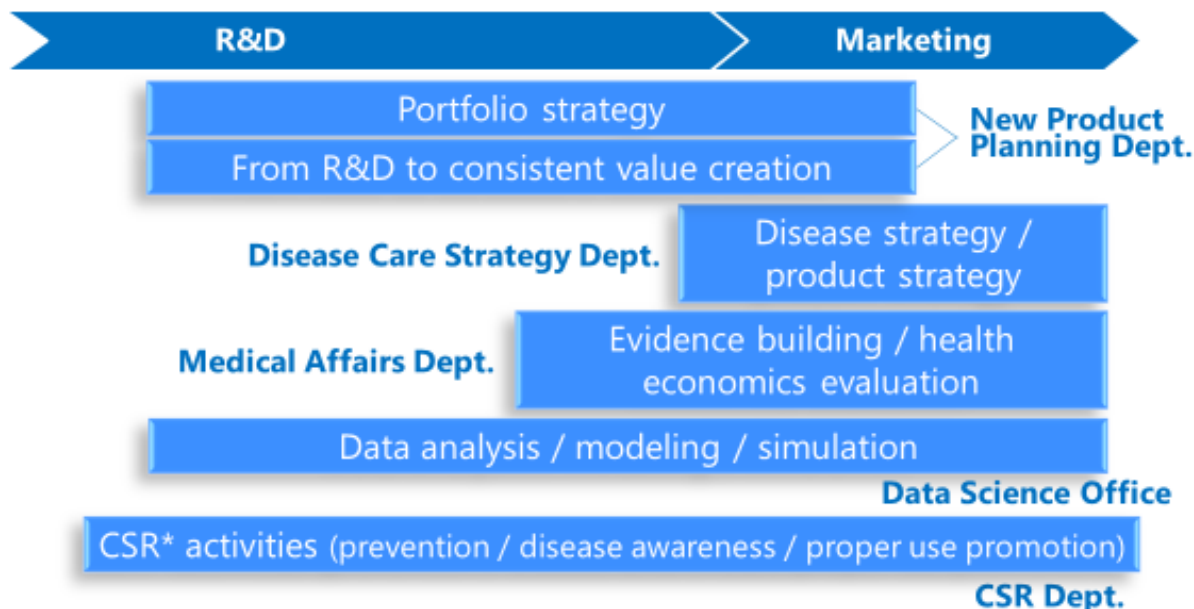
This is page 35. Once again, that we are forecasting lower sales and profits, but this is how we intend to start the first year of our new medium-term business plan.

Establishment of Integrated Disease Care Division



Mechanism for effectively delivering required products/information globally

➤ Cross-value chain, customer-oriented, evidence-focused, data-driven

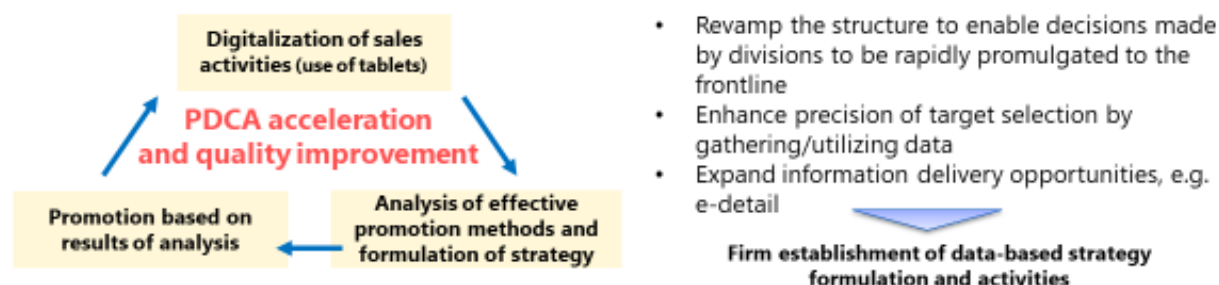


This is page 37, and it presents our initiative for FY2020. Because it's called the Integrated Disease Care Division, it's not going to be particularly focused on sales. Rather, it's going to combine various elements to create a disease strategy, and then consider how to communicate that disease strategy to the market. It's going to perform new product planning in a manner similar to marketing. And what we called product strategy at one time, will be handled by the Disease Care Strategy Department. You might think that we've just changed the name, but that's not the case. Instead of only thinking about products, it's going to be thinking about a disease, too, so everything relating to medical affairs and data science will be under its purview. And with regard to infectious diseases and CNS, in particular, efforts in the area of CSR are extremely important, we're going to produce an integrated disease care strategy that covers all these areas, and perhaps could be said to encompass all of the company's activities.

Improved Productivity and Sales Growth for Domestic Business



Reorganization of sales structure



Cymbalta®, Intuniv®

Cymbalta® activity policy

Focus on activities that proved effective in FY2019

- Deliver information based on needs and level of understanding of physicians
 - Distribute information from KOL via web lectures etc.
- Communicate effectiveness through use
- Expand share in four-drug market for chronic back pain

Intuniv® activity policy

- Determine target facilities more precisely
 - Ensure differentiation by emphasizing that the mechanism of action and effectiveness are different from those of other drugs
- Increase awareness of product (adult, pediatric)
Increase adoption efficiency (adult)

This is page 38. Regarding domestic sales activities, given that a lot of people are working from home, I think it's a really good time to rethink our approach to providing information. Physicians will no longer be wanting to meet MRs if they're only going to be talking about drugs. I think physicians are going to become more selective, asking themselves who it can provide them with information that is actually useful to them. With disease strategy as a base, we intend to communicate matters that we really want to convey in the form of electronic information, and rethink the notion of conveying these sorts of things personally when meeting face to face.

