



# **FY2019 Financial Results**

**(April 2019 – March 2020)**

May 11, 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.5-13)**
- 2. Actions and Progress in FY2019 (P.14-17)**
- 3. FY2020 Financial Forecasts (P.18-26)**
- 4. Shareholder Return (P.27, 28)**

# 1. Overview of FY2019 Financial Results

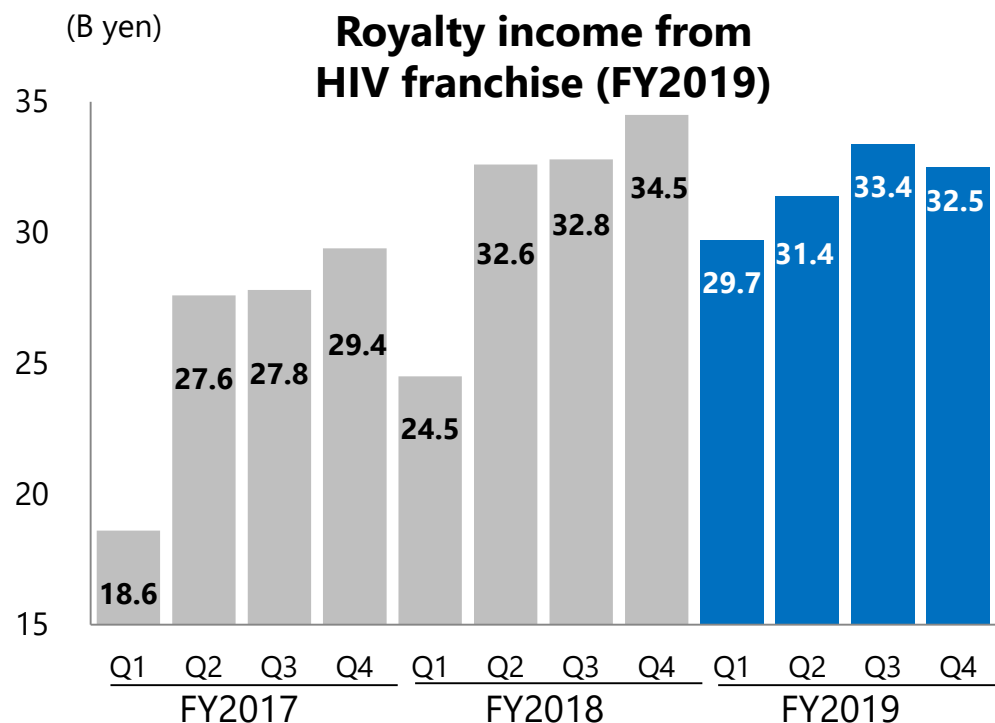
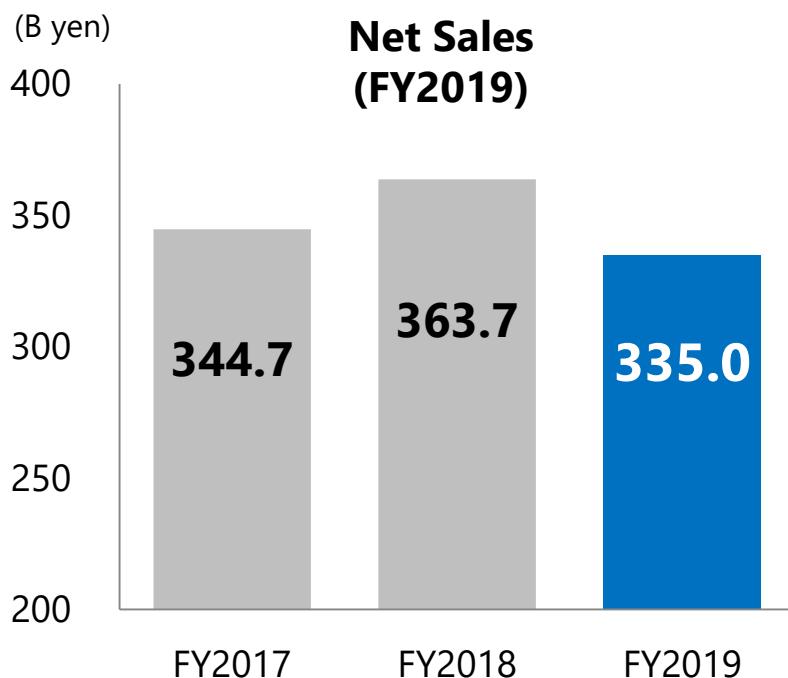
# Highlight (1)

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



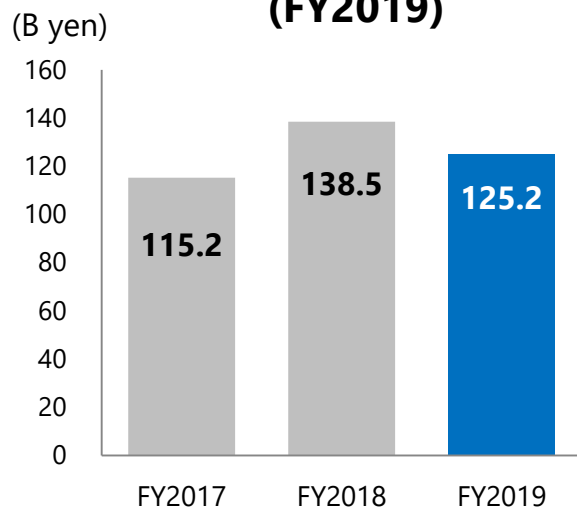
# Highlight (2)

