



# **FY2018 Financial Results**

**(April 2018 – March 2019)**

May 10, 2019

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President and CEO



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# **1. Overview of FY2018 Financial Results**

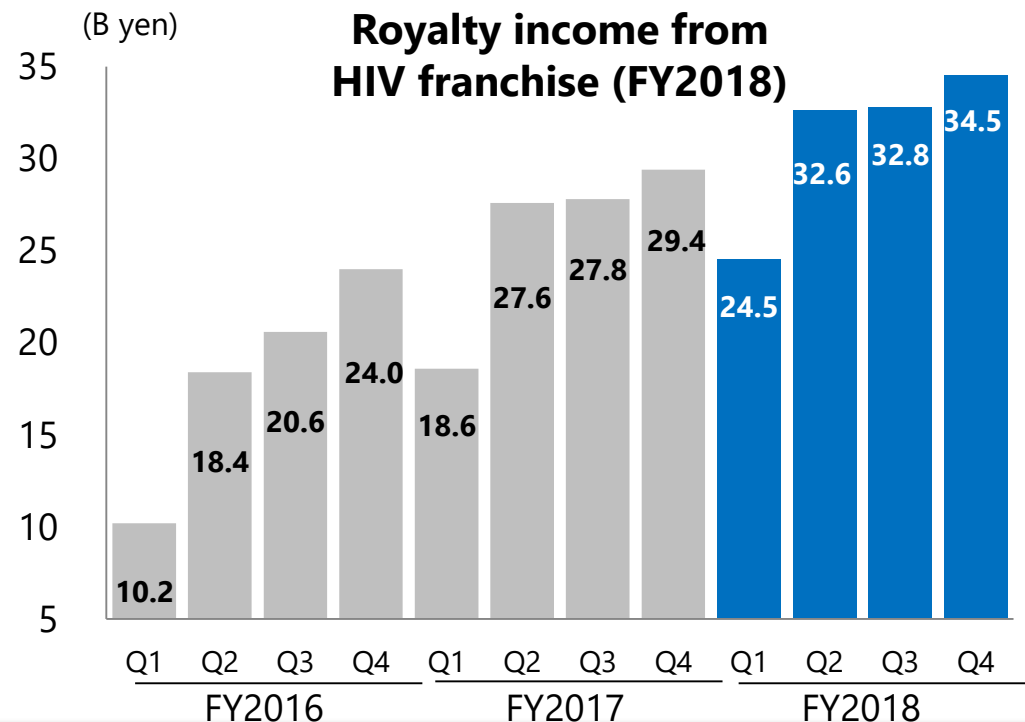
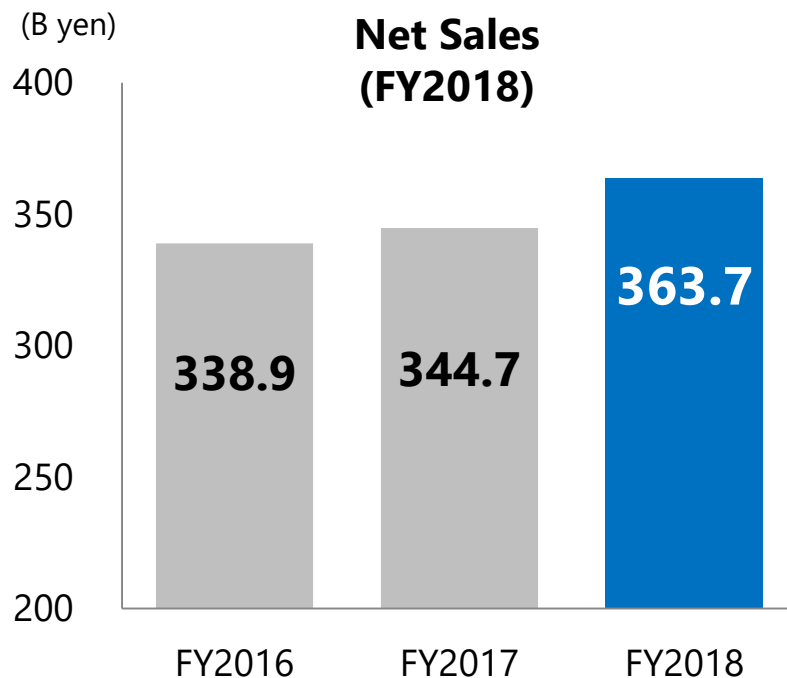
# Highlight (1) : Constant Top-line Growth



◆ Net sales : **363.7 B yen** <sup>vs prior FY</sup> (+5.5%)

**Increased for  
4 consecutive years**

◆ Royalty income : **124.4 B yen** <sup>vs prior FY</sup> (+20.3%)  
from HIV franchise

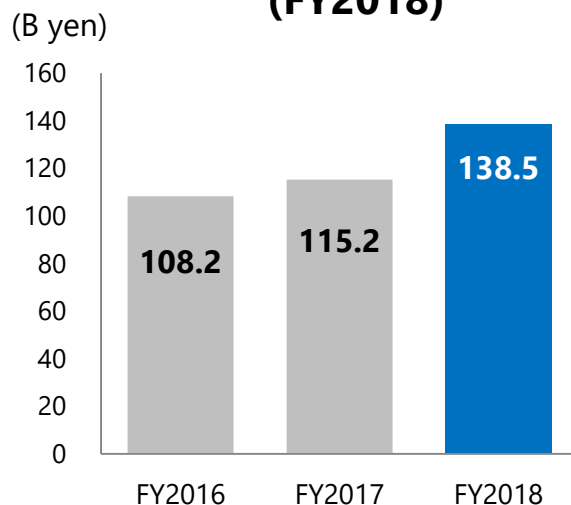


# Highlight (2) : All Profit Measures Were Higher Than the Levels Achieved in Prior Years

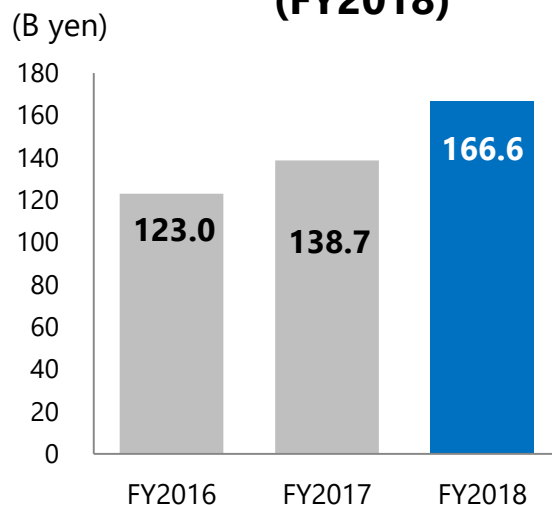


- ◆ Operating income: **138.5 B yen** vs prior FY (+20.2%), higher than the levels achieved in prior Fiscal Years for 4 consecutive years
- ◆ Ordinary income: **166.6 B yen** vs prior FY (+20.1%), higher than the levels achieved in prior Fiscal Years for 7 consecutive years
- ◆ Profit attributable to owners of parent: **132.8 B yen** vs prior FY (+21.9%), higher than the levels achieved in prior Fiscal Years for 3 consecutive years

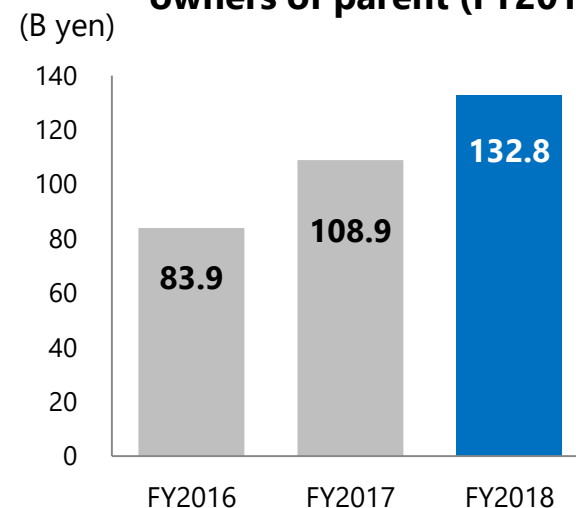
**Operating income  
(FY2018)**



**Ordinary income  
(FY2018)**



**Profit attributable to  
owners of parent (FY2018)**



# Highlight (3) : KPIs - Results in FY2018



		FY2020 target	FY2018 target*	FY2018 results	FY2017 results
<b>Growth</b>	<b>Sales of new products**</b>	200 B yen	72.1 B yen	<b>83.1 B yen</b>	52.9 B yen
	<b>Ordinary Income</b>	150 B yen	140.0 B yen	<b>166.6 B yen</b>	138.7 B yen
<b>Efficiency</b>	<b>ROIC***</b>	Over 13.5%	Over14.5%	<b>16.5%</b>	14.9%
	<b>CCC****</b>	5.5 months	6.1 months	<b>8.9 months</b>	6.2 months
	<b>Original pipeline ratio</b>	Over 50%	Over 50%	<b>69%</b>	74%
<b>Shareholder return</b>	<b>ROE</b>	Over 15.0%	Over17.0%	<b>20.9%</b>	19.4%
	<b>DOE</b>	Over 4.0%	4.3%	<b>4.6% (planned)</b>	4.6%



# Highlight (3) : KPIs - CCC -

## Efficiency

		FY2020 Target	FY2018 Target	FY2018 Results	FY2017 Results	FY2016 Results
CCC		5.5 months	6.1 months	8.9 months	6.2 months	6.7 months

$$\text{CCC} = \text{Receivables conversion period} + \text{Inventory conversion period} - \text{Payables conversion period}$$

Main variation factor: **Significant decrease in cost of sales due to changes in the lineup of major products**

- Increase in sales of new products with low cost of sales, decrease in sales of Crestor® and Irbetan® franchise with high cost of sales
- Decrease in cost of sales: 77.8 B yen in FY2016→54.9 B yen in FY2018

**We have improved receivables conversion period and payables conversion period addressed to control stock properly, as a results, CCC had been decreasing steadily. However, the recent rapid changes in the lineup of major products has had an impact on CCC.**

**Considering the current situation, FY2020 Target was changed from 5.5 months to 7.0 months**

- **Pursue top-level CCC in the healthcare sector** by controlling stock in cooperation with our manufacturing subsidiary Shionogi Pharma Co., Ltd.

