



FY2019 Financial Results

(April 2019 – March 2020)

May 12, 2020

Isao Teshirogi, Ph.D.

President and CEO



Impact of COVID-19



Impact on business in FY2019

- **Supply chain**
 - No impact on procurement of raw ingredients etc., production, or inventory – no hindrance to stable supply
- **Promotion**
 - Responded to needs of physicians and medical institutions, utilization of e-detail
 - Possible impact on influenza family sales due to confusion among the public
- **R&D**
 - Some delays in gathering case information from clinical trials in Western countries

Business operations in FY2020

Respond to the state of emergency in the first year of our new medium-term business plan* as an opportunity to increase productivity, and reinforce our foundation for growth

- Ensure stable supply through supply-chain management that anticipates a protracted outbreak
- Identify unmet needs of physicians and enhance the efficiency of information delivery through Stream-I tools and e-detailing
- Revise allocations of trial recruitment targets amongst countries and consider virtual clinical studies
- Identify non-critical operations that can be suspended and step up the managerial and personnel-development capabilities of managers in the telework period

Our Efforts to Fight COVID-19



Discovery of novel therapeutic drugs

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

Discovery of Prophylactic Vaccine

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

Offering antibody test kit

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

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

Agenda



- 1. Overview of FY2019 Financial Results (P.5-16)**
- 2. Actions and Progress in FY2019 (P.17-26)**
- 3. FY2020 Financial Forecasts (P.27-35)**
- 4. Actions in FY2020 (P.36-42)**
- 5. Shareholder Return (P.43, 44)**



1. Overview of FY2019 Financial Results

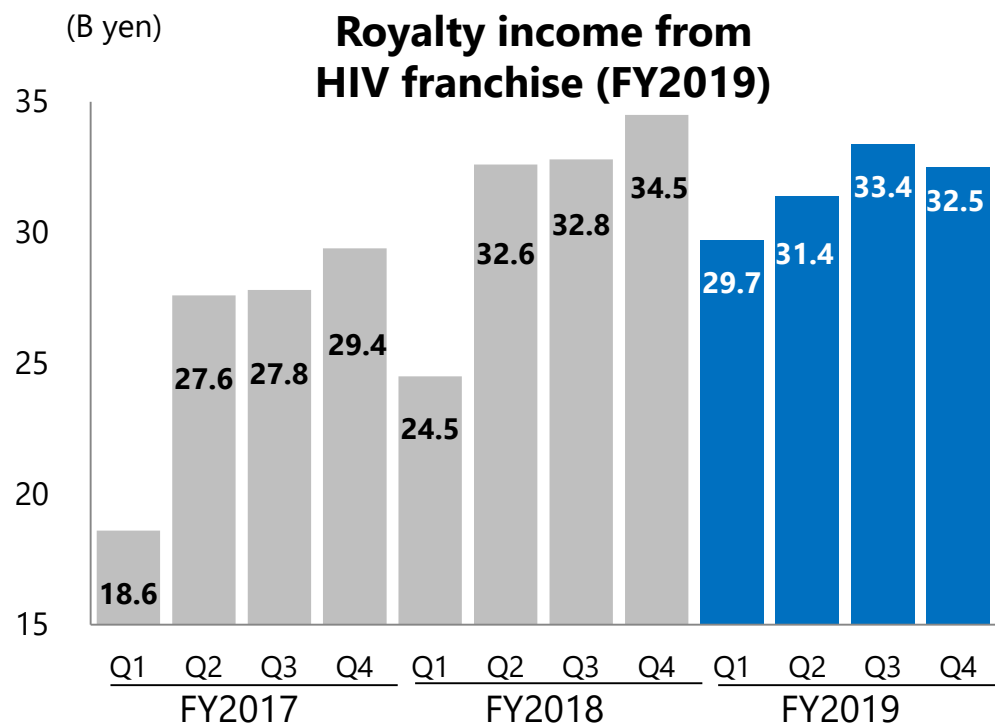
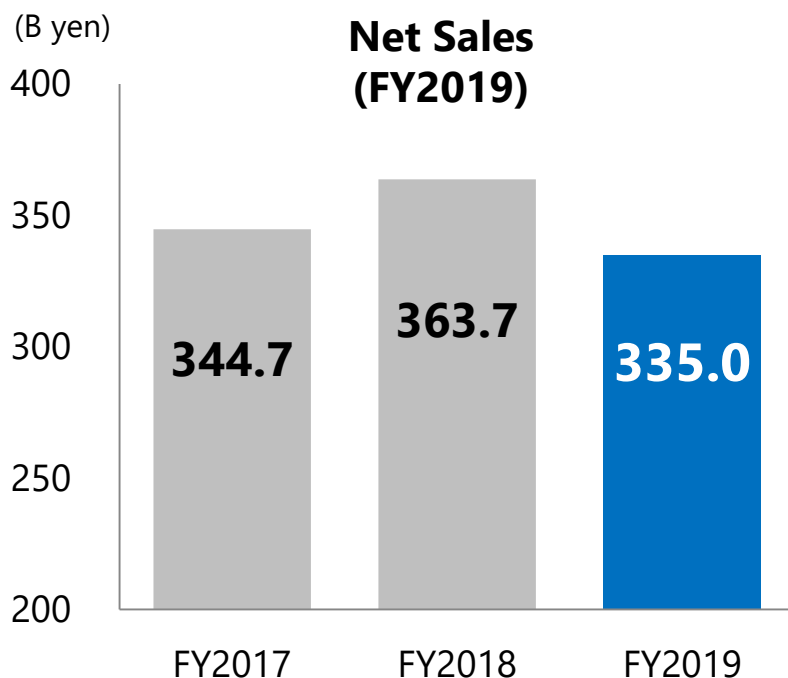
Highlight (1)

Japan Generally Accepted Accounting Principles (JGAAP)



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

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



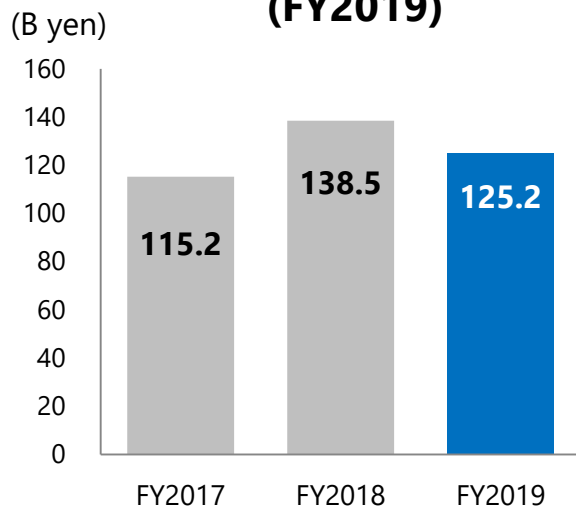
Highlight (2)

JGAAP

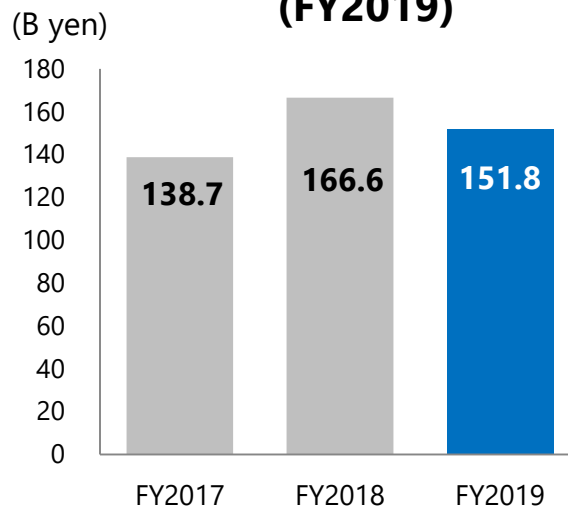


- ◆ Operating income: **125.2 B yen** (-9.6%) vs prior FY
- ◆ Ordinary income: **151.8 B yen** (-8.9%) vs prior FY
- ◆ Profit attributable to owners of parent: **121.3 B yen** (-8.6%) vs prior FY

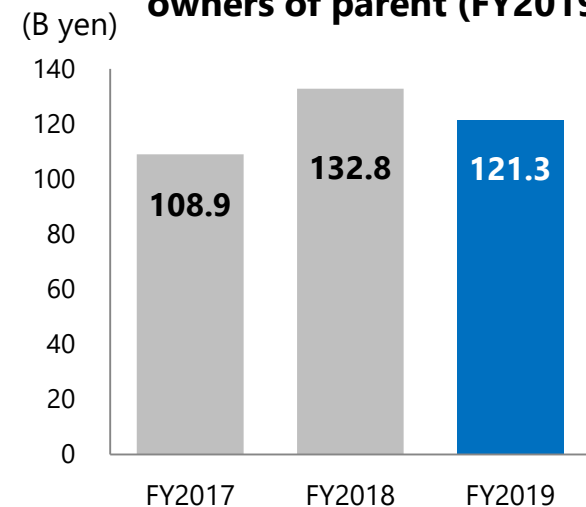
Operating income (FY2019)



Ordinary income (FY2019)



Profit attributable to owners of parent (FY2019)



Financial Results (Consolidated)



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

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

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

Statement of Income (Consolidated)