JGAAP

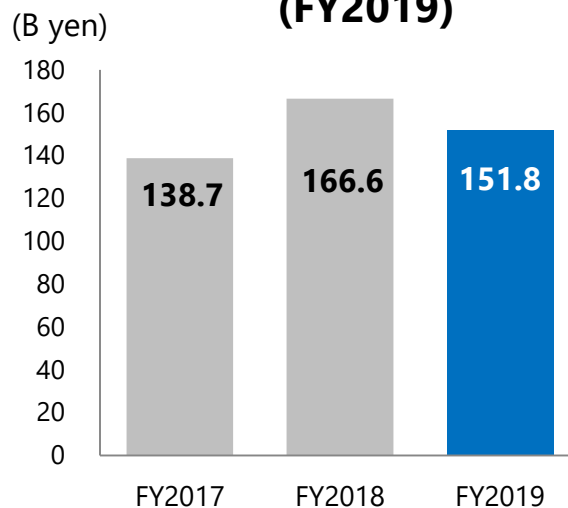


- ◆ Operating income: **125.2 B yen** (-9.6%) vs prior FY
- ◆ Ordinary income: **151.8 B yen** (-8.9%) vs prior FY
- ◆ Profit attributable to owners of parent: **121.3 B yen** (-8.6%) vs prior FY

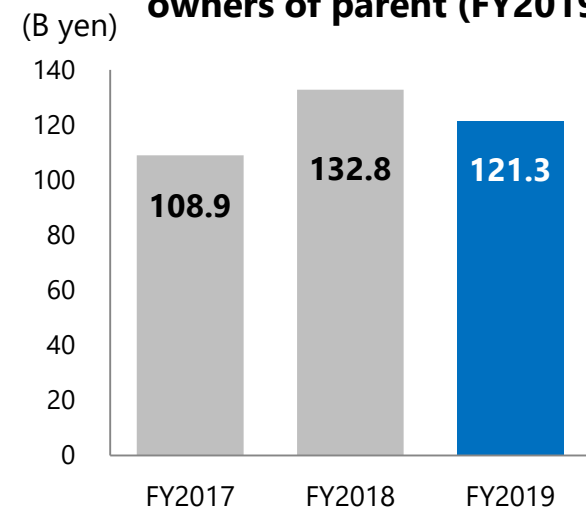
### Operating income (FY2019)



### 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)
<b>Sales</b>	<b>365.5</b> 14.6	<b>355.0</b> 16.2	<b>335.0</b> 16.9	94.4	363.7 15.1	(7.9)	(28.8)
<b>Cost of sales</b>	<b>53.5</b>	<b>57.5</b>	<b>56.7</b>	98.6	54.9	3.3	1.8
<b>Gross profit</b>	<b>312.0</b> 45.1	<b>297.5</b> 43.9	<b>278.3</b> 45.7	93.5	308.8 46.8	(9.9)	(30.6)
<b>SG&amp;A expenses</b>	<b>165.0</b> 31.6	<b>156.0</b> 30.4	<b>153.0</b> 31.6	98.1	170.3 28.0	(10.1)	(17.3)
Selling & administrative expenses	<b>115.5</b> 13.5	<b>108.0</b> 13.5	<b>105.8</b> 14.1	98.0	102.0 18.8	3.8	3.9
R&D expenses	<b>49.5</b>	<b>48.0</b>	<b>47.2</b>	98.3	68.3	(30.9)	(21.1)
Ordinary R&D expenses	<b>49.5</b>	<b>48.0</b>	<b>47.2</b>	98.3	51.4	(8.2)	(4.2)
Strategic investment	-	-	-	-	16.9	-	(16.9)
<b>Operating income</b>	<b>147.0</b> 40.2	<b>141.5</b> 39.9	<b>125.2</b> 37.4	88.5	138.5 38.1	(9.6)	(13.3)
<b>Non-operating income &amp; expenses</b>	<b>23.5</b>	<b>25.5</b>	<b>26.5</b>	104.0	28.0	(5.4)	(1.5)
<b>Ordinary income</b>	<b>170.5</b> 46.6	<b>167.0</b> 47.0	<b>151.8</b> 45.3	90.9	166.6 45.8	(8.9)	(14.8)
<b>Profit attributable to owners of parent</b>	<b>133.0</b>	<b>133.0</b>	<b>121.3</b>	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



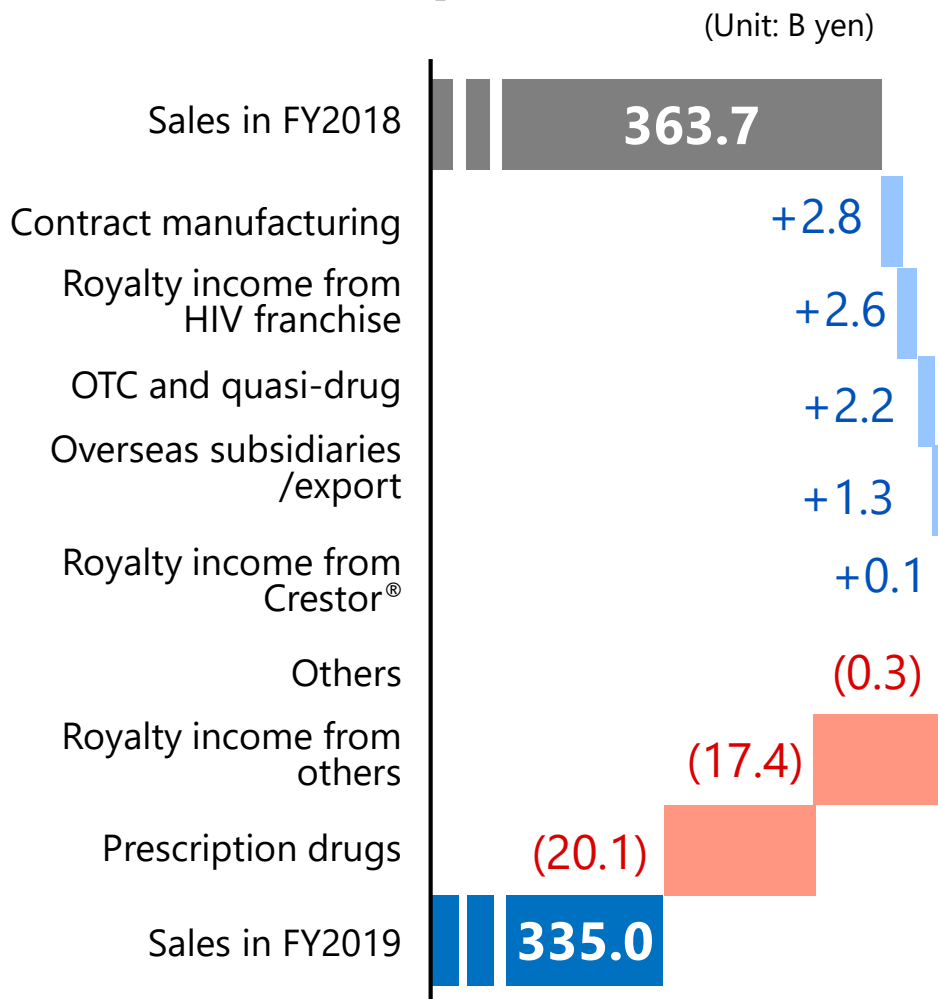
(Unit: B yen)

