

3rd Quarter of Fiscal 2019 Financial Results

Conference Call

February 3, 2020

SHIONOGI

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2. **FY2019 Financial Forecasts (P.17-25)**

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1. Overview of Q3 FY2019 Financial Results

3rd Quarter of Fiscal 2019 Financial Results

1. Overview of Q3 FY2019 Financial Results
2. FY2019 Financial Forecasts

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)

Statement of Income

(Unit: B yen)

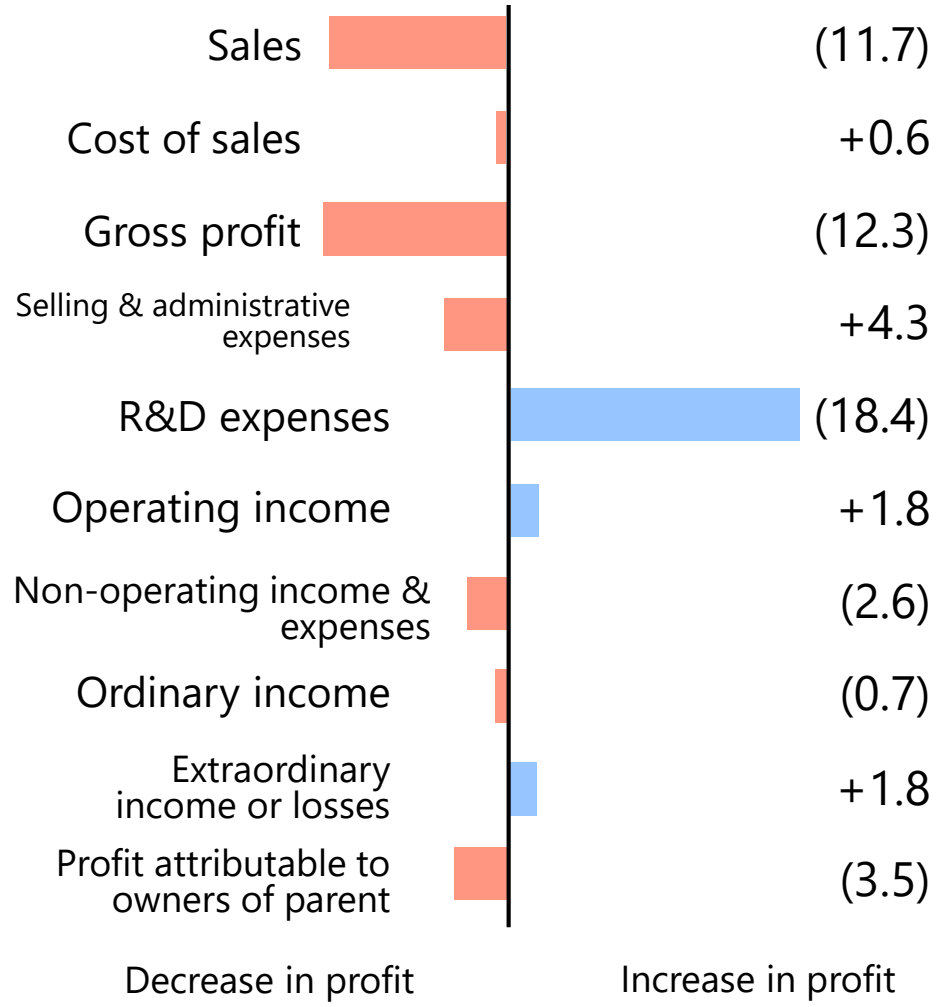
	FY2019			FY2018	Y on Y	
	Full year forecasts (revised on Oct. 30)*	Apr.-Dec. results	Achievement (%)	Apr.–Dec. results	Change (%)	Change (B yen)
Sales	367.0	**253.5**	69.1	265.2	(4.4)	(11.7)
	15.3	16.2		15.2		
Cost of sales	56.0	**41.0**	73.2	40.4	1.5	0.6
Gross profit	311.0	**212.5**	68.3	224.9	(5.5)	(12.3)
	43.9	44.7		48.0		
SG&A expenses	161.0	**113.3**	70.4	127.4	(11.1)	(14.2)
	30.5	31.0		28.1		
Selling & administrative expenses	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

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

- **Y on Y comparison**

(Unit: B yen)



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

Sales by Segment

(Unit: B yen)

	FY2019			FY2018	Y on Y	
	Full year forecast (revised on Oct. 30)*	Apr.-Dec. results	Achievement (%)	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)**