JGAAP (Unit: B yen)	FY2019		Results	Achievement (%)	FY2018	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Feb. 3)			Results	Change (%)	Change (B yen)
Sales	365.5 14.6	355.0 16.2	335.0 16.9	94.4	363.7 15.1	(7.9)	(28.8)
Cost of sales	53.5	57.5	56.7	98.6	54.9	3.3	1.8
Gross profit	312.0 45.1	297.5 43.9	278.3 45.7	93.5	308.8 46.8	(9.9)	(30.6)
SG&A expenses	165.0 31.6	156.0 30.4	153.0 31.6	98.1	170.3 28.0	(10.1)	(17.3)
Selling & administrative expenses	115.5 13.5	108.0 13.5	105.8 14.1	98.0	102.0 18.8	3.8	3.9
R&D expenses	49.5	48.0	47.2	98.3	68.3	(30.9)	(21.1)
Ordinary R&D expenses	49.5	48.0	47.2	98.3	51.4	(8.2)	(4.2)
Strategic investment	-	-	-	-	16.9	-	(16.9)
Operating income	147.0 40.2	141.5 39.9	125.2 37.4	88.5	138.5 38.1	(9.6)	(13.3)
Non-operating income & expenses	23.5	25.5	26.5	104.0	28.0	(5.4)	(1.5)
Ordinary income	170.5 46.6	167.0 47.0	151.8 45.3	90.9	166.6 45.8	(8.9)	(14.8)
Profit attributable to owners of parent	133.0	133.0	121.3	91.2	132.8	(8.6)	(11.5)

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



• Y on Y comparison (Unit: B yen)

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

Decrease in profit

Increase in profit

Main Variation Factors (Y on Y)

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

Main Variation Factors (revised budget)

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

Sales by Segment



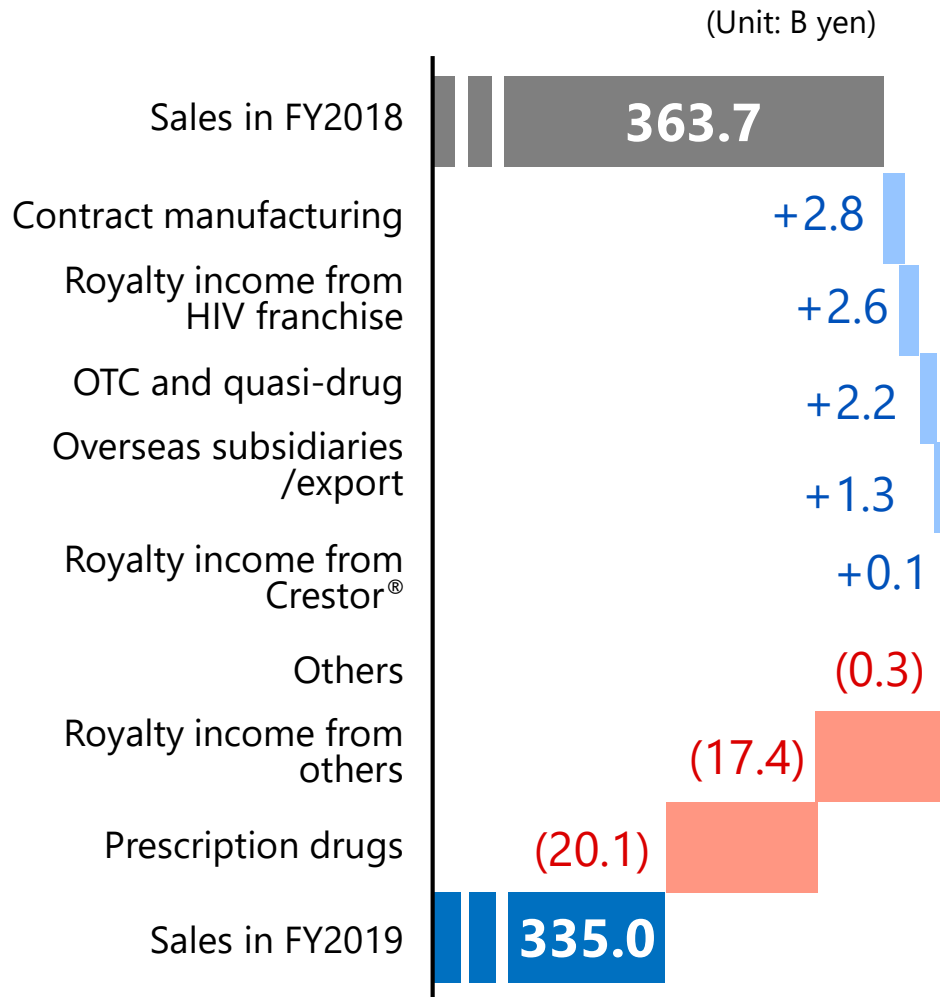
(Unit: B yen)

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

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



• Y on Y comparison



Main Variation Factors (Y on Y)

- **Royalty income**
 - Decrease of milestone income* from Roche for Xofluza®
 - Sales growth and termination of the threshold period of HIV franchise
- **Prescription drugs**
 - Sales increase of Cymbalta® and Intuniv®
 - Sales decrease of Flu-F
- **Contract manufacturing**
 - Export increase of Xofluza®
- **Overseas subsidiaries/export**
 - C&O: Sales increase of rabeprazole
 - Shionogi Inc.: One-time income related to Symproic®**

Main Variation Factors (revised budget)

- **Prescription drugs**
 - Sales decrease of Flu-F

Sales of Prescription Drugs in Japan



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

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

Failure to Meet Revised Target for Xofluza®



Assumptions for revised target (18.0 B yen)

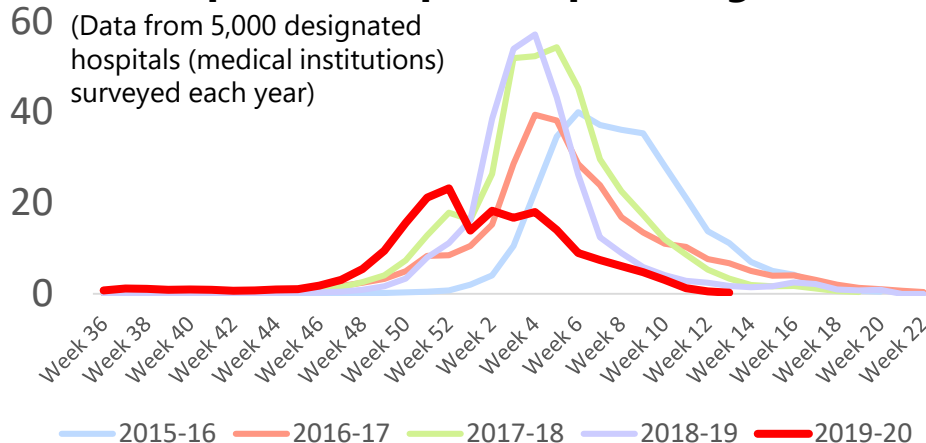
- Seasonal influenza epidemic from January in 2019/2020 season is similar as that of the previous season
- As in typical years, increase in proportion of adolescent and adult patients from January
- Restoration of market share to same level as the previous season in adolescent/adult market

Gaps to revised target

• Gap [1]: Seasonal epidemic of influenza

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

No. of patients reported per designated hospital



Cumulative estimates of no. of patients treated*

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

2019/2020 season: Approx. 7.28 M persons

2018/2019 season: Approx. 11.7 M persons

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

Failure to Meet Revised Target for Xofluza®



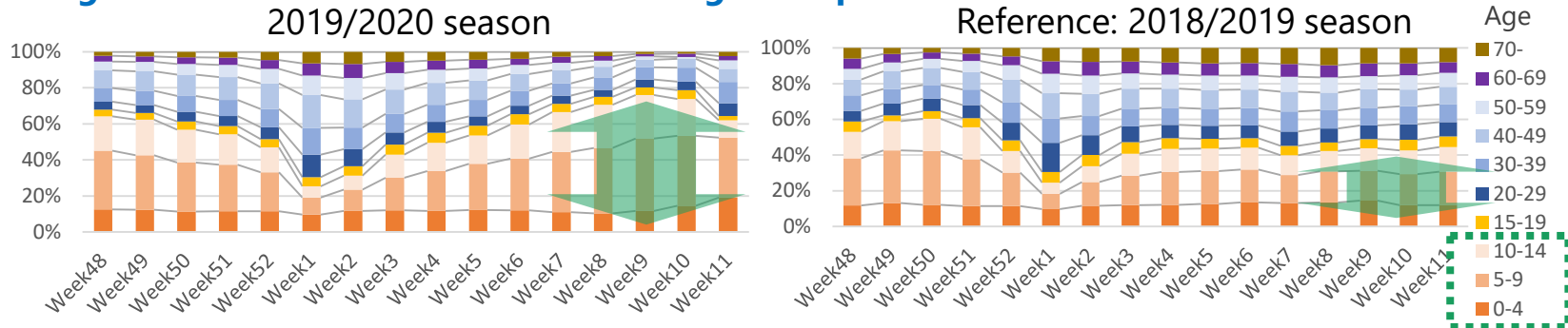
Gaps to revised target

• Gap [2]: Trend in no. of adolescent/adult patients

- As seen in the 2018/2019 season, persons aged 15 years or older accounted for 80%* of patients prescribed Xofluza® this season
- Children as a proportion of infected patients remained high after January this season (graphs below)