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

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

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

## 2. Actions and Progress in 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<sup>®</sup> amongst medical professionals, this did not lead to an increase in prescriptions
- **Cymbalta<sup>®</sup>**
  - 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<sup>®</sup>**
  - 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<sup>®</sup>**
  - 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**



# 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
<b>Sales</b>	335.0	<b>Revenue</b>	333.3	(1.6)
<b>Cost of sales</b>	56.7	<b>Cost of sales</b>	56.8	0.1
<b>Gross profit</b>	278.3	<b>Gross profit</b>	276.5	(1.8)
<b>Selling &amp; administrative expenses</b>	105.8	<b>Selling, general &amp; administrative expenses</b>	98.1	(7.8)
<b>R&amp;D expenses</b>	47.2	<b>R&amp;D expenses</b>	47.9	0.7
		<b>Other income &amp; expenses</b>	0.8	0.8
<b>Operating income</b>	125.2	<b>Operating profit</b>	131.4	6.1
		<b>Core operating profit</b>	128.2	
<b>Non-operating income &amp; expenses</b>	26.5			(26.5)
<b>Extraordinary profit / loss</b>	6.8			(6.8)
		<b>Finance income &amp; costs</b>	28.2	28.2
<b>Income taxes</b>	37.3	<b>Income taxes</b>	37.2	(0.0)
<b>Profit attributable to owners of parent</b>	121.3	<b>Profit attributable to owners of parent</b>	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)
<b>Revenue</b>	<b>323.5</b>	<b>155.6</b>	333.3	(3.0)	(9.8)
	17.2	16.5	17.0		
<b>Cost of sales</b>	<b>55.7</b>	<b>25.7</b>	56.8	(1.9)	(1.1)
<b>Gross profit</b>	<b>267.8</b>	<b>129.9</b>	276.5	(3.2)	(8.7)
	47.6	48.0	43.8		
<b>SG&amp;A expenses</b>	<b>153.9</b>	<b>74.7</b>	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
<b>Other income &amp; expenses</b>	<b>(3.5)</b>	<b>(1.4)</b>	0.8	(567.5)	(4.3)
	34.1	34.6	39.4		
<b>Operating profit</b>	<b>110.3</b>	<b>53.8</b>	131.4	(16.0)	(21.0)
	34.1	34.6	38.5		
<b>Core operating profit</b>	<b>110.3</b>	<b>53.8</b>	128.2	(13.9)	(17.8)
<b>Finance income &amp; cost</b>	<b>26.0</b>	<b>7.8</b>	28.2	(7.8)	(2.2)
	42.1	39.6	47.9		
<b>Profit before tax</b>	<b>136.3</b>	<b>61.6</b>	159.5	(14.6)	(23.2)
<b>Profit attributable to owners of parent</b>	<b>103.6</b>	<b>44.9</b>	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<sup>®</sup> and Crestor<sup>®</sup>)
- 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<sup>®</sup> and Intuniv<sup>®</sup>
  - › Overseas business: Increase in expenses due to investment on pre/after-launch marketing activities for Fetcroja<sup>®</sup> 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)
<b>Prescription drugs</b>	123.9	53.1	106.2	16.6	17.7
<b>Overseas subsidiaries/export</b>	24.0	11.3	30.8	(21.8)	(6.7)
<b>Shionogi Inc.</b>	5.1	2.6	10.1	(49.1)	(5.0)
<b>C&amp;O</b>	11.9	5.7	13.1	(9.2)	(1.2)
<b>Contract manufacturing</b>	15.4	7.9	17.6	(12.2)	(2.1)
<b>OTC and quasi-drug</b>	10.4	4.9	9.7	7.5	0.7
<b>Royalty income</b>	148.3	77.8	166.9	(11.1)	(18.6)
<b>HIV franchise</b>	126.3	64.2	128.1	(1.4)	(1.8)
<b>Crestor<sup>®</sup></b>	16.9	11.1	22.3	(24.4)	(5.4)
<b>Others</b>	5.2	2.5	16.5	(68.7)	(11.3)
<b>Others</b>	1.3	0.7	2.2	(39.0)	(0.8)
<b>Total</b>	<b>323.5</b>	<b>155.6</b>	<b>333.3</b>	<b>(3.0)</b>	<b>(9.8)</b>

# Revenue Forecast of Prescription Drugs in Japan (IFRS)



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

(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<sup>®</sup>
- FINIBAX<sup>®</sup>
- Seftem<sup>®</sup>
- Baktar<sup>®</sup>
- ISODINE<sup>®</sup>
- Rapiacta<sup>®</sup>
- Flumarin<sup>®</sup>
- Shiomarin<sup>®</sup>
- Flagyl<sup>®</sup>
- SARS-CoV-2 antibody test kit\*\*\*
- Brightpoc<sup>®</sup> Flu•Neo
- Flomox<sup>®</sup>
- Vancomycin
- Fluconazole<sup>®</sup>