# Financial Results (Consolidated)



(Unit: B yen)

	FY2018			Achievement	FY2017	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Oct. 29)	Results		Results	Change (%)	Change (B yen)
Sales	346.5	354.0	363.7	102.7%	344.7	5.5%	19.1
Operating income	119.0	124.5	138.5	111.3%	115.2	20.2%	23.3
Ordinary income	140.0	148.5	166.6	112.2%	138.7	20.1%	27.9
Profit attributable to owners of parent	111.0	118.5	132.8	112.0%	108.9	21.9%	23.9

- Sales and each profit measure were higher than FY2017
- Each profit measure was higher than the levels achieved in prior fiscal years
  - Operating income: for 4 consecutive years
  - Ordinary income: for 7 consecutive years
  - Profit attributable to owners of parent: for 3 consecutive years

Exchange rate (average)	FY2018 forecasts	FY2018 results
USD (\$) – JPY (¥)	105	110.93
GBP (£) – JPY (¥)	145	145.72
EUR (€) – JPY (¥)	130	128.45



# Statement of Income (Consolidated)



(Unit: B yen)

	FY2018		Results	Achievement (%)	FY2017	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Oct. 29)			Results	Change (%)	Change (B yen)
<b>Sales</b>	<b>346.5</b>	<b>354.0</b>	<b>363.7</b>	102.7	344.7	5.5	19.1
	16.7	16.1	15.1		21.4		
<b>Cost of sales</b>	<b>58.0</b>	<b>57.0</b>	<b>54.9</b>	96.3	73.9	(25.7)	(19.0)
<b>Gross profit</b>	<b>288.5</b>	<b>297.0</b>	<b>308.8</b>	104.0	270.8	14.1	38.1
	48.9	48.7	46.8		45.1		
<b>SG&amp;A expenses</b>	<b>169.5</b>	<b>172.5</b>	<b>170.3</b>	98.7	155.5	9.5	14.8
	29.6	29.4	28.0		27.7		
Selling & administrative expenses	<b>102.5</b>	<b>104.0</b>	<b>102.0</b>	98.1	95.6	6.7	6.4
	19.3	19.4	18.8		17.4		
R&D expenses	<b>67.0</b>	<b>68.5</b>	<b>68.3</b>	99.7	59.9	14.0	8.4
Ordinary R&D expenses*	<b>47.0</b>	<b>50.4</b>	<b>51.4</b>	102.0	59.9	(14.2)	(8.5)
Strategic investment	<b>20.0</b>	<b>18.1</b>	<b>16.9</b>	93.5	-	-	16.9
	34.3	35.2	38.1		33.4		
<b>Operating income</b>	<b>119.0</b>	<b>124.5</b>	<b>138.5</b>	111.3	115.2	20.2	23.3
<b>Non-operating income &amp; expenses</b>	<b>21.0</b>	<b>24.0</b>	<b>28.0</b>	116.8	23.5	19.4	4.6
	40.4	41.9	45.8		40.2		
<b>Ordinary income</b>	<b>140.0</b>	<b>148.5</b>	<b>166.6</b>	112.2	138.7	20.1	27.9
<b>Profit attributable to owners of parent</b>	<b>111.0</b>	<b>118.5</b>	<b>132.8</b>	112.0	108.9	21.9	23.9

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



## Y on Y comparison

(Unit: B yen)

Sales	+19.1
Cost of sales	(19.0)
Gross profit	+38.1
Selling & administrative expenses	+6.4
R&D expenses	+8.4
Operating income	+23.3
Non-operating income & expenses	+4.6
Ordinary income	+27.9
Extraordinary income or losses	+5.1
Profit attributable to owners of parent	+23.9
Decrease in profit	Increase in profit

## Main Variation Factors (Y on Y)

- **Sales**
  - Increase in royalty income from HIV franchise
  - Income from Roche for Xofluz<sup>TM</sup>
  - One-time payment from Purdue upon the termination of previous alliance for Symproic<sup>®</sup>
  - Decrease in sales of prescription drugs in Japan
- **Cost of sales**
  - Japan business: sales decline and changes in the lineup of major products
- **SG & A expenses**
  - **Selling & administrative expenses**
    - › Investment in new products (preparation for launch etc.)
  - **R&D expenses**
    - › Ordinary R&D expenses: decreased due to early completion of HR\* study for Xofluz<sup>®</sup>
    - › Strategic investment: net increase (16.9 B yen)
- **Non-operating income & expenses**
  - Increase in ordinary dividend due to sales growth of HIV franchise, including one-time event
- **Extraordinary income or loss**
  - Profit on sale of investment securities
  - Sale of the Nanjing Factory of C&O in China
  - Impairment of goodwill in Shionogi Inc.: Environmental change for Fortamet<sup>®</sup> Authorized Generic

# Sales by Segment



(Unit: B yen)

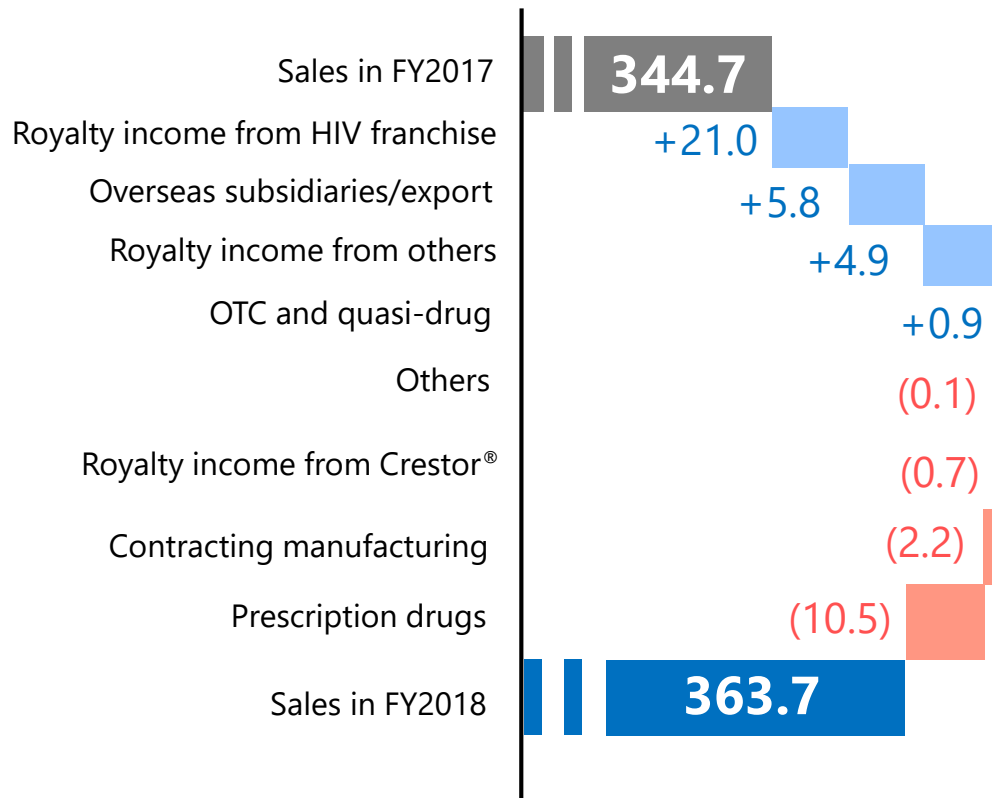
	FY2018		Results	Achievement (%)	FY2017	Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Oct. 29)			Results	Change (%)	Change (B yen)
<b>Prescription drugs</b>	<b>119.3</b>	<b>119.3</b>	<b>128.7</b>	107.9	139.2	(7.6)	(10.5)
<b>Overseas subsidiaries/export</b>	<b>29.8</b>	<b>31.3</b>	<b>29.4</b>	94.0	23.6	24.6	5.8
Shionogi Inc.	10.9	12.4	11.8	95.0	10.6	11.2	1.2
Osphena <sup>®</sup>	4.1	4.1	3.0	72.7	3.7	(18.5)	(0.7)
C&O	12.4	12.4	11.5	92.8	6.9	67.2	4.6
<b>Contract manufacturing</b>	<b>12.1</b>	<b>12.9</b>	<b>14.8</b>	114.4	16.9	(12.8)	(2.2)
<b>OTC and quasi-drug</b>	<b>7.4</b>	<b>7.4</b>	<b>8.1</b>	110.1	7.2	12.0	0.9
<b>Royalty income</b>	<b>175.5</b>	<b>180.6</b>	<b>180.3</b>	99.8	155.0	16.3	25.2
HIV franchise	124.9	124.9	124.4	99.6	103.5	20.3	21.0
Crestor <sup>®</sup>	21.1	21.1	22.0	104.0	22.6	(2.9)	(0.7)
Others	29.5	34.6	33.9	97.8	29.0	16.9	4.9
<b>Others</b>	<b>2.5</b>	<b>2.5</b>	<b>2.5</b>	98.9	2.6	(5.6)	(0.1)
<b>Total</b>	<b>346.5</b>	<b>354.0</b>	<b>363.7</b>	<b>102.7</b>	<b>344.7</b>	<b>5.5</b>	<b>19.1</b>

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



## • Y on Y comparison

(Unit: B yen)



## Main Variation Factors (Y on Y change)

- **Royalty income**
  - Sales growth of HIV franchise
  - Income from Roche for Xofluza™
- **Overseas subsidiaries/export**
  - **US business**
    - One-time payment from Purdue upon the termination of the prior alliance for Symproic®
    - Decrease in royalty income from an Fortamet® Authorized Generic
- **Contract manufacturing**
  - API\* export of dolutegravir in FY2017 partially included requirements for FY2018
- **Prescription drugs**
  - Sales growth of strategic products
  - Sales decrease due to NHI price revision
  - Sales decrease of Crestor® and Irbetan® due to share capture by generic drugs

# Sales of Prescription Drugs in Japan



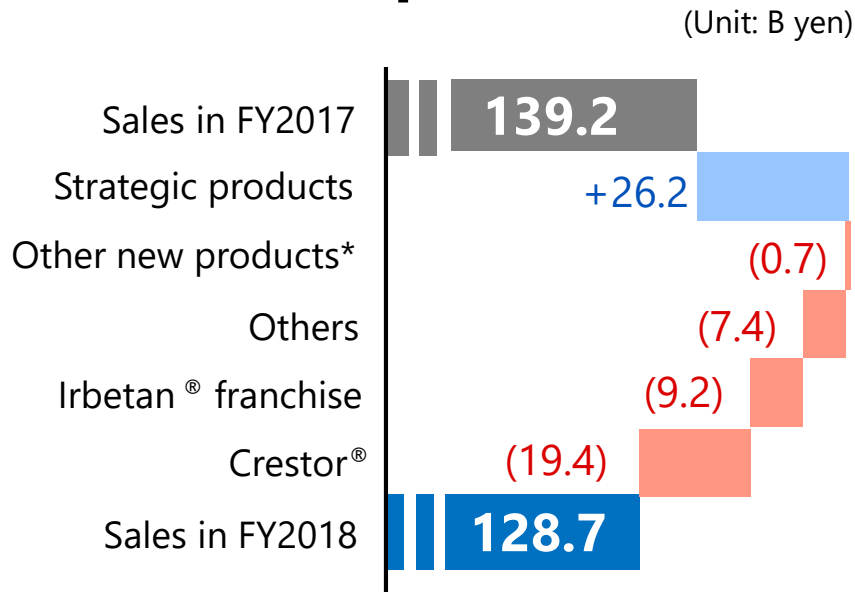
(Unit: B yen)