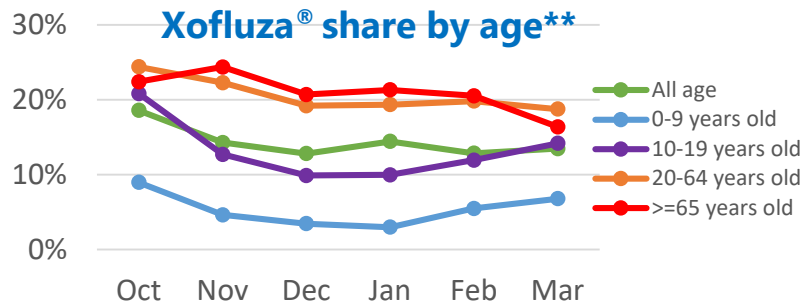
Graph produced based on no. of patients reported per designated hospital used in the Ministry of Health, Labour and Welfare's influenza outbreak level maps (48th week: 2019/11/25-12/1, 11th week: 3/9-3/15)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/kekaku-kansenshou01/houdou.html

Age breakdown of no. of estimated diagnosed patients



• Gap [3]: Increasing understanding regarding reduced susceptibility viruses amongst medical professionals

- While progress was made in increasing understanding of reduced susceptibility viruses amongst medical professionals, no clear increase in prescription due to early termination of the epidemic



Results of surveys of physicians***

Proportion of physicians who responded that they "correctly understand data on variant/resistant strains:
35.3% (October 2019) ⇒ 52.9% (December 2019)
⇒ 63.4% (March 2020)

Variant Strains in 2019/2020 Season



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

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

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

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

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

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

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

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

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

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

2. Actions and Progress in FY2019

1. Sales
2. Investment
3. Business innovation

*See Appendix p.52 for goals we set at the beginning of FY2019

1. Sales

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

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

Actions and Progress in FY2019 (2/2)



2. Investment (R&D)

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

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

3. Business innovation

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



Became more proactive about creating new value in healthcare

Investment Outcome -Advancing R&D Activities



Major progress of pipeline in FY2019*

Core pipeline to change the treatment paradigm

Preclinical (Late phase)	Preclinical (Candidate)	Phase I	Phase II	Phase III	Submission	
<p>Non-clinical studies are ongoing for initiation of Phase I study in FY2020</p>	<p>S-540956 Nucleic acid adjuvant</p>	<p>Non-clinical studies are ongoing for initiation of Phase I study in FY2020</p>	<p>S-600918 Refractory chronic cough</p>	Phase IIb initiated (Global)	<p>Fetroja® /Fetroja®</p> <ul style="list-style-type: none"> US: Approved cUTI caused by susceptible Gram-negative microorganisms** US: Application for additional indication for nosocomial pneumonia** EU: Approval of aerobic Gram-negative bacterial infections** 	
	<p>S-723595 NASH</p>		<p>S-600918 Sleep Apnea Syndrome</p>	Phase IIa initiated (JP)		
	<p>S-872600 Influenza prophylactic vaccine</p>		Candidate created	<p>zuranolone Depression</p>		Phase II initiated (JP)
	<p>S-874713 Psycho-neurological diseases</p>		Candidate created	<p>naldemedine Postoperative ileus</p>		Phase IIa initiated
	<p>S-309309 Obesity</p>		Candidate created	<p>Redasemtide Epidermolysis bullosa</p>		Good results in doctor-led clinical trials
	<p>Non-clinical studies are ongoing for initiation of Phase I study early in FY2020</p>		<p>BPN14770 Alzheimer's disease</p>	<p>Candidate created</p>		<p>Redasemtide Acute ischemic stroke</p>
<p>Regulatory T cell inhibitor Cancer</p>		<p>S-770108 Idiopathic pulmonary fibrosis</p>	Preparation for initiation of lung deposition test (UK)		<p>Infectious disease</p>	
		<p>S-648414 HIV infection</p>	Phase I initiated (US)		<p>Psycho-neurological disease</p>	
<p>Regulatory T cell inhibitor Cancer</p>	<p>S-637880 Neuropathic pain</p>	<p>S-637880 Neuropathic pain</p>	Phase I multiple dose study initiated (JP)	<p>New growth area</p>		
			Preparation for initiation of global Phase II study			

Enrich PoC products, promote LCM, create promising non-clinical pipeline

* Includes progress through May 11, 2020

** patients 18 years of age or older who have limited or no alternative treatment options
cUTI: complicated urinary tract infection, PoC: Proof of concept, LCM: Life cycle management

Investment Outcome - to Establish Global Presence



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

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

Progress with global development of Xofluza[®]

Taiwan

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

Japan

- sNDA for prophylactic use (Oct. 2019)

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

US

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

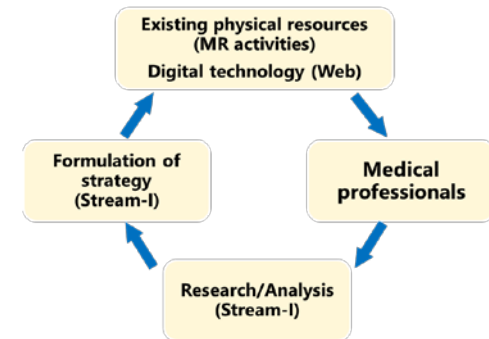
EU

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

Establishment of Stream-I

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

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



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

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

UMN Pharma's technology (BEVS*)

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

<Action in FY2019>

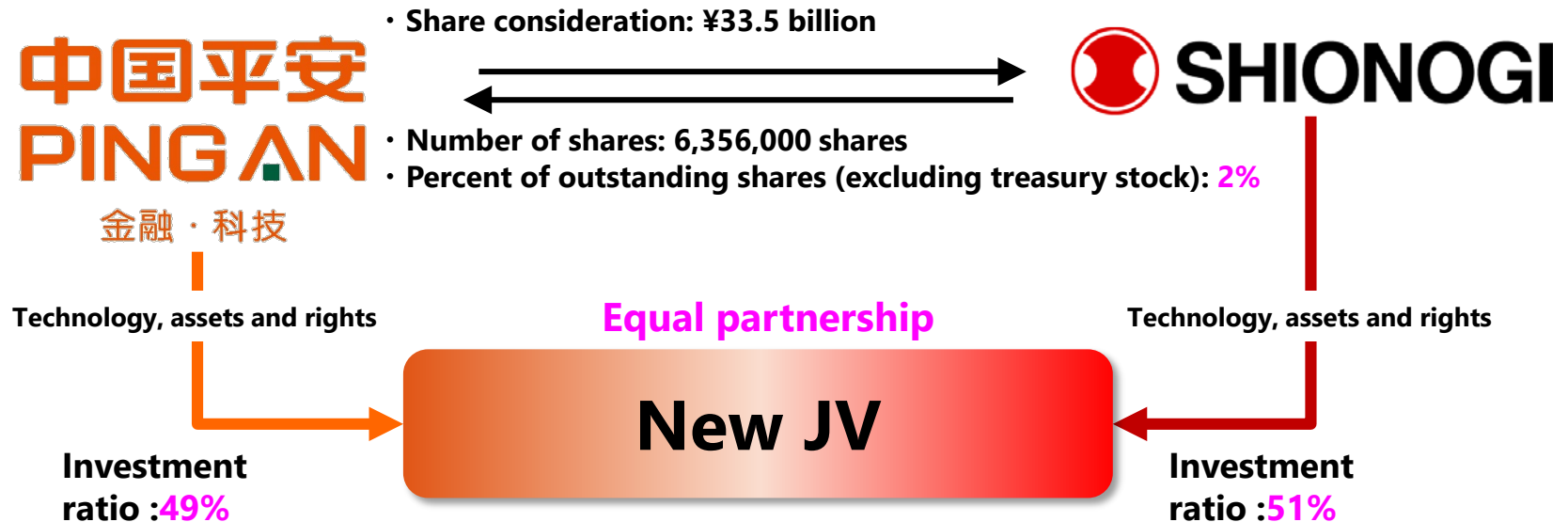
- **Initiated development of recombinant-protein vaccine for COVID-19**
- ⇒ Accelerating vaccine research with the goal of initiating clinical trials in 2020
- **Discovered candidates for development as prophylactic vaccines for influenza**

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



Establishment of Joint Venture (JV)

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



Business plan

- ① Data-driven* drug discovery and development
- ② Manufacturing and quality control systems enhanced by AI technology
- ③ Sales and distribution platforms using O2O **

New Value Created by JV



AI Healthcare platform



- Customer-based healthcare data
- State-of-the-art IT/AI technology
- Online clinical infrastructure



Drug discovery-based pharmaceutical company



- Demonstrated capability to create best-in-class innovative drugs
- High R&D productivity and accumulated know-how
- Patient-driven drug discovery strategies

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

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

KPIs - Results in FY2019 -



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

Looking back on FY2019 and Looking Ahead to FY2020



FY2019 summary

Achieved

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

Tasks remaining

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

FY2020 focal points for achieving sustainable growth

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

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

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

3. FY2020 Financial Forecasts

Adoption of International Financial Reporting Standards (IFRS)



Changes in FY2019 performance due to application of IFRS

(Unit: B yen)

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

Definition of core operating income following application of IFRS

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

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

Financial Forecasts (IFRS)



(Unit: B yen)

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

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

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

Income Statement Forecast (IFRS)



(Unit: B yen)

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

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



• Y to Y comparison

(Unit: B yen)

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

Decrease in profit Increase in profit

Main Variation factors (Y on Y)

• Revenue (-9.8 B yen)

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

• SG & A expenses (+8.0 B yen)

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

Revenue Forecast by Segment (IFRS)



(Unit: B yen)

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

Revenue Forecast of Prescription Drugs in Japan (IFRS)