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

\*\* Launched in Dec., 2019

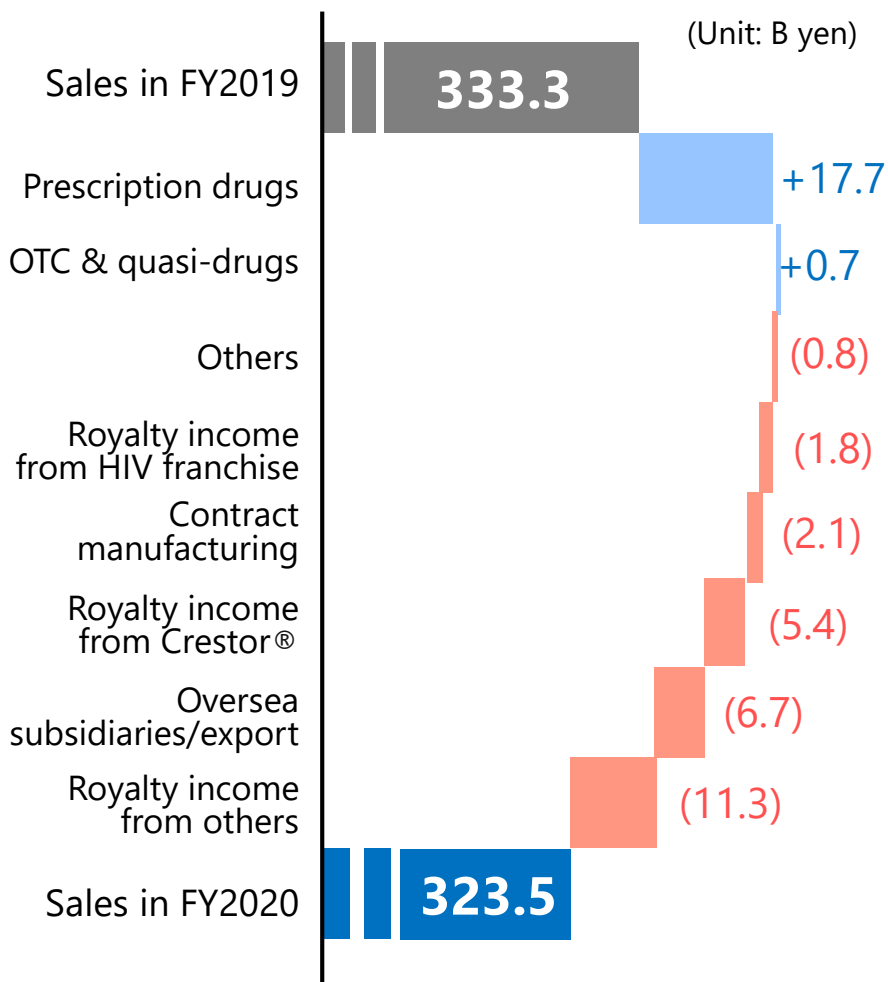
\*\*\* Pre-launch, collecting clinical data



# 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)
<b>Revenue</b>	<b>323.5</b>	<b>155.6</b>	<b>333.3</b>	(3.0)	(9.8)
<b>Operating profit</b>	<b>110.3</b>	<b>53.8</b>	<b>131.4</b>	(16.0)	(21.0)
<b>Core operating profit</b>	<b>110.3</b>	<b>53.8</b>	<b>128.2</b>	(13.9)	(17.8)
<b>Profit before tax</b>	<b>136.3</b>	<b>61.6</b>	<b>159.5</b>	(14.6)	(23.2)
<b>Profit attributable to owners of parent</b>	<b>103.6</b>	<b>44.9</b>	<b>122.3</b>	(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 (¥)	<b>107</b>	<b>108.72</b>
GBP (£) – JPY (¥)	<b>130</b>	<b>138.15</b>
EUR (€) – JPY (¥)	<b>120</b>	<b>120.82</b>