	FY2018		Results	FY2017		Y on Y	
	Forecasts (May 9)	Forecasts (Revised on Oct. 29)		Achieve ment (%)	Results	Change (%)	Change (B yen)
Cymbalta <sup>®</sup>	26.0	26.0	24.1	92.7	23.5	2.4	0.6
Intuniv <sup>®</sup>	5.0	6.1	5.3	86.4	1.9	179.2	3.4
Xofluza <sup>®</sup>	13.0	13.0	26.3	202.3	2.4	N/A*	23.9
Rapiacta <sup>®</sup>	1.1	1.1	2.0	181.6	3.3	(38.9)	(1.3)
Brightpoc <sup>®</sup> Flu	1.1	1.3	1.2	93.3	1.1	4.3	0.0
OxyContin <sup>®</sup> franchise	9.1	8.7	7.3	84.1	8.7	(15.9)	(1.4)
Symproic <sup>®</sup>	1.2	1.6	1.6	100.4	0.6	163.5	1.0
<b>Total of strategic products</b>	<b>56.4</b>	<b>57.7</b>	<b>67.8</b>	<b>117.4</b>	<b>41.6</b>	<b>63.1</b>	<b>26.2</b>
Actair <sup>®</sup>	0.15	0.18	0.19	105.2	0.12	56.0	0.1
Mulpleta <sup>®</sup>	0.23	0.19	0.15	80.1	0.16	(4.6)	(0.0)
Pirespa <sup>®</sup>	6.0	5.9	5.7	96.7	6.5	(12.2)	(0.8)
<b>Total of new products</b>	<b>62.8</b>	<b>64.0</b>	<b>73.8</b>	<b>115.3</b>	<b>48.3</b>	<b>52.8</b>	<b>25.5</b>
Crestor <sup>®</sup>	9.7	9.7	9.9	102.2	29.3	(66.3)	(19.4)
Irbetan <sup>®</sup> franchise	6.4	6.0	5.4	89.5	14.6	(63.1)	(9.2)
<b>Others</b>	<b>40.4</b>	<b>39.6</b>	<b>39.6</b>	<b>100.0</b>	<b>47.0</b>	<b>(15.7)</b>	<b>(7.4)</b>
<b>Prescription drugs</b>	<b>119.3</b>	<b>119.3</b>	<b>128.7</b>	<b>107.9</b>	<b>139.2</b>	<b>(7.6)</b>	<b>(10.5)</b>

# Y on Y Comparison and Main Variation Factors (Sales of Prescription Drugs in Japan)



## Y on Y comparison



## Progress vs Revised forecasts\*\*



### Main Variation Factors (Y on Y change)

- Strategic products
  - Sales increases of Cymbalta®, Intuniv® and Symproic® compared with FY2017
  - Contribution of Xofluza®
- Others
  - Sales decrease due to NHI price revision
- Crestor®, Irbetan® franchise
  - Sales decrease due to share capture by generic drugs

### Main Variation Factors (vs. Revised forecasts\*\*)

- Strategic products
  - Cymbalta® and Intuniv® : slower growth
  - Oxycontin® franchise: sales decrease due to share capture by generic drugs
  - Influenza family: relatively smooth sales growth due to seasonal flu epidemic

# Japanese Business: Driving Sales Growth by Our Own Earning Power



## Sales of prescription drugs in Japan (Y on Y comparison)

The impact of share capture  
by generic competitors  
hit a plateau in 1H FY2018



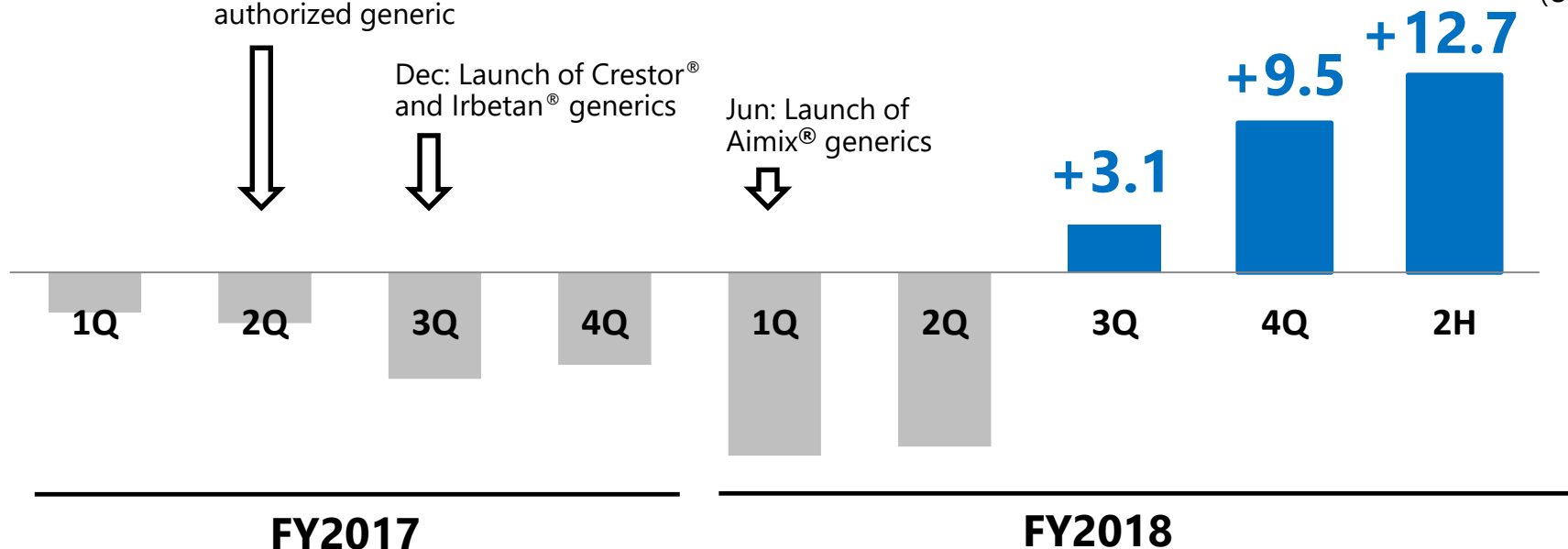
Sales-growth phase by  
our own earning power

Sep: Launch of Crestor®  
authorized generic

Dec: Launch of Crestor®  
and Irbetan® generics

Jun: Launch of  
Aimix® generics

(Unit: B yen)



## Achieved profit increase for two consecutive quarters

# Key Actions in FY2018 – Towards FY2019 (1/3)



## Japanese Business

- **Cymbalta®:**
  - Increased prescriptions by 15% or more from the previous year
  - Share capture in chronic low back pain with large market size was lower than expected, due to need to shift physicians' perception that Cymbalta® should be used for the treatment of refractory pain and psychogenetic pain
- **Intuniv®:**
  - Attained top share in the non-stimulant market for pediatric ADHD
  - Sales were lower than expected, because Intuniv® was mainly used in combination therapy, and the dose level was lower than expected
- **Influenza family:**
  - Sales grew compared to the previous year due to seasonal flu epidemic and exceeded the forecasts
- **Opioid family:**
  - Sales decrease due to share capture by generic drugs
  - Switching to Oxycontin®TR

**Achieved sales growth of new products  
by focusing resources on strategic products**



# Key Actions in FY2018 – Towards FY2019 (2/3)



## US Business

- **Cefiderocol: Progressed towards approval in FY2019 (QIDP\* designation)**
- **Symproic®:**
  - Sustained and then grew sales after transition from Purdue by market access efforts and efficient promotion with contract sales reps
  - Alliance with BioDelivery Sciences International (BDSI) in Apr. 2019
- **Mulpleta®:** Initiated full-scale promotion in Dec. 2018
- **Osphena®:** Supplemental indication “moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy”: approved

## EU Business

- **Cefiderocol : MAA submission acceptance**
  - “Accelerated Assessment” designation
- **Rizmoic®: Approval**
  - Alliance with Sandoz in Mar. 2019
- **Mulpleta® : Approval**
- **Sales increase of prescription drugs (Y on Y change: +0.5 B yen)**

## China & Taiwan Business

- **Mulpleta®:**
  - Preparation for NDA submission in China
- **C&O®:**
  - Sales increase of Rabeprazole
- **Baloxavir marboxil:**
  - NDA submitted for OwH\*\* patients in Taiwan

**Progressed development of pipeline for further growth of overseas business and achieved breakeven in US business by total cost management**

# Key Actions in FY2018 – Towards FY2019 (3/3)

## R&D: Investment to discover next growth drivers to prepare for continuous success for beyond 2020

- **Steady progress of R&D especially for 8 high-priority projects\***
- **Defined goal to pursue of strategic investments and concluded 10 new alliances for beyond 2020**
  - ✓ Hsiri, Nemesis, SAGE, Rohto, Vast, Ube, Tetra, PeptiDream, Nagasaki Univ., Akili  
(See appendix p. 71 for details)
- **Steady progress of HIV franchise**
  - Further contribution for HIV treatment/prophylaxis by DTG/CAB franchise



**Further strengthen, expand, and accelerate drug-discovery both on our own and through external collaboration**

# Challenges for Mid- to Long-Term Growth



**Japanese/Overseas  
business**

**Strengthen Japanese business and  
establish a global presence**

**R&D**

**Develop next growth drivers**

**Business  
Innovation**

**Create new value and  
reinforce management foundation**

## 2. FY2019 Financial Forecasts

# Financial Forecasts



(Unit: B yen)

	FY2019 forecasts		FY2018	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Sales	365.5	159.0	363.7	0.5	1.8
Operating income	147.0	52.0	138.5	6.1	8.5
Ordinary income	170.5	63.0	166.6	2.4	3.9
Profit attributable to owners of parent	133.0	49.0	132.8	0.2	0.2

**Achieve income and profit growth by sales growth of new products, and continue to achieve record-high profits**

Exchange rate (average)	FY2019 forecasts	FY2018 results
USD (\$) – JPY (¥)	110	110.93
GBP (£) – JPY (¥)	145	145.72
EUR (€) – JPY (¥)	130	128.45

# **3. FY2019 Business Plan**

# Changes in Shionogi's Business Environment in FY2019



- **Sales**

- Plan for revision of drug prices along with consumption tax increase (Oct.)
- Additional indication of Intuniv<sup>®</sup> for adults, launch of Vyvanse<sup>®</sup>

- **Investment**

- Designate highest-priority projects from the current high-priority projects (8 projects at present), and actively invest in these projects
- Invest in cefiderocol prior to approval and launch

- **Business innovation**

- Application of international accounting standards (IFRS) from FY2019
  - > Disclosure under IFRS from FY2020
- Shionogi Pharma operations commenced

# 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**



# Statement of Income Forecasts



(Unit: B yen)