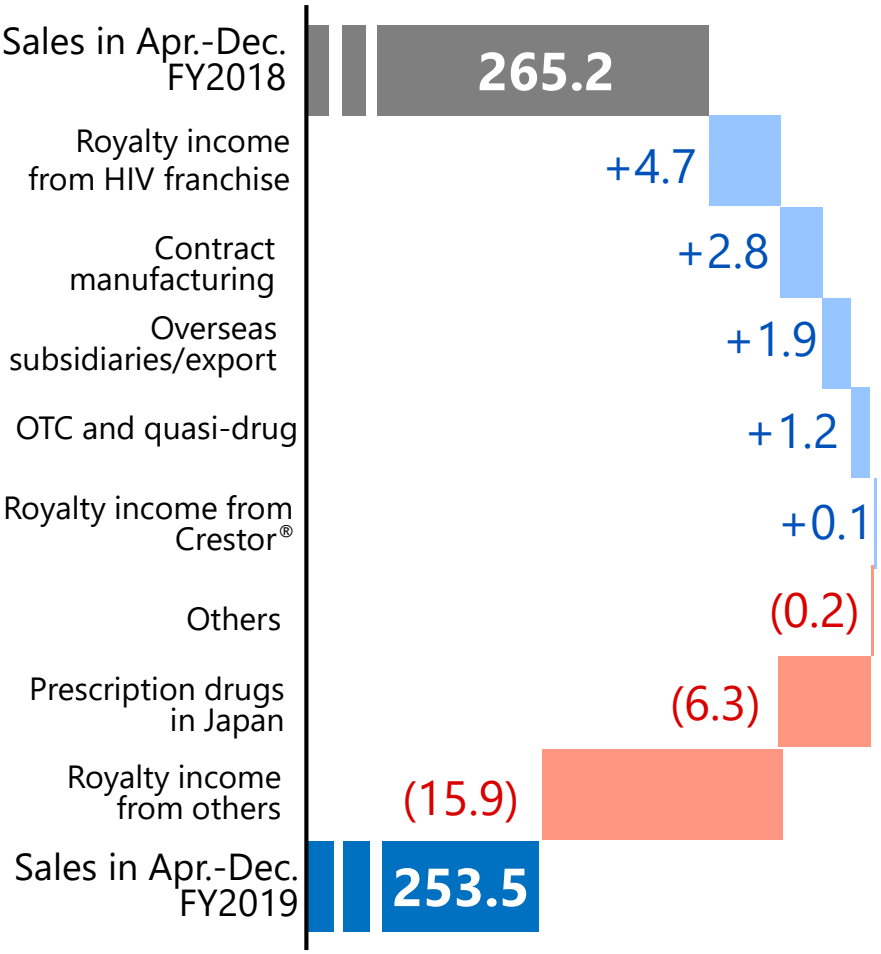
* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)

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

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®

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* Royalty income from Roche as milestones of R&D achievement
** HR: High risk (patients at high risk for influenza-related complications)
*** FY2018: One-time payment from Purdue, FY2019: One-time payment from BDSI

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)**

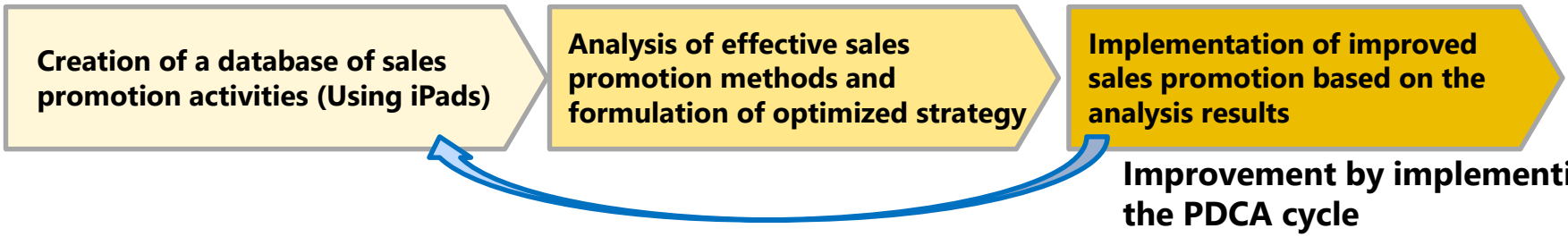
* Forecasts announced on Oct. 30, 2019 (Revision was announced on Feb. 3, 2020)
** Launched on Dec., 2019

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)**

Cymbalta®

Gain market share amongst the four main drugs* for chronic low back pain patients based on recommendations in the Chronic Pain Treatment Guidelines

Intuniv®

Gain market share by communicating the novel mechanism and efficacy to medical professionals

- Pediatric patients: Achieve top market share in naïve patients
- Adult patients: Capture market share based on foundation achieved in pediatric patients

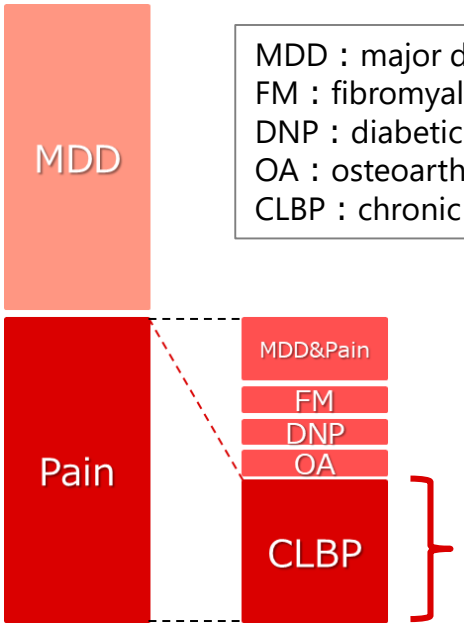
* Main pain drugs: Cymbalta®, Lyrica®, mirogabalin besilate, and tramadol

Issues in Domestic Business

Issues of Cymbalta®: Variation Factors from Forecast

Main market and target markets for Cymbalta®

(Image)



MDD：major depressive disorder
FM：fibromyalgia
DNP：diabetic neuropathy
OA：osteoarthritis
CLBP：chronic low back pain

