

Matsuo: Now, please let us begin. Firstly, today's agenda is listed on page 2. After providing an overview of the financial results for the third quarter of FY2019, I will explain about the revision to our full-year financial forecasts.


Now, I will provide an overview of the financial results for the third quarter.

Financial Results (Consolidated)



(Unit: B yen)

	FY2019			FY2018	Y on Y	
	Full year forecasts (revised on Oct. 30)*	Apr.-Dec. results	Progress vs. forecasts	Apr.-Dec. results	Change (%)	Change (B yen)
Sales	367.0	253.5	69.1%	265.2	(4.4%)	(11.7)
Operating income	150.0	99.2	66.2%	97.4	1.9%	1.8
Ordinary income	171.5	114.9	67.0%	115.7	(0.6%)	(0.8)
Profit attributable to owners of parent	135.0	90.8	67.3%	94.3	(3.7%)	(3.5)

- Operating income was higher than the levels achieved in prior fiscal years
 - Sales were behind due to sales decrease of prescription drugs in Japan
- 
 Full year forecasts have been revised (to be described in detail)

Exchange rate (average)	FY2019 forecasts (revised on Oct. 30)	FY2019 Apr.-Dec. results
USD (\$) – JPY (¥)	107.0	108.66
GBP (£) – JPY (¥)	133.0	137.76
EUR (€) – JPY (¥)	120.0	121.04



* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)

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Firstly, a summary of the consolidated financial results are shown on page 4. Looking at the columns from left to right, the full-year forecasts for FY2019 revised on October 30, 2019, results for April through December 2019 and the progress against full-year forecasts are listed, and then the results for April through December 2018, change in percentage and change in billion yen are also shown as a reference.

Specifically, sales for the April-December 2019 period amounted to 253.5 billion yen, and the progress rate against forecasts was 69.1%. On a year-on-year basis, sales were down 4.4% or decreased by 11.7 billion yen.

Meanwhile, operating income for the April-December 2019 period stood at 99.2 billion yen, and the progress rate against forecasts was 66.2%. On a year-on-year basis, operating income was up 1.9% or increased by 1.8 billion yen. Ordinary income for the April-December 2019 period was 114.9 billion yen, and the progress rate against forecasts was 67.0%. On a year-on-year basis, ordinary income was down 0.6% or decreased by 0.8 billion yen. Against this backdrop, profit attributable to owners of parent for the April-December 2019 period amounted to 90.8 billion yen, and the progress

rate against forecasts was 67.3%. On a year-on-year basis, profit attributable to owners of parent was down 3.7% or decreased by 3.5 billion yen.

While operating income increased year-on-year, both ordinary income and profit attributable to owners of parent decreased year-on-year. This was attributable to the fact that sales remained lower than the full-year forecasts due to the slow progress in sales of prescription drugs in Japan. In light of such progress status, we have revised our full-year financial forecasts as we explain in detail afterwards.

In terms of the average exchange rate during the period under review, the three currencies listed on the table at right bottom remained appreciated against the yen.

Statement of Income



(Unit: B yen)

	FY2019			FY2018		Y on Y	
	Full year forecasts (revised on Oct. 30)*	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results	Change (%)	Change (B yen)	
Sales	367.0	253.5	69.1	265.2	(4.4)	(11.7)	
	15.3	16.2		15.2			
Cost of sales	56.0	41.0	73.2	40.4	1.5	0.6	
Gross profit	311.0	212.5	68.3	224.9	(5.5)	(12.3)	
SG&A	43.9	44.7		48.0			
expenses	161.0	113.3	70.4	127.4	(11.1)	(14.2)	
Selling & administrative expenses	30.5	31.0		28.1			
	112.0	78.7	70.3	74.5	5.7	4.3	
	13.4	13.6		20.0			
R&D expenses	49.0	34.6	70.5	53.0	(34.8)	(18.4)	
Ordinary R&D expenses	49.0	34.6	70.5	38.2	(9.5)	(3.6)	
Strategic investment	-	-	-	14.8	-	(14.8)	
	40.9	39.1		36.7			
Operating income	150.0	99.2	66.2	97.4	1.9	1.8	
Non-operating income & expenses	21.5	15.6	72.8	18.2	(14.1)	(2.6)	
	46.7	45.3		43.6			
Ordinary Income	171.5	114.9	67.0	115.7	(0.6)	(0.7)	
Profit attributable to owners of parent	135.0	90.8	67.3	94.3	(3.7)	(3.5)	



* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)
 ** Ordinary R&D expenses: Total R&D expenses excluding strategic investment

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Let's move on to the statement of income on page 5.

Sales for the April-December 2019 period decreased by 11.7 billion yen year-on-year to 253.5 billion yen, and the progress rate against forecasts was 69.1%.

While we received milestone payments from Roche in association with the R&D achievements related to Xofluza as in the previous fiscal year, the amount of payments for the current fiscal year has significantly reduced on a year-on-year basis, which turned out to be the main reason for the decline in sales.

We strived to make up to the decrease in sales with increases in sales from overseas subsidiaries and OTC and quasi-drugs as well as the growth in royalty income from HIV franchise. However, as a result of a year-on-year decline in sales of prescription drugs in Japan, Xofluza in particular, we could not sufficiently make up for the decline in the aforementioned milestone payments. We will talk about the details later.

Meanwhile, cost of sales for the April-December 2019 period increased by 0.6 billion yen year-on-year to 41.0 billion yen, and the progress rate against forecasts was 73.2%. Cost of sales increased year-on-year reflecting an increase in exports of Xofluza and the growth in sales of older antibiotics and OTC and quasi-drugs whose cost of sales are relatively high. The progress rate against forecasts has also risen rather quickly.

As a result, gross profit for the April-December 2019 period decreased by 12.3 billion yen year-on-year to 212.5 billion yen.

SG&A expenses for the April-December 2019 period decreased by 14.2 billion yen year-on-year to 113.3 billion yen, and the progress rate against forecasts was 70.4%. Selling & administrative expenses increased by 4.3 billion yen year-on-year to 78.7 billion yen.

R&D expenses for the April-December 2019 period decreased by 18.4 billion yen year-on-year to 34.6 billion yen, which resulted in a significant decline in SG&A expenses. This decrease is attributable mainly to the reaction to strategic investment of 14.8 billion yen which was recorded in the previous fiscal year. While ordinary R&D activities have progressed in accordance with the plan, ordinary R&D expenses for the April-December 2019 period decreased 3.6 billion yen year-on-year.

As a result of the foregoing, operating income for the April-December 2019 period stood at 99.2 billion yen, and the progress rate against forecasts was 66.2%. While sales diminished year-on-year, operating income rose by 1.8 billion yen year-on-year thanks to a decline in R&D expenses.

Next, non-operating income & expenses for the April-December 2019 period decreased by 2.6 billion yen year-on-year to 15.6 billion yen. In terms of dividends from ViiV, while we received the amount mostly in line with our expectations for the current fiscal year, we had received a one-time dividend in addition to ordinary dividends in the previous fiscal year. Due to the effect of this one-time dividend, non-operating income & expenses for the April-December 2019 period decreased year-on-year. This year-on-year decline was also affected by the appreciation of the yen against other currencies compared to the exchange rates during the same period of the previous fiscal year.

As a result, ordinary income decreased by 0.7 billion yen year-on-year to 114.9 billion yen.

Profit attributable to owners of parent decreased by 3.5 billion yen year-on-year to 90.8 billion yen. The year-on-year decline in profit attributable to owners of parent was attributable to the fact that the previous fiscal year's tax deduction due to R&D investment was larger than the current period under review and the amount of income taxes for the current period under review increased as a reaction.

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



• Y on Y comparison

(Unit: B yen)

Sales	(11.7)
Cost of sales	+0.6
Gross profit	(12.3)
Selling & administrative expenses	+4.3
R&D expenses	(18.4)
Operating income	+1.8
Non-operating income & expenses	(2.6)
Ordinary income	(0.7)
Extraordinary income or losses	+1.8
Profit attributable to owners of parent	(3.5)
Decrease in profit	Increase in profit

Main Variation Factors in Oct.-Dec. (Y on Y) ※ Main Variation Factors in Q3

- **Sales**
 - Sales decrease of prescription drugs in Japan ※
 - FY2018, 2019: Income from Roche for Xofluza* *
- **Cost of sales**
 - Export increase of Xofluza*
 - Sales increase of Flumarin* and OTC and quasi-drug
- **SG & A expenses**
 - **Selling & administrative expenses**
 - › Increased in preparation for overseas launch
 - › Increased in alignment with sales growth
 - **R&D expenses**
 - › FY2018: Strategic investment [14.8 B yen]
- **Non-operating income & expenses**
 - FY2018: One-time dividend from ViiV
 - Exchange-rate fluctuations
- **Income taxes**
 - FY2018: Increase of tax deduction due to R&D investment

Main Factors Affecting the Achievement of Full-Year Forecasts

- **Sales**
 - Slow progress in sales of prescription drugs in Japan



* Royalty income from Roche as milestones of R&D achievement

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Next, let's look at page 6 which summarizes the year-on-year comparison and main variation factors for the statement of income. The items with a "※" indicate main variation factors for this quarter.