	FY2019		FY2018	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
<b>Sales</b>	<b>365.5</b>	<b>159.0</b>	363.7	0.5	1.8
	14.6	16.0	15.1		
<b>Cost of sales</b>	<b>53.5</b>	<b>25.5</b>	54.9	(2.5)	(1.4)
<b>Gross profit</b>	<b>312.0</b>	<b>133.5</b>	308.8	1.0	3.2
	45.1	51.3	46.8		
<b>SG&amp;A expenses</b>	<b>165.0</b>	<b>81.5</b>	170.3	(3.1)	(5.3)
Selling & administrative expenses	31.6	35.5	28.0		
	115.5	56.4	102.0	13.3	13.5
	13.5	15.8	18.8		
R&D expenses	49.5	25.1	68.3	(27.6)	(18.8)
Ordinary R&D expenses*	49.5	25.1	51.4	(3.7)	(1.9)
Strategic investment	-	-	16.9	-	(16.9)
	40.2	32.7	38.1		
<b>Operating income</b>	<b>147.0</b>	<b>52.0</b>	138.5	6.1	8.5
<b>Non-operating income &amp; expenses</b>	<b>23.5</b>	<b>11.0</b>	28.0	(16.2)	(4.5)
	46.6	39.6	45.8		
<b>Ordinary income</b>	<b>170.5</b>	<b>63.0</b>	166.6	2.4	3.9
<b>Profit attributable to owners of parent</b>	<b>133.0</b>	<b>49.0</b>	132.8	0.2	0.2

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

## • Y on Y comparison

(Unit: B yen)

Sales	+1.8
Cost of sales	(1.4)
Gross profit	+3.2
Selling & administrative expenses	+13.5
R&D expenses	(18.8)
Operating income	+8.5
Non-operating income & expenses	(4.5)
Ordinary income	(3.9)
Extraordinary income or losses	(3.8)
Profit attributable to owners of parent	+0.2
Decrease in profit	Growth in profit

## Main Variation Factors (Y on Y)

- **Sales (+1.8 B yen)**
  - Sales growth of prescription drugs in Japan
  - Decrease in milestone income from Roche for Xofluza™
- **SG & A expenses (-5.3 B yen)**
  - Selling & administrative expenses (+13.5 B yen)
    - › Japanese business: Increase in expenses due to sales increase of strategic products especially for Cymbalta and Intuniv
    - › Overseas business: Investment in launch marketing activities in US and EU
  - R&D (-18.8 B yen)
    - › Elimination of category of strategic investment (16.9 B yen in FY2018)
- **Extraordinary income or losses (-3.8 B yen)**
  - › Profit on sale of investment securities in FY2018

# Sales by Segment Forecasts



(Unit: B yen)

	FY2019		FY2018	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
<b>Prescription drugs</b>	<b>144.1</b>	<b>53.7</b>	<b>128.7</b>	12.0	15.4
<b>Overseas subsidiaries/export</b>	<b>31.4</b>	<b>16.0</b>	<b>29.4</b>	6.6	2.0
Shionogi Inc.	9.9	6.3	11.8	(16.2)	(1.9)
Mulpleta®	1.0	0.25	0.08	N/A*	0.9
C&O	14.6	6.8	11.5	27.0	3.1
<b>Contract manufacturing</b>	<b>14.3</b>	<b>9.1</b>	<b>14.8</b>	(3.0)	(0.4)
<b>OTC and quasi-drugs</b>	<b>9.7</b>	<b>4.6</b>	<b>8.1</b>	19.7	1.6
<b>Royalty income</b>	<b>163.6</b>	<b>74.3</b>	<b>180.3</b>	(9.2)	(16.7)
HIV franchise	126.5	61.3	124.4	1.6	2.0
Crestor®	22.0	11.0	22.0	0.2	0.0
Others	15.1	2.1	33.9	(55.4)	(18.8)
<b>Others</b>	<b>2.4</b>	<b>1.2</b>	<b>2.5</b>	(3.2)	(0.1)
<b>Total</b>	<b>365.5</b>	<b>159.0</b>	<b>363.7</b>	<b>0.5</b>	<b>1.8</b>

# Sales Forecasts for Prescription Drugs in Japan



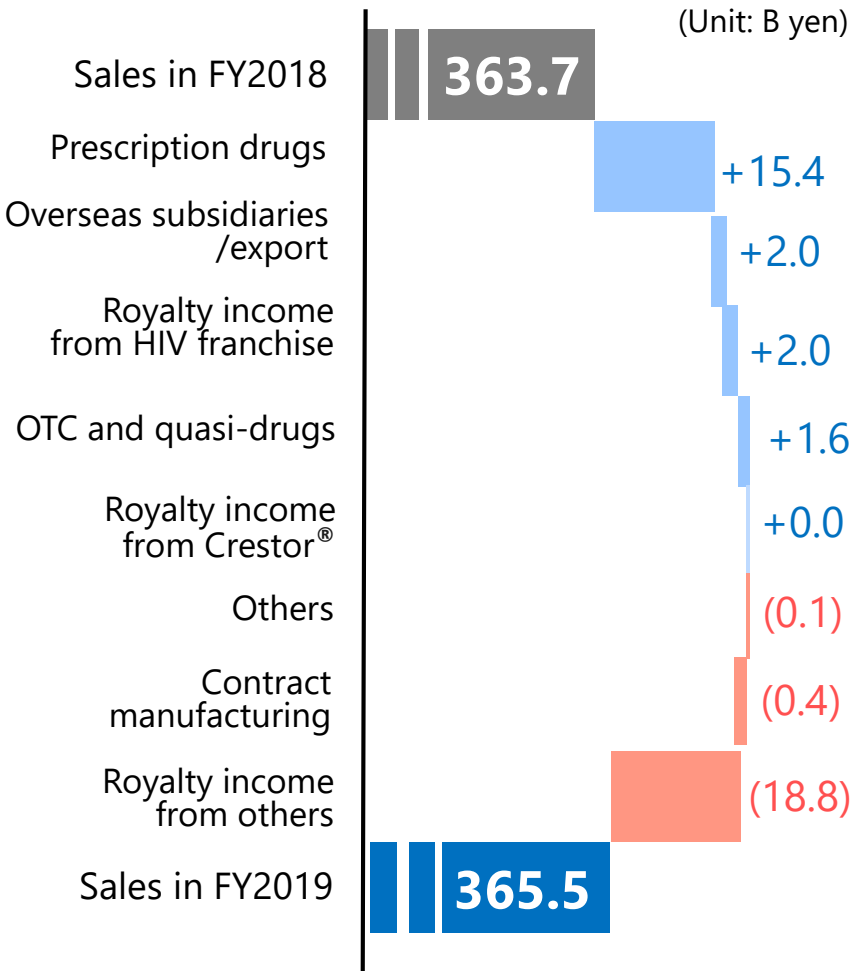
	FY2019		FY2018	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
<b>Cymbalta<sup>®</sup></b>	<b>29.3</b>	<b>13.0</b>	24.1	21.6	5.2
<b>Intuniv<sup>®</sup></b>	<b>13.6</b>	<b>4.6</b>	5.3	157.2	8.3
<b>Xofluza<sup>®</sup></b>	<b>28.0</b>	<b>0.28</b>	26.3	6.5	1.7
<b>Rapiacta<sup>®</sup></b>	<b>2.6</b>	<b>0.05</b>	2.0	27.7	0.6
<b>Brightpoc<sup>®</sup> Flu</b>	<b>1.8</b>	<b>0.18</b>	1.2	56.2	0.7
<b>Strategic products total</b>	<b>75.7</b>	<b>18.2</b>	58.9	28.6	16.8
<b>OxyContin<sup>®</sup> franchise</b>	<b>6.7</b>	<b>3.6</b>	7.3	(7.4)	(0.5)
<b>Symproic<sup>®</sup></b>	<b>2.3</b>	<b>1.1</b>	1.6	43.8	0.7
<b>Actair<sup>®</sup></b>	<b>0.27</b>	<b>0.12</b>	0.19	38.3	0.1
<b>Mulpleta<sup>®</sup></b>	<b>0.33</b>	<b>0.17</b>	0.15	115.4	0.2
<b>Pirespa<sup>®</sup></b>	<b>6.9</b>	<b>3.5</b>	5.7	21.0	1.2
<b>New products total</b>	<b>92.2</b>	<b>26.7</b>	73.8	25.0	18.4
<b>Crestor<sup>®</sup></b>	<b>10.0</b>	<b>5.2</b>	9.9	1.3	0.1
<b>Irbetan<sup>®</sup> franchise</b>	<b>4.9</b>	<b>2.6</b>	5.4	(8.3)	(0.4)
<b>Others</b>	<b>36.9</b>	<b>19.2</b>	39.6	(6.8)	(2.7)
<b>Prescription drugs</b>	<b>144.1</b>	<b>53.7</b>	<b>128.7</b>	<b>12.0</b>	<b>15.4</b>

(Unit: B yen)

# Y on Y Comparison and Main Variation Factors (Sales by Segments)



## • Y on Y comparison



### Main Variation Factors (Y on Y change)

- **Prescription drugs (+15.4 B yen)**
  - Sales growth of Cymbalta®, Intuniv®, and influenza family
- **Overseas subsidiaries/export (+2.0 B yen)**
  - US/EU: One-time payment from alliance partners for Symproic®/Rizmoic®
  - C&O: Sales increase of Rabeprazole
- **Royalty income (-16.7 B yen)**
  - Sales growth of HIV franchise
  - Decrease of milestone payment from Roche for Xofluza™

# Financial Forecasts

(Unit: B yen)

	FY2019 forecasts		FY2018	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yne)
Sales	365.5	159.0	363.7	0.5	1.8
Operating income	147.0	52.0	138.5	6.1	8.5
Ordinary income	170.5	63.0	166.6	2.4	3.9
Profit attributable to owners of parent	133.0	49.0	132.8	0.2	0.2

**Achieve income and profit growth by sales growth of new products, and continue to achieve record-high profits**

Exchange rate (average)	FY2019 forecasts	FY2018 results
USD (\$) – JPY (¥)	110	110.93
GBP (£) – JPY (¥)	145	145.72
EUR (€) – JPY (¥)	130	128.45

# Financial Forecasts for FY2019



- Net Sales (363.7 to 365.5)**

(Unit: B yen)

<b>FY2018 Results</b>	<b>1H Results</b> 168.2	<b>2H Results</b> 195.5	
<b>FY2019 Forecasts</b>	<b>1H Forecasts</b> 159.0	<b>2H Forecasts</b> 206.5	<b>+ 1.8</b>
	Decrease in milestone payment from Roche	Sales growth of new products	