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

(Unit: B yen)

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

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

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

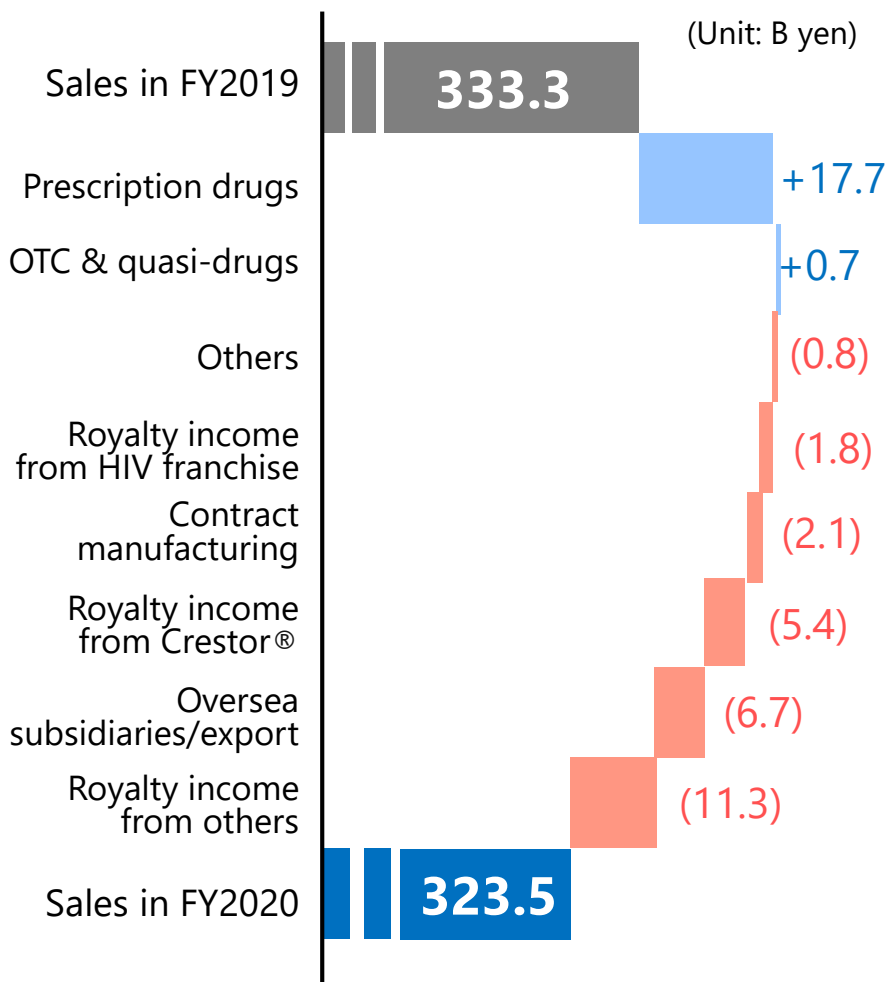
** Launched in Dec., 2019

*** Pre-launch, collecting clinical data

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



• Y on Y comparison



Main Variation factors (Y on Y)

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

Financial Forecasts (IFRS)



(Unit: B yen)

	FY2020 forecasts		FY2019	Y on Y	
	Full year	1H	Results*	Change (%)	Change (B yen)
Revenue	323.5	155.6	333.3	(3.0)	(9.8)
Operating profit	110.3	53.8	131.4	(16.0)	(21.0)
Core operating profit	110.3	53.8	128.2	(13.9)	(17.8)
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Exchange rate (average)	FY2020 forecasts	FY2019 results
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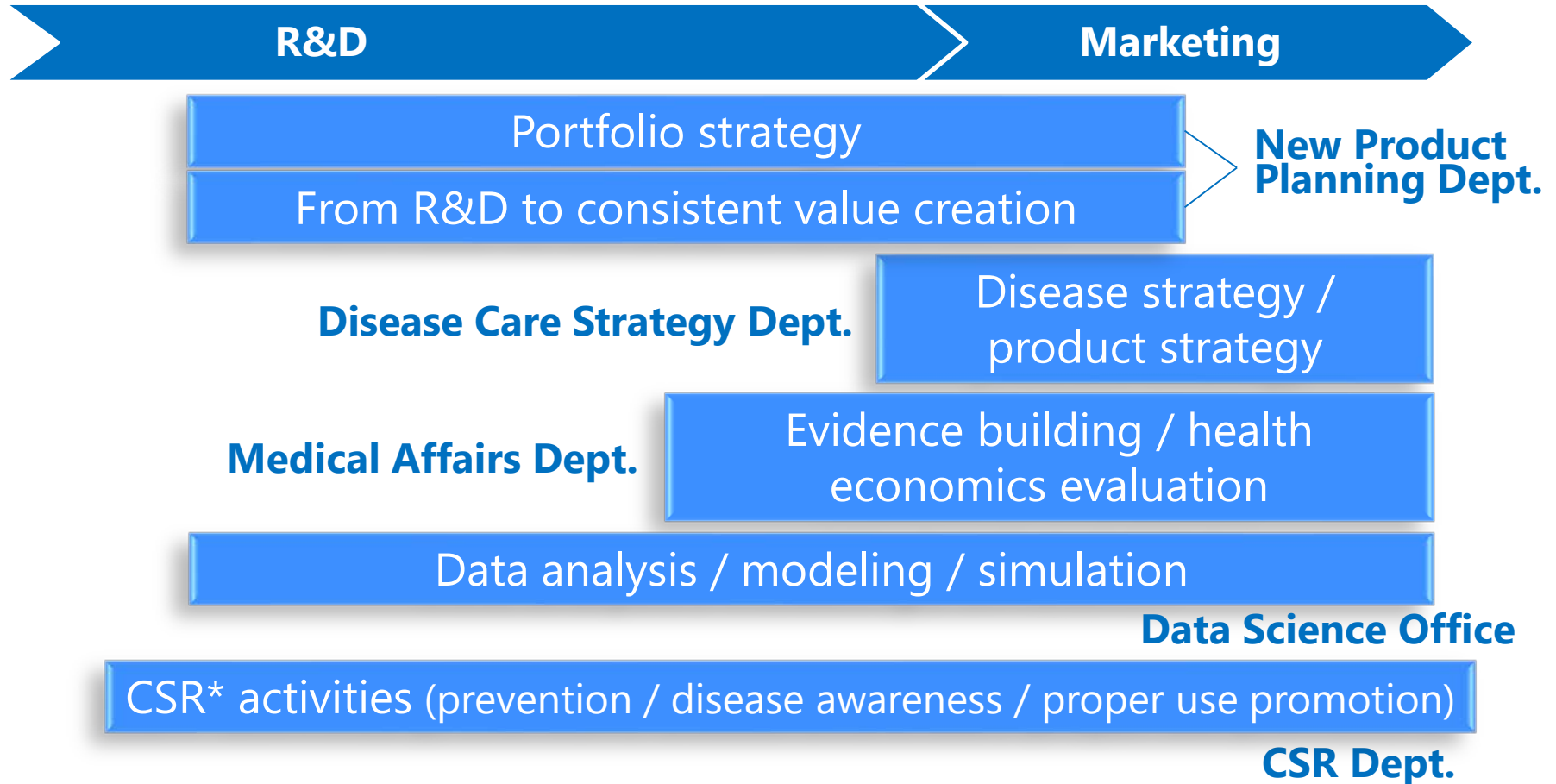
4. Actions in FY2020

Establishment of Integrated Disease Care Division



Mechanism for effectively delivering required products/information globally

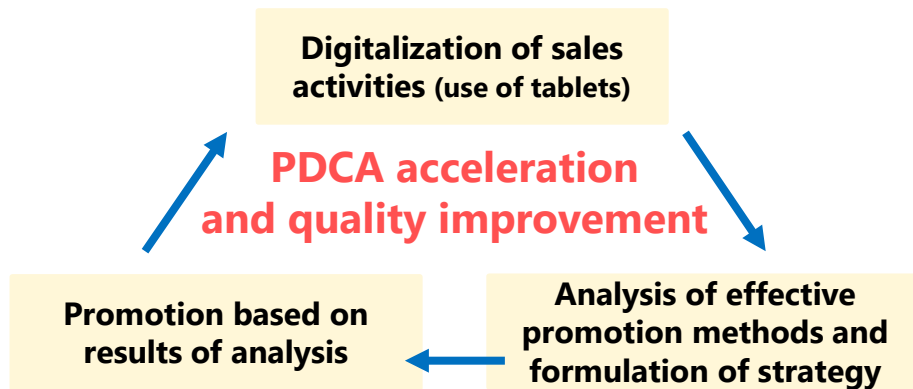
- Cross-value chain, customer-oriented, evidence-focused, data-driven



Improved Productivity and Sales Growth for Domestic Business



Reorganization of sales structure



- Revamp the structure to enable decisions made by divisions to be rapidly promulgated to the frontline
- Enhance precision of target selection by gathering/utilizing data
- Expand information delivery opportunities, e.g. e-detail

Firm establishment of data-based strategy formulation and activities

Cymbalta[®], Intuniv[®]

Cymbalta[®] activity policy

Focus on activities that proved effective in FY2019

- Deliver information based on needs and level of understanding of physicians
- Distribute information from KOL via web lectures etc.