As explained earlier, the decrease in sales was attributable to a decline in sales of prescription drugs in Japan and the year-on-year difference in milestone payments from Roche for Xofluza.

On the cost front, while selling & administrative expenses increased as a result of the overseas pre-launch activities mainly for Cefiderocol and the growth of sales of prescription drugs, R&D expenses decreased due to the effects of strategic investment in the previous fiscal year, which resulted in an increase in operating income on a year-on-year basis.

Non-operating income & expenses were affected by the reaction to the one-time dividend from ViiV as well as foreign exchange fluctuations.

Meanwhile, while extraordinary income or losses was favorable year-on-year, profit attributable to owners of parent decreased year-on-year reflecting the increase in income taxes as explained earlier.

Sales by Segment



(Unit: B yen)

(Unit: B yen)

	FY2019		Achievement (%)	FY2018	Y on Y	
	Full year forecast (revised on Oct. 30)*	Apr.-Dec. results		Apr.-Dec. results	Change (%)	Change (B yen)
Prescription drugs	144.1	82.0	56.9	88.3	(7.2)	(6.3)
Overseas subsidiaries/export	31.3	24.0	76.4	22.1	8.4	1.9
Shionogi Inc.	10.2	8.5	83.2	9.4	(9.8)	(0.9)
Mulpleta®	1.0	0.43	43.3	0.02**	-**	0.4
C&O	14.5	10.2	70.1	8.2	24.7	2.0
Contract manufacturing	15.4	12.0	77.8	9.2	30.5	2.8
OTC and quasi-drug	9.7	7.5	77.6	6.3	19.8	1.2
Royalty income	164.2	126.4	76.9	137.5	(8.1)	(11.1)
HIV franchise	126.3	94.5	74.8	89.9	5.2	4.7
Crestor®	21.8	16.6	75.9	16.4	0.8	0.1
Others	16.1	15.3	94.8	31.2	(51.0)	(15.9)
Others	2.2	1.7	77.2	1.9	(8.4)	(0.2)
Total	367.0	253.5	69.1	265.2	(4.4)	(11.7)



* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)

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

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Now, I would like to explain about the results of sales by segment using a slide on page 7.

Firstly, sales of prescription drugs in Japan for the April-December 2019 period were 82.0 billion yen, and the progress rate against forecasts was 56.9%. As explained earlier, sales was down 7.2% and decreased by 6.3 billion yen on a year-on-year basis.

This was attributable mainly to the slow progress in sales of Xofluza for the third quarter compared to the same period of the previous fiscal year. I will talk about the variation factors by product afterwards.

Next, sales from overseas subsidiaries and exports for the April-December 2019 period increased by 1.9 billion yen year-on-year to 24.0 billion yen, and the progress rate against forecasts was 76.4%.

Sales from Shionogi Inc. in the U.S. for the April-December 2019 period decreased by 0.9 billion yen year-on-year. We received one-time payments for Symproic from Purdue and BioDelivery Sciences International in FY2018 and the current fiscal year, respectively. The difference in these payments was the main reason behind the decline in sales.

Meanwhile, sales from C&O in China for the April-December 2019 period increased by 2.0 billion yen (up 24.7%) year-on-year as a result of steady growth in sales of rabeprazole, making significant contribution to the increase in sales.

Sales from contract manufacturing for the April-December 2019 period increased by 2.8 billion yen (up 30.5%) year-on-year to 12.0 billion yen thanks to an increase in exports of Xofluza.

Sales of OTC and quasi-drugs for the April-December 2019 period amounted to 7.5 billion yen. Sales increased by 1.2 billion yen year-on-year with the contribution of the health food business which was launched in January 2019 and an expansion of new products in the category.

Meanwhile, royalty income for the April-December 2019 period decreased by 11.1 billion yen year-on-year to 126.4 billion yen. The main factor behind the decrease in income was the difference in milestone payments from Roche in association with the R&D achievements related to Xofluza.

Please also take a look at year-on-year changes in royalty income from others at the bottom of this table.

Meanwhile, royalty income from HIV franchise for the April-December 2019 period was 94.5 billion yen. Royalty income increased by 4.7 billion yen year-on-year, showing steady growth. This was attributable to solid global sales by ViiV and an increase in royalty amount as a result of the termination of the threshold period of HIV franchise. Royalty income from Crestor for the April-December 2019 period stood at 16.6 billion yen, virtually unchanged from the previous fiscal year.

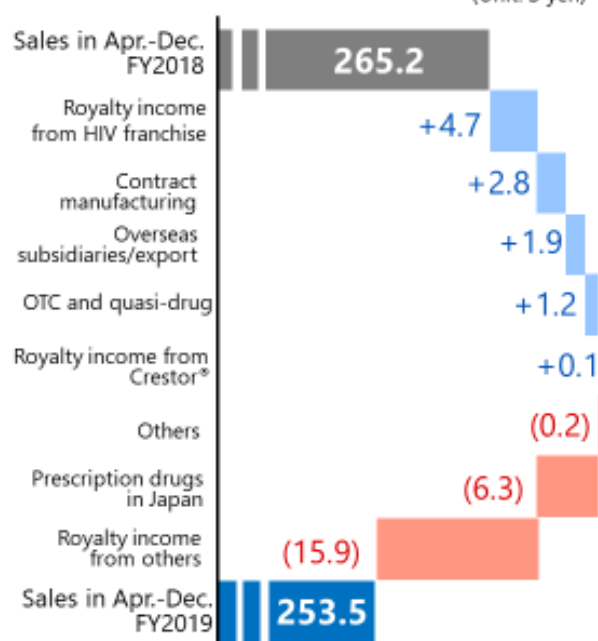
Based on the above, total sales decreased by 11.7 billion yen year-on-year to 253.5 billion yen.

Y on Y Comparison and Main Variation Factors (Sales by Segment)



• Y on Y comparison

(Unit: B yen)



Main Variation Factors in Oct.-Dec. (Y on Y) ※ Main Variation Factors in Q3

- **Royalty income**
(Increase factor)
 - FY2019: Income from Roche for Xofluza**
(Approval for the treatment of HR**) ※
 - Sales growth and termination of the threshold period of HIV franchise
- (Decrease factor)
 - FY2018: Income from Roche for Xofluza**
(Submission and launch in US, HR study completed)
- **Prescription drugs**
 - Sales decrease of Xofluza*
 - Sales Increase of Cymbalta* and Intuniv*
- **Contract manufacturing**
 - Export increase of Xofluza*
- **Overseas subsidiaries/export**
 - C&O: Sales increase of rabeprazole
 - Shionogi Inc.
> One-time payment about Symproic***

Main Factors Affecting the Achievement of Full-Year Forecasts

- **Prescription drugs**
 - Slow progress in sales of Cymbalta* and Intuniv* and Xofluza*

Next, let's look at page 8 which summarizes the year-on-year comparison and main variation factors for sales by segment. Similar to the previous page, items with a “※” indicate main variation factors for this quarter.

As you can see the bottom of this chart, royalty income decreased year-on-year due mainly to a significant decline in milestone payment from Roche. In addition, sales of prescription drugs in Japan decreased year-on-year. These decreases in sales were partly offset by increases in royalty income from HIV franchise, sales from contract manufacturing, overseas subsidiaries and exports, and OTC and quasi-drugs.

It was our original plan to aim to further reduce the margin of decrease in sales by increasing sales of prescription drugs in Japan. However, as the slow progress in sales of prescription drugs in Japan has been recognized, we consider this as a main factor that could affect the achievement of full-year financial forecasts revised on October 30, 2019. We will look at sales by product on the next page.

Sales of Prescription Drugs in Japan



(Unit: B yen)

	FY2019		FY2018		Y on Y	
	Full year forecasts (revised on Oct. 30)*	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results	Change (%)	Change (B yen)
Cymbalta®	29.3	20.2	68.9	18.6	8.5	1.6
Intuniv®	13.6	7.1	51.8	3.9	79.5	3.1
Vyvanse®	0.05	0.01	10.1	—**	—**	0.0
Xofluza®	28.0	0.38	1.4	9.9	(96.2)	(9.6)
Rapiacta®	2.6	1.0	38.2	0.77	29.7	0.2
Brightpoc® Flu	2.2	0.77	35.5	0.58	31.7	0.2
Total of strategic products	75.7	29.4	38.8	33.8	(13.1)	(4.4)
OxyContin® franchise	6.4	4.9	76.2	5.8	(16.0)	(0.9)
Symproic®	2.3	1.6	70.5	1.2	34.0	0.4
Actair®	0.26	0.19	73.1	0.14	32.3	0.0
Mulpleta®	0.23	0.11	45.5	0.13	(16.3)	(0.0)
Pirespa®	7.0	5.0	71.2	4.5	10.8	0.5
Total of new products	91.9	41.1	44.8	45.6	(9.7)	(4.4)
Crestor®	9.5	6.8	71.7	7.8	(13.2)	(1.0)
Irbetan® franchise	4.6	3.3	72.0	4.4	(23.8)	(1.0)
Others	38.1	30.7	80.6	30.5	0.6	0.2
Prescription drugs	144.1	82.0	56.9	88.3	(7.2)	(6.3)



* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)

** Launched on Dec., 2019

On page 9, sales of prescription drugs in Japan are shown.