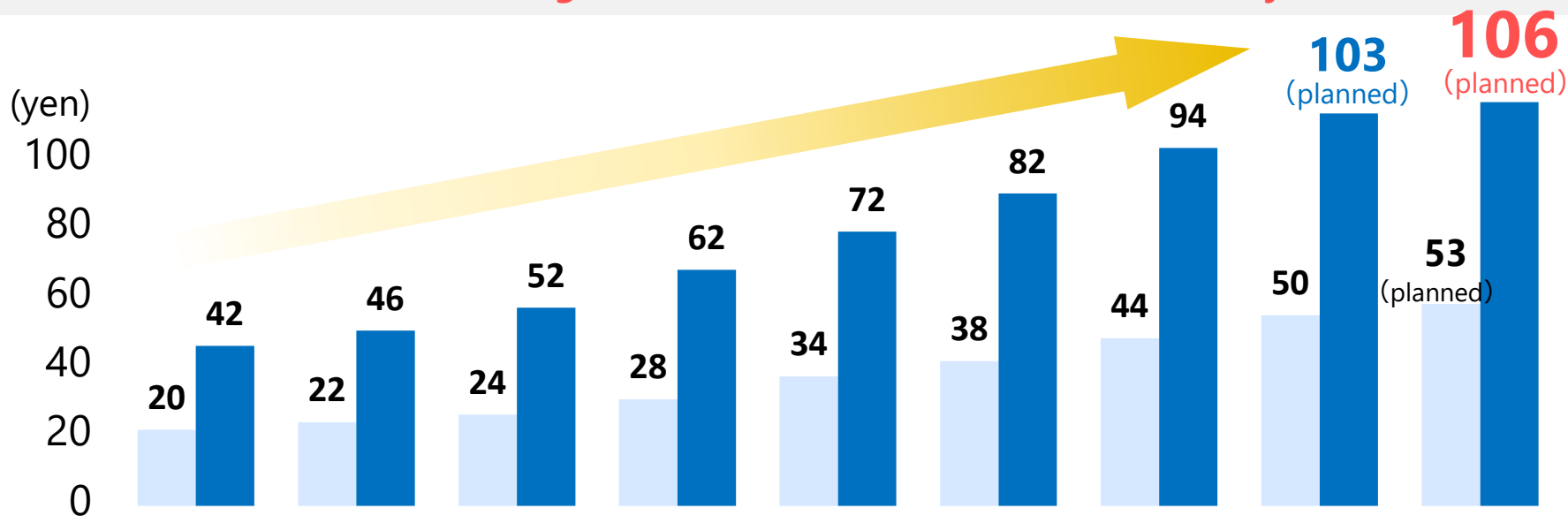
# 4. Shareholder Return

# 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**



# Appendix

# KPIs - Results in FY2019 -



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

# Revisions of FY2019 Targets (JGAAP)



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

## 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

Ordinary R&D expenses

51.4

47.2

Selling & administrative expenses

102.0

105.8

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\*

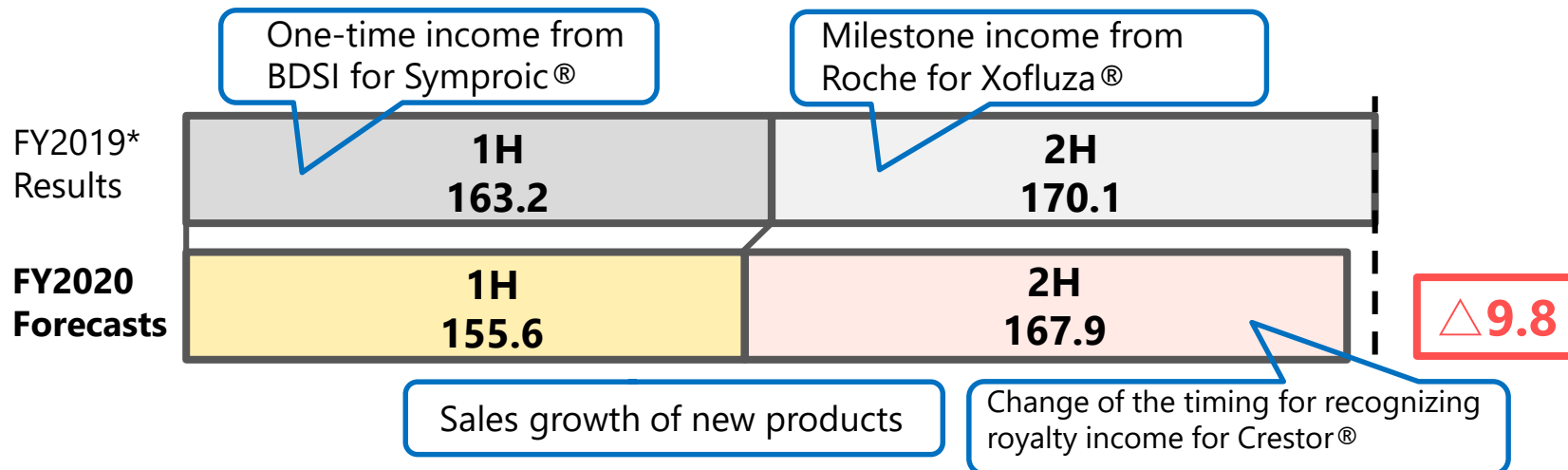


# FY2020 Forecasts (IFRS)



## • Revenue (333.3→323.5)

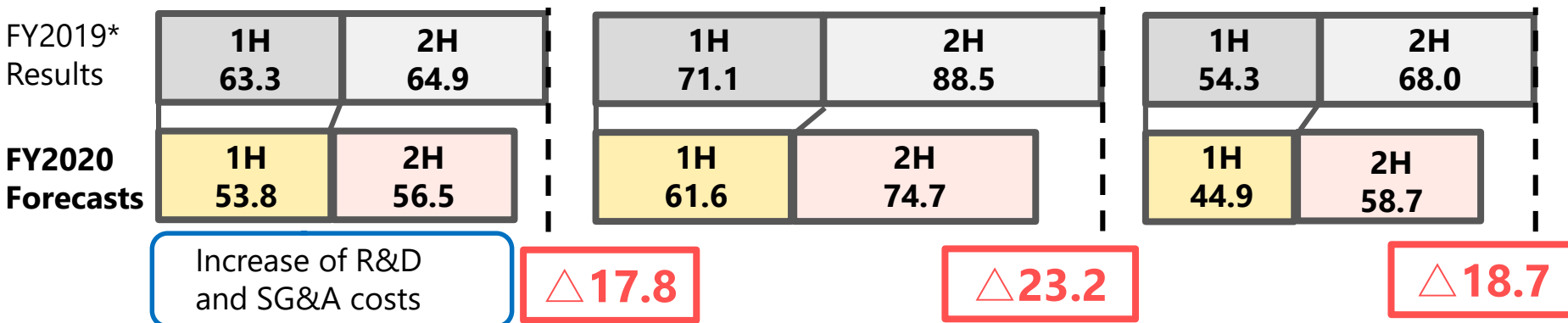
(Unit: B yen)