- Operating Income (138.5 to 147.0)**

- Ordinary Income (166.6 to 170.5)**

- Profit attributable to owners of parent (132.8 to 133.0)**

<b>FY2018 Results</b>	<b>1H Results</b> 57.3	<b>2H Results</b> 81.2		<b>1H Results</b> 70.1	<b>2H Results</b> 96.5		<b>1H Results</b> 57.9	<b>2H Results</b> 74.9	
<b>FY2019 Forecasts</b>	<b>1H Forecasts</b> 52.0	<b>2H Forecasts</b> 95.0	<b>+ 8.5</b>	<b>1H Forecasts</b> 63.0	<b>2H Forecasts</b> 107.5	<b>+ 3.9</b>	<b>1H Forecasts</b> 49.0	<b>2H Forecasts</b> 84.0	<b>+ 0.2</b>
	Strategic investment (16.9 B yen in FY2018)	Marketing activities in overseas business							

**Income and profit growth will be achieved in the full-year, although decreases in income and profit are forecasted in 1H**

# KPIs - Target for FY2019 -



		FY2020 target	FY2019 target	FY2018 Results	FY2017 results
<b>Growth</b>	<b>Sales of new products*</b>	200 B yen	<b>100.6 B yen</b>	83.1 B yen	52.9 B yen
	<b>Ordinary Income</b>	150 B yen	<b>170.5 B yen</b>	166.6 B yen	138.7 B yen
<b>Efficiency</b>	<b>ROIC**</b>	Over 13.5%	<b>Over 15.0%</b>	16.5%	14.9%
	<b>CCC***</b>	5.5 months → <b>7.0 months</b>	<b>Below 7.6 months</b>	8.9 months	6.2 months
	<b>Original pipeline ratio</b>	Over 50%	<b>Over 50%</b>	69%	74%
<b>Shareholder return</b>	<b>ROE</b>	Over 15.0%	<b>Over 18.0%</b>	20.9%	19.4%
	<b>DOE</b>	Over 4.0%	<b>Over 4.3%</b>	4.6% (planned)	4.6%



# Action Plans for Each Division

1. Japanese and Overseas Business
2. R&D
3. Business Innovation

## Maximizing its value in the pain area

- **Steady increase of prescriptions in the pain area**
  - Over 15% increase in volume from the previous year
- **On the other hand, Cymbalta® is mainly used for the treatment of chronic low back pain due to psychogenic causes**



- **Make the superior analgesic effects of Cymbalta®, not only based on antidepressant effects, fully understood**
  - Mechanism of Cymbalta® addressing the underlying pathology of chronic pain

<Chronic Pain Treatment Guidelines (issued in March 2018)>

Only drug ranked at the highest level (1A) in both categories of Musculoskeletal pain (CLBP, OA, etc.) and Neuropathic pain (DNP, etc.)

**Establish a presence in the pain area  
in addition to the depression area**

## To maximize value in the ADHD area

### **Intuniv<sup>®</sup> (non-stimulant)**

- Prepare for approval of supplemental indication in adults
- Pediatric patients: Gain top market share in naïve patients
- Adult patients: Capture market share in naïve and switch patients based on foundation achieved in pediatric patients

### **Vyvanse<sup>®</sup>\* (stimulant)**

- Proper indication for patients in need based with strict control of distribution management in collaboration with medical specialists

### **SDT-001 (digital treatment app)**

- Innovative to offer treatment based on digital technology
- Start Phase II study in FY2019



**By offering multiple treatment options,  
enable patients to receive appropriate treatment  
along with appropriate information**

## -Life Cycle Management & Further Insights Into PA/I38 Variants

Status	Clinical assessments	(★) Data to be shown prior to 2019/2020 flu season
Ongoing	<b>Additional analysis for the completed clinical studies</b> <ul style="list-style-type: none"> <li>Including next generation sequencing</li> </ul>	Additional analysis on PA/I38 variants for the completed clinical studies Additional analysis (CAPSTONE-1, CAPSTONE-2, pediatric studies) (★)
Ongoing	<b>Post exposure prophylaxis</b>	Assessing prophylactic efficacy of baloxavir and the risk of transmission of PA/I38 variants. (★)
Ongoing	<b>Drug susceptibility surveillance</b>	Resistance monitoring in the clinical setting. (★)
Ongoing	<b>Pediatric studies at higher doses</b>	Assesses safety, PK and efficacy at higher dose.
Ongoing	<b>Severely ill &amp; hospitalized patients</b>	Explores combination therapy with NAIs and multiple dosing in hospitalized patients.
Planned	<b>Reduced transmission</b>	Clinical assessment for reduced transmission to household contacts from patients treated with baloxavir and possible risk of transmission of PA/I38 variants.

Status	Non-clinical assessment	(★) Data to be shown prior to 2019/2020 flu season
Ongoing	<b>Combination with NAI &amp; Multiple Dosing Regimens</b>	Explores combination with NAI & multiple dosing regimens for severely ill model in mice. (★)
Ongoing	<b>Transmission study in ferret models</b>	Explores effect of baloxavir on transmission and assess risk of transmission of I38 variants in ferrets

**Continue a robust development plan that includes surveillance, clinical and non-clinical assessments and report the data through medical meetings and scientific papers**

# Overseas Business



	US	EU, China, Taiwan etc.
<b>Cefiderocol</b>	<ul style="list-style-type: none"> <li>• Approval</li> <li>• Pre-launch activities</li> </ul>	<EU> Approval, pre-launch activities
<b>Baloxavir Marboxil</b>	<ul style="list-style-type: none"> <li>• Commercialization by Roche group, maximize its value through collaboration</li> </ul>	<Taiwan> Approval is planned in FY2019, pre-launch activities
<b>Lustrombopag</b> (Product name in US: Mulpleta®)	<ul style="list-style-type: none"> <li>• Keep our own promotion and make efforts for market uptake supported by 'Mulpleta Assist' program</li> </ul>	<EU> Launch is planned in FY2019 <China> Preparations for submission
<b>Naldemedine</b> (Product name in U.S.: Symproic®, Product name in EU: Rizmoic®)	<ul style="list-style-type: none"> <li>• Apr. 2019: Partnering with BioDelivery Sciences International (BDSI) for OIC commercialization → Market uptake through Sandoz's commercial expertise in the field of opioid analgesics</li> </ul>	<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
<b>Cefcapene Pivoxil*</b>		<ul style="list-style-type: none"> <li>• China: Approval is planned in FY2019 (granule product for children)</li> </ul>

**A highly efficient operation through combination of our own promotion and collaboration with business partners**

## Infectious disease

- **Xofluza<sup>®</sup>**
  - Approval in Taiwan
  - Approval of granule product in Japan (patients: <20 kg)
  - sNDA submission for prophylaxis in Japan
- **Cefiderocol**
  - Approval in US and EU
  - Completion of Phase III studies
    - ① infections caused by CR gram-negative pathogens, ② HAP/VAP/HCAP
  - Start of pediatric Phase III study
- **S-004992**
  - Go/no-go decision based on the results of ongoing non-clinical studies
- **Novel HIV drug**
  - Start of Phase I study in US

# Acceleration of R&D - Targets for FY2019 2/2



## Pain/CNS

- **S-812217**  
(Depression)
  - Completion of Phase I study→Start of Phase III study (Japan)
- **S-600918**  
(Refractory/unexplained chronic cough)
  - Completion of Phase IIa study (Japan)→Start of Phase IIb study (global)
- **S-637880**  
(Neuropathic pain)
  - Start of Phase I MAD study (Japan)→Start of Phase II study (global)
- **SDT-001**  
(ADHD)
  - Start of Phase II study (Japan)

## Frontier

- **S-540956**  
(Nucleic acid adjuvant)
  - Acceleration of non-clinical studies for start of Phase I study in FY2020
- **S-770108**  
(Idiopathic pulmonary fibrosis)
  - Start of lung deposition study (UK)
- **ADR-001**  
(Decompensated liver cirrhosis)
  - Progress of Phase I/II study by Rohto, preparation for NDA submission (Japan)

## Peptide

- **Peptide**
  - Start of late phase research programs utilizing PDPS\* technology for finding pre-clinical candidates in FY2020

# DTG/CAB Franchise - HIV Treatment Platform (update with most recent ViiV disclosures)



**Tivicay<sup>®</sup>, Triumeq<sup>®</sup> Launch: 2013~**

- Key drug for 3-drug regimen

**Juluca<sup>®</sup> (DTG/RPV) Launch: 2017~**

- First 2-drug regimen for maintenance therapy

**DTG/3TC Launch: 2019~**

- First 2-drug regimen for naïve patients
- Sep. 2018: MAA submission in EU (naïve patients)
- Apr. 2019: Approved by Apr. 2019 (naïve patients) (Product name: Dovato<sup>®</sup>)
- In FY2019: Positive opinion from CHMP, planned to be approved in EU
  - : GEMINI 96-week results (naïve patients)
  - : TANGO 48-week results, Start SALSA (switch patients)

**CAB+RPV Launch: 2019~**

- First long acting injection (monthly or bimonthly)
- Apr. 2019: NDA submission in US (monthly injection)
- In FY2019: MAA submission in EU (monthly injection)
  - : ATLAS 2M results (bimonthly injection for switch patients)

**CAB prophylaxis Launch: 2021~**

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

**Continued excellent progress in expanding the platform and its value**



# Business Innovation

- Sophistication of business management, use of IT -



## Sophistication of business management

- **Improve sophistication of business management by introducing the international accounting standards (IFRS)**
  - Introduce IFRS from FY2019 (Disclosure under IFRS from FY2020)
  - Control global finance and integrate accounting standards among group companies
    - > Decision making based on rapid analysis and forecast of financial conditions and forecasts

## Use of IT for greater contribution to health care and improved work efficiency

- **Contribute to health care through non-pharmacological approach**
  - Promote the development of potential digital treatment products (SDT-001)
  - Visualize patient conditions to help physicians have a better understanding
- **Improve productivity and predictive capability**
  - Efforts to reform sales activities
  - Use of AI to reform and improve the efficiency of operations
    - > product shipment prediction/planning, etc


# Business Innovation



## - Shionogi Pharma Operations Commenced -

**Shionogi Company Policy: Evolve “research, produce, and promote”**

### Shionogi Pharma founded

Taking over Shionogi's production technologies and quality  シオノギファーマ株式会社  
Moving toward further advancement

**Produce at  
affordable prices**

**Proactively introduce  
new technologies**

**Aspire to become top-level CDMO\* in Japan**

**Flexibly respond to  
changes in product  
LCM\*\***

**Ensure stable supply  
for the global market**

**Aiming to improve product value through technology development, Shionogi group will continue to produce pharmaceuticals and healthcare products, and contribute to the maintenance and promotion of people's health**

# Business Innovation

## - Diversity & Inclusion -



### Promote diversity & inclusion throughout the company

#### Diversity & inclusion is crucial for the creation of innovation

- Establish a vision to be shared by all employees in working for the promotion of diversity & inclusion
- Deepen the understanding of employees through efforts in each organization on relevant themes, including promoting women's participation and diverse workstyles.
- Joined "Diversity Western-Japan Study Group\*" in 2017, using a collaborative approach to working-from-home, understanding LGBT\*\*, and unconscious bias\*\*\*