Firstly, let's look at our strategic products. Sales of Cymbalta for the April-December 2019 period were 20.2 billion yen, and the progress rate against forecasts was 68.9%. Although this product has been on the market for 10 years, we continued to expand our market share and managed to increase

sales by 8.5% or 1.6 billion yen year-on-year. While we managed to increase sales on a year-on-year basis, the progress rate against forecasts has been unsatisfactory.

Next, sales of Intuniv for the April-December 2019 period increased by 79.5% or 3.1 billion yen year-on-year to 7.1 billion yen. However, the progress rate against forecasts was 51.8%, indicating a significant delay in progress.

Vyvanse was launched in December.

In terms of influenza family, while our sales forecasts are slightly larger in the fourth quarter, sales of Xofluza for the April-December 2019 period amounted to 0.38 billion yen, with a substantial decrease of 9.6 billion yen on year-on-year basis. During the same period of the previous fiscal year, there was an initial shipment in preparation for the beginning of the first flu season following the launch of the product and we could take advantage of advance sales. However, it is regrettable that sales saw such a substantial decrease on a year-on-year basis. We will explain in detail about our issues and countermeasures afterwards.

Sales of Rapiacta and Brightpoc have been increased by nearly 30% year-on-year.

Total sales of strategic products for the April-December 2019 period amounted to 29.4 billion yen. Despite an increase in sales of Cymbalta and Intuniv, total sales were down 13.1% or decreased by 4.4 billion yen year-on-year.

As in the case of Xofluza, I will explain about the issues and countermeasures for Cymbalta and Intuniv afterwards.

While sales of OxyContin franchise decreased by 0.9 billion yen year-on-year, due to the effects of generic drugs, sales for the April-December 2019 period amounted to 4.9 billion yen, and the progress rate against forecasts was 76.2%, which is in line with our expectations.

Total sales of new products including Symproic, Actair, Mulpleta and Pirespa in addition to OxyContin franchise and strategic products for the April-December 2019 period decreased by 9.7% or 4.4 billion yen year-on-year to 41.1 billion yen.

Sales of Crestor and Irbetan franchise have been mostly in line with our expectations despite the impact of generic penetration.

On the other hand, sales of other products saw an increase in demand as a result of an antibiotic supply problem in another company. Sales have remained solid due to the aforementioned increase in demand as well as the growth in sales of some products.

Consequently, sales of prescription drugs in Japan for the April-December 2019 period decreased by 6.3 billion yen year-on-year to 82.0 billion yen due mainly to the effects of the year-on-year decrease in sales of Xofluza.

While sales of other business segments remained steady, sales of prescription drugs in Japan, especially those of the three key products that we have been focused on, have been behind schedule. We are taking this situation very seriously and have conducted in-depth analysis. While we have

already taken actions, this is a major factor behind the revision of our financial forecasts. Therefore, I will explain the details from the next page.

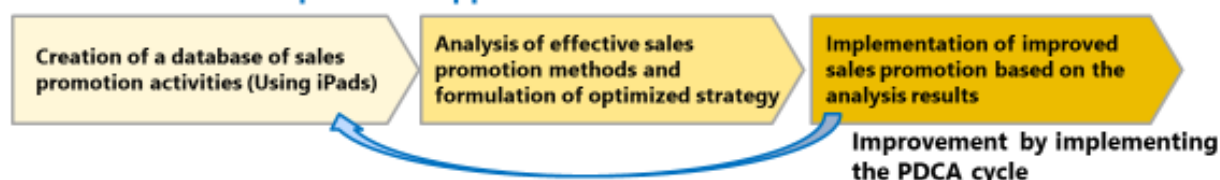
Issues in Domestic Business



Human Health Care Division

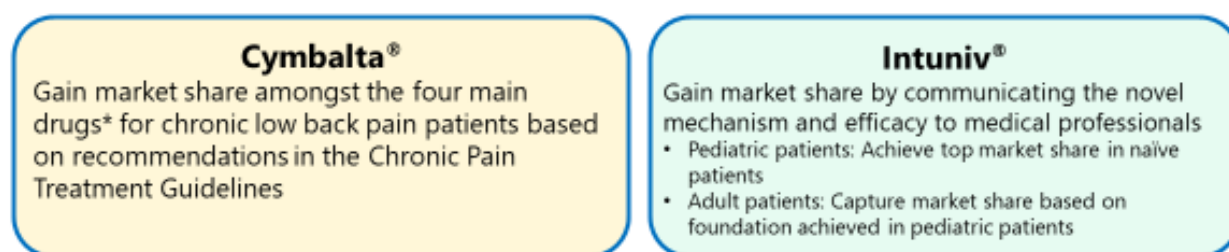
- **Our action plan in FY2019**

Achieving effective sales promotion based on data collection, analysis, and use of the results to revise and improve our approach



Strategic Products with the Highest Priority: Cymbalta® and Intuniv®

- **Initial forecasts/policy (Cymbalta®: 29.3 B yen, Intuniv®: 13.6 B yen)**



First let's take a look at page 10. This slide presents our policy for the domestic business in FY2019 and our initial forecasts and policy for Cymbalta and Intuniv. As we have explained at financial results briefings thus far, in the prescription drugs segment in Japan, we are steadily implementing a PDCA cycle by creating a database of activities in this segment overall. We are realizing effective promotions and undertaking measures that contribute to the growth of sales of strategic products. In accordance with these measures, we aimed to expand our share by promoting the accompanying efficacy of Cymbalta, by leveraging the recommendation given in the Chronic Pain Treatment guidelines as a strength, and Intuniv, which offers an action mechanism, that differs from other drugs.

By implementing the PDCA cycle for these promotional activities we have been able to recognize issues at various steps for each of our products. We are already reflecting actions for improvement in these activities. However, this has not contributed to an improvement in sales momentum as we had anticipated, and we now believe it will take slightly more time for improvements to emerge. As we indicated earlier, this is triggering a delay in progress.

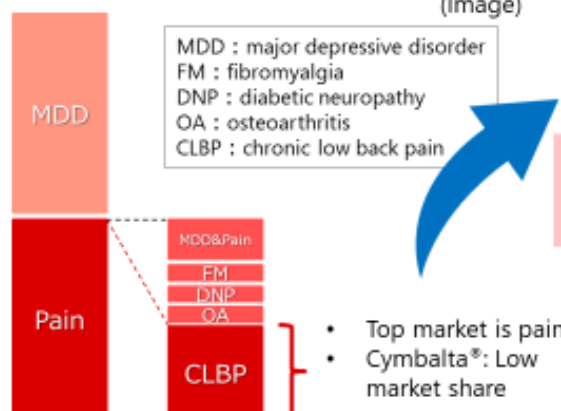
I will now explain the conditions for each product. Let's turn to page 11.

Issues in Domestic Business



Issues of Cymbalta®: Variation Factors from Forecast

Main market and target markets for Cymbalta®
(Image)



• **Focus on CLBP**

• **Communicate the superior analgesic efficacy for low back pain caused by organic factors**

⇒ Deliver the positioning message that Cymbalta® is a first-line chronic pain drug

KPI

Rate of building understanding amongst focus doctors: 64%
Market share amongst four drugs for CLBP*: 29%

[As of Dec. 2019]

Rate of building understanding amongst focus doctors: <30%
Market share in all pain patients** taking main four drugs: 17.7%

- Top market is pain
- Cymbalta®: Low market share

Insufficiency of the quality and quantity of promotion

- Not motivating doctors to prescribe Cymbalta® due to burdensome explanations for safety information and indications delivered from doctors to patients, resulting not changing the impression that Cymbalta® is primarily for patients for whom other pain drugs fail

Insufficient speed in redesigning the strategy and plans

- Not enough focus on switching patients taking other three drugs emphasis on naïve patients



* Main pain drugs: Cymbalta®, Lyrica®, mirogabalin besilate, and tramadol

** Change the definition of KPI and data source at the timing of revision of FY2019 financial forecast in order to grasp the progress of KPI speedy

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First I will discuss Cymbalta. This is the 10th year that the drug has been on the market. During the current fiscal year, the NHI drug price was revised downward approximately 1.5%, but sales grew 8.5% year-on-year. Nonetheless, sales and activities were behind scheduled versus plans, which we recognize as an issue.

In FY2019, we aim to boost sales. We poured energies into the domain for chronic lower back pain treatment, which is the largest market in scale and also a market in which Cymbalta has had a low share of sales. We deployed a message that promoted Cymbalta as a first-line treatment for chronic lower back pain owing to its analgesic action for lower back pain caused by organic factors. However due to the cumbersome explanations doctors give to patients on the drug's safety and indications, we were unable to motivate doctors to prescribe the drug and we faced delays in getting out our message.

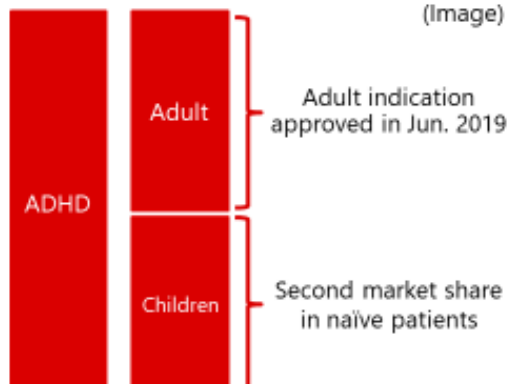
Consequently, our promotion was lacking both qualitatively and quantitatively. Moreover, despite this situation, we lacked speed in revamping this strategy.