## • Core operating profit (128.2→110.3)

## • Profit before income (159.5→136.3)

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

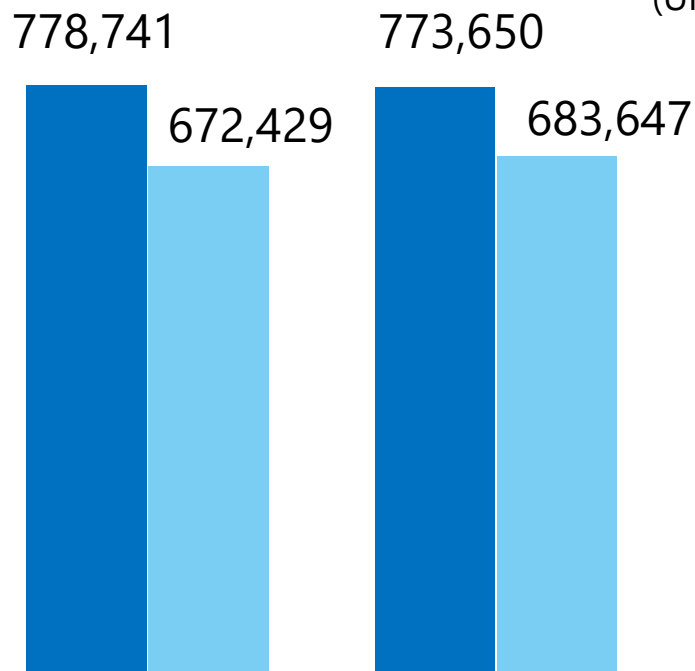


# Financial Statements (Consolidated, JGAAP)



■ Total assets    ■ Net assets

(Unit: M yen)



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

	End of Mar. 2019	End of Mar. 2020
Shareholders' equity ratio	85.7%	<b>88.3%</b>

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)

# 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

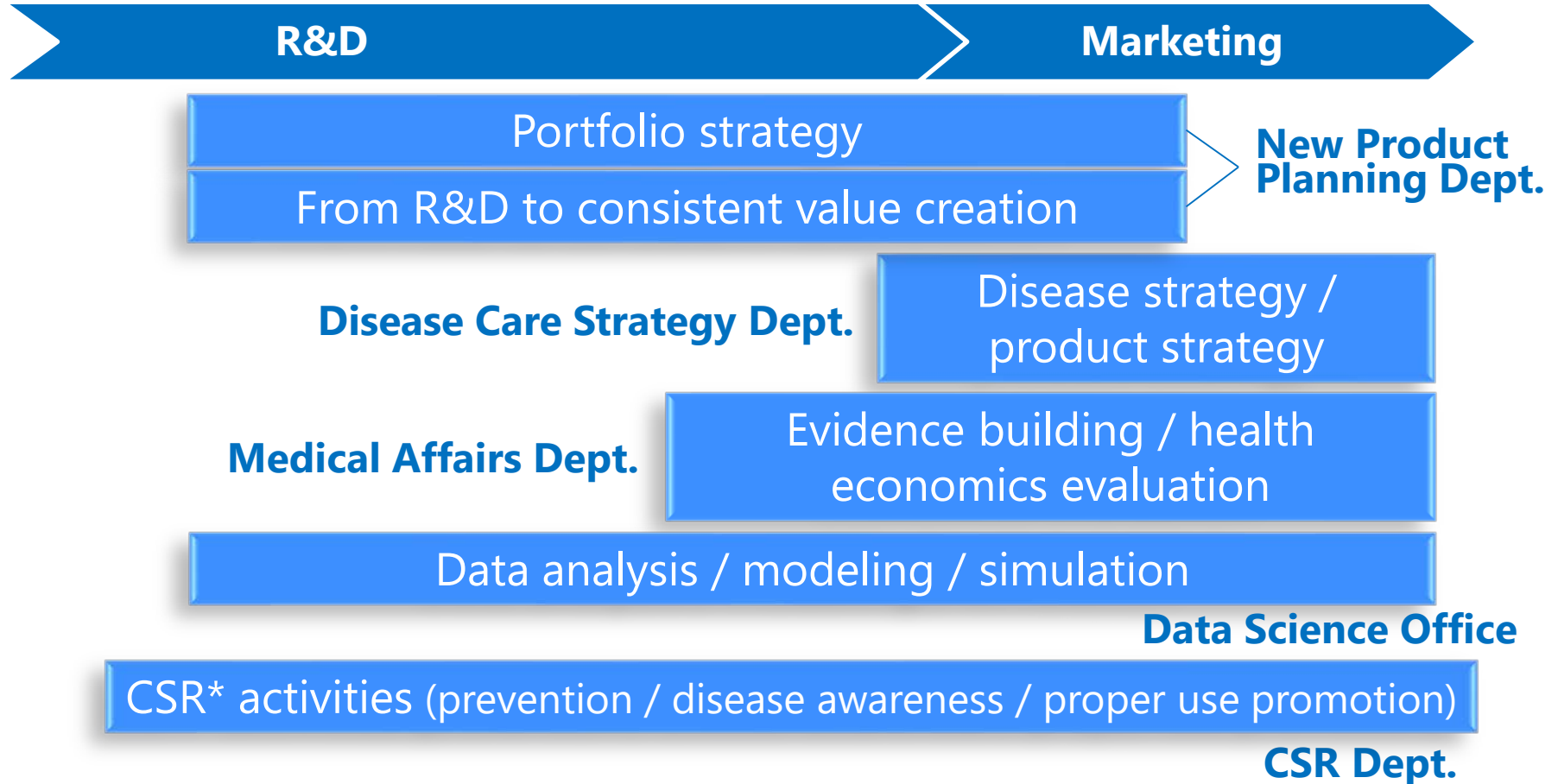
**Only a few isolates with less susceptibility to the drug were identified, and none of them were confirmed as being widespread**