Cymbalta, Intuniv, and of course, infectious disease drugs such as Xofluza, will comprise the three pillars, and with Cymbalta at least centered on pain, in our case, CNS-related agents, namely S-812217 or BPN14770 will also be increasing, and we intend to once again review our MR activities in the depression field. Intuniv can also be administered for adult ADHD, so including that, we will be treating this as neuropsychiatric disease. We intend to capture this entire disease field.

Improved Productivity and Sales Growth for Domestic Business



Xofluza®

- **Issues that became apparent during FY2019**
 - Increasing understanding regarding reduced susceptibility viruses amongst medical professionals, but this is not leading to an increase in prescriptions
 - Currently, around a third of physicians do not have a correct understanding of data on variant/resistant strains in relation to Xofluza®
- **Information so far obtained through surveillance**
 - Outbreaks of reduced susceptibility viruses had not been identified from launch of Xofluza® until the 2019/2020 season
 - ✓ No spread of reduced susceptibility viruses between seasons or during seasons was identified
- **Activity policy for this fiscal year**
 - Based on the results of surveillance during the 2019/2020 season, swiftly announce the latest evidence about the drug at conferences and in papers
 - Utilize Stream-I etc. to deliver information aligned to the level of understanding and needs of physicians
 - Obtain additional approval for prophylactic use ahead of the 2020/2021 season

It is challenging to sustain sufficient medical system for treating infectious diseases, including influenza, during the COVID-19 pandemic

Maintain patients' benefit by delivering the latest information about infectious diseases and providing prompt diagnosis/treatment

This is page 39, and regarding Xofluza, I have to tell you straight that FY19 was an extremely tough year. What is really good news is that the results of surveillance show that it isn't like amantadine, where resistance, once obtained, carries over to the following year, the year after that, and forever after. It's more the Tamiflu type. We think that bumpy cycles, where resistance occurs one year but not the next, will continue. And if that's the case, having neuraminidase and cap-dependent endonuclease, which have a different mechanism but a similar degree of safety, will be an immense benefit for mankind, so having explained that, regarding our activity policy, after at least producing a paper and evidence, if there's a chance of it being used for influenza in 2020 and 2021, we intend to recommend the use of Xofluza.

Transformation of Overseas Business



China business

- Establish new joint venture (conclude joint venture agreement): Probably before Jul. 2020
- Desired direction
 - Construct new distribution platform and sell Shionogi Group's products including generic drugs supplied by C&O
 - Swiftly launch new drugs that we have developed in the Chinese market
 - Leverage wealth of healthcare data and strengths such as AI diagnosis to discover/develop new drugs

In partnership with Ping An Insurance Company of China, establish a new healthcare platform model in China and the rest of Asia, markets that are predicted to grow faster than any other

US business / EU business

US

- Obtain additional approval for Fetroja® as a treatment for nosocomial pneumonia, and strengthen its presence in the hospital domain
- Step up licensing negotiations to augment hospital portfolio

EU

- Prepare to launch Fetroja® in major European countries
- Ensure availability of Fetroja® pre-launch through an Early Access Program for the treatment of carbapenem resistant Gram negative infections in patients with limited treatment options including those with secondary bacterial infection following on infections with COVID-19

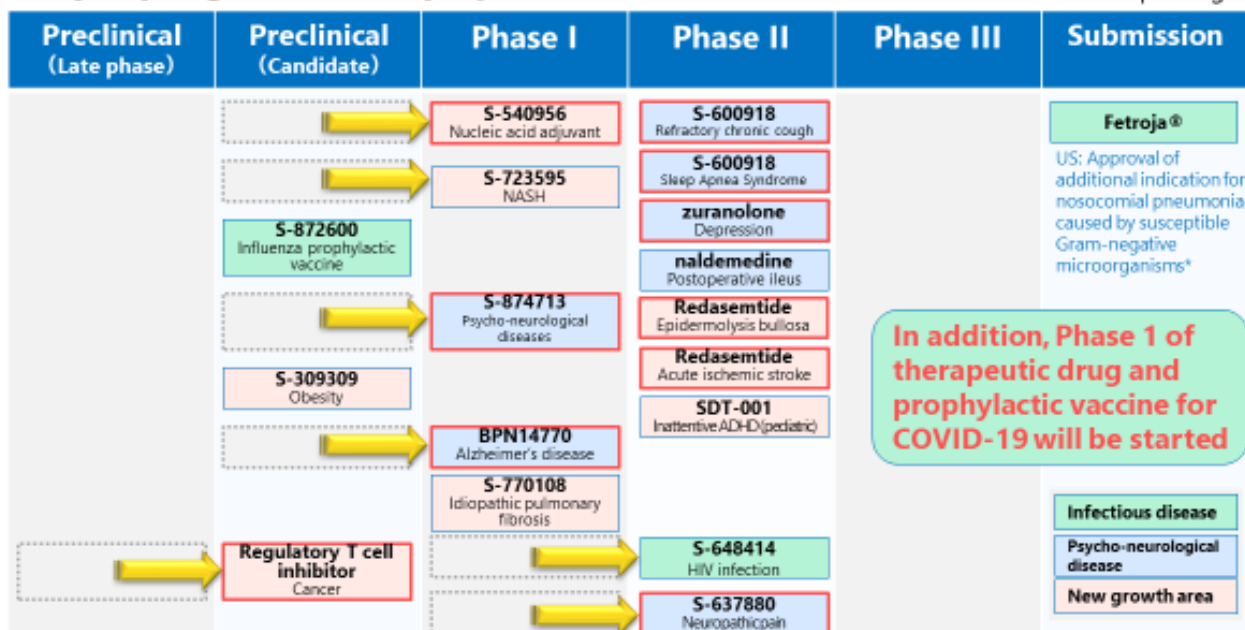
This is page 40. Regarding China, I've discussed it many times, so I'll omit mention of it here. As for the US and the EU, the issue is what sort of products to add to Fetroja/Fetroja, which is the main product. We making steady progress with discussions with each of the country's governments, so it will be easy, in a variety of senses, to make sales, and in that respect I think things are moving a little faster in the EU, though as we proceed, if there are opportunities to introduce products, we intend to take full advantage of them.