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

- **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%

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

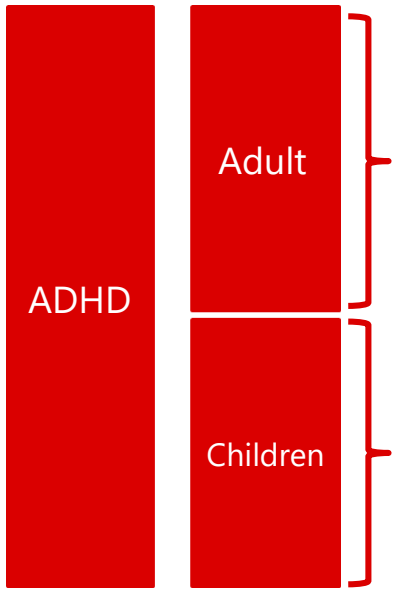
* Main pain drugs: Cymbalta®, Lyrica®, mirogabalin besilate, and tramadol
** Change the definition of KPI and data source at the timing of revision of FY2019 financial forecast in order to grasp the progress of KPI speedy

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 (chidren): 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

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%)

KOL: Key opinion leader

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)

Issues in Domestic Business

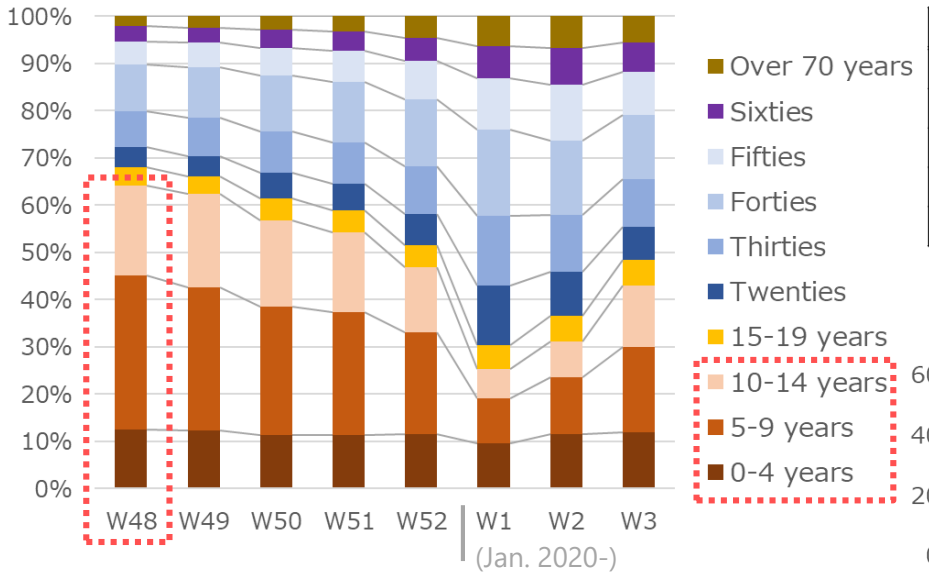
Xofluza®: Variation Factors from Forecast 2

– 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%*)

Estimated ratio of consulted patients by age (2019/2020)

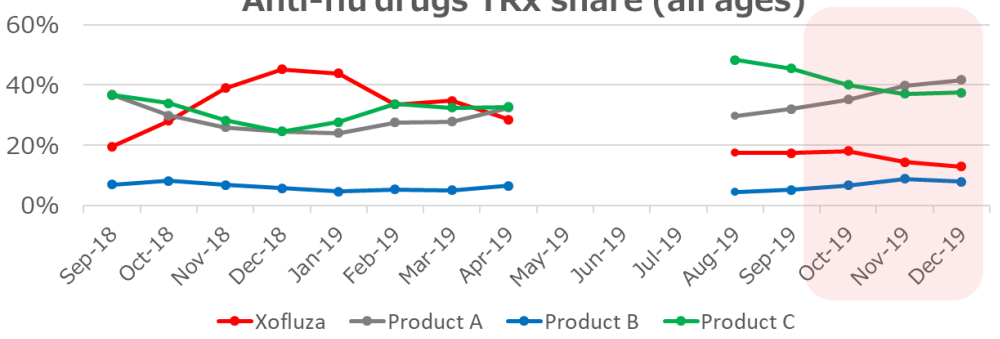


The chart was created based on the estimated number of outpatients in the MHLW's influenza epidemic level map (At Week 48: 2019/11/25–12/1)

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%

Anti-flu drugs TRx share (all ages)



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

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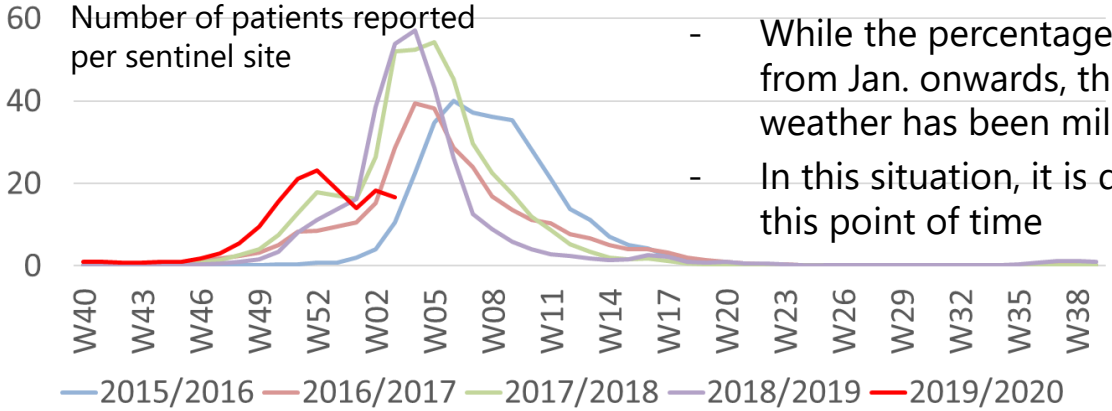
Issues in Domestic Business