# Establishment of Integrated Disease Care Division

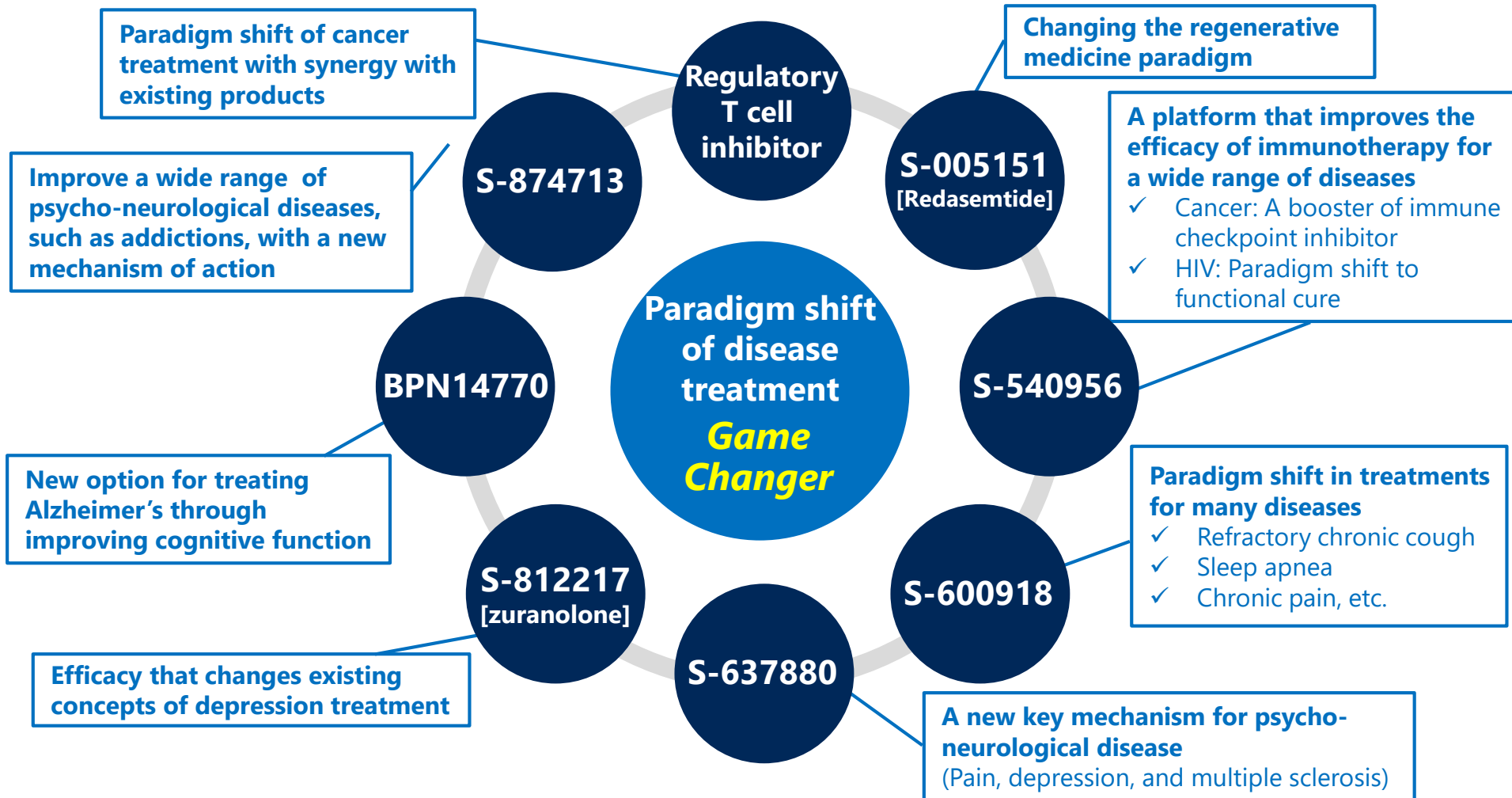


## Mechanism for effectively delivering required products/information globally

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



# The World We Envision Based on Our Core Pipeline



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

# Pipeline (as of May 11, 2020)



## Japan



- Phase 1**
- S-600918**  
Neuropathic pain
  - S-637880**  
Neuropathic pain
  - S-010887**  
Neuropathic pain
  - S-770108**  
Idiopathic pulmonary fibrosis

- Phase 2**
- 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

- Phase 3**
- Cefiderocol**  
Aerobic Gram-negative bacterial infection
  - Xofluza®**  
Influenza virus infection (High-dose for children)
  - Cymbalta®**  
Depression (pediatric)
  - S-588410**  
Esophageal cancer

- Submission**
- 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**

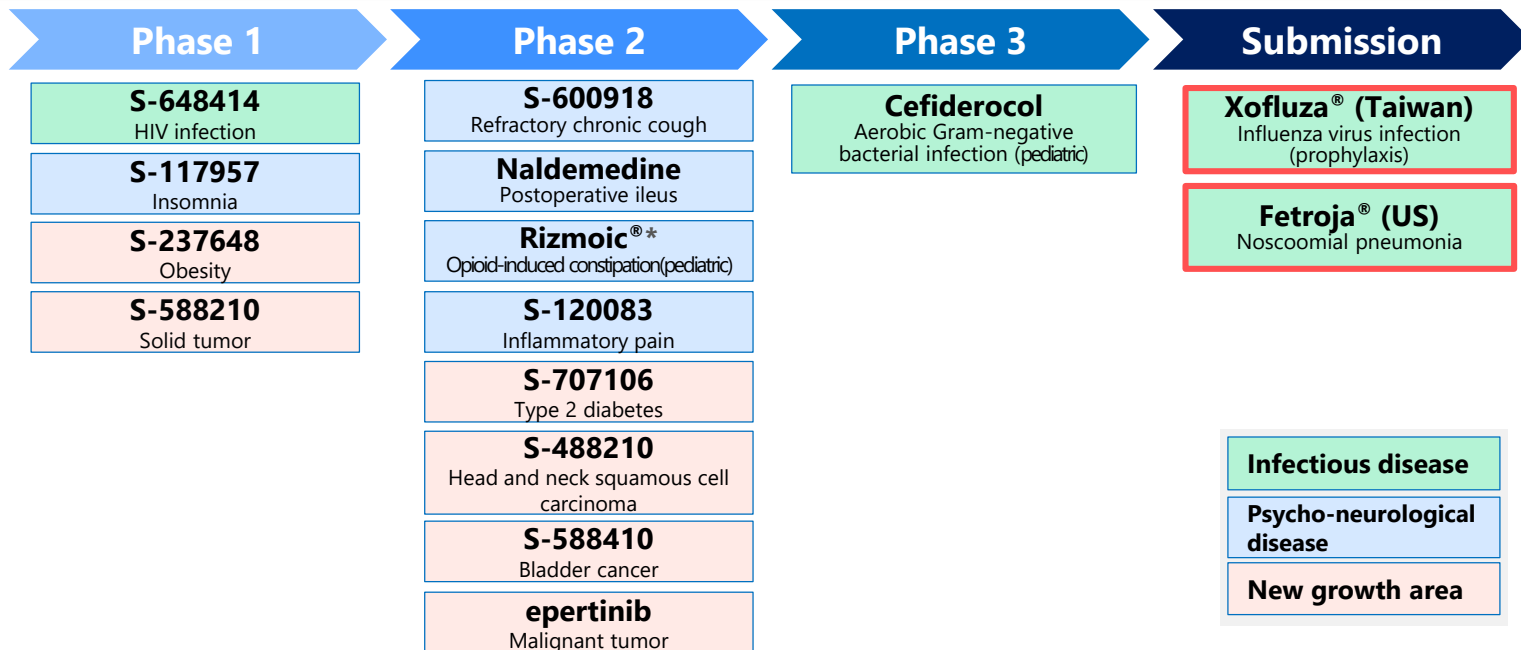
Stage change (Changes from February 3, 2020)