Promote R&D Activities | Increase Pipeline in Late Stage



Major progression steps planned for FY2020

 Core pipeline to change the treatment paradigm



Accelerating R&D to overcome HIV product patent cliffs



* patients 18 years of age or older who have limited or no alternative treatment options

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This is page 41. As I've already mentioned, this fiscal year we're going to push forward in the area of vaccines, though they are not included here, and also therapeutic drugs, and our main focus will be on S-600918, which is in Phase 2, S-812217, and S-005151, which is redasemtide, as well as S-648414, and BPN14770, which is shown on the left side.

Positioning of FY2020



A year for reaffirming our focus on meeting the challenge of the HIV-product patent cliff, and for pulling the Shionogi Group together for transformation

Strong commitment to “high productivity”

Domestic/ overseas business	Achieve sales growth through new products <ul style="list-style-type: none">• Establish Integrated Disease Care Division and reorganize Pharmaceutical Commercial Division<ul style="list-style-type: none">- Proposal of total care for diseases- Global consistent brand strategy- Firmly establish data-based strategy formulation and activities• Transform overseas business, including through the establishment of a new business model in China
R&D	Accelerate R&D for discovery and progression of growth drivers

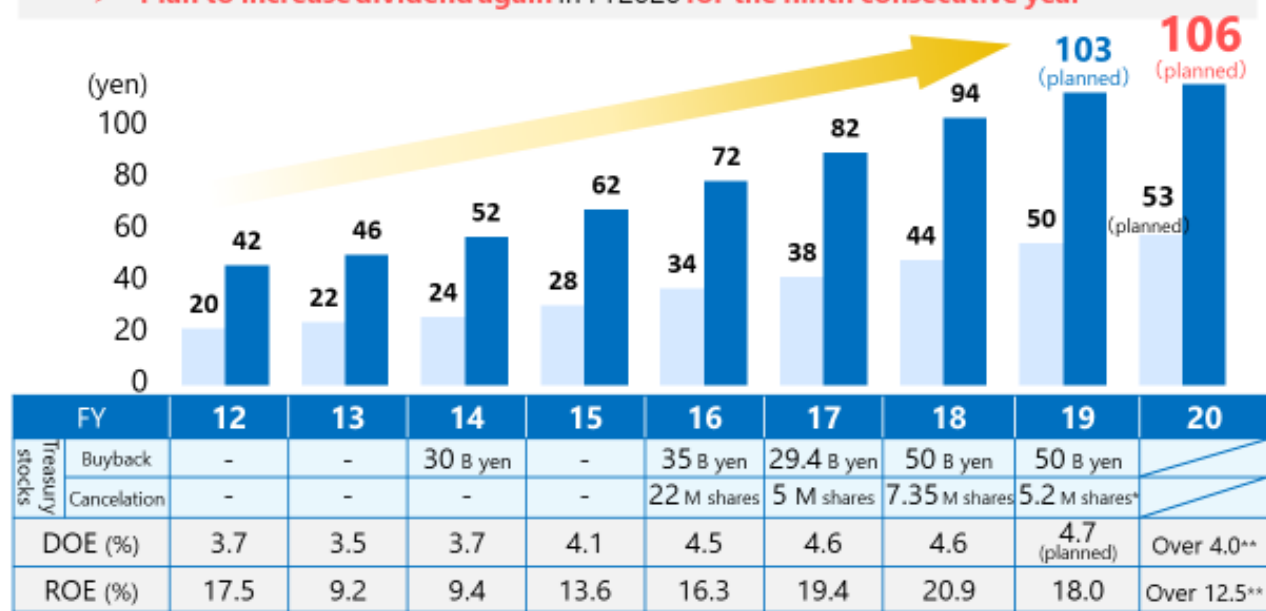
**Overall picture of transformation to be described
in the new medium-term business plan
(Scheduled to be announced on June 1, 2020)**

And this is page 42. Regarding the positioning of FY2020, with this being the first fiscal year of the medium-term plan, it's going to be a year in which it'll feel like we're starting from zero in various areas. Fortunately, and as I've said repeatedly, in the realms of vaccines, China, and peptides, things are progressing really well, so we're gradually laying more and more of the groundwork, so we're positioning this as a year in which we make this progress tangible and begin delivery.

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**



SHIONOGI

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

** Planned figures based on IFRS

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Finally, I'd like to talk about shareholder returns. This is page 44, and we're going to continuously and constantly increase dividends, and boost total shareholder returns. At the moment, provided we can obtain approval at the shareholders meeting, we're planning to pay a year-end dividend of 53 yen, so I think that 53 yen will be our starting point when considering the interim dividend, which is coming up next. We'd like to begin FY2020 with a dividend plan of 53 yen and 53 yen, so 106 yen in total, an increase of 3 yen. But depending on results, we may reconsider this. And as for share buybacks, we're going to take into account market conditions, other companies, feedback from shareholders, and so on, and consider things flexibly. At the present time, all I can tell you as that we're planning to increase dividends.