Communicate effectiveness through use



Expand share in four-drug market for chronic back pain

Intuniv[®] activity policy

- Determine target facilities more precisely
- Ensure differentiation by emphasizing that the mechanism of action and effectiveness are different from those of other drugs



Increase awareness of product (adult, pediatric)
Increase adoption efficiency (adult)

Improved Productivity and Sales Growth for Domestic Business



Xofluza®

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

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

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

China business

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

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

US business / EU business

US

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

EU

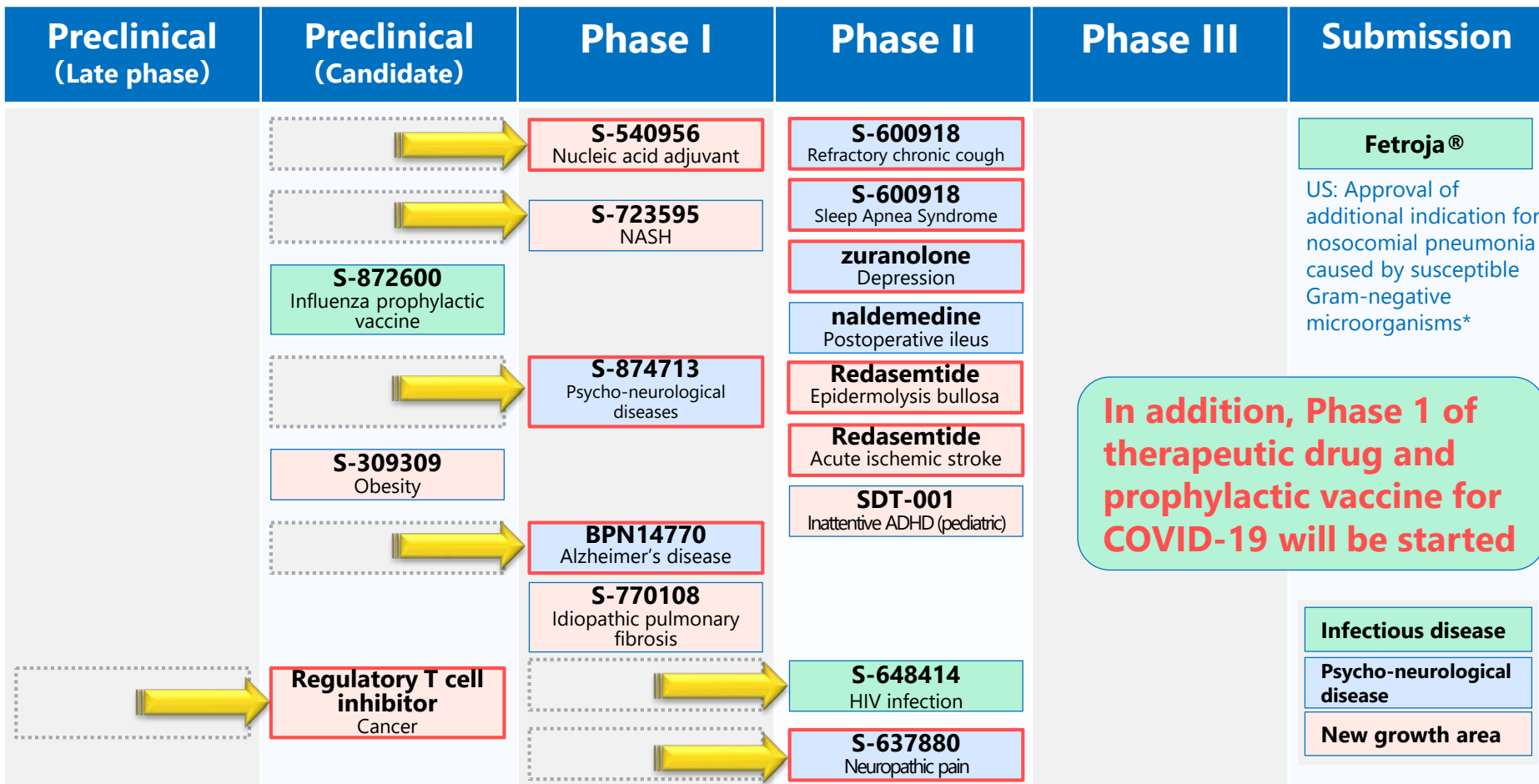
- Prepare to launch Fetroja® in major European countries
- Ensure availability of Fetroja® pre-launch through an Early Access Program for the treatment of carbapenem resistant Gram negative infections in patients with limited treatment options including those with secondary bacterial infection following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

Promote R&D Activities | Increase Pipeline in Late Stage



Major progression steps planned for FY2020

Core pipeline to change the treatment paradigm



- Infectious disease
- Psycho-neurological disease
- New growth area

Accelerating R&D to overcome HIV product patent cliffs

Positioning of FY2020



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

Strong commitment to “high productivity”

Domestic/
overseas
business

Achieve sales growth through new products

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

R&D

Accelerate R&D for discovery and progression of growth drivers

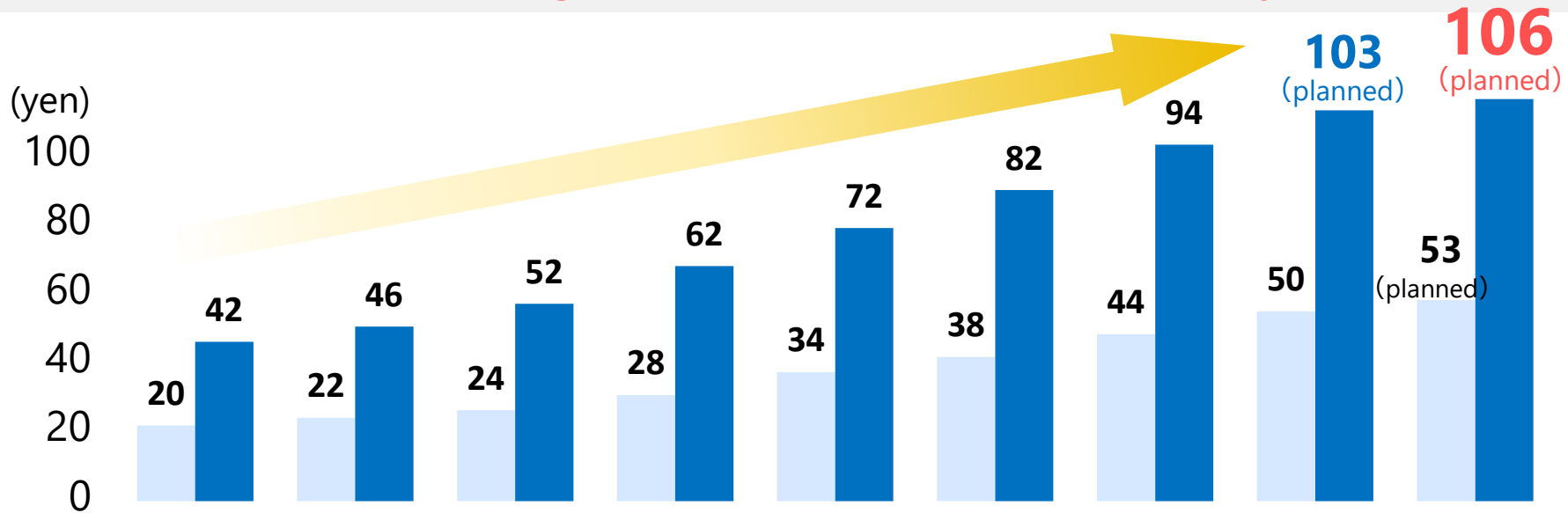
Overall picture of transformation to be described in the new medium-term business plan (Scheduled to be announced on June 1, 2020)

5. Shareholder Return

Flexible and Prompt Capital Strategy



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



FY		12	13	14	15	16	17	18	19	20
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	
	Cancellation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.7 (planned)	Over 4.0**
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	18.0	Over 12.5**

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

** Planned figures based on IFRS



Appendix

Revisions of FY2019 Targets (JGAAP)



	FY2019 Forecasts			FY2018
	Initial (May 9)	1 st revise (Oct. 30)	2 nd revise (Feb. 3)	Results
Sales	365.5	367.0	355.0	363.7
Operating income	147.0	150.0	141.5	138.5
Ordinary income	170.5	171.5	167.0	166.6
Profit attributable to owners of parent	133.0	135.0	133.0	132.8

Initial forecast (May 9)

Achieve higher revenues and profits from increased sales of new products to make up for a drop in milestone income from Roche

Revised forecast (Oct. 30)

Upward revision to reflect strong progress in 1H and reprioritization of growth investment

Revised forecast (Feb. 3)

Downward revision to reflect slower progress in domestic business
Achieve highest ever profit while investing in growth

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



Sales (Unit: B yen)

363.7

(Sales of Prescription Drugs in Japan: 128.7)

335.0

(Sales of Prescription Drugs in Japan: 108.6)

Operating income
(Excluding one-time factors)

106.5

(Sales of Prescription Drugs in Japan: 108.6)

107.3

Operating income
(One-time factors)

32.0

18.0

Strategic investment

16.9

47.2

Ordinary R&D expenses

51.4

105.8

Selling & administrative expenses

102.0

Cost of sales

54.9

56.7

FY2018

FY2019

<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*

Conversion from JGAAP to IFRS (P/L)



Changes in FY2019 performance due to application of IFRS

(Unit: B yen)