Xofluza®: Change of Epidemics over the Years



- While the percentage of adult patients is expected to increase from Jan. onwards, this season has seen localized flares and the weather has been milder than usual
- In this situation, it is difficult to forecast nationwide spread from this point of time

The chart was created based on the number of reports per sentinel site in the MHLW's influenza epidemic level map (Week 40: 2019/9/30–10/6)

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

* Press release: The Results of Analyses of PA/I38X-substituted Viruses in XOFLUZA® Clinical Studies

2. FY2019 Financial Forecasts

3rd Quarter of Fiscal 2019 Financial Results

1. Overview of Q3 FY2019 Financial Results
2. FY2019 Financial Forecasts

Revision of Sales Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2019 Forecasts			FY2018		Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*	Results	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.

Revision of Sales by Segment

(Unit: B yen)

	FY2019 Forecasts				FY2018	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*	Results	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.

Revision of Statement of Income

(Unit: B yen)

	FY2019 Forecasts				FY2018	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*	Results	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.

Promote Overseas Business

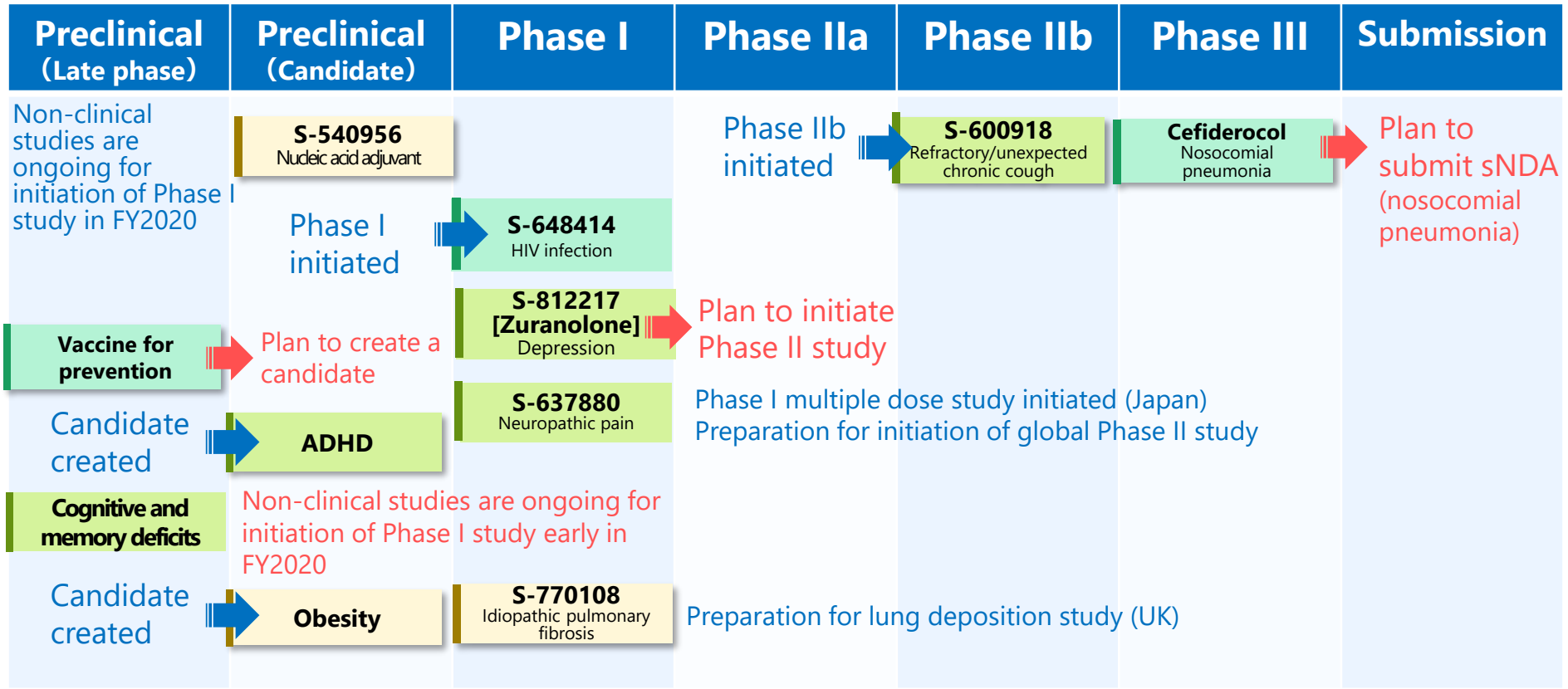
	US	EU, China, Taiwan etc.
Cefiderocol (Product name in US: Fetroja®)	・**Approved in Nov. 2019** ・Pre-launch activities have proceeded smoothly towards the product launch in this FY. ✓ Marketing strategies finalized ✓ Promotional materials developed ✓ Recruitment of sales force ongoing	・EU: Pre-launch activities continues towards approval in Apr. – Jun. 2020.
Baloxavir Marboxil (Product name in US: Xofluza®, in Taiwan: 紓伏效®)	・Commercialization by Roche group, maximize its value through collaboration	<EU>NDA submission in EU by Roche group <Taiwan>Launch in Nov. 2019
Lustrombopag (Product name in US: Mulpleta®, in EU: Mulpleo®)	・Keep our own promotion and make efforts for market uptake supported by 'Mulpleta Assist' program	<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®)	・Apr. 2019: Partnering with BioDelivery Sciences International（BDSI）for OIC commercialization → Market uptake through BDSI's commercial expertise in the field of opioid analgesics	<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* **		・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**