That's all. My apologies for rushing, but that concludes my remarks.

Q&A

Kyokawa: I would now like to move on to the Q&A portion of this briefing session. The Q&A section will be conducted in line with each operator's presentation.

Emcee: The first question we will take is from Yamaguchi-san from Citigroup Securities Japan.

Yamaguchi: Yamaguchi from Citigroup. My first question is about Xofluza. You provided various explanations and I believe I gained a good understanding. However, you mentioned that doctor prescription trends are having more impact on sales than market factors. Regarding this, given changes in data-backed guidelines, as a measure for this year, is it your intention to update prescription trends and various other opinions within a year? Will this action take several years same as for Tamiflu unfortunately?

In addition, although it is unclear despite the disclosure of sales, this represents the majority of sales growth. Are you targeting the ¥10 billion level or ¥10 billion-plus from ¥400 million from 260?

Sawada: I will answer your question. Regarding the latter part, we are looking at this in general. That's great. I knew you would understand. Looking at prescription trends for the season in the previous year, in the first half, I believe there was naturally a large, vague uncertainty about the phrase "reduced susceptibility virus."

Naturally, it is essentially to slowly alleviate this vague uncertainty. From the end of January, we have been providing some explanations and making changes to tools we supply. Consequently, I feel that things are starting to look up a little. Unfortunately, at the same time, we were dealing with whether COVID-19 would spread or if the flu season would come to an end. Regrettably, last year's flu season was over before we were unable to monitor these two trends. Taking this into account, we were also set to release new papers and other information. Therefore, along with this, we plan to continue to carry out that trend by providing further explanations, and aim to use this to contribute to the next season.

Yamaguchi: Currently there does not seem to be much in the way of guidelines. It appears the only directive is that it is not recommended for children. Among these activities, do you anticipate that the description of guideline will change comparatively routine matters or irregular?

Sawada: We have actually been told that the committee, at the least, will provide revisions based on adequate data. I think this is naturally something that should be carried out. Conversely, taking into account meetings by experts involving COVID-19, I believe that associations on infectious disease and other groups are likely to review the algorithm itself, in other words, what approach to use to diagnose patients and what types of treat to employ. Accordingly, I think Shionogi should provide necessary information.

Yamaguchi: I understand. Next I would like to ask about the medium-term business plan. I understand that it will be released on June 1. Meanwhile, the Ping An matter is to take the form of a joint venture by July. It was stated that this is likely to be best driver.

In light of this, can we expect a medium-term business plan that, to a certain extent, significantly focuses on the Ping An business?

Teshirogi: We have already disclosed the figures for the first fiscal year. At the moment, we are focusing on a 10-year horizon while temporarily maintaining our numerical targets for the first five years. The figures for the remaining five years will naturally reflect the outcome of our undertaking with Ping An or reflect whether we plan to globally deploy a vaccine. I think you should view the numerical targets as an interpretation of this.

Yamaguchi: Okay. Lastly, I assume you discussed this at the R&D meeting you brought up at the start in the section on COVID-19. Regarding this drug therapy, more headway has been made than discussed at the R&D meeting. In other words, you initially aimed to clinical trials before the end of the fiscal year.

However, a fair amount of progress has been made since then, and you are starting to see the prospects for launching clinical trials. Shionogi has recently commented on this but is it okay to assume that you are making a fair amount of progress in comparison to when you conducted the R&D meeting?

Teshirogi: I believe so. We are currently working, centering on small molecules. We are able to speedily move through the SAR cycle. As one would expect, we were quick to take action and a fairly good drug began to appear. However, we need to run animal and clinical testing to ascertain the safety of the drug but from the point of efficacy, we are naturally seeing results. We are conducting a fundamental toxicity screening so in our own way we are paving the way for use with humans. Going forward, we aim to accelerate animal testing and clinical trials.

Yamaguchi: So putting it simply, I believe there was talk about whether this would firmly work for coronaviruses or if it would have a broader efficacy, including for SARS and MERS. Does this mean it will be suited for use in treating coronaviruses?

Teshirogi: The efficacy is slightly poor for general common cold coronaviruses, such as the existing coronaviruses or alphacoronavirus. However, for SARS and MERS, which are betacoronaviruses, it basically covers all these categories.

Yamaguchi: So it covers these viruses. I understand. Thank you.

Emcee: The next question is from Ueda-san from Goldman Sachs. Ueda-san, please state your question.

Ueda: Ueda from Goldman Sachs. I would also like to start by asking about a drug therapy for COVID-19. After that I would like to ask about the status of development for a vaccine and diagnostic agent. Can you tell me the positioning of each of these drugs?

In the case of drug therapies, currently drug companies are repositioning existing drugs and conducting development for their use in treating COVID-19. In this case, for example, what is your positioning, including for the mechanism of action?

In the case of a vaccine, I assume that this will be a domestically-made product therefore from this standpoint, what will be the significance of this going forward?

As for a diagnostic agent, companies such as Roche and Abbott are developing products with a high specificity and that are fairly sensitive. Considering that these products may soon be available for use in Japan, how do you plan to position your own product?