Issues in Domestic Business



Issues with Intuniv®: Variation Factors from Forecast

Main market and target market in Intuniv®
(Image)



**Communicate the efficacy of Intuniv®
to all focus doctors in ADHD market**

KPI

Market share in naïve patients (children): 60%
Rate of target facilities listing the product in the
drug formulary (adult): 90%

[As of Dec. 2019]

Market share in naïve patients (children): 42.4%
Rate of target facilities listing the product in the drug
formulary (adult): 60.1%

Insufficient communication of the key message

- Children: Not accelerating the shift from combination with other drugs to Intuniv® monotherapy in naïve patients
- Adult: Deceleration of growth due to insufficient disease awareness and understanding the characteristics of Intuniv®

Insufficient cooperation between head office and sales reps

- Did not rapidly identify the facilities with little or no sales rep access
- Lack of clear directions and appropriate support plans

Next, let's look at Intuniv on page 12. Sales of this drug are increasing at a pace of roughly 80% year-on-year. On a monetary basis, it is growing into to a point where it is on the heels of Concerta. However, our promotion of the evidence of this drug's action mechanism needs to be enhanced. We believe that unless we do so, we will not be able to capture share away from leader Concerta or Strattera.

In addition, following the approval of additional indication in June 2019 for use on adults, we aimed to expand our market share by smoothly launching Intuniv in the adult market based on our track record in the pediatric market. However, we were unsuccessful in fully instilling disease awareness or understanding of the drug's characteristics. Consequently, we were unable to fully boost the ratio of usage at hospitals, which was the main factor for a delay in progress.

In addition, we also believe there was a lack in the efforts to provide accurate instructions and the support necessary to carry out these activities. We cannot deny that there was insufficient speed in redesigning the strategy and plans.

Issues in Domestic Business



Cymbalta® and Intuniv®:

To Achieve the Revised Forecast (Cymbalta® : 29.3 B yen → 27.3 B yen
Intuniv® : 13.6 B yen → 10.6 B yen)

Common issues with the approach to these two drugs

Ineffective communication of key messages to focus doctors

Not addressing identified issues rapidly and flexibly

- In parallel with strengthening to deliver the positioning message for naïve patients, suggest a prescription for patients taking other drugs and encourage communications between doctors and patients to increase opportunities that doctors awaken to analgesic effect of Cymbalta®
- Capture new prescription share and increase the number of hospitals using Intuniv® by refocusing facilities and doctors
- Enhance quality of sales force activities and disseminate information efficiently from KOLs by holding web conferences and other events (Cymbalta® and Intuniv®)

Cymbalta®

Increase market share amongst the main four drugs for all pain patients in the key clinical departments (the orthopedics and internal medicine departments) by 2% or more
(Dec. 2019: 17.7% → Mar. 2020: 19.8% or more)

Intuniv®

Children: Increase market share of naïve patients and Intuniv® monotherapy in the facilities listing the product in the drug formulary by 8% (Dec. 2019: 42.4% → Mar. 2020: 50%)
Adult: Increase facilities listing the product in the drug formulary (Rate in target facilities: Dec. 2019: 60.1% → Mar. 2020: 80%)

Next, page 13 sorts our issues for both of these drugs. The issues with both these drugs are nearly the same. The two issues are epitomized by the statements in blue. Namely, it comes down to these two points: the “ineffective communication of key messages to focus doctors” and “not addressing identified issues rapidly and flexibly.”

The three bullet points outline the measures we are implementing to resolve these two issues. By implementing these solutions we plan to achieve the outcomes indicated at the bottom of the page. Furthermore, by attaining the goals for each of these drugs, we aim to fulfill our revised plan.

We also are working to undertake the development of a strong head office, including reorganization in FY2020.

Issues in Domestic Business



Strategic Product of the Highest Priority: Xofluza®

- **Initial forecast/policy (28.0 B yen)**

- Promotion focusing on safety information including variant viruses with reduced susceptibility to Xofluza®
- Provide up-to-date information on clinical, non-clinical and surveillance studies as they become available
- In pediatric patients with the A/H3N2 subtype, especially in younger children (about 10% of the total number of patients*), communicate precautions for administration as the detection rate of variant viruses are relatively high
- For other types / subtypes and patient ages, project splitting the market share equally with neuraminidase inhibitors

Xofluza®: Variation Factors from Forecast 1 (special factors between seasons)

- The previous fiscal year (FY) was the first year with a full season of product sales. In the 3Q of that FY, early-stage distribution of the product was made to medical institutions
- In January of the previous FY, production and supply were increased to cope with pressure on supply and demand. However, the flu epidemic came to an end earlier than expected, which resulted in wholesale inventory exceeding the proper one.
- The flu epidemic arrived earlier than expected this season. During this period, the Japanese associations announced their statements / guidelines including cautions for administration of the product to children under 12 years old, and the media covered academic publications in conjunction with these statements / guidelines on a mass scale.



* Estimated based on a JammNet (Health Insurance Receipt Data) 14

Please turn to page 14. I would now like to talk about Xofluza.

I would likely once again explain in detail trends for this drug, taking into account the drug's performance in 3Q. This time around, we made substantial revisions to our plans for Xofluza. I would like to start by explaining the assumptions in our initial plan.

First, during the previous flu season, we received some criticism related to the provision of information. In light of this, in FY2019, we are deploying activities that primarily focus on the provision of safety information, including viruses with a low susceptibility to Xofluza. As a part of this, we are publicly disclosing data and providing up-to-date information in a timely manner. Regarding viruses with a low susceptibility to Xofluza, there was a high detection rate in pediatric patients with the H3 type virus, especially among children under the age of five. In light of this, we are aware that there is a need to promote awareness of precautions. We are therefore fully communicating this to doctors.

Meanwhile, for other patients with other type/subtype virus and patients other than pediatric patients 5 or under, we initially developed plans based on the assumption that we would split the market share equally with neuraminidase inhibitors.

Consequently, in 3Q we booked Xofluza sales of around ¥400 million, which was a decline of ¥9.6 billion year-on-year. This mainly reflects the factors I just explained. After the launch of the drug in FY2018, our first shipment rolled out in time for the first full flu. In addition, shipments were fairly

large in January 2019. Prescriptions also grew, squeezing supply. As a result, we quickly increased production and improved our supply system.

However, despite this, the flu epidemic ended sooner than expected right after we boost supply. This resulted in a high level of wholesale inventory. This gap in inventory reflects the one-off factors between the previous and current flu seasons. According, the drop in sales was a substantial ¥9.6 billion.

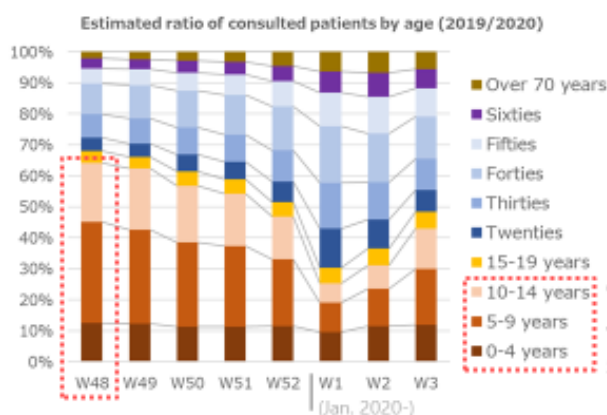
On top of this, in FY2019, there was considerable media coverage on statements by Japanese associations and academic papers on precautions about prescribing the drug to children 12 and under. We understand that sales were also impacted by this.

Issues in Domestic Business



Xofluza®: Variation Factors from Forecast 2

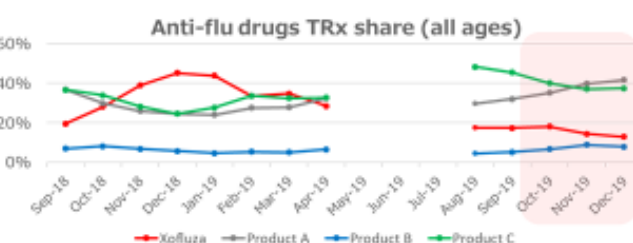
- Communications to HCPs regarding variant viruses are still not sufficiently clear
 - > Children accounted for a large percentage of patients during the period between Oct. and Dec.
- (In the 2018/2019 season, annual ratio of children under 12 years old to all influenza patients was estimated to be approximately 25%*)



The chart was created based on the estimated number of outpatients in the MHLW's influenza epidemic level map (At Week 48: 2019/11/25–12/1)

TRx share as of Dec. 2019 (by age)

	Product A	Product B	Product C	Xofluza
All ages	41.7%	7.9%	37.5%	12.9%
0-9 years old	22.1%	8.7%	65.6%	3.6%
10-19 years old	59.0%	16.3%	14.3%	10.4%
20-64 years old	48.2%	4.4%	28.0%	19.4%
>=65 years old	37.3%	2.4%	39.5%	20.7%



* Source: JammNet (Health Insurance Receipt Data)
2018/2019 season

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15

Next, let's look at page 15. We are consistently undertaking activities to provide accurate information based on science to HCPs on topics including variant viruses. Meanwhile, as shown on the left-hand side of page 15, looking at October-December 2019, based on patient age groups, we can see that during this period there were a large number of pediatric patients, more than in an average year.