#### 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 a inclusive spirit and generate abundant ideas; and, driven by such spirit and ideas, create new value and grow with society for our collective future.**

\*Founded in 2004 by companies in Kansai area to share knowledges and experiences with each other. Now there are 48 corporation members (as of Mar. 2019)

\*\*LGBT is an acronym that stands for lesbian, gay, bisexual, and transgender

\*\*\*Learned stereotypes that are automatic, unintentional, deeply engrained, universal, and influence behavior

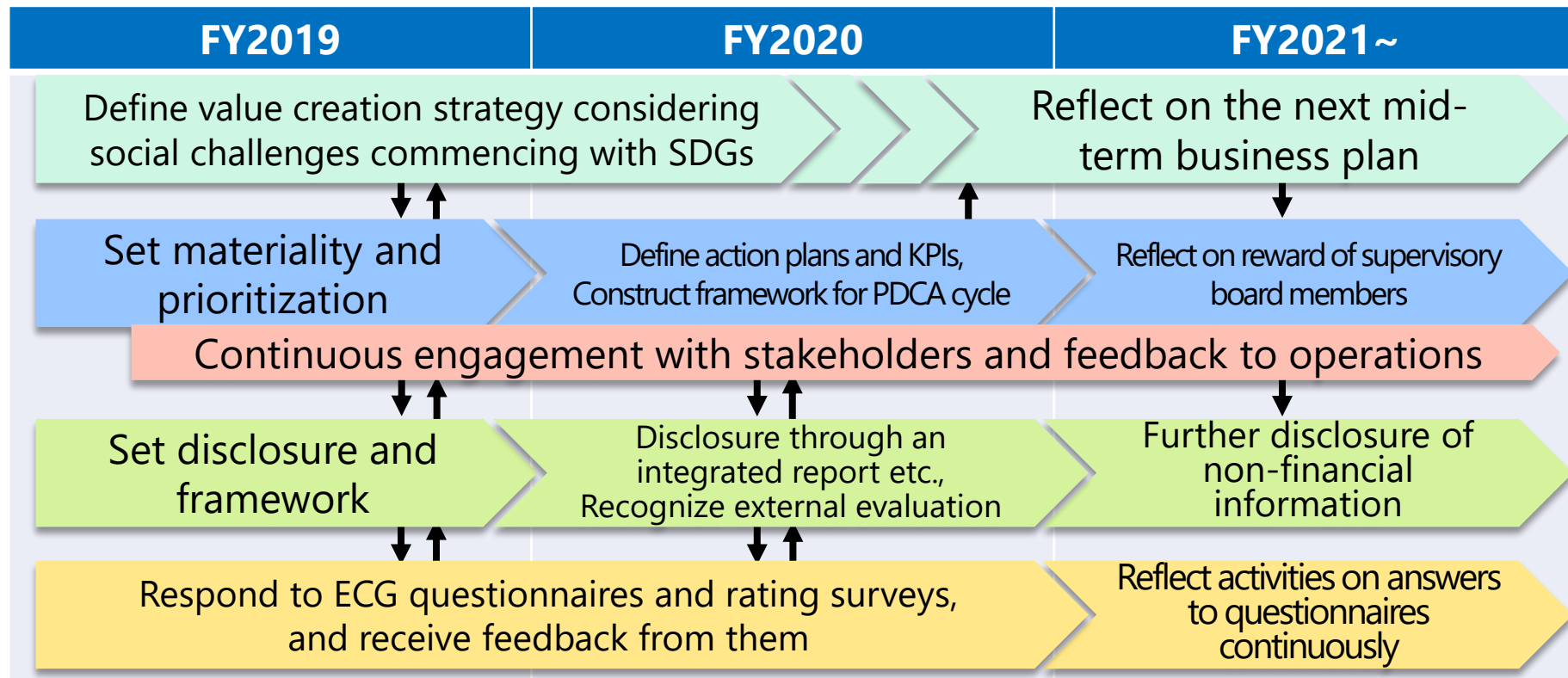
# Business Innovation



## - Promote Activities Related to ESG (Action Plans) -

**Go back to the core purpose of business, to grow sustainably with society**

**Remember that our activities are based on SDGs\*,  
and further promote activities related to ESG\*\***



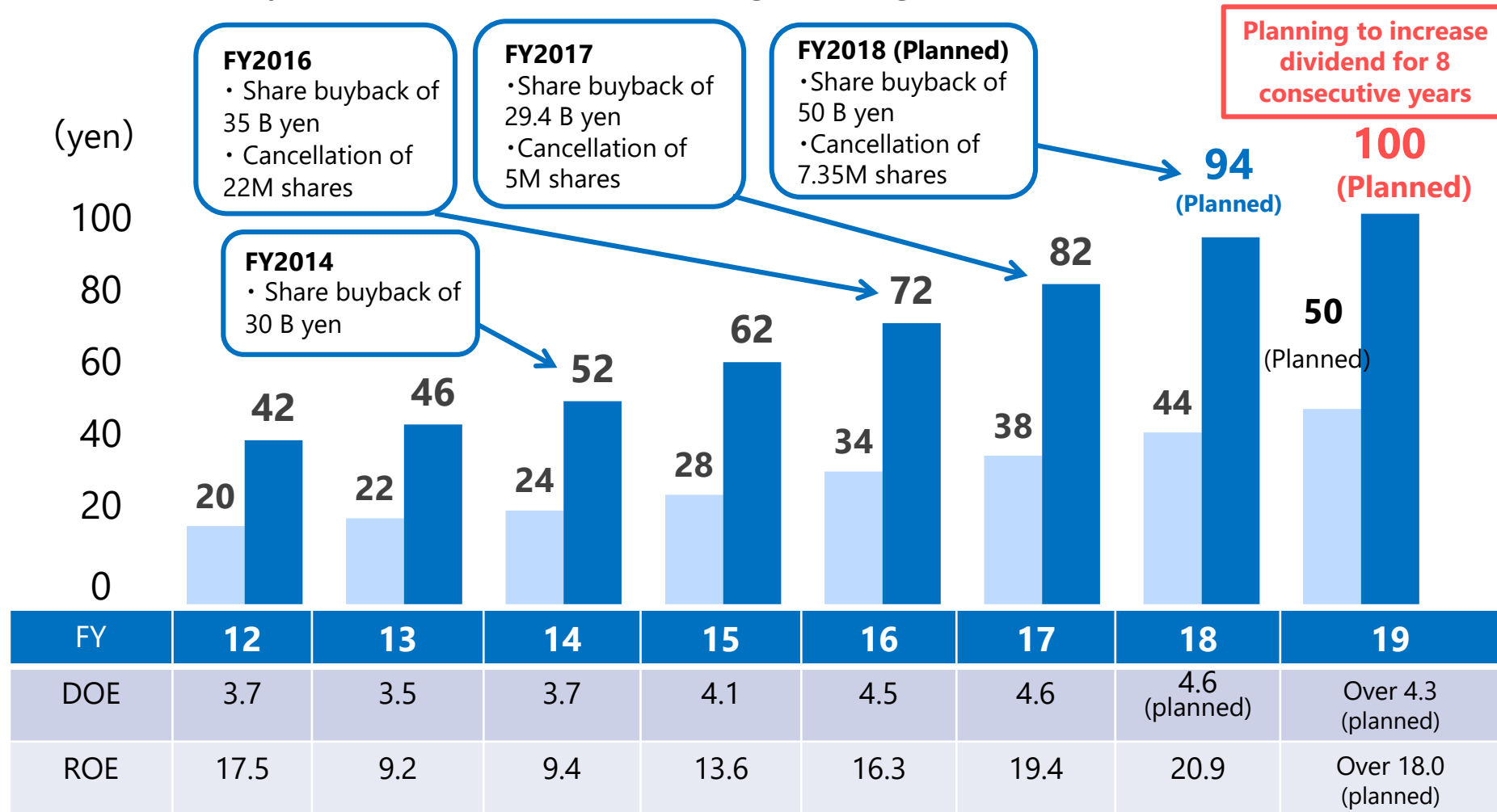
**Help to realize a sustainable society as a company which can provide corporate value and social value**

## 4. Shareholder Return

# Shareholder Return Policy Through Which Shareholders Can Feel Our Growth

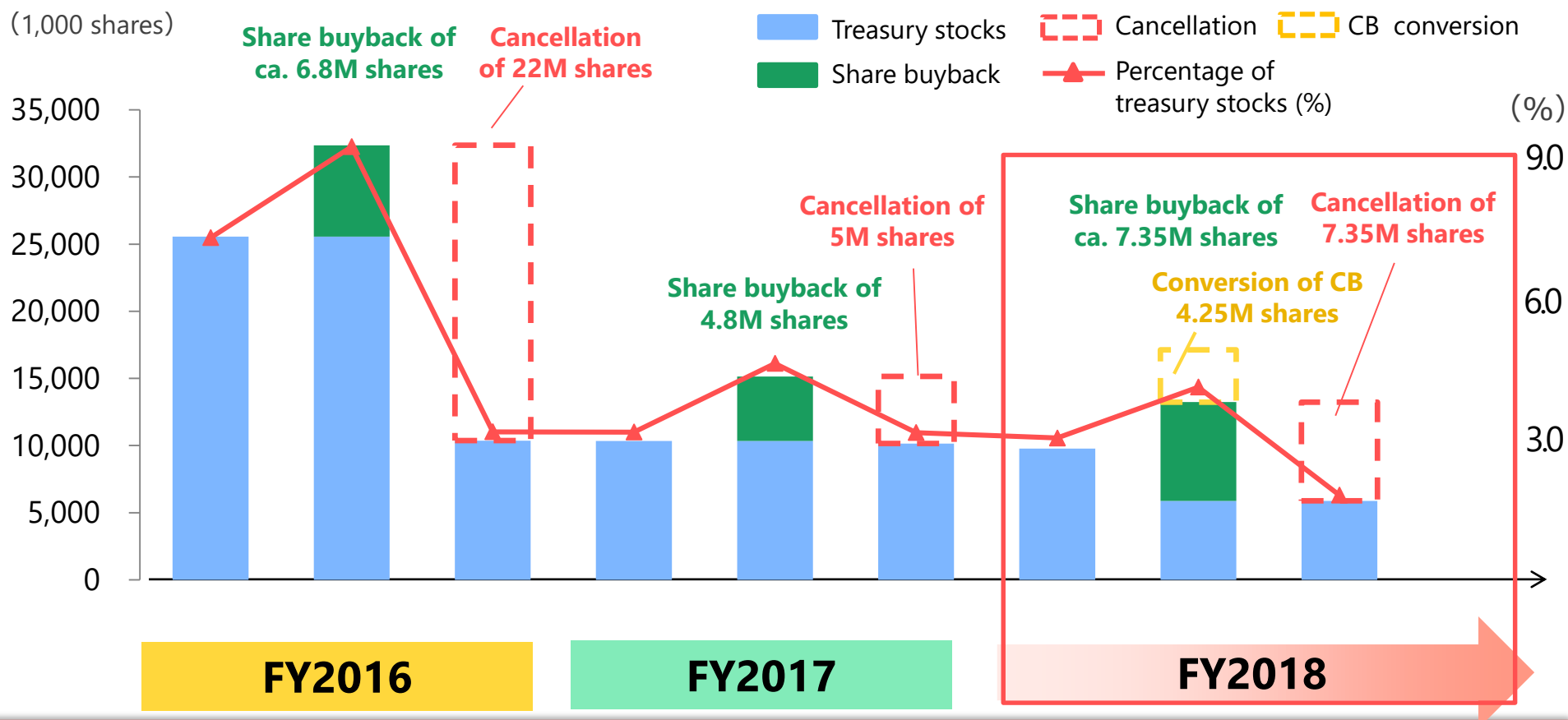


- Plan to **increase dividend for 8 consecutive years and reach 100 yen in FY2019**
- Continuously increase dividend according to our growth