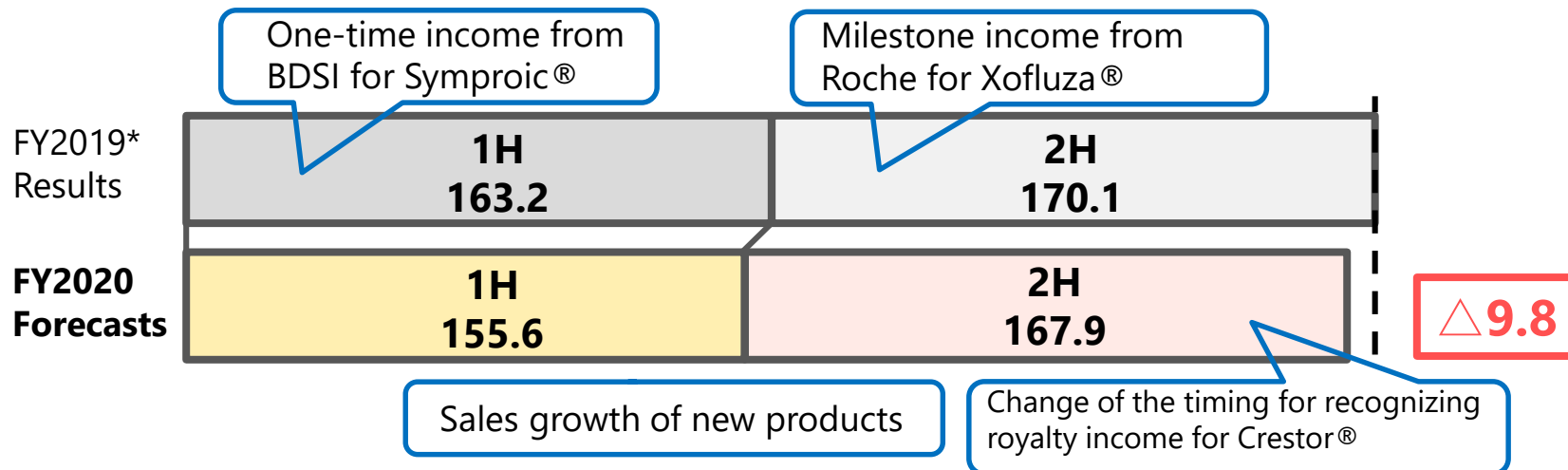
Consolidated Statement of Income	Sales	Cost of sales	Selling and administrative expenses	R&D expenses	Other revenue/expenses	Operating income	Non-operating and extraordinary income	Financial expenses	Tax expenses	Net income
JGAAP	335.0	56.7	105.8	47.2	-	125.2	33.3	-	37.3	121.3
Adjustment to deduction of sales promotion expenses from sales	(2.9)		(2.9)							
Booking of RYT on accruals basis, change in accounting of the hedge	1.3					1.3		(1.1)	0.1	0.2
Non-amortization of goodwill			(1.8)			1.8				1.8
Change in depreciation period for intangible assets			(4.2)			4.2			1.2	2.9
Change in method of treatment for retirement benefit expenses			1.4	0.6		(1.9)			(0.6)	(1.4)
Capitalization of launch expenses				(0.4)		0.4			0.1	0.3
Conversion of interest/dividend income, interest expense, etc.							(29.2)	29.2		
Transfer of gains on sales of investment securities to comprehensive income							(3.7)		(1.6)	(2.1)
Conversion of non-operating/extraordinary income					0.8	0.8	(0.8)			
Other	0	0.1	(0.3)	0.5		(0.5)	(0.6)		0.9	(0.7)
Total variance	(1.6)	0.1	(7.8)	0.7	0.8	6.1	(33.3)	28.2	(0.0)	1.0
IFRS*	333.3	56.8	98.1	47.9	0.8	131.4	-	28.2	37.2	122.3

FY2020 Forecasts (IFRS)



• Revenue (333.3→323.5)

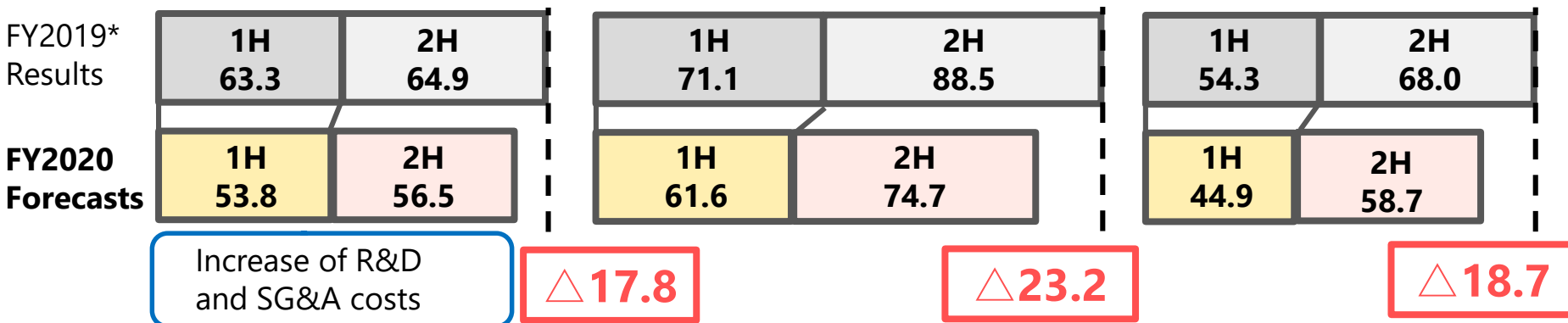
(Unit: B yen)



• Core operating profit (128.2→110.3)

• Profit before income (159.5→136.3)

• Profit attributable to owners of parent (122.3→103.6)

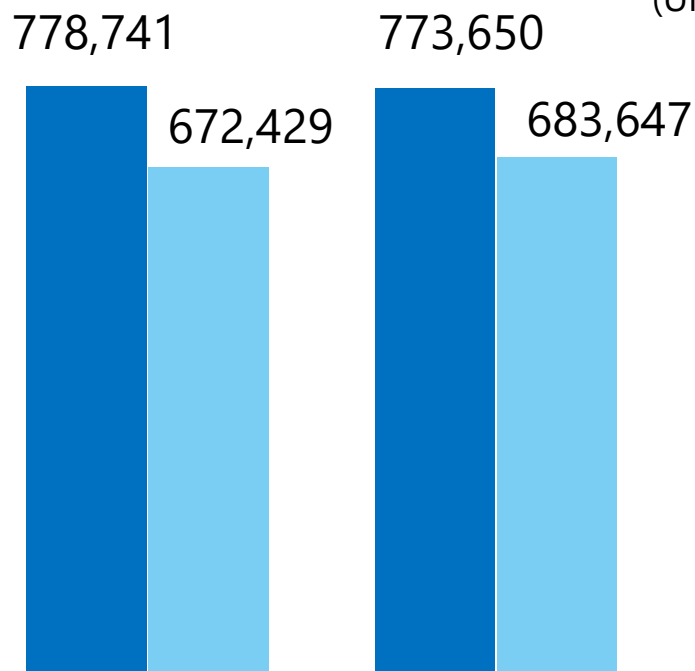


Financial Statements (Consolidated, JGAAP)



■ Total assets ■ Net assets

(Unit: M yen)



End of Mar. 2019 **End of Mar. 2020**

Unit: M yen		End of Mar. 2019	End of Mar. 2020	Change
Total assets	Current assets	461,743	485,932	24,188
	Non-current assets	316,997	287,717	(29,279)
Liabilities	Current liabilities	89,107	72,653	(16,453)
	Non-current liabilities	17,203	17,349	145
Net assets	Shareholders' equity	652,371	694,489	42,117
	Others	20,058	(10,841)	(30,900)

	End of Mar. 2019	End of Mar. 2020
Shareholders' equity ratio	85.7%	88.3%

Conversion from JGAAP to IFRS (B/S)



JGAAP (End of Mar. 2020)

(Unit: B yen)

Non-current assets 287.7 Investment securities 117.7 Intangible assets 29.8	Equity 683.6
Current assets 485.9	Non-current liabilities 17.3
	Current liabilities 72.7

Total assets

892.8

773.7

IFRS* (Consolidated statement of financial position)

Non-current assets 374.9 Investment securities 210.6 Intangible assets 47.0	Equity 783.1
Current assets 517.9	Non-current liabilities 30.0
	Current liabilities 79.7

Non-current assets (fixed assets) increased mainly due to market price evaluation of unlisted stocks and recording of in-process R & D expenses as intangible fixed assets. **Along with that, capital items also increased.**