Teshirogi: To be honest, COVID-19 is a great learning experience for Shionogi in terms of developing a drug therapy. We are finding that it is likely that the effects of an antiviral agent and treatment for COVID-19 are not one in the same.

What we are currently developing is an antiviral drug. Consequently, it works to reduce the volume of the virus in the patient particularly during the initial stage. For some patients, I believe this will dramatically improve symptoms. However, for example, there are COVID-19 patients that experience a cytokine storm. In these cases, although drugs such as Xofluza reduce the virus to zero, patients continue to experience coughing and itchy nose symptoms. At present, we need to come up with a positive therapy for patients that will cover all infections.

We are currently designing an antiviral that will fairly specifically reduce the amount of a coronavirus. If reducing the amount of the virus in the patient's body is the goal, then we can naturally use an antiviral such as Xofluza or neuraminidase inhibitor, which are safe and reduce the amount of virus. As this is our first target, if we can make this happen, then our drug will be the first choice for a fair number of patients. However, regarding influenza, the prognosis when symptoms become more severe, we believe that this is not very effective. We are therefore considering development drugs and development drug candidates,

including those that can be used as a total solution.

As for a vaccine, Sanofi and the GSK framework were disclosed during the middle of April. These are vaccines with a gene-modified protein. There nearly occupy a full block. Sanofi is selling this as an influenza vaccine. It uses the exact same manufacturing method. Naturally a different protein is being used. And the cells used to manufacture this protein also differ. However, the concept is exactly the same. For instance, there are a variety of vaccines, including a DNA vaccine, mRNA vaccine, and adenovirus vaccine. In contrast with these types of vaccines, we recognize the vaccine we are creating to be relatively safe and the manufacturing method is already established.

In this sense, development speed is fast. In addition, given our experience thus far in gene-modified proteins and influenza drugs, it is fairly easy for us to set a goal for mass production. Another key point is the price at which the drug is provided. I believe it will be possible to provide this vaccine at a fairly lower price than mRNA.

Based on this, we plan to start by aiming to domestically produce vaccine for 10 million people. I think this can also be applied for a somewhat larger volume. Given that you analysts already know, I will be straightforward. Depending on the adjuvant that is used with this vaccine, the amount of protein will differ. The change in the volume of proteins will result in a change in the amount of vaccine that can be produced. If we can control the amount of gene-modified proteins to a certain extent by using the vaccine in combination with a good adjuvant, then the vaccine can be supplied to a larger number of people. We need to determine how to design this vaccine. We first need to speed up development to quickly provide vaccine to the medical frontlines. Then, we need to develop vaccine in the second phase. Consequently, we are carrying out development while also focusing on the lifecycle of these two vaccines.

If we can somehow embark on clinical trials before year-end and create an antibody, moreover neutralizing antibodies, then I believe we will be able to at least start supplying those in the medical frontlines as soon as possible. Sawada will discuss the diagnostic agent.

Sawada: As you mentioned, global companies are making a very high precision diagnostic agent. For the time being, we aim to release a diagnostic agent for research trial purposes, as opposed to employing clinical trials of current agents. We plan to work from these to make further improvements. We plan to make changes in line with needs going forward.

Ueda: Thank you. Is it correct to understand that this company could possibly employ a different approach or tackle the development of a COVID-19 drug therapy going forward?

Teshirogi: Yes. We are currently planning to call this a drug therapy to prevent severe infection. We are actually teaming up with a venture company in the US. Our existing drug therapies will be reviewed to see if there is anything interesting and can possibly be used to prevent serious infection. We would not do this ourselves. We would license this out to the venture company. One idea would be to put anything interesting back out onto the global market.

Ueda: Thank you. My second question is about Cefiderocol. You said this has not been factored into FY2020 sales. Headway is being made to achieve full-fledged sales and to expand the drug's indications for use in pneumonia. How should its market potential be viewed? Can you discuss this, along with the progress you are making negotiating selling prices with the governments of each country?

Sawada: Thank you. As you know, in the US, Cefiderocol is only effective for cUTI. I do not believe there are patients in poor condition that are showing benefits. In light of this, the numbers are not very big. Should its indication be expanded to pneumonia, I believe there would be a substantial increase. As you know, we need to note this, including stewardship. I would like to refrain from discussing this further as it will go into monetary aspects.

In Europe, given the COVID-19 issue, we are not making headway with specific drug price negotiations. However, for those governments that are proposing a full incentive scheme, we have started preliminary discussions. That is where we stand at the moment.

Ueda: Thank you. That is all from me.

Emcee: The next question will be from Kotani-san of Nomura Securities. Please go ahead.

Kotani: Kotani from Nomura Securities. I actually have about a hundred questions, but I will limit this to three.

My first question is obviously about Dolutegravir. Given the current market consensus, if anything, it seems to me that the figures for Dolutegravir's volume is flat. It does not appear to be increasing by that much. I wanted further to explore its potential growth. The IAS 2020 meeting in July has been scheduled to be conducted online. I think a variety of information will be provided at the meeting but what can we expect? I assume that an extension of data on last year's TAF switch test in the TANGO trial will be provided. Given the gaps in side-effects already shown in clinical testing, this is a negative direction for Dolutegravir. I believe GSK is filing for approval of TANGO. Even if this is approved, isn't it possible that there will not be a major shift to Dovato?

Also, currently the issue, particularly of the accumulation of body fat in HIV patients, has become a topic globally. Regarding TAF, in the use of Gilead's drug, there have been cases where patients accumulated a fair amount of body fat. Also a fair understanding of triglycerides, fat in the blood stream, has also been gathered from data. Do you think this will trigger a shift to Dovato? Also, can you explain what is necessary? This is my first question.