# Flexible and Prompt Capital Policy

Proceed to the shareholder return policy for which shareholders can feel mid- to long-term profit growth, including buyback and cancellation shares and reducing cross-shareholdings



# **Appendix**

## **- Addressing Social Problems and Enhancing Corporate Value -**



# Addressing Social Problems and Enhancing Corporate Value



## Further focus on addressing social problems by a CSR department

~Grow sustainably contributing to a more vigorous society  
and become a company whose contribution is recognized by society~

### [Efforts by CSR department]

- Remind that our activities are based on SDGs, and select and address social problems to be solved

**Mother to Mother  
SHIONOGI Project**

**EHS\* initiatives**

**Projects for barrier-free  
communication**



**Promote proper  
use of medicine**

**Support children's  
bright future**



## Current situation in Africa

- The maternal mortality rate in Africa is 102 times\* greater than in Japan
- In Narok, the rate of pregnant women to undergo pregnancy checkup, birth rate in health clinics, and the rate of women with a low birth weight were lower than the average in Kenya\*\*

## Activities in Mother to Mother (Shionogi Project)

- A portion of the proceeds from the sales of Popon® series is donated to support the health of mothers and children in Africa.
- Contribute in an effort to reduce infant, child, and maternal mortality rate in Kenya by supporting International NGO, 'World Vision'
  - Provide basic medical services (construct health clinic, conduct regular medical examination)
  - Guidance on sanitation and education about nourishment in local communities, and educate health experts and support income-generating activities
- Proceed epidemiological study by supporting Nagasaki Univ. and International NGO, 'World Vision'
  - Contribute to health improvement in Kenya by accumulating data about public sanitation

**Support activities to improve access to medications in  
Africa in order to support maternal and child health**

**Mother  
toMother**  
SHIONOGI Project

# Efforts for proper use of medicine



## “SHIONOGI AMR\* position paper”

- **Disclosed our thoughts and efforts for AMR in “SHIONOGI position paper” globally**
  - We will continue to take a leadership role in efforts for AMR throughout R&D, proper use, and distribution of antibiotics in order to ensure that both individual patients and society as a whole will continue to benefit from effective AMR drugs.



SHIONOGI AMR position paper: <http://www.shionogi.co.jp/en/company/csr/activities/amr.html>

## Collaboration with Aichi Prefecture for proper use of narcotic analgesics

- **Business Collaboration Agreement Concerning the Prevention of Drug Abuse**
  - Raise awareness and educate the general public about the prevention of drug abuse
  - Raise awareness and educate the general public about the judicious use of drugs



**Pursuing these efforts by establishing the “Unit for Judicious Use”**

Isao Teshirogi, President and CEO of Shionogi Pharmaceutical, and Omura, Mayor of Aichi Prefecture (in photo from left to right)

Creating a more  
vigorous society

# Support for Children's Bright Future



## Create a more vigorous society for patients suffering from ADHD and CNS diseases

### Osaka

From Jan, 2017



(from left)  
Mr. Matsui, Governor of  
Osaka; Mr. Teshirogi,  
President & CEO of  
Shionogi

### Shiga

From Feb, 2018



(from left)  
Ms. Sawada, Director,  
Executive Vice President of  
Shionogi; Mr. Fujimoto,  
Manager of Department of  
Public Health Care and  
Welfare of Shiga

### Kagawa

From Mar, 2018

Sanuki city, Higashikagawa city  
Ookawa Medical Association



(from left)  
Mr. Miyazaki, President of  
Ookawa Medical Association;  
Mr. Teshirogi, President &  
CEO of Shionogi; Mr. Oyama,  
Mayor of Sanuki city; Mr.  
Fujii, Mayor of Higashikagawa  
city

### Hiroshima

From Mar, 2018



(from left)  
Mr. Yuzaki, Governor of  
Hiroshima; Mr.  
Teshirogi, President &  
CEO of Shionogi

### Iwate

From May 2018



(from left)  
Mr. Fukuda, Senior  
Executive Officer of  
Shionogi; Mr. Tasso,  
Governor of Iwate

FY2018

Established by 'Office for Children's Bright Future'  
Collaborations with other local governments are under discussion



## ◆ For elimination of communication barrier in medical institutions

- Held the CBF\* Seminar around Japan (11 times in FY2018, 3 times in FY2017)  
Voices from medical institutions: "I realized so many things I did not know or misunderstood how large the difficulties in hearing are."
- Produced a poster illustrating the flow of a barium stomach examination for people unable to hear audio instructions. (Fig. 1) The poster is used at the Kinki Kenko Kanri (health management) Center.

## ◆ For elimination of internal communication barriers

- Produce a video showing the project activities to be delivered to all employees
- Promote to utilize tools to compensate information such as a tool to transcribe speech



(Fig. 1)

**Promote this project through enlightening employees about barrier free by inviting employees willing to participate in the CBF project**



# Efforts on EHS

## SHIONOGI group EHS policy (excerpt)

In support of Shionogi's mission to supply the best possible medicine to protect the health and well-being of the patients we serve, Shionogi strives to conduct business activities in a manner that gives consideration to protection of the global environment, prevention of pollution, and support of the health and safety of our employees and the local communities in which Shionogi Group companies operate.

### Shionogi Group EHS Action Targets

1. Promote energy conservation and global warming control measures
2. Strengthen resource conservation and waste treatment/disposal measures
3. Manage chemical substances appropriately
4. Develop EHS management systems
5. Promote healthy aquatic environments
6. Contribute to biodiversity preservation
7. Eliminate accidents resulting in worktime loss
8. Initiatives covering the supply chain
9. Promote health and productivity management

### Efforts to solve social problems and enhance corporate value



Efforts for EHS (Shionogi website)

<http://www.shionogi.co.jp/en/company/csr/activities/environment.html>

Shionogi joined to the international activity, "AMR Industry Alliance", and set strict effluent standards for antibiotics at Shionogi and manufacturing subcontractor

# Company Sport: Shionogi Women's Softball Club



- 70 years since foundation
- Division 1, Japan Women's Softball League





# To Address Social Challenges



**Grow sustainably as a  
drug discovery-based  
pharmaceutical  
company contributing to  
a more vigorous society  
through improved  
healthcare**





# Appendix

- Pipeline Progress -
- Y on Y change in sales of prescription drugs in Japan -
- Definition of New Products -
- Strategic Investment -
- Recognition by External Organizations -

# Major Progress in Q4 FY2018\* (Pipeline)



Global

## Cefiderocol

- NDA/MAA submission acceptance in US/EU

## Naldemedine (Rizmoic®)

- Approval in EU

## Lusutrombopag

- Approval in EU

## Vyvanse®

- Approval in Japan

In Japan

## S-637880

- Completion of Phase I study

## S-600918

- PoC was confirmed (Refractory/unexplained chronic cough)

## S-005151

- Start of Phase II study

Out-licensed

## Xofluza™

- sNDA submission acceptance (HR patients)

## DTG/3TC

- Approval in US (naïve patients)
- Positive opinion from CHMP

## CAB+RPV

- NDA submission in US (naïve and experienced patients)

Infections disease

Pain/CNS

Frontier

# Major Progress in Q4 FY2018\* (Others)



- **February**

- Comprehensive Cooperation Agreement in the Field of Infectious Disease Focused on Malaria with Nagasaki University
- Participation in Library-Sharing Program
- Provided by CAC Croit

- **March**

- Akili and Shionogi Announce Strategic Partnership to Develop and Commercialize Digital Therapeutics in Key Asian Markets

- **April**

- Commencement of Operations of Shionogi Pharma Co., Ltd.
- Licensing of Symproic® (naldemedine) to BioDelivery Sciences International Inc.
- Licensing of Rizmoic® (naldemedine) in Germany, the UK, and the Netherlands to Sandoz

- **May**

- Capital investment and business alliance with Aillis Inc., a venture capital of AI medical equipment

# Target Milestones for FY2018 : Approvals and Submission



Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Mulpleta® (Thrombocytopenia associated with chronic liver disease)			Achieved (US, Aug.) (EU, Feb.)	US (2017.12) EU (2018.1)	US EU
Naldemedine (Rizmoic®) (Opioid-induced constipation)			Achieved (Feb.)	EU (2017.3)	EU
Lisdexamfetamine (ADHD [pediatric])			Achieved (Feb.)	Japan (2017.4)	Japan
Xofluzo™ (Influenza virus infection)		Achieved (Oct.)	Global: ongoing	US (2018.4)	US
Xofluzo™, granule (Influenza virus infection)		Achieved (Sep.)	Japan: ongoing	Japan	Japan
Cefiderocol (Complicated urinary tract infections, including pyelonephritis)			Achieved (Dec.)	Global: ongoing	US
Intuniv® (ADHD [adult])			Achieved (Aug.)	Japan: Extension study, ongoing	Japan

# Target Milestones for FY2018 : Phase I ~ III



Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Xofluza® (Influenza virus infection [prophylaxis])			Japan: initiated	Achieved (Q2)	
OxyContin® TR (Treatment of moderate to severe chronic pain)			Japan: initiated	Achieved (Q1)	
S-120083 (Inflammatory pain)		US: completed		Achieved (Q3)	
S-588410 (Bladder cancer)		Japan, EU: completed		Achieved (Q4)	
S-600918 (Refractory/unexpected chronic cough, Neuropathic pain)		Japan: initiated		Achieved (Q1) (Refractory/unexplained chronic cough)	
S-770108 (Idiopathic pulmonary fibrosis)	Japan: completed			Achieved (Q3)	
S-637880 (Neuropathic pain)	Japan: completed			Achieved (Q4)	
S-005151 (Acute ischemic stroke)	Japan: initiated			Achieved (Q1)	
S-004992 (Tuberculosis)	Asia (China): initiated				