Basic Strategy in FY2019

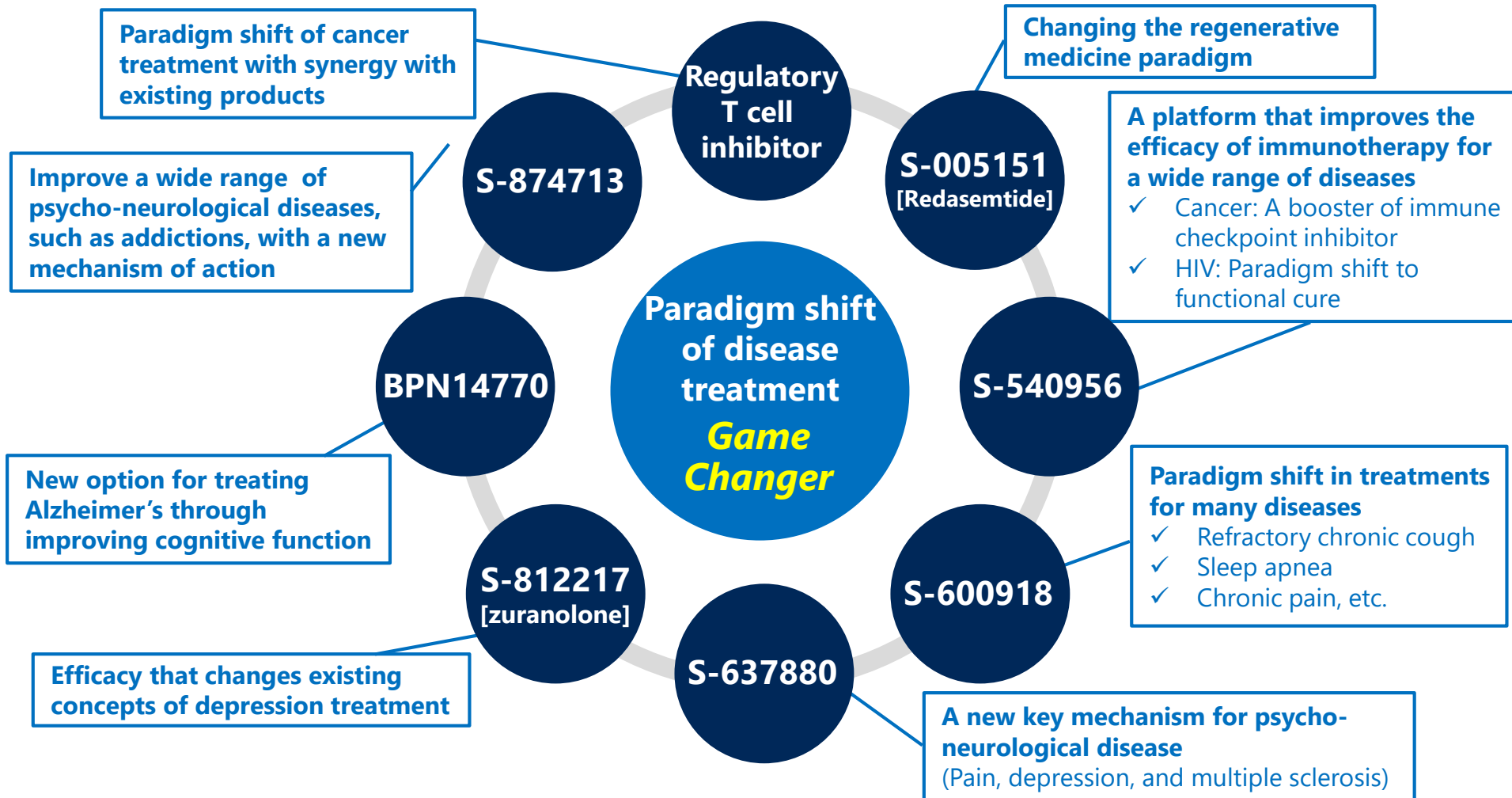


- **Sales**
 - Achieve increases in sales and profits by “**expanding sales of new products**” and “**further increasing management efficiency**”
- **Investment**
 - Advance pipeline assets that will become growth drivers beyond 2020
 - Establish a global presence in priority areas
- **Business innovation**
 - Improve operating process through the introduction of International Financial Reporting Standards (IFRS*)
 - Create new value in healthcare by using IT
 - Advance business of group companies including Shionogi Pharma
 - Promote diversity & inclusion to create innovation
 - Promote activities related to ESG** for sustainable growth



Aggressive year to drive for sustainable growth beyond 2020, while exercising our “own earning power generate during SGS2020

The World We Envision Based on Our Core Pipeline



**Breaking the existing concept of diseases
with high unmet medical needs**

Business Innovation

– Further Promotion of ESG Activities –



Main accomplishments in FY2019

- **Integration with management strategy**
 - Specification and disclosure of material issues (materiality)
 - Engagement with investors and other stakeholders and reflection of results in management
 - Establishment of Sustainability Management Office in the Corporate Strategy Division (April 2020)
- **External ratings for ESG/sustainability**
 - CDP questionnaire: climate change A- (previous year was C), water security A (highest grade)
 - MSCI ESG rating: AA (previous year was A)
 - Corporate Governance of the Year® 2019: Selected for Grand Prize Company award
 - Selected for and high rating in AMR Benchmark 2020*
 - Recognized under the 2020 Certified Health & Productivity Management Outstanding Organizations Recognition Program (White 500) (4th consecutive year)
- **Other initiatives**
 - Participation in UN Global Compact
 - Improvement of Integrated Report: Expanded information disclosure to adhere to the IIRC framework (International <IR> Framework) and societal demands, presented value creation stories

Policy for FY2020

- Incorporate ESG into new medium-term business plan and determine KPIs
- Further engage with investors and other stakeholders
- Expand information disclosure and step up responses to various ESG-related surveys



Business Innovation - Promotion of Diversity & Inclusion -



Shionogi Diversity Vision

**Understand yourself and others, and celebrate individual diversity.
Allow the wide variety of unique qualities to inspire creativity and innovation.**

**We will
have an unbiased understanding of others, knowing that everyone has a different perspective;
connect and resonate with diverse personalities to foster an inclusive spirit and generate abundant ideas;
and, driven by such spirit and ideas, create new value and grow with society for our collective future.**

<Initiatives and achievements in FY2019>

- **The Diversity Council, a Group-wide organization, spearheaded activities**
 - Launched initiatives on a Group-wide basis
 - Individual organizations executed initiatives connected with various themes, such as promoting diverse work styles
- **Encouraged employees to take ownership of their careers**
 - Introduced self-investment support scheme under which the company partially funds career development activities chosen by employees
- **Signed and joined The Valuable 500, an international initiative for promoting inclusion for persons with disabilities**

Become a company that continuously innovates and grows by stretching and expanding the strengths of employees to bring various types of expertise together

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

Dovato[®] (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)
- Nov. 2019: Initiated SALSA (switch patients)



Nov. and Dec. 2019:
Recommended by guidelines
in EU and US

CAB+RPV Launch: 2020~

- First long acting injection (monthly or bimonthly)
- Jul. 2019: MAA submission in EU (monthly, switch patients)
- Mar. 2020: Approved in Canada
- Mar. 2020: ATLAS-2M 48-week results (switch patients) presented at CROI
FLAIR 96-week results (naïve patients) presented at CROI
- Middle of 2020: Planning NDA resubmission in US (monthly, switch patients)
→Launch is anticipated early 2021

CAB prophylaxis Launch: 2021~

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

Major Progress in Q4 FY2019* (Others)



- **Mar.**
 - Partnership agreement between Yabu city, Hyogo, and Shionogi for the improvement of community healthcare
- **Apr.**
 - New maternal and child healthcare program kicks off in Kilifi county, Kenya, The Mother to Mother SHIONOGI Project entered its second phase with the aim of improving health access
 - Issued the Shionogi Group smoke-free declaration with the aim of achieving a zero smoking rate among its employees

Target Milestones for FY2019: Approval and Submission



Product (indication)	Phase 1	Phase 2	Phase 3	Submission	Approval	
Vyvanse® (ADHD(pediatric))			Achieved (Mar.)	Japan (2017.4)	Japan (2019.3)	
Intuniv® (ADHD(adult))			Achieved (Jul.)	Japan (2018.8)	Japan (2019.6)	
Cefiderocol (US: [1] cUTI, including pyelonephritis caused by susceptible Gram-negative microorganisms* , [2] Nosocomial pneumonia*) (EU: [3] Aerobic Gram-negative bacterial infection*)			Approval (US) sNDA submission (US) Approval (EU)	Global: CR study completion Global: Nosocomial pneumonia study completion US ①(2018.12) ②(2020.3) EU ③(2019.3)	US ①(2019.11) EU ③(2020.4)	
Xofluza® (Influenza virus infection) [1] granule (weight under 20kg) [2] prophylaxis			Achieved (Oct.)	Japan : High-dose study for children: completion Prophylaxis study completion	①Japan (2018.8) ②Japan (2019.10)	①Japan
OxyContin®TR (Treatment of moderate to severe chronic pain)			Achieved (May)	Japan : Completion	Japan (2019.5)	

Target Milestones for FY2019: Phase 1 - 3



Product (indication)	Phase 1	Phase 2	Phase 3	Submission	Approval
S-812217 [zuranolone] (Depression)	Japan: Single and multiple dose study completion	Japan: initiate	Achieved (2020.4.1)		
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	Achieved (Q2)	
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				



Target Milestones for FY2019: Phase 1 - 3



Product (indication)	Phase 1	Phase 2	Phase 3	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			Phase I repeated dose study initiated (Q4)
Naldemedine (POI*)		Global : initiate			Achieved (Q3)
S-648414 Novel HIV Drug (HIV virus infection)	US : initiate	Achieved (Q2)			
SDT-001 (ADHD)		Japan : initiate			Achieved (Q4)



Pipeline (as of May 11, 2020)



Japan



- S-600918**
Neuropathic pain
- S-637880**
Neuropathic pain
- S-010887**
Neuropathic pain
- S-770108**
Idiopathic pulmonary fibrosis

- S-812217 [zuranolone]**
Depression
- S-600918**
Refractory chronic cough
- S-600918**
Sleep Apnea Syndrome
- SDT-001**
Inattentive ADHD (pediatric)
- Redasemtide**
Epidermolysis bullosa
- Redasemtide**
Acute ischemic stroke
- S-237648**
Obesity
- S-588410**
Bladder cancer
- SR-0379**
Cutaneous ulcer
- ADR-001****
Decompensated liver cirrhosis

- Cefiderocol**
Aerobic Gram-negative bacterial infection
- Xofluza®**
Influenza virus infection (High-dose for children)
- Cymbalta®**
Depression (pediatric)
- S-588410**
Esophageal cancer

- Xofluza®**
Influenza virus infection (prophylaxis)
- Xofluza®**
Influenza virus infection (Granules, < 20 kg)
- OxyContin® TR**
Moderate to severe chronic pain

Preclinical*

- S-872600**
Influenza prophylactic vaccine
- S-874713**
Psycho-neurological diseases
- BPN14770**
Alzheimer's disease
- S-872881**
Alzheimer's dementia
- S-109802**
Post-stroke spasticity
- Regulatory T cell inhibitor**
Cancer
- S-540956**
Nucleic acid adjuvant
- S-309309**
Obesity
- S-723595**
NASH

- Infectious disease**
- Psycho-neurological disease**
- New growth area**

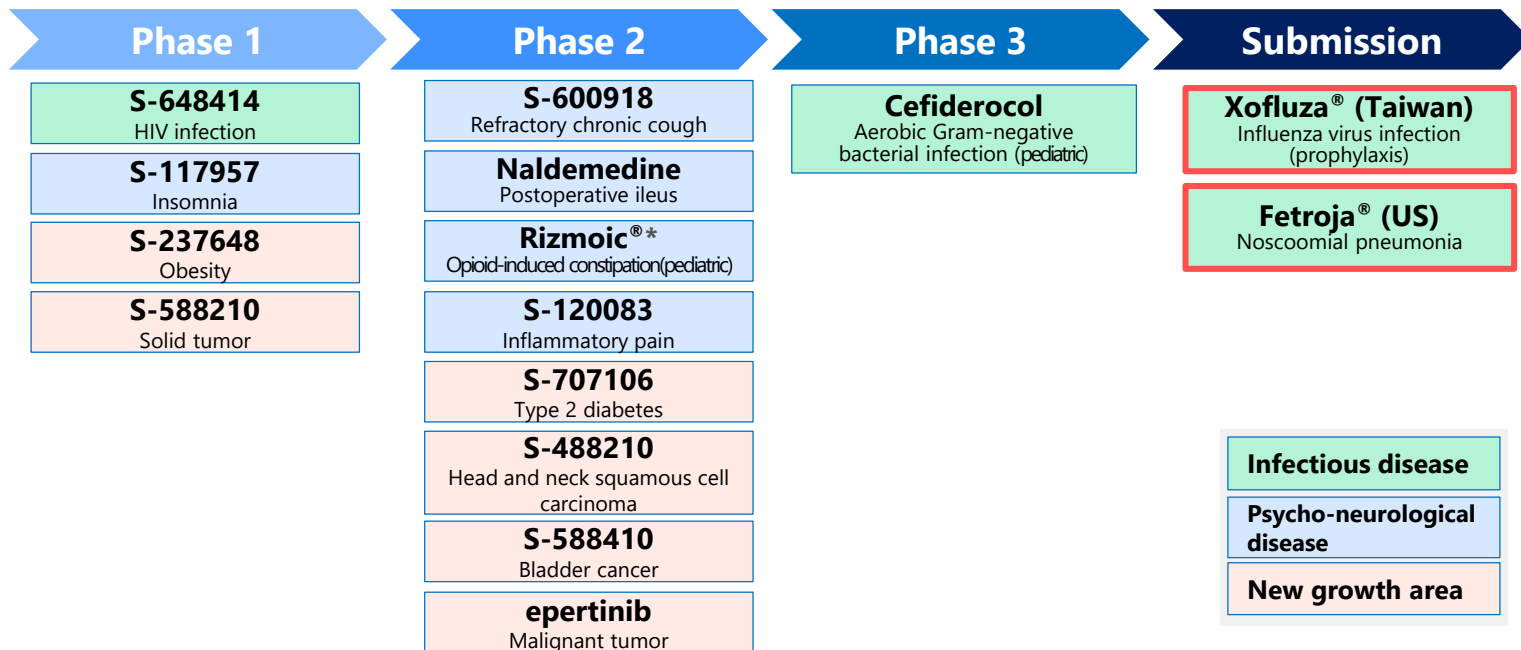
Stage change (Changes from February 3, 2020)

Zuranolone (Depression): Phase II initiated
S-600918 (Sleep apnea): Phase IIa initiated

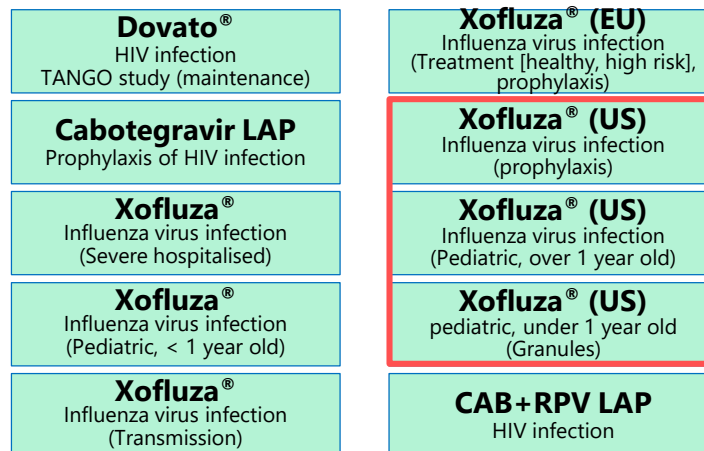
Pipeline (as of May 11, 2020)



Overseas



Out license



Stage change (Changes from February 3, 2020)

Fetroja® (HAP): Phase III → submission (US)
 Fetroja® (Aerobic Gram-negative bacterial infection):
 Submission → Approval (EU)
 Xofluza® (Influenza virus infection): Submission (Taiwan)
 : Additional submission (US)
 GSK3342830 (Multidrug-resistant Gram-negative bacterial infections):
 Discontinued

FY2020 Pipeline Target Milestones



Phase	Pipeline	Indication	Milestone	✓ : achieved
Submission~ Approval	Fetroja® (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval	
	Fetroja® (cefiderocol)	Aerobic Gram-negative bacterial infection*	EU: Approval ✓	
	Xofluza® granule	Influenza virus infection (pediatric, <20 kg)	Japan: supplemental approval	
	Xofluza®	Influenza virus infection (prophylaxis)	Japan: supplemental approval	
	Oxycontin® TR	Analgesia in chronic pain	Japan: supplemental approval	
	Cymbalta®	Depression (pediatric)	Japan: Submission	
Phase 1~3	S-637880	Neuropathic pain	Japan: Completion of Phase 1 MAD	
	S-600918/S-637880	Neuropathic pain	Japan: Initiation of Phase 2	
	S-648414	HIV infection	US: Initiation of Phase 2 (PoC)	
	S-770108	Idiopathic pulmonary fibrosis	UK: Initiation of lung deposition study	
	S-540956	HIV infection, cancer	Initiation of Phase 1 (Region Not Decided)	
	S-874713	Psycho-neurological disease	Japan: Initiation of Phase 1	
	BPN14770	Alzheimer's disease	Japan: Initiation of Phase 1	
	S-723595	NASH	Japan: Initiation of Phase 1	

Target Milestones for Launch of Products



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



Definition of New Products (in Updates to SGS2020)



Pain/ CNS

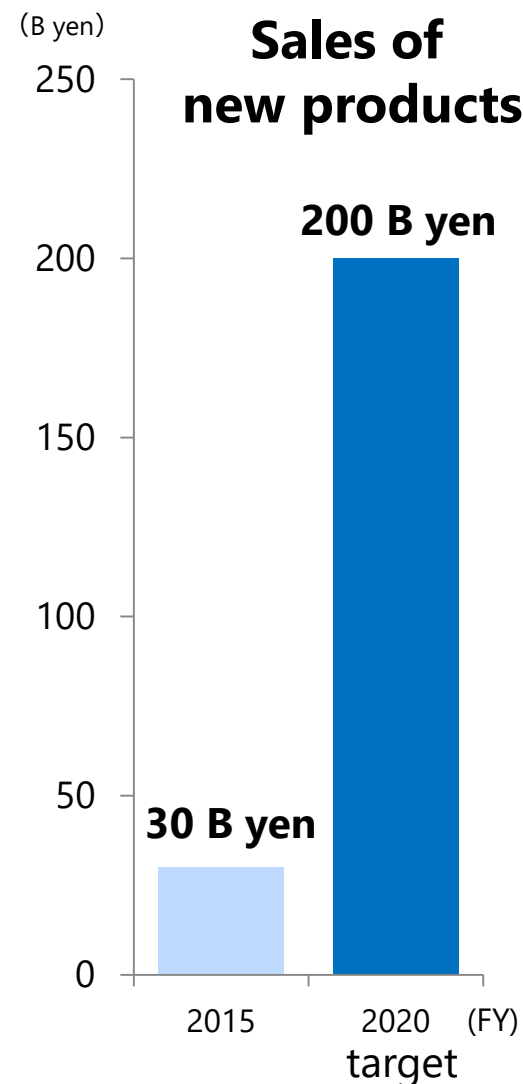
- Cymbalta[®]
- OxyContin[®] tamper resistant formulation, OxiNorm[®], OxiFast[®]
- Naldemedine*
- Intuniv[®], Vyvanse[®]

Infectious diseases

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

Others

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



Forward-Looking Statements



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