Teshirogi: I think you likely have a better understanding of this. I really don't want to say this but a rather nasty battle is unraveling in the frontlines. Rivals are not necessarily taking turns insulting each other but these sorts of issues are occurring day-to-day. Gilead has been constantly blaming us, saying a resistant virus may appear. On our side, we have been stating that TAF is not as harmless as they claim. Patients do gain weight, their body fat increases, and is slightly long term. While is it better than Truvada, it still hinders liver function. This battle has been unfolding in the frontlines.

I would think this talk would not be a big deal for ViiV but due to the delay with Cabotegravir, all the personnel employed to handle Cabotegravir are now stuck handling Dovato. Consequently, in terms of the number of calls and the number of battles in the frontlines, ViiV is not inferior to Gilead. We are also basically on the same level. At the very least, in contrast with ViiV, given the negative points of TAF, we believe that if we can promote more full-fledged focus on Dovato, we can trigger a shift to Dovato.

No matter what, we need to release Cabotegravir this year, even if it is in December. For the time being, the battle between Dovato and TAF will likely continue. I do not think this will change owing to the release of new data.

Kotani: I think this reflects the low level of Dovato's PBM, insurance coverage, and tiering. Is it correct to acknowledge that changes are gradually being made to these areas?

Teshirogi: Yes that is correct. We are putting a fair amount of energies into this.

Kotani: Thank you. My second question has to do with Xofluza. I can understand the impact from the reduction of various medical examinations. Currently, various companies are saying a number of things concerning influenza. Could you please comment?

Roche has fairly high expectations for Xofluza. On their conference call, they said that up to now they had believed it was just a common cold and no medicines were prescribed in EU. Due to the sudden spread of COVID-19, and particularly on transmission between family members, regulatory authorities finally

understood once it was explained in this manner based on the data that within a 24-hour period, this type of influenza virus shedding is 1/1,000. This has been a slight tailwind for demand in Europe.

Meanwhile, in Sanofi's conference call, the company said it is rapidly increasing its production of flu vaccine. Sanofi, as is the case with GSK, expected to post strong sales this year. This is likely due to many people taking preventive measures. What is the impact to Xofluza sales?

Also, given that coronavirus and influenza both develop in the upper respiratory tract, it is likely drugmakers will scramble for the same resources. I still think that the influenza virus will lose out to coronavirus. Can you comment on this?

Sawada: First, the potential of Xofluza in Europe. It is as you stated. Even if a person wanted to go to the hospital today, they cannot. Given this situation, there is little-to-no opportunity for doctors to prescribe influenza drugs. Currently, patients are being told to stay home and rest. However, it is expected that, owing to this and the impact of the coronavirus, online medical exams are likely to become highly in demand, particularly in Europe. In light of this, we believe that this will give way to opportunities to prescribe Xofluza. Accordingly, we anticipate there is potential for the market to form going forward.

Another factor will be whether or not a patient is administered an influenza vaccine at that time. Based on our experience of actually conducting clinical trials, we believe there is actually little-to-no impact whether or not a patient is given a flu vaccine. Given the level of current flu vaccines, there is minimal impact as to whether or not a person contracts the flu. The vaccination may prevent the flu symptoms from becoming severe. This is an anticipated benefit and we believe this is why they are using it for the flu. We believe there is little benefit for suppressing the onset of the disease.

As for what if a patient contracts both coronavirus and influenza, in the beginning there were no cases in Wuhan where it was reported a patient had contracted both coronavirus and influenza. The data for Qingdao is a slightly separate issue. Looking at this data, it is very interesting in that, as a parameter, there was data for around 60 cases. It was found that more than 50% of these patients had contracted the Influenza B virus and just under half had contracted the Influenza A virus. At one point, there was talk that the coronavirus was more significant. This data likely reflects the overlapping of the flu season. We are currently looking for similar data elsewhere. At present, we are working under the premise that people can contract both viruses simultaneously.

Kotani: Thank you. My third question is regarding a coronavirus vaccine. As you said, it is the same as Sanofi's BEVS platform. UMN also has a vaccine that is nearly similar. The issue is likely production facilities. Looking at the Akita factory, multiplying 600 liters times 3 for the influenza quadrivalent vaccine we come up with a total that is in the hundreds of thousands. If a single vaccine is around 2 million yen, and there is an adjuvant, the question is just how much further can this be expanded. It seems that there will not be enough supply to vaccinate all of Japan.

I have two thoughts on this. Previously there was a company called UNIGEN, a subsidiary of UMN Pharma many years ago. Today the subsidiary is called API Co., Ltd. This subsidiary has vats with a working volume of 18,000 liters. The company should have two vats. However, API has a contract with Sanofi to produce flu vaccine. I am not really clear on this but is it possible to conduct production at this company?

Also, there is a possibility that the need to construct a new plant will arise. Can you comment on this?

Teshirogi: This is difficult to answer. In Japan, the only factories that have the potential to carry out production this year are those that you mentioned. These are naturally only our radar. It will be tough if we do not use these facilities. Even if we were to rush construction starting from a factory building, it would still take 2 and half years according to our data. There for an increase in production capacity, along with the construction of a factory building, would be difficult. We are consulting with the

government to see what facilities are available for use while also carrying out our own measures. This is all I can say on the matter today. We will disclose data on this and other related matters going forward.