# Pipeline (as of May 9, 2019)



Preclinical (target indication*)	Phase I	Phase II	Phase III	Submission
Influenza virus infection	<b>Global</b>  <b>S-004992**</b> Tuberculosis  <b>S-117957</b> Insomnia  <b>S-237648</b> Obesity  <b>S-588210</b> Solid tumor  <b>Rizmoic®</b> Opioid-induced constipation (pediatric)	<b>S-120083</b> Inflammatory pain  <b>S-707106</b> Type2 diabetes  <b>S-488210</b> Head and neck squamous cell carcinoma  <b>epertinib</b> Malignant tumor  <b>S-588410</b> Bladder cancer	<b>Cefiderocol</b> Multidrug-resistant Gram-negative bacterial infections	<b>Cefiderocol (US/EU)</b> Multidrug-resistant Gram-negative bacterial infections  <b>Baloxavir Marboxil (Taiwan)</b> Influenza virus infection
HIV virus infection				
<b>RS virus infection</b>				
Bacterial infection				
Mycobacterium disease				
Fungus infection				
Vaccine for prevention				
Peptide				
ADHD	<b>In Japan</b>  <b>S-812217</b> Depression  <b>S-600918</b> Neuropathic pain  <b>S-637880</b> Neuropathic pain  <b>S-010887</b> Neuropathic pain  <b>S-770108</b> Idiopathic pulmonary fibrosis	<b>Cefiderocol</b> Multidrug-resistant Gram-negative bacterial infections  <b>S-600918</b> Refractory/unexpected chronic cough  <b>S-005151</b> Acute ischemic stroke  <b>S-237648</b> Obesity  <b>S-525606</b> Allergic rhinitis caused by Japanese cedar allergen  <b>S-588410</b> Bladder cancer  <b>SR-0379</b> Cutaneous ulcer  <b>ADR-001***</b> Decompensated liver cirrhosis	<b>Cefiderocol</b> Multidrug-resistant Gram-negative bacterial infections  <b>Xofluza™</b> Influenza virus infection (prophylaxis)  <b>Xofluza™</b> Influenza virus infection (New dosage for children)  <b>Cymbalta®</b> Depression (pediatric)  <b>Oxycodone</b> Moderate to severe chronic pain  <b>S-588410</b> Esophageal cancer	<b>Oxycodone</b> Moderate to severe chronic pain  <b>Intuniv®</b> ADHD (adult)   <ul style="list-style-type: none"> <li>Infectious diseases</li> <li>Pain/CNS</li> <li>Other</li> </ul>
Opioid				
Alzheimer's disease				
Cognitive and memory deficits				
Post-stroke spasticity				
Peptide				
Obesity				
<b>S-723595</b> NASH				
Cancer metastasis				
<b>S-540956</b> Nucleic acid adjuvant				
Peptide				

# Pipeline -Out-licensed (as of May 9, 2019)









Preclinical	Phase I	Phase II	Phase III	Submission
	<b>GSK3342830</b> Multidrug-resistant Gram-negative bacterial infections		<b>DTG/3TC</b> Treatment for HIV infection TANGO study (maintenance)	<b>DTG/3TC (EU)</b> Treatment for HIV infection
			<b>CAB LAP</b> Prevention for HIV infection	<b>Xofluza™</b> Influenza virus infection (High risk patients)
			<b>Xofluza™</b> Severe influenza virus infection	<b>CAB+RPV LAP</b> Treatment for HIV infection
			<b>Xofluza™</b> Influenza virus infection (pediatric)	<ul style="list-style-type: none"> <li>• Infectious diseases</li> <li>• Pain/CNS</li> <li>• Others</li> </ul>

Stage progression (from Jan. 31, 2019)	Cefiderocol : Phase II→Submission (US), Phase III→Submission (EU) Naldemedine (Rizmoic®) :→Approved (EU) Lustrombopag: Submission→Approved (EU) Lisdexamfetamine: Submission→Approved (Japan) S-005151: Phase I→Phase II (Japan) Xofluza™: Phase III (high risk patients)→sNDA (US) DTG/3TC: Submission→Approved (US) CAB+RPV: Phase III→Submission (US)
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# Target Milestones for FY2019 : Approval and Submission




Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Lisdexamfetamine (ADHD(pediatric))				Japan(2017.4) 	Japan
Intuniv® (ADHD(adult ))				Japan(2018.8) 	Japan
Cefiderocol ((US: Complicated urinary tract infections, including pyelonephritis, EU: Multidrug-resistant Gram-negative bacterial infections)			Global: CR study completion Global: HAP/VAP/HCAP study completion	US(2018.12) EU(2019.3) 	US EU
Xofluza® (Influenza virus infection) ①granule (weight under 20kg) ②granule (new dosage for children (weight under 20kg)) ③prophylaxis			Japan : High-dose study for children completion Prophylaxis study completion	①Japan(2018.8)  ②Japan ③Japan 	①Japan
OxyContin®TR (Treatment of moderate to severe chronic pain)			Japan : completion	 Japan	





# Target Milestones for FY2019 : Phase I~III



Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
S-812217 (Depression)	Japan: Single and multiple dose study completion		 Japan: initiate		
Rizmoic®/Naldemedine (Opioid-induced constipation(pediatric))	EU: Phase I/II study Initiate				
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			
SR-0379 Skin ulcers(Pressure ulcers, diabetic ulcers, etc))		Japan: POC study completion			
S-770108 (Idiopathic Pulmonary Fibrosis)	UK: Lung deposition study initiate				



# Target Milestones for FY2019 : Phase I~III



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

# Target Milestones for Launch of Products



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

# Japanese Business: Driving Sales Growth by Our Own Earning Power



(Unit: B yen))

Prescription Drugs in Japan	2H FY2017 Results	2H FY2018 Results	Y on Y comparison
New products (including strategic products)	27.7	51.2	<b>+23.5</b>
Crestor®, Irbetan® franchise	14.1	7.0	<b>(7.1)</b>
Others	24.2	20.5	<b>(3.7)</b>
<b>Total</b>	<b>66.0</b>	<b>78.7</b>	<b>+12.7</b>

# Definition of New Products (in Updates to SGS2020 )



## Pain/ CNS

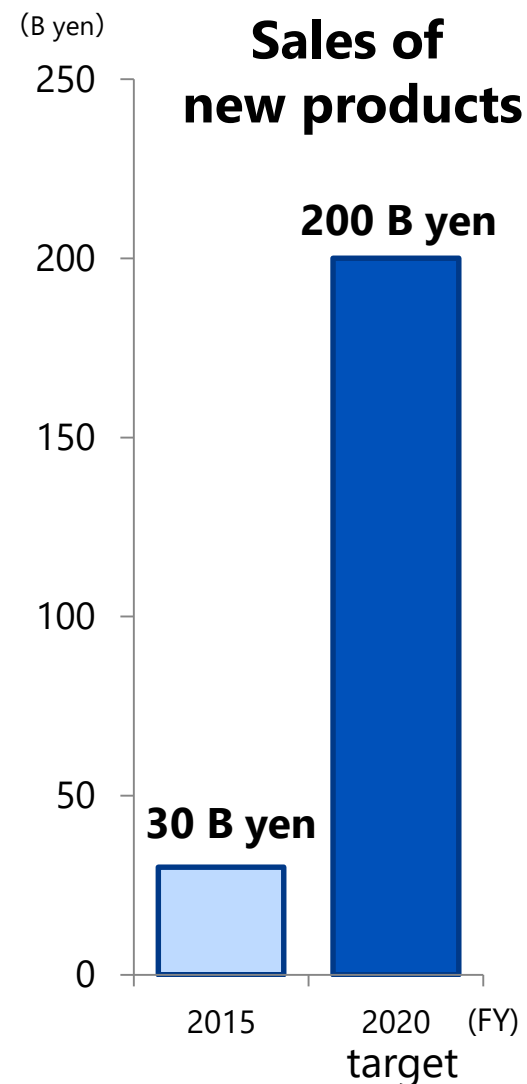
- Cymbalta<sup>®</sup>
- OxyContin<sup>®</sup> tamper resistant formulation, OxiNorm<sup>®</sup>, OxiFast<sup>®</sup>
- Naldemedine\*
- Intuniv<sup>®</sup>, Vyvanse<sup>®</sup>

## Infectious diseases

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

## Others

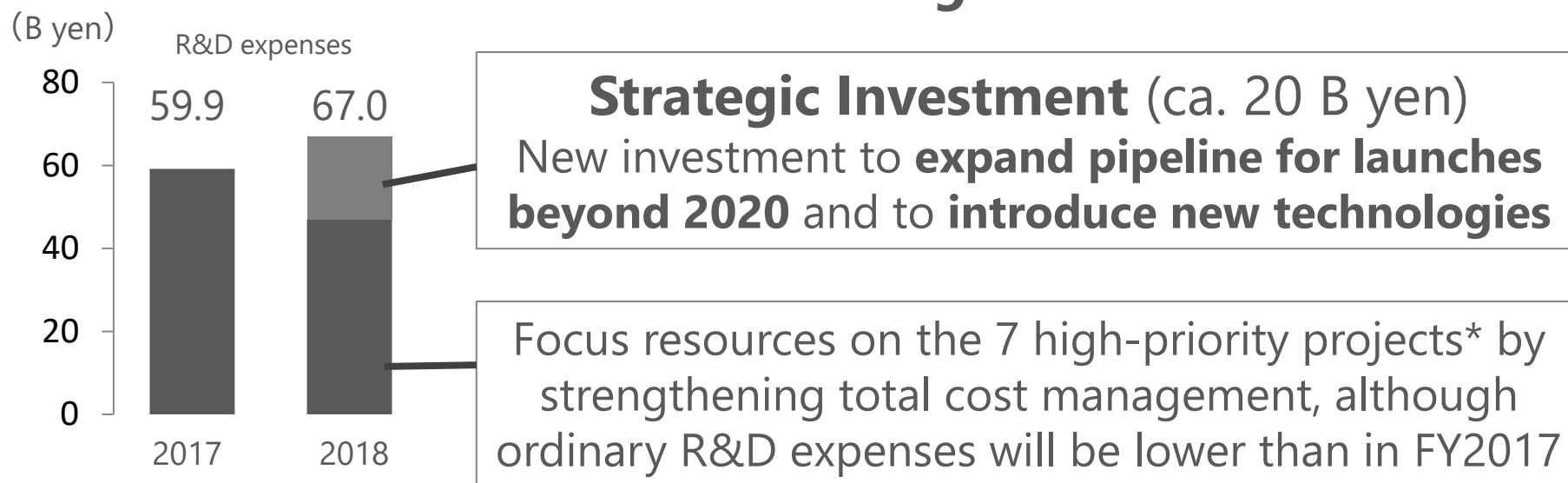
- Pirespa<sup>®</sup>
- Mulpleta<sup>®</sup>
- Actair<sup>®</sup>
- Glashvista<sup>®</sup>
- Osphena<sup>®</sup> (Senshio<sup>®</sup>)



Development of Xofluza™ is in its final stage

Favorable opportunity to invest in other growth drivers

## New investment to expand pipeline for sustainable growth