Amid this environment, we believe there was strong influence from media reports on recommendations/guidelines from scientific conferences on the careful administration of Xofluza to children 12 and under, and on dissertations from academic sources. We recognize that our efforts to

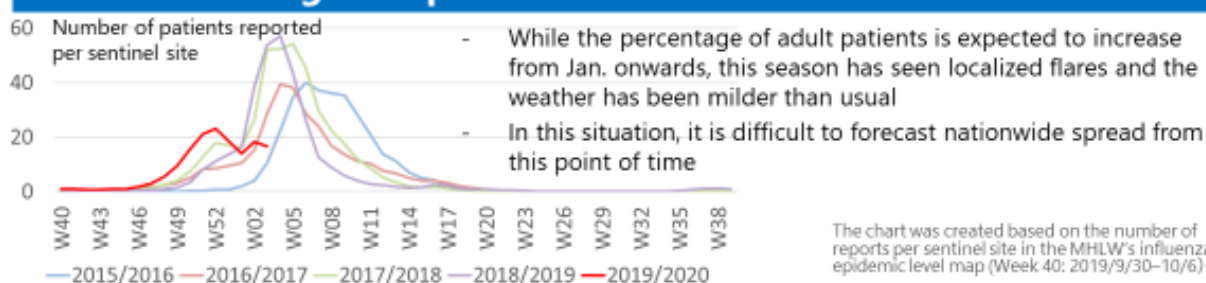
provide correct information and instill understanding among medical practitioners continues to be insufficient.

In and after January, however, the data shows that there was an increase in the percentage of adult patients. We believe that, given this trend, our modest measures to provide information thus far have begun to bear fruit.

Issues in Domestic Business



Xofluza®: Change of Epidemics over the Years



Xofluza®: To Achieve the Revised Forecasts (28.0→18.0 B yen)

- Respond sincerely to concerns of resistance to this product as well as those regarding viral transmission and focus on providing evidence-based information via suitable communication activities
 - > In line with the previous flu season, the spread of variant viruses with reduced susceptibility to various areas has not been confirmed at present (As of 28 Jan. 2020, only one case has been reported in surveillance, in a patient with A/H1N1)
 - > Clinical studies have confirmed that even in case variant viruses were detected after taking this product, this product demonstrates clinical benefit and a consistent safety profile*
- Following communication of the above points to address current concerns around resistance, highlight the product's key features confirmed in clinical studies including that it is the only drug that reduced the incidence of influenza-related complications and that it has a therapeutic effect on type B virus

Collect safety information including surveillance progress report* and strengthen communication activities, which will support the proper use of Xofluza® and maximize the product value for the medium to long-term

Meanwhile, in the current flu season, there have been many localized flares, making it difficult to say for sure whether the flu will spread nationwide. In addition, given the warm winter weather, trends going forward are difficult to forecast. Taking this into account, given our delayed progress up to 3Q and the above flu trends, we downwardly revised our Xofluza forecast ¥10 billion.

As for the reduced susceptibility viruses, there have been no reports of the spread of variant viruses in the current flu season, as was the case in the previous flu season. In the current flu season, only one case of a variant virus was reported in surveillance. However, the detection rate was lower in comparison with other drugs.

Clinical studies also indicate that Xofluza has superior features. We are therefore reinforcing our explanation activities. In addition, we are conducting measures to gather safety information,

including surveillance progress reports, and to communicate this information. We believe this will contribute to the promoting the correct use of this drug and maximize product value in the medium/long term.

This concludes my explanation of the issues surrounding our 3 strategic products and our action policy to resolve these issues.

Revision of Sales Forecasts for Prescription Drugs in Japan



(Unit: B yen)

	FY2019 Forecasts			Change*	FY2018 Results	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)			Change (%)	Change (B yen)
Cymbalta®	29.3	29.3	27.3	(2.0)	24.1	13.3	3.2
Intuniv®	13.6	13.6	10.6	(3.0)	5.3	100.6	5.3
Vyvanse®	0.38	0.05	0.05	-	**-	**-	0.05
Xofluza®	28.0	28.0	18.0	(10.0)	26.3	(31.6)	(8.3)
Rapiacta®	2.6	2.6	2.6	-	2.0	27.7	0.6
Brightpoc® Flu	1.8	2.2	2.2	-	1.2	84.0	1.0
Total of strategic products	75.7	75.7	60.7	(15.0)	58.9	3.1	1.8
OxyContin® franchise	6.7	6.4	6.4	-	7.3	(12.1)	(0.9)
Symproic®	2.3	2.3	2.3	-	1.6	43.8	0.7
Actair®	0.27	0.26	0.26	-	0.19	35.5	0.1
Mulpleta®	0.33	0.23	0.23	-	0.15	50.2	0.1
Pirespa®	6.9	7.0	7.0	-	5.7	23.0	1.3
Total of new products	92.2	91.9	76.9	(15.0)	73.8	4.2	3.1
Crestor®	10.0	9.5	9.5	-	9.9	(4.0)	(0.4)
Irbetan® franchise	4.9	4.6	4.6	-	5.4	(13.5)	(0.7)
Others	36.9	38.1	38.1	-	39.6	(4.0)	(1.6)
Prescription drugs	144.1	144.1	129.1	(15.0)	128.7	0.3	0.4



* Difference between the forecast revised on Feb. 3, 2020 and the forecast announced on Oct. 30, 2019.
 ** Launched in Dec. 2019.

18

Next, taking these conditions into account, we revised our earnings forecast. Let's move on to page 18.

This table presents the revisions we made to our sales forecasts in the prescription drugs segment. As we explained thus far about our three strategic products, given the performance in April-December 2019, we downwardly revised our sales forecast for the prescription drugs segment by ¥15.0 billion. This reflects respective downward revisions to our sales forecasts for Cymbalta of ¥2.0 billion, Intuniv of ¥3.0 billion, and Xofluza of ¥10.0 billion.

Revision of Sales by Segment



(Unit: B yen)

	FY2019 Forecasts				FY2018 Results	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*		Change (%)	Change (B yen)
Prescription drugs	144.1	144.1	129.1	(15.0)	128.7	0.3	0.4
Overseas subsidiaries/export	31.4	31.3	31.3	-	29.4	6.5	1.9
Shionogi Inc.	9.9	10.2	10.2	-	11.8	(13.8)	(1.6)
Mulpleta®	1.0	1.0	1.0	-	0.08	-**	0.9
C&O	14.6	14.5	13.3	(1.2)	11.5	16.1	1.8
Contracting manufacturing	14.3	15.4	16.9	1.5	14.8	14.3	2.1
OTC and quasi-drug	9.7	9.7	9.7	-	8.1	19.7	1.6
Royalty income	163.6	164.2	165.7	1.5	180.3	(8.1)	(14.5)
HIV franchise	126.5	126.3	127.1	0.8	124.4	2.1	2.6
Crestor®	22.0	21.8	22.0	0.2	22.0	0.3	0.1
Others	15.1	16.1	16.6	0.5	33.9	(50.9)	(17.2)
Others	2.4	2.2	2.2	-	2.5	(8.7)	(0.2)
Total	365.5	367.0	355.0	(12.0)	363.7	(2.4)	(8.7)



* Difference between the forecast revised on Feb. 3, 2020 and the forecast announced on Oct. 30, 2019.
 ** The full-scale promotion was initiated in Dec. 2018.

19

Let us move on to the next page, page 19.

As for sales by segment, in comparison to the downward revision of prescription drugs in Japan by 15 billion yen as I mentioned earlier, we revise also the figures for contract manufacturing and royalty income. These are revised upward by 1.5 billion yen each, an increase of 3.0 billion yen in total.

We do not revise the total sales for overseas subsidiaries and export, but reduced the figure for C&O in China reflecting the impact of foreign exchange rates. Because this decrease is offset by the increase in the export segment, we do not revise the total forecast figure for overseas subsidiaries and export.

Finally, we would like to revise the total sales downward by 12 billion yen, to 355 billion yen.