* NICE: The National Institute for Health and Clinical Excellence
** SMC: Scottish Medicines Consortium *** Product name in Japan: Flomox®

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)

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

(Unit: B yen)

	FY2019 Forecasts				FY2018	Y on Y	
	Original (May 9)	Revised (Oct. 30)	Revised (Feb. 3)	Change*	Results	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

* Difference between the forecast revised on February 3, 2020 and the forecast announced on October 30, 2019

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)

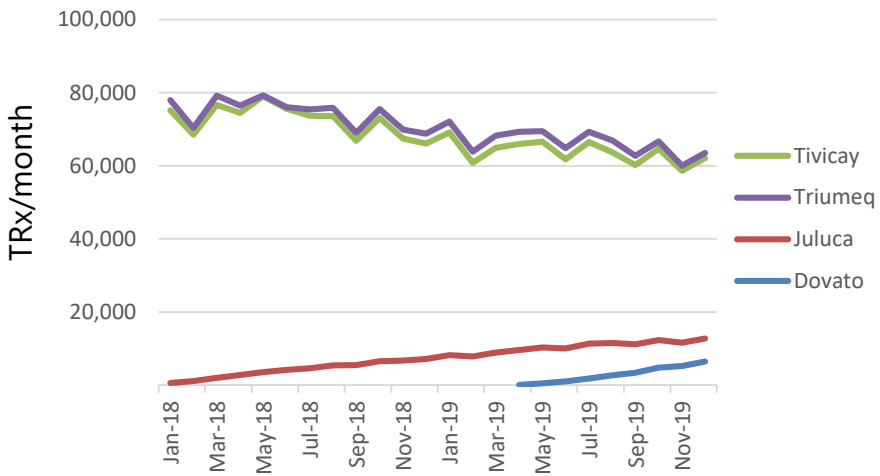
Progress from Oct. 31. 2020 to Feb. 3. 2020

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

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

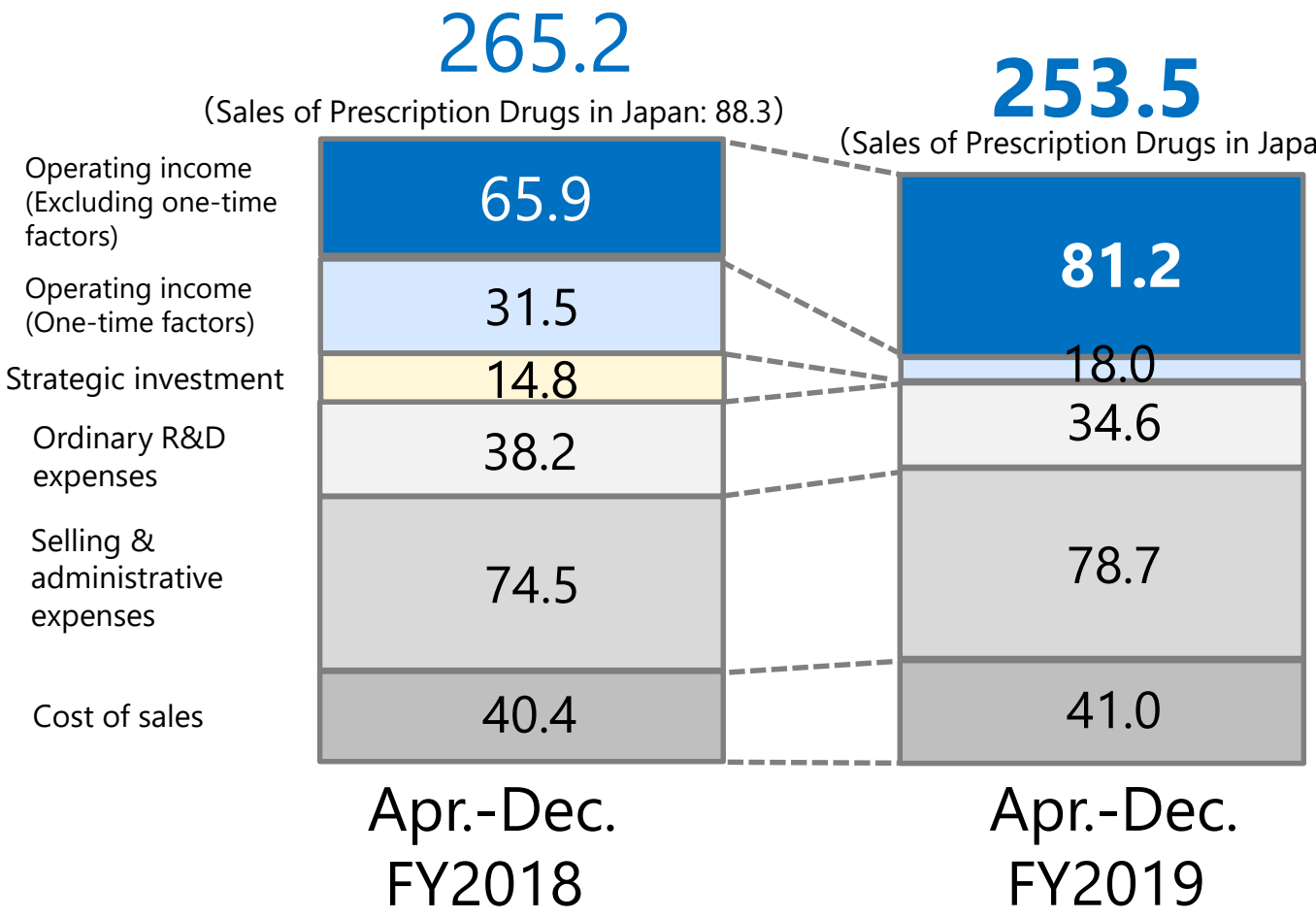
** https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf

Appendix

- Year-On-Year Comparisons (One-time Factors)
- Financial Statement (Consolidated)
- Major Progress in Q3 FY2019
- Target Milestones for Development of Pipeline in FY2019
- Progress of Pipeline
- Launch Plan
- Definition of New Products

Year-On-Year Comparisons (One-time Factors)

Sales (Unit: B yen)



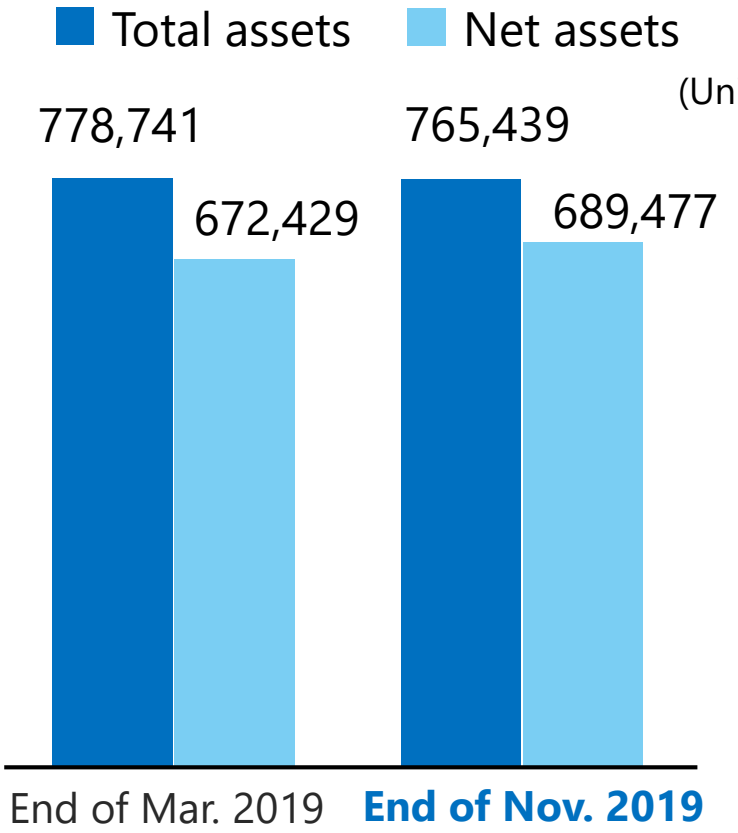
＜Main One-time Factors＞

FY2018：
- Income from Roche
- One-time payment from Purdue
- Strategic investment

FY2019：
- Income from Roche
- Termination of the threshold period for the calculation of royalty payment of HIV franchise by ViiV
- One-time payment from BDSI*

* BioDelivery Sciences International Inc.

Financial Statements (Consolidated)



Unit: M yen		End of Mar. 2019	End of Nov. 2019	Change
Total assets	Current assets	461,743	461,102	(641)
	Non-current assets	316,997	304,336	(12,660)
Liabilities	Current liabilities	89,107	59,359	(29,747)
	Non-current liabilities	17,203	16,602	(601)
Net assets	Shareholders' equity	652,371	683,321	30,950
	Others	20,058	6,155	(13,902)

	End of Mar. 2019	End of Nov. 2019
Shareholders' equity ratio	85.7%	**90.0%**

Major Progress in Q3 FY2019* (Pipeline)

	Phase I	Phase II	Phase III	Submission	Approval, Launch
Global		**Naldemedine** ・Initiation of Phase I study (US) (Post operative ileus) **Rizmoic® (Naldemedine)** ・Initiation of Phase I/II study (EU) (Opioid-induced constipation (pediatric))			**Fetroja® (Cefiderocol)** ・Approval in US **紓伏效® (Xofluza®)** ・Launch in Taiwan **Mulpleo® (Lusutrombopag)** ・Positive appraisals recommendation by NICE** and SMC*** **Rizmoic® (Naldemedine)** ・Launch in EU
In Japan		**SDT-001** ・Initiation of Phase II study			**Vyvanse®** ・Launch in Japan
Out-licensed					**DOVATO®** ・Recommendation in the guidlines in US and EU ・Approval in Japan (naïve)
				Xofluza® ・NDA submission in EU (Influenza virus infection)	

Infections disease
Pain/CNS
Frontier

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* Progress from Oct. 31, 2019 to Feb. 3. 2020

** NICE：The National Institute for Health and Clinical Excellence

*** SMC：Scottish Medicines Consortium

Major Progress in Q3 FY2019* (Others)

- **November**
  - Cooperated in MHLW's HIV/AIDS measures project on establishment of new HIV test system
- **December**
  - Introduced a system with 24-hour response to customer inquiries using artificial intelligence (AI)
  - Submitted the declaration of the *White Logistics Movement*
- **January**
  - Our approaches to combat AMR were highly appraised by the Access to Medicine Foundation.