Kotani: Thank you. My last question. I apologize for taking this much time. I would like confirm if S-648414 will be on time for PoC in Q4? Also, at this stage, will you disclose the mechanism of action? Also, regarding S-600918, I understand you plan to commence a sleep apnea trial. I understand this is not to cure sleep apnea but to treat related symptoms mainly high blood pressure and other metabolic disorders. Have you seen any benefits in this area? I just wanted to confirm these areas.

Teshirogi: Regarding S-648414, at present it is on schedule. At the stage of mechanisms of action, I believe we will probably be able to cover all intellectual properties, at which time we will disclose information. As for the sleep apnea trial, at Phase 2a, as one would expect, it is difficult to achieve a prognosis of nervous system events. At Phase 2a, we are clarifying the number and reduction of events. Other benefits will be ascertained after this.

Kotani: Thank you.

Emcee: The next question will come from Hashiguchi-san of Daiwa Securities. Hashiguchi-san please go ahead.

Hashiguchi: I have two questions.

First, can you give an estimate of the impact to sales and costs by COVID-19? Regarding pharmaceuticals, other than those for infectious diseases, what impact do you believe COVID-19 had on their sales? You detailed the changes to approaches being undertaken during this opportunity, including sales methods. However, what positive and negative impact will this have on costs?

Teshirogi: My explanation must not have been clear. This was included when much consideration was given to issues internally. We estimated how long COVID-19 will last and what impact it will have on each product. After a fair amount of consideration, the impact to costs and sales has been incorporated at this stage.

Hashiguchi: On page 5 of the earnings report, it says that the impact from COVID-19 has not been factored into our earnings forecast. Is this a mistake?

Teshirogi: We have given this our consideration in our own way but if we were to write that we have incorporated all factors, our stakeholders would be angry with us when something occurred other than what we stated. That is why we chose this wording. Sorry if it was misleading.

Hashiguchi: Thank you. My second question is in regard to Crestor royalties. What is your estimate for FY2020?

Hanasaki: As was explained earlier, Crestor royalties will expire at the end of December 2020. After that, we will receive some royalties but they will be in line with Crestor sales.

Hashiguchi: However, based on that calculation and the plan you presented this time around, it seems that there is little-to-no Crestor royalty income in Q4. In other words, looking at the full fiscal year ending March 31, 2022, in contrast with FY2020, a decrease in Crestor royalty will have a great impact on a profit. Is my understanding correct?

Teshirogi: Yes that is correct. At the most, we expect to only receive around 1.0 billion yen or 2.0 billion yen in Crestor royalty income.

Hashiguchi: That is for FY2021, correct.

Teshirogi: FY2021 and thereafter.

Hashiguchi: I understand. Thank is all from me. Thank you.

Emcee: The next question is from Wakao-san from Mitsubishi UFJ Morgan Stanley Securities. Go ahead.

Wakao: Wakao from Mitsubishi. Thank you for your explanation.

My first question is about the COVID-19 prophylactic vaccines. Can you please provide a more detailed development schedule? I believe, according to media reports, Shionogi plans to provide a limited supply in FY2020. Meanwhile, during the briefing, I believe you said you will enter clinical trials this year. Based on this, you will enter clinical trials this year. In light of this, are you planning to provide a limited supply during January-March 2021?

Also, can you give me your opinion or outlook for revenues from this COVID-19 vaccine? I don't think there will be a large volume during your initial limited usage. Do you anticipate sales growth after you implement a full-fledged production increase and organize your production system in and after FY2021?

Teshirogi: The schedule is basically as you described it. Sawada and I are putting pressure on people to speed up this schedule. At this stage, all I can say is the schedule is how you current envisage it.

Regarding revenues, basically providing vaccine for 10 million people in January-March 2021 is not realistic and I do not think we will meet this schedule. As with influenza A H1N1 pdm09 virus, we will offer limited supply first to medical professionals according to priority decided by the government. The volume to provide depends on production capacity. We do not believe contribution will be nil. However, if you are talking about full-fledged contribution, I think targeting FY2021 and beyond is more realistic.

Wakao: I understand. So it is correct to understand that you will generate profit according to the volume to provide? Overseas, there are some companies that are doing this for no profit. So, it is correct to understand that as long as a certain volume of vaccine is sold, you will generate profit?

Teshirogi: Yes. From our standpoint, we believe this business is expected, at the very least, to offer us profit margins that exceed those for flu vaccines.

Wakao: I understand. My next question is, if possible, can you discuss the next potential targets using the BEVS of UMN? During the briefing, you said you were initially pouring all energies on influenza. You went on to say all your energies will go into COVID-19. There is a possibility that products will emerge due to the COVID-19 pandemic and that you will have to implement capital investments. I believe you will also need to revamp your production system. However, what will your targets be in the post-COVID-19 era?

Teshirogi: At present, our focus is on specific products for COVID-19 and influenza. As with flu viruses, it's possible that the coronavirus will also mutate. So the question is it is truly okay simply to produce a vaccine specifically for COVID-19 and be done with it. We initially put UMN under our auspices with the goal of creating new vaccines for the rotavirus and norovirus while also considering how to deal with respiratory viruses.

Concrete items in our product lineup, currently are vaccines for COVID-19 and flu. To be honest we need to see if we have the leeway to figure out how to expand our vaccine business, including for the previous mentioned rotavirus.

Wakao: Thank you. Lastly, I would like to ask about BPN14770 acquired from Tetra. I believe you mentioned Phase 2 in your earlier briefing. Do you plan to form an alliance with Tetra further out? What are your ideas for the next clinical trial?