Revision of Statement of Income



(Unit: B yen)

	FY2019 Forecasts				FY2018 Results	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*		Change (%)	Change (B yen)
Sales	365.5	367.0	355.0	(12.0)	363.7	(2.4)	(8.7)
	14.6	15.3	16.2		15.1		
Cost of sales	53.5	56.0	57.5	1.5	54.9	4.8	2.6
Gross profit	312.0	311.0	297.5	(13.5)	308.8	(3.7)	(11.3)
	45.1	43.9	43.9		46.8		
SG&A expenses	165.0	161.0	156.0	(5.0)	170.3	(8.4)	(14.3)
	31.6	30.5	30.4		28.0		
Selling & administrative expenses	115.5	112.0	108.0	(4.0)	102.0	5.9	6.0
	13.5	13.4	13.5		18.8		
R&D expenses	49.5	49.0	48.0	(1.0)	68.3	(29.7)	(20.3)
Ordinary R&D expenses	49.5	49.0	48.0	(1.0)	51.4	(6.6)	(3.4)
Strategic investment	-	-	-	-	16.9	-	(16.9)
	40.2	40.9	39.9		38.1		
Operating income	147.0	150.0	141.5	(8.5)	138.5	2.1	3.0
Non-operating income & expenses	23.5	21.5	25.5	4.0	28.0	(9.1)	(2.5)
	46.6	46.7	47.0		45.8		
Ordinary income	170.5	171.5	167.0	(4.5)	166.6	0.3	0.4
Profit attributable to owners of parent	133.0	135.0	133.0	(2.0)	132.8	0.2	0.2



* Difference between the forecast revised on Feb. 3, 2020 and the forecast announced on Oct. 30, 2019.

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Page 20 shows the statement of income after the downward revision of sales. While reducing sales in Japan, export and contract manufacturing are raised, resulting in a slight increase in costs.

In terms of expenses, selling expenses are reduced in response to the decrease in sales, resulting in a decrease of 4 billion yen. For other costs, on the other hand, we will make focused investments for further growth. Consequently, the revised forecasts are 141.5 billion yen for operating income, a 8.5 billion yen decrease from the initial forecast, 167 billion yen for ordinary income, a 4.5 billion yen decrease, and 133 billion for profit attributable to owners of parent, a 2 billion yen decrease.

Promote Overseas Business



	US	EU, China, Taiwan etc.
Cefiderocol (Product name in US: Fetroja®)	<ul style="list-style-type: none"> • Approved in Nov. 2019 • Pre-launch activities have proceeded smoothly towards the product launch in this FY. <ul style="list-style-type: none"> ✓ Marketing strategies finalized ✓ Promotional materials developed ✓ Recruitment of sales force ongoing 	<ul style="list-style-type: none"> • EU: Pre-launch activities continues towards approval in Apr. – Jun. 2020.
Baloxavir Marboxil (Product name in US: Xofluza®, in Taiwan: 紓伏效®)	<ul style="list-style-type: none"> • Commercialization by Roche group, maximize its value through collaboration 	<ul style="list-style-type: none"> • <EU> NDA submission in EU by Roche group • <Taiwan> Launch in Nov. 2019
Lustrombopag (Product name in US: Mulpleta®, in EU: Mulpleo®)	<ul style="list-style-type: none"> • Keep our own promotion and make efforts for market uptake supported by 'Mulpleta Assist' program 	<ul style="list-style-type: none"> • <EU> Preparations for product launch in FY2020 • Positive appraisals recommending the use by NICE* and SMC* • UK: Preparation for shipment was completed. • <China> Preparations for Phase III
Naldemedine (Product name in US: Symproic®, in EU: Rizmoic®)	<ul style="list-style-type: none"> • Apr. 2019: Partnering with BioDelivery Sciences International (BDSI) for OIC commercialization → Market uptake through BDSI's commercial expertise in the field of opioid analgesics 	<ul style="list-style-type: none"> • <EU> Mar. 2019: Partnering with Sandoz for commercialization in Germany, England, and the Netherlands → Market uptake through Sandoz's commercial expertise in the field of opioid analgesics • UK: Launch in Oct. 2019
Cefcapene Pivoxil***		<ul style="list-style-type: none"> • China: Approval is planned in FY2020 (granule product for children) • NDA submission

- **A highly efficient operation through combination of our own promotion and collaboration with business partners**
- **Establish the Fetroja® business at an early stage and build a global presence**

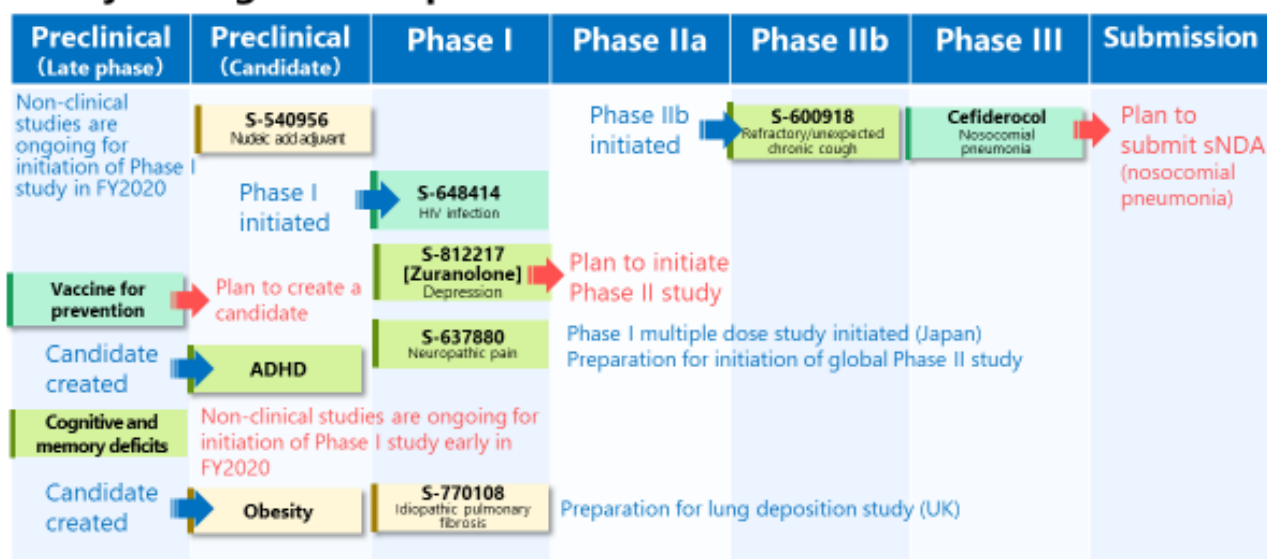
While advancing overall cost control, we pursue growth in the overseas business segment as shown on page 21. Especially, toward the launch of Cefiderocol in the US within this fiscal year, preparations are being steadily made.

The progress of our initiatives for other regions and items is also presented here. So please take a look at it. We will continue to steadily promote these businesses.

Promote R&D Activities



Major Progress of Pipeline in FY2019



Steady progress in R&D

(Details will be explained in the R&D Day scheduled for Mar. 19, 2020)

Page 22 shows the progress in research and development activities. As you can see here, interesting results have been continuously reported from research laboratories, while development of priority pipeline has been steadily advancing. As we announced the other day, we will hold an R&D Day on March 19, where we will explain on more details including the progress in other pipeline as well as those in the slide.

Revision of Forecasts (Announced on Feb. 3, 2020)



(Unit: B yen)

	FY2019 Forecasts				FY2018 Results	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*		Change (%)	Change
Sales	365.5	367.0	355.0	(12.0)	363.7	(2.4)	(8.7)
Operating income	147.0	150.0	141.5	(8.5)	138.5	2.1	3.0
Ordinary income	170.5	171.5	167.0	(4.5)	166.6	0.3	0.4
Profit attributable to owners of parent	133.0	135.0	133.0	(2.0)	132.8	0.2	0.2

Plan to achieve record-high levels of operating income while promoting R&D activities and investment for the growth

Exchange rate (average)	FY2019 forecasts (May 9)	FY2019 forecasts (Revised on Oct. 30)	Q3 FY2019 Results
USD (\$) –JPY(¥)	110.0	107.0	108.66
GBP (£) –JPY(¥)	145.0	133.0	137.76
EUR (€) –JPY(¥)	130.0	120.0	121.04

Page 23 shows a summary of the revised forecasts. This year, we had to revise forecasts for sales and all income items downward for the first time since fiscal 2011. But since issues are clear, we will take appropriate measures to solve them. We will not suspend necessary investments. By overcoming this situation, we plan to achieve record-high levels of profit while promoting R&D activities and investment for further growth.

HIV Franchise: Progress of 2-Drug Regimens



Tivicay[®], Triumeq[®] Launch: 2013~

- Key drug for 3-drug regimen

Juluca[®] (DTG/RPV) Launch: 2017~

- First 2-drug regimen for maintenance therapy

DTG/3TC Launch: 2019~

- First 2-drug regimen for naïve patients
- Apr. 2019: Approved in US (naïve patients)
- Jul. 2019: Approved in EU (naïve patients and switch patients)
 - : TANGO 48-week results (switch patients)
 - : GEMINI 96-week results (naïve patients)
- Oct.-Dec. 2019: Start SALSA (switch patients)

Nov. Dec. 2019:
Recommended by
guidelines (US, EU)

CAB+RPV Launch: 2020~

- First long acting injection (monthly or bimonthly)
- Apr. 2019: NDA submission in US (monthly injection, naïve patients and switch patients),
 - ⇒ Dec. 2019: Receipt of CRL, work closely with the FDA to determine the appropriate next steps for this NDA
- Jul. 2019: MAA submission in EU (monthly)
- Aug. 2019: ATLAS 2M results (bimonthly injection for switch patients)

CAB prophylaxis Launch: 2021~

- First long-acting injectable for prophylaxis (bimonthly injection)



Progress from Oct. 31, 2020 to Feb. 3, 2020

CRL: complete response letter DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine, CAB: cabotegravir

24

Finally, I would like to update the situation of HIV franchise on two pages from page 24.