* Progress from Oct. 31, 2019 to Feb. 3. 2020
** 2020 Antimicrobial Resistance Benchmark
https://accesstomedicinefoundation.org/publications/2020-antimicrobial-resistance-benchmark

Target Milestones for FY2019: Approval and Submission

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Vyvanse® (ADHD(pediatric))			Achieved (Mar.)	Japan(2017.4)	Japan
Intuniv® (ADHD(adult))			Achieved (Jul.)	Japan(2018.8)	Japan
Cefiderocol (US: Complicated urinary tract infections, including pyelonephritis , EU: Aerobic Gram-negative bacterial infection)	Approval (US) (Nov.) Nosocomial pneumonia study: completion of enrolment		Global: CR study completion Global: Nosocomial pneumonia study completion	US(2018.12) EU(2019.3)	US (2019.11) EU
Xofluza® (Influenza virus infection) ①granule (weight under 20kg) ②prophylaxis			Japan： High-dose study for children: completion	①Japan(2018.8)	①Japan
		Achieved (Oct.)	Prophylaxis study completion	②Japan(2019.10)	
OxyContin®TR (Treatment of moderate to severe chronic pain)		Achieved (May)	Japan： Completion	Japan	

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Progress from Oct. 31, 2019 to Feb. 3, 2020

Planned

Completed

Target Milestones for FY2019: Phase I - III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
S-812217 [zuranolone] (Depression)	Japan: Single and multiple dose study completion ⇨	Japan: initiate			
Rizmoic® (Opioid-induced constipation(pediatric))	EU: Phase I/II study Initiate		**Achieved (Q3)**		
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections(pediatric))			Global: Safety and PK study initiate		
S-600918 (Neuropathic pain or Refractory Chronic Cough)		Japan: POC* study completion Global: Dose-finding Study initiate	**Achieved (Q2)**		
SR-0379 (Skin ulcers (Pressure ulcers, diabetic ulcers, etc))		Japan: POC* study completion	**Achieved (Q3)**		
S-770108 (Idiopathic Pulmonary Fibrosis)	UK: Lung deposition study initiate				

□ Progress from Oct. 31, 2019 to Feb. 3, 2020

* Proof of concept

⇨ Planned

Target Milestones for FY2019: Phase I - III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Redasemtide [S-005151] (stroke)	Japan：Study in Healthy adults (Including the elderly) completion	Japan：initiate	Achieved (Q1)		
S-637880 (Neuropathic pain)	Japan：Multiple dose study completion	Global：initiate			
Naldemedine (POI*)		Global：initiate	Achieved (Q3)		
Novel HIV Drug (HIV virus infection)	US：initiate	Achieved (Q2)			
SDT-001 (ADHD)		Japan：initiate	Achieved (Jan.)		

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Progress from Oct. 31, 2019 to Feb. 3, 2020

Planned

Completed

* Post operative ileus

Pipeline (as of Feb. 3, 2020)

Preclinical (target indication*)	Phase I	Phase II	Phase III	Submission
Influenza virus infection	**Global**	**Naldemedine** Post operative ileus	**Cefiderocol** Nosocomial pneumonia	**Cefiderocol (EU)** Aerobic Gram-negative bacterial infection
HIV infection	**S-648414** HIV infection	**Rizmoic®** Opioid-induced constipation (pediatric)		
RS virus infection	**S-117957** Insomnia	**S-600918** Refractory/unexpected chronic cough		
Bacterial infection	**S-237648** Obesity	**S-120083** Inflammatory pain		
Mycobacterium disease	**S-588210** Solid tumor	**S-707106** Type2 diabetes		
Fungus infection		**S-488210** Head and neck squamous cell carcinoma		
Vaccine for prevention		**epertinib** Malignant tumor		
Peptide		**S-588410** Bladder cancer		
ADHD	**In Japan**	**STD-001** Inattentive ADHD (pediatric)	**Cefiderocol** Nosocomial pneumonia	**Oxycontin®TR** Moderate to severe chronic pain
Opioid	**S-812217 [Zuranolone]** Depression	**Cefiderocol** Complicated urinary tract infections	**Xofluza®** Influenza virus infection (High-dose for children)	**Xofluza®** Influenza virus infection (prophylaxis)
Alzheimer's disease	**S-600918** Neuropathic pain	**S-600918** Refractory/unexpected chronic cough	**Cymbalta®** Depression (pediatric)	**Xofluza®** Influenza virus infection (granule, <20 kg)
Cognitive and memory deficits	**S-637880** Neuropathic pain	**S-005151 [Redasemtide]** Acute ischemic stroke	**S-588410** Esophageal cancer	
Post-stroke spasticity	**S-010887** Neuropathic pain	**S-005151 [Redasemtide]** Epidermolysis bullosa		
Peptide	**S-770108** Idiopathic pulmonary fibrosis	**S-237648** Obesity		
Obesity		**S-588410** Bladder cancer		
S-723595 NASH		**SR-0379** Cutaneous ulcer		
Cancer metastasis		**ADR-001**** Decompensated liver cirrhosis		
S-540956 Nucleic acid adjuvant				
Peptide				