Teshirogi: We are currently continuing discussions on the relationship between our two companies. We will disclose the status of our relationship once we are able to. To be honest, we want to conduct Phase 2 in Japan. I believe that the protocols for the trial will be similar as those in the US but we want to refine the trial period the methods for setting the placebo control. In light of this, we would like to conduct Phase 2 one more time.

Wakao: I see. So you still see potential in BPN14770. However, the data is a bit unclear so you wish to run the trial again and reconsider the data. Is that correct?

Teshirogi: Yes, that is correct.

Wakao: Thank you. That is all from me.

Emcee: The next question will come from Muraoka-san from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka: Muraoka from Morgan Stanley.

Sorry to make you repeat yourself but I would like to ask about the COVID-19 vaccine. Assuming you start a clinical trial from now and make limited use possible by March 2021, do you only need to confirm a rise in the antibody titer when administering the vaccination to healthy volunteers?

There are some that believe an attenuated virus should be administered to gain actual proof. What type of data do you plan to accumulate?

Teshirogi: What you said first is precisely what we are currently thinking. I think we need to confirm neutralizing antibodies are produced. Basically, as you said, we will likely be able to receive limited and conditional approval via the administration of the vaccine 1 or 2 times, and confirmation that antibodies are properly formed.

Dr. Yokokura of the Japan Medical Association clearly stated that if Japan is to host the Olympics then a vaccine needs to be properly developed. Taking this to heart, we recognize the need to develop a vaccine by FY2021 that will allow Japan to host various events. We plan to push forward while consulting with the government and doctors. This is a bit repetitive but we are basically thinking of an approach just as you mentioned.

Muraoka: Also, earlier you mentioned profit margins and that you aimed for a profit margin that was on a par with flu vaccines. It seems too early to discuss unit price. For instance, the government has stockpiling of Avigan. The price is around 10,000 yen person. However, look at the government's budget, can we expect the unit price to be around this level. Since it is a prophylactic vaccine, the price should be slightly lower than the drug. Can you explain your thoughts on the price?

Teshirogi: What have not held any talks so it's unclear but the figures you just stated are a possibility as a regular starting point.

Muraoka: One last question. Assuming the Ping An deal is completed in June or July, when you announce your first quarter earnings results in August, is there a possibility of slight revisions to your earnings forecasts?

Teshirogi: That is our goal. At the latest, you will know by November, when we release our results for the first half. However, if we can put a budget together earlier, I think we will be able to factor this in, in August, when we are scheduled to announce our first quarter earnings results.

Muraoka: I understand. That is all from me. Thank you.

Emcee: We are also out of time. The final question will be from Arai-san of Merrill Lynch Japan Securities. Please go ahead.

Arai: Early during the briefing, you mention your are considering two BDs. Can you share details about this with us if possible? In other words, is it a drug you can expect some synergy with Fetroja? Or are you considering a completely differ BD?

You are probably not allowed to discuss most of this right now. However, if possible, can you share any direction that might be taken, which can be disclosed?

Teshirogi: I am really sorry I cannot discuss this. We are undertaking some deals for the US market and Japan market.

Arai: The details are not open for disclosure, correct.

Teshirogi: That's right.

Arai: Also, regarding the COVID-19 vaccine, I vaguely recall there was an issue with the possibility of rhabdovirus contamination at UMN Pharma. There was a lot of back and forth when joint development was being conducted with Astellas Pharma. Is it okay to assume the COVID-19 vaccine has cleared this hurdle?

Teshirogi: That is a good point. Thank you. Actually, Fullblok developed by Sanofi is produced using a cell line which has not been proven to be rhabdovirus-free. The trial is being conducted globally. We have been clearly instructed by the PMDA to not review unless UMN proves elimination of rhabdovirus. In light of this, we are establishing a rhabdovirus-free cell line.

Now that we have confirmed this, we are moving to acquire UMN. Even on a global level, only our cell line is rhabdovirus-free.

Arai: I understand. Thank you. Lastly, this may veer slightly off course from earnings results but can you discuss plans for e-marketing. Given remote medical exams and remote diagnosis, I am referring to is your collaboration with Aillis, an AI medical device venture which you formed a partnership with in the first half of 2019. For example, in the diagnosis of influenza, in the post COVID-19 era, I see this as an area of high demand or impact. I believe Shionogi has a priority right for negotiation for a future license agreement with Aillis. Are your opinions changing, pre- versus post- COVID-19 pandemic? Can you share this data?

Teshirogi: There is absolutely no change. Regardless of the COVID-19 pandemic, it has been my belief, as well as Sawada's, that we should embark on online services for infectious diseases. In other words, we focused on why it is necessary to have to go to the hospital when you have the flu, are suffering from a high fever and joint pain. If a patient leaves their home they run the risk of spreading their virus until they reach the hospital. Furthermore, they end up spreading their virus inside the hospital. We envisage a system for diagnosing patients at their home, and if medication is necessary, delivering it to their homes. Naturally, the primary physician would have to confirm whether the patient has underlying illnesses. There need to be restrictions but at some point this will become mainstream globally. This is our commitment. The COVID-19 pandemic only confirmed our belief. Consequently, we have not changed our viewpoint.

Arai: Thank you. That is all from me.

Emcee: No one else has questions. Kyokawa-san, if you will.

Kyokawa: If that is all, then I would like to end this Q&A session. Thank you all.

Emcee: Well this ends our Q&A session and concludes the Shionogi financial results briefing for FY2019. Thank you for taking time out of your busy schedules to participate.

[END]