First, Dovato was successfully listed as a recommended drug in guidelines in Europe and US.

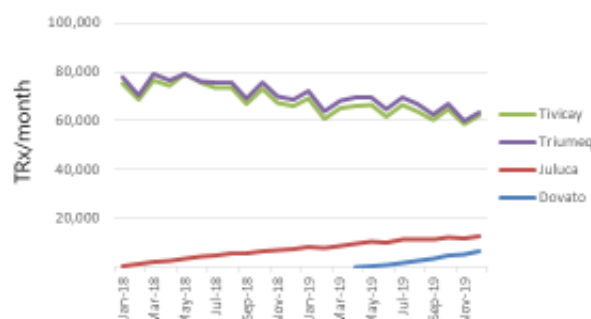
Regarding Cabotegravir and Rilpivirine for long acting injection, on the other hand, FDA issued a Complete Response Letter relate to Chemistry Manufacturing and Controls at the end of last year. At present, consultation between ViiV and FDA is under way toward approval.



Progress of HIV Franchise

Changes in total prescriptions of DTG franchise

Changes in TRx for DTG franchise in the US*
(from Jan. 2018 to Dec. 2019)



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- Growth of our two drug regimens is encouraging in that it more than offsets the decline in our 3 drug regimen as we transition to the new portfolio
- **Dovato® recommended by guidelines (EU,US)**
 - Nov. 2019: recommended by EACS Guidelines 2019* (EU)
 - Dec. 2019: recommended by Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV** (US)

**Sales-regrowth phase
by standardizing 2 drug regimen**

Towards approval of CAB+RPV in US

- Because of FDA's observation on the manufacturing method, the approval is delayed.
- The observation was related to the manufacturing method. There is no impact on safety and efficacy which were confirmed in clinical studies.
- ViiV is working towards approval in 2020.



DTG: dolutegravir, CAB: cabotegravir, RPV: rilpivirine
 * https://www.eacsociety.org/files/2019_guidelines-10.0_final.pdf
 ** <https://aidsinfo.nih.gov/contentfiles/tvguidelines/adultandadolescentgl.pdf>

25

This is the last slide, page 25. We expect Dovato will grow into a very important product for both ViiV and Shionogi. As for the Cabotegravir injection drug, the points questioned by FDA are related to Chemistry Manufacturing and Controls and have no impact on safety and efficacy confirmed in clinical studies. ViiV is therefore working towards acquisition of approval by the end of 2020.

This is the end of my explanation. Thank you very much.

Q&A

Kyokawa: : And that concludes our explanation of the slides. Now we're going to move on to the Q&A session.

Emcee: The first question is from Mr. Yamaguchi of Citi group. So Mr. Yamaguchi, please go ahead.

Mr. Yamaguchi: I'm Yamaguchi of Citi. For my first question, I'd like to confirm two matters with regard to Xofluza.

The first concerns wholesaler inventory. For Q3 it's 0.38 billion yen, but was that actually sold? Or how much of that amount for inventory was actually left behind, well, obviously you know from actual sales and actual inventory, but if you know how much that was, please tell me.

Matsuo: I'll answer that question. First, regarding the consumption of inventory in 3Q, regarding that, I think that most of the portion exceeding the appropriate inventory for reserve in case of influenza going around was sold. I'll refrain from stating a specific amount with consideration for relations with wholesalers.

Mr. Yamaguchi: I see. I understand. And as for sales forecast of Xofluza in Q4 alone, I guess the amount remaining was close to sales in Q4 last fiscal year. In other words, 17-something billion yen is, I guess, remaining. Considering that influenza was widespread and share of Xofluza was fairly high last season, I think that the same thing could not happen in this Q4, if the current information is right.

Put another way, is the current sales forecast for Xofluza really achievable? What do you think?

Hanasaki: Thank you for your question. Certainly, looking at prevalence in January, the situation seems a little severe, but as I mentioned when talking up prevalence for each age group a little earlier, from January onwards adult patients normally increase to 60 to 70 percent, or even 80 percent. Among adolescents aged 12 years or older as well as adults, even when they take Xofluza and are found to be infected with variant viruses, the drug is still effective. This has also been proven in clinical trials.

And information from the National Institute of Infectious Diseases states that there has only been one sample with variant viruses in the case of Xofluza. Moreover, because the main strain going around at the moment is Type-A H1, we think that the share for adolescent over 12 and adult patients will increase.

So for that reason, we want to make this figure one of our targets as we take action going forward.

Mr. Yamaguchi: That patient mix has created a favorable direction for you in Q4, isn't it?

Hanasaki: That's right.

Mr. Yamaguchi: I see. Second, among your drugs and pipeline, do you have any that might be effective against the new coronavirus?

Sawada: : As things stand now, it seems that the molecules targeted by Xofluza are absent from the coronavirus, so I think the likelihood of Xofluza being effective is fairly low.

And the same goes for HIV and so on. Until it's actually administered, we don't know, so if we find out, we will make an announcement.

Mr. Yamaguchi: So you don't know. I see. Thank you very much.

Emcee: The next question is from Mr. Hashiguchi of Daiwa Securities. Mr. Hashiguchi, please go ahead.

Mr. Hashiguchi: : I'm Hashiguchi. Thank you.

My first question concerns your targets for this term for Xofluza. Could you tell me how much share you were assuming for the 4th quarter when you put together this sales forecast?

Hanasaki: One of our assumptions is a market share of 50%.

Mr. Hashiguchi: Thank you very much. And as for my second question, you've recently upped your forecast for contract manufacturing. To what drugs does this relate, and what are the reasons for the upward revision?

Matsuo: I'll answer this question. One of the factors included is exports of Xofluza. And as for the Dolutegravir API, there was a substantial increase in the first half, which should also be present in Q4 in the second half, so we've increased the amount.

Mr. Hashiguchi: Do you know what the background is to this pickup in Xofluza exports.

Matsuo: We've had a lot of orders from Roche.

Mr. Hashiguchi: Finally, about the new coronavirus, I often hear investors saying that they've got high hopes for Shionogi as an infectious-disease specialist, and earlier on you said you'd be trying it out on HIV, but besides the potential for existing drugs like that to be effective, have you, for example, started work on developing new vaccines or therapeutic drugs? Are you doing anything like that?

Sawada: At present we haven't even received a sample of the virus, so unfortunately we haven't been able to make a start in that area, and we don't have any plans to do so right now.

Hanasaki: On January 30th it was reported that the National Institute of Infectious Diseases had isolated the virus, and we also intend to keep updated with the latest information as we consider what to do next.

Mr. Hashiguchi: I see. Thank you very much. That's all from me.

Emcee: The next question is from Mr. Ueda of Goldman Sachs. Mr. Ueda, please go ahead.

Mr. Ueda: I'm Ueda of Goldman Sachs. My first question concerns Xofluza. On Page 15 of the slides it states that understanding among medical professionals of variant viruses remains inadequate.

In which specific points is understanding still not being obtained? On Page 16 you describe a number of measures, and it seems that you are predicting a substantial improvement from the 3rd quarter to 4th quarter. Please tell me what you are going to emphasize in particular in order to achieve the forecast actually.

Sawada: At the initial stage, there were people who believed that variant viruses with a low susceptibility not only to Xofluza but also to other drugs would emerge, and there are also people who believe they are widespread in the field, but a challenge for us is that we can make direct contact with only doctors. Variant viruses are definitely not widespread. As I mentioned earlier, the emergence rate in cases of non-administration is not even 1% in the case of H1.

However, we also want to raise awareness of things such as the fact the percentage with a low susceptibility to other drugs is a little high in certain strains. But because it's still not 100%, we want to lift it to 100%. We intend to make an effort to get a bit closer to this going forward.

Mr. Ueda: I see. Thank you very much. My second question concerns HIV. I don't think there's been much time since Dovato was included in the guidelines, but could you tell me if there has been any change, say around the time of inclusion in the guidelines?

Sawada: I'm sorry, but please give us a bit more time.

Mr. Ueda: I see. Thank you very much. Finally, I'd like to ask about Cefiderocol. I want to know what sort of price negotiations are being conducted in the U.S., and regarding the reimbursement price in Europe, at the 2nd-quarter briefing you said that concrete discussions were ongoing, so if any progress has been made, could you tell me about it?

Sawada: Regarding the U.S., and this is probably going to dash your hopes, I don't think there has been, but I'm going to refrain from mentioning final amounts today.

As for Europe, we're in the middle of moving forward, but we're absolutely not at the point where we can see what the final amount is going to be. In Europe, in particular, things take a bit of time, so I think it's difficult for me to give you specific figures today. Please forgive me.

Mr. Ueda: I understand. Could you tell me roughly how long it will be in Europe until the price becomes clear?

Sawada: Usually, for about a year following launch, various discussions take place, so for that reason, I think it will lag behind the U.S. by about one year. But regardless of that, in the U.K. and Germany we can still sell the product. It's just that we won't know what the redemption price is for another year.

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

Emcee: The next question comes from Mr. Sakai of Credit Suisse. So please go ahead, Mr. Sakai.