- Infectious diseases
- Pain/CNS
- Other

Progress from Oct. 31, 2019 to Feb. 3, 2020

** In Phase I/II

* Target indication may include some projects

Pipeline
- Major Out-Licensed Pipeline (as of Feb. 3, 2020)

Preclinical	Phase I	Phase II	Phase III	Submission
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		**Dovato®** Treatment for HIV infection TANGO study (maintenance)	**Xofluza® (EU)** Influenza virus infection
			CAB LAP Prevention for HIV infection	**CAB+RPV LAP** Treatment for HIV infection
			Xofluza® Severe influenza virus infection	
			Xofluza® Influenza virus infection (pediatric)	
			Xofluza® Influenza virus infection (transmission)	

- **Infectious diseases**
- **Pain/CNS**
- **Others**

Stage progression (from Oct. 30 2019)	Fetroja® [Cefiderocol] (Complicated Urinary Tract Infections (cUTI), including Pyelonephritis): Submission→Approval (US) Dovato® Submission→Approval (Japan) Xofluza® (Influenza virus infection): Submission (EU) Naldemedine (Post operative ileus): Phase II initiated (US) Rizmoic® (Opioid-induced constipation (pediatric)): Phase I/II initiated (EU) SDT-001 (Inattentive ADHD (pediatric)): Phase II initiated (Japan) S-525606 (Allergic rhinitis caused by Japanese cedar allergen): Discontinuation

Progress from Oct. 31, 2019 to Feb. 3, 2020

DTG: dolutegravir 3TC: lamivudine CAB：cabotegravir RPV: rilpivirine

Target Milestones for Launch of Products

FY2017 (Achieved)	FY2018 (Achieved)	FY2019
In Japan		
Symproic® **Intuniv®** ADHD (pediatric) **Oxycodone** Tamper resistant formulation **Actair®** Pediatric allergic rhinitis caused by house-dust mite allergen **Xofluza® (adult, pediatric)**		**Intuniv®** ADHD (adult) **Launched** **Vyvanse®** ADHD (pediatric) **Launched**
Global		
Symproic® (US)	**Mulpleta®** (US)	**Cefiderocol (US)** **Lusutrombopag (EU)** **Baloxavir marboxil** (Taiwan) **Launched** **Rizmoic® (EU)** **Launched**
Out-licensed		
Juluca® (DTG/RPV) (US)	**Juluca® (DTG/RPV)** (EU, Japan) **Osphena®** (US) Vaginal dryness associated with postmenopausal VVA **Xofluza®** (US, OwH*)	**Dovato® (DTG/3TC)** (US, EU) **Launched** **CAB+RPV** (US) **Xofluza®** (US, HR**) **Launched**

DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine

*OwH: Otherwise healthy patients ** HR: High risk (patients at high risk for influenza-related complications)

Definition of New Products (in Updates to SGS2020)

Pain/ CNS

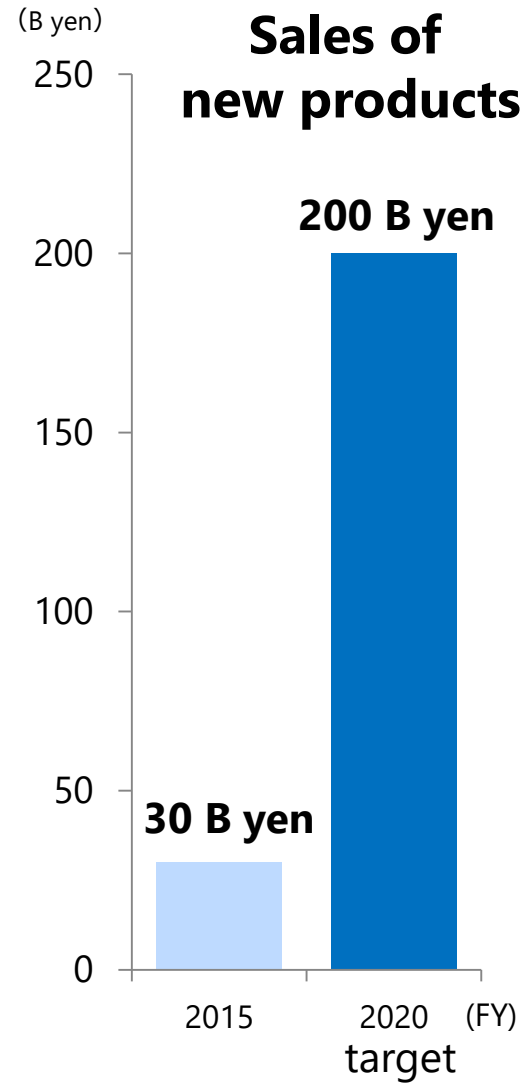
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine*
- Intuniv®, Vyvanse®

Infectious diseases

- Xofluza®
- Cefiderocol
- Rapiacta®, flu diagnosis kit

Others

- Pirespa®
- Mulpleta®
- Actair®
- Osphena® (Senshio®)



* Product name of naldemedine: Symproic® in Japan and US, Rizmoic ® in EU

Forward-Looking Statements

- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
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