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

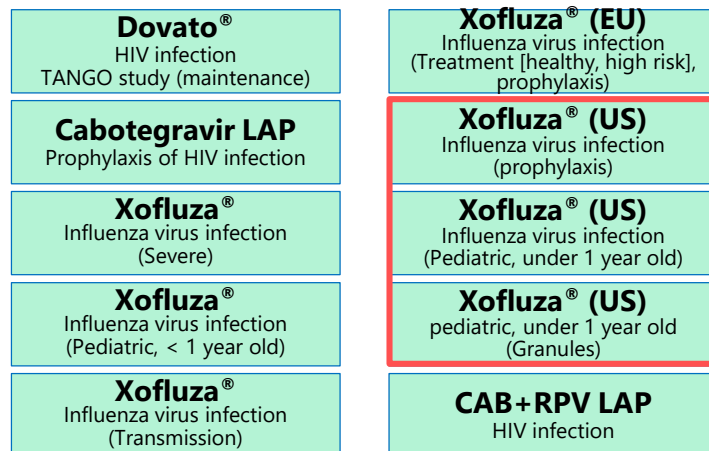
# Pipeline (as of May 11, 2020)



## 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 <sup>®</sup> (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval	
	Fetroja <sup>®</sup> (cefiderocol)	Aerobic gram-negative bacterial infection*	EU: Approval ✓	
	Xofluza <sup>®</sup> granule	Influenza virus infection (pediatric, <20 kg)	Japan: supplemental approval	
	Xofluza <sup>®</sup>	Influenza virus infection (prophylaxis)	Japan: supplemental approval	
	Oxycontin <sup>®</sup> TR	Analgesia in chronic pain	Japan: supplemental approval	
	Cymbalta <sup>®</sup>	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	



# Definition of New Products (in Updates to SGS2020)



## Pain/ CNS

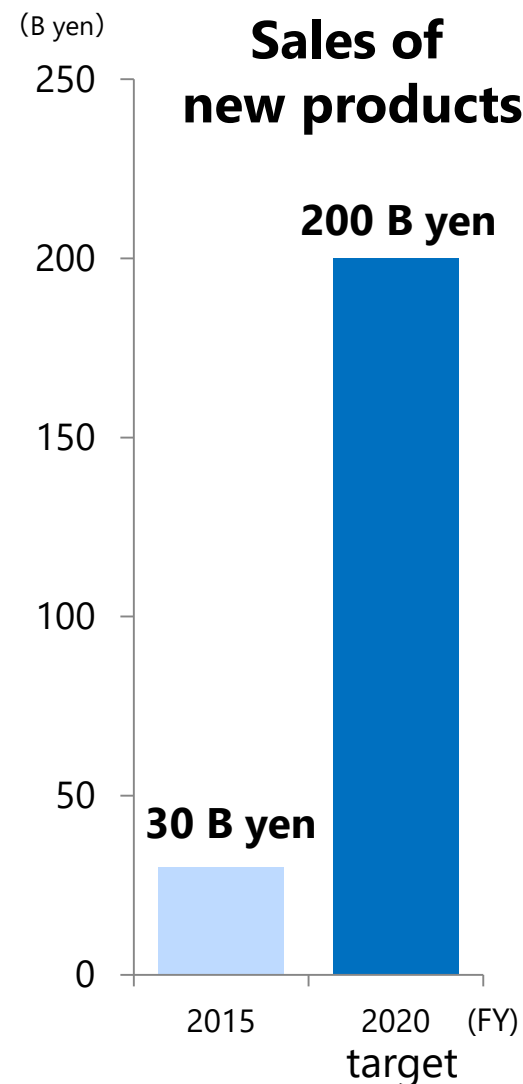
- Cymbalta<sup>®</sup>
- OxyContin<sup>®</sup> tamper resistant formulation, OxiNorm<sup>®</sup>, OxiFast<sup>®</sup>
- Naldemedine\*
- Intuniv<sup>®</sup>, Vyvanse<sup>®</sup>

## Infectious diseases

- Xofluza<sup>®</sup>
- Cefiderocol
- Rapiacta<sup>®</sup>, flu diagnosis kit

## Others

- Pirespa<sup>®</sup>
- Mulpleta<sup>®</sup>
- Actair<sup>®</sup>
- Osphena<sup>®</sup> (Senshio<sup>®</sup>)



# 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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