Mr. Sakai: I'm Sakai. First, I'd like you to tell me about the situation with Cabotegravir. It hasn't been long since the complete response letter was received, so I guess ViiV hasn't had any meetings with the FDA yet.

Given that this is an issue relating to the manufacturing method, rather than the drug's efficacy or safety, if it meets the rules for resubmission, so-called FDA Class II resubmission, the review will probably take around six months. Could you first confirm that this is also your understanding?

Sawada: To be honest, it's difficult for me to say any more than what's been announced by ViiV. That being said, you can assume that we're ultimately aiming for approval within the year.

Mr. Sakai: When you say within the year, do you mean the 2020 calendar year?

Sawada: Yes.

Mr. Sakai: I see. Thank you very much. Another question I have concerns S-812217 licensed from SAGE. The release regarding the MOUNTAIN Study was issued at the end of last year, and it looked extremely complex, and I didn't really understand it.

Basically, in the development program, there were studies of 20mg dose and 30mg dose, and there were about five studies. The announcement ultimately said that it did not meet the primary endpoint. However, according to your materials, you will conduct Phase II domestically in Japan.

Does this mean, for example, that you have already seen the MOUNTAIN Study data and that you have already decided, to some extent, what you should do in Japan? For example, the dose is 30mg, isn't it? And efficacy has probably been properly confirmed over there. So I'd appreciate it if you could give me some sort of hint as to what your future approach is going to be in this regard.

And before I finish, one more thing. This concerns Xofluza. I've understood the situation in Japan. But overseas, in the October-December quarter I think Roche has only achieved sales of two million Swiss francs, and I think this must be quite below your expectations. And even though influenza wasn't that prevalent, please tell me how you view this situation.

Sawada: Starting with S-812217, we've actually been planning to conduct Phase II since before these results came out, so even with this new data, we don't believe we should change our plans.

Overseas, after having various discussions with the FDA, I think they'll decide what to do going forward. As part of that process, seen as part of a global package, we want to try and produce something that we can share.

Mr. Sakai: If my memory is correct, I understand that it was originally decided to perform Phase II in Japan so as to maximize commercial value in Japan, and that this would happen regardless of the trial results or the MOUNTAIN results. Is that right?

Sawada: Exactly.

Mr. Sakai: I see.

Hanasaki: Regarding Roche's sales in the U.S., Type B is fairly prevalent, and recently Type B and then Type A H1 have becoming the dominant strains. In that sense, considering variant viruses, I think that this might be a favorable infection pattern for Xofluza.

Mr. Sakai: So we can still expect sales to some degree in January and February. Is that what you're saying?

Hanasaki: That's right. From now on.

Mr. Sakai: I understand. Thank you very much.

Emcee: The next question is from Mr. Muraoka of Morgan Stanley. So Mr. Muraoka, please go ahead.

Mr. Muraoka: I'm Muraoka of Morgan Stanley. If you look at Roche's accounts, I think they say that sales were only 10 million Swiss francs globally for the year of 2019. The sales in the U.S. were 8 million Swiss francs. In connection with that, does getting plenty of orders from Roche mean that even if sales on Roche's end are that low, from this January onwards, the situation overseas, particularly in the U.S., is fairly promising? Including when taking into account what was just said about Type A and Type B.

Matsuo: Yes, that's right.

Mr. Muraoka: I see. Next I'd like to talk about how you're going to perform after the end of this next three months. Given the subtracted 4th-quarter R&D expenses and SG&A, and your continued ability to exercise cost control, the numbers have fallen, but I get the impression that you still have room to curb costs further. Even if you can't get a 50% domestic share in January to March, I think that considerable adjustments could be made in the area of these costs. Is that assumption accurate?

Hanasaki: With regard to that point, we regard it as an investment for the future, so we've included it in costs. Of course, if the level of sales, for example, of Xofluza starts having an impact, as I said earlier, we want, as a company, to aim achieve our highest level of bottom-line profit ever.

Mr. Muraoka: I see. Thank you very much. Finally, at the end of April I think you're planning to unveil your next medium-term plan. Given the situation this term, if you're going to set out a growth strategy in the medium-term plan, and I know that, for example, there are things you can say and can't say at this point, but what sort of things can we expect. It'd be helpful if I could even just a hint.

Sawada: Sorry, but you'll get a hint in March.

Mr. Muraoka: So at the R&D meeting, it'll be things like this or that exciting drug seems super effective.

Sawada: Yes. I'd like you to look forward to March.

Mr. Muraoka: I see. Thank you very much. That's all from me.

Emcee: The next question is from Mr. Kotani of Nomura. So Mr. Kotani, please go ahead.

Mr. Kotani: I'm Kotani of Nomura. My first point concerns Xofluza. I'm sorry, but halfway through the conversation I became unable to hear, so I might be asking the same question someone else has.

Looking at domestic prescription shares for different age groups, which are shown on Page 15, I think the fall in the zero-to-nine age group can't be held. And for 10 and up and 20 and up as well, I

think the share has probably gone down, but looking at this alone, I think that the talk of variants might have been conveyed in a fairly distorted fashion.

Going forward, with the forecasts for this year, when considering the forecasts for further ahead than that, this talk of I38-substituted virus, well, to be honest, I can't see it being resolved. The I38-substituted virus obviously appears, and while I understand that it won't be dominant, how long will it take? I feel that it will also take a fair amount of time for it to become well known among doctors.

First, is it your understanding that I38-substituted virus itself won't become dominant? And after that, how will this information be passed on? If things stay as they are, I worry that there won't be much of an increase from next year onwards, but could you tell me your view with regard to this. That's my first question.

Sawada: As you say, it's a fact that misunderstanding is fairly widespread. I mentioned this briefly at the beginning, but two fears have been spreading around. These are that administering Xofluza will result in the appearance of viruses that other drugs are completely ineffective for, and that these viruses will become rampant.

Regarding the question of whether it's something that other drugs won't work for, in the case of so-called antimicrobial drugs, if a variant enters through an emission pump, a considerable number of drugs will cross, and resistance will emerge. But in the case of viruses, it's about whether there's action on the target molecules. So just because a variant emerges, it's not the case that resistance against other classes of drug will be acquired. In that sense, I believe this is an area in which viruses with a low susceptibility to multiple drugs are unlikely to emerge.

In addition, when variant viruses are compared with original wild versions, their ability to multiply is poor, or they become viruses of about the same level. To actually become prevalent, a virus needs to be more infectious than the wild versions, so taking that into account, it's difficult to imagine that this variant strain will become dominant.

Last year, in fact, the drug was used by more than four million patients, and looking at what's actually happening this year, so far no one has been identified as being infected with a variant virus of H3, though the statistics are scant. And as for H1, the rate is currently 0.3%, with only one case. For that reason, I believe that, at least based on the data for this year, that you can view the risk of prevalence as low.

Mr. Kotani: Is this the recent release from Professor Kawaoka at the University of Tokyo? I'm currently reading that types of variant viruses need to have greater reproductive capacity than the original virus that was susceptible to the drug. And so far, such a virus has not been discovered, it says. After that, it says that it is therefore a drug that is highly effective in adults, so in a sense, the professor has written something like that. If such information spreads, will there be a slightly better chance of recovery?

Sawada: That's right. Shortly, it will become possible to publish data on high risks study. So including that, I think it will be important to properly explain what sort of data there is.

Mr. Kotani: I see. My second question concerns Xofluza in the U.S. During the 3rd-quarter conference call with Roche, they said that they were feeling pretty positive about Xofluza. What one

of them said was that in the case of a new drug, they have a gentlemen's agreement over there, and under this agreement, which has existed for years, they won't sell the drug DTC within six months of receiving approval. But they said that in this case, this won't apply. High risk is acceptable, and they'll sell it DTC.

And when I investigated, I found that they ran a commercial campaign at the end of October, but that they didn't get many sales, though I don't know what the situation with sales is like now.

So why are sales in the U.S. lackluster? What's the reason for this? Is it also down to the talk of variants? Or is it just that Genentech and Roche haven't put much effort in? Or is there another reason?

Sawada: Variants are actually not much of a problem. In fact, even with the CDC, it's included in their recommendations, so on that point it's not the case that market share is low because of the mutation issue.

Rather, in the U.S. market, completely generic drugs are available, so I think that you need to be ready for that to some extent when brand-name products come in.

And as for high-risk patients, until this comes out fully on paper, I hear that it won't be included in the text of these recommendations from the CDC. Once this is announced, I also think that these CDC recommendations for high-risk patients will be strengthened, so also factoring that in, I hope that they will grow sales over the medium to long term.

Mr. Kotani: I have a third question, and it'll be my last. I wanted to know whether you'll tell us this in March. I think that talk of some sort of vaccine will emerge, and is it the case that you'll tell us in March what sort of product it will be?

Sawada: Yes, we will.

Mr. Kotani: Thank you very much.

Kyokawa: Thank you very much. This is Kyokawa. It seems we're still receiving questions, but we've already gone over the time allotted, so if you have any more questions, please direct them to our Corporate Communications Department. My apologies for the inconvenience.

And with that I'd like to bring the Q&A session to a close. Thank you very much.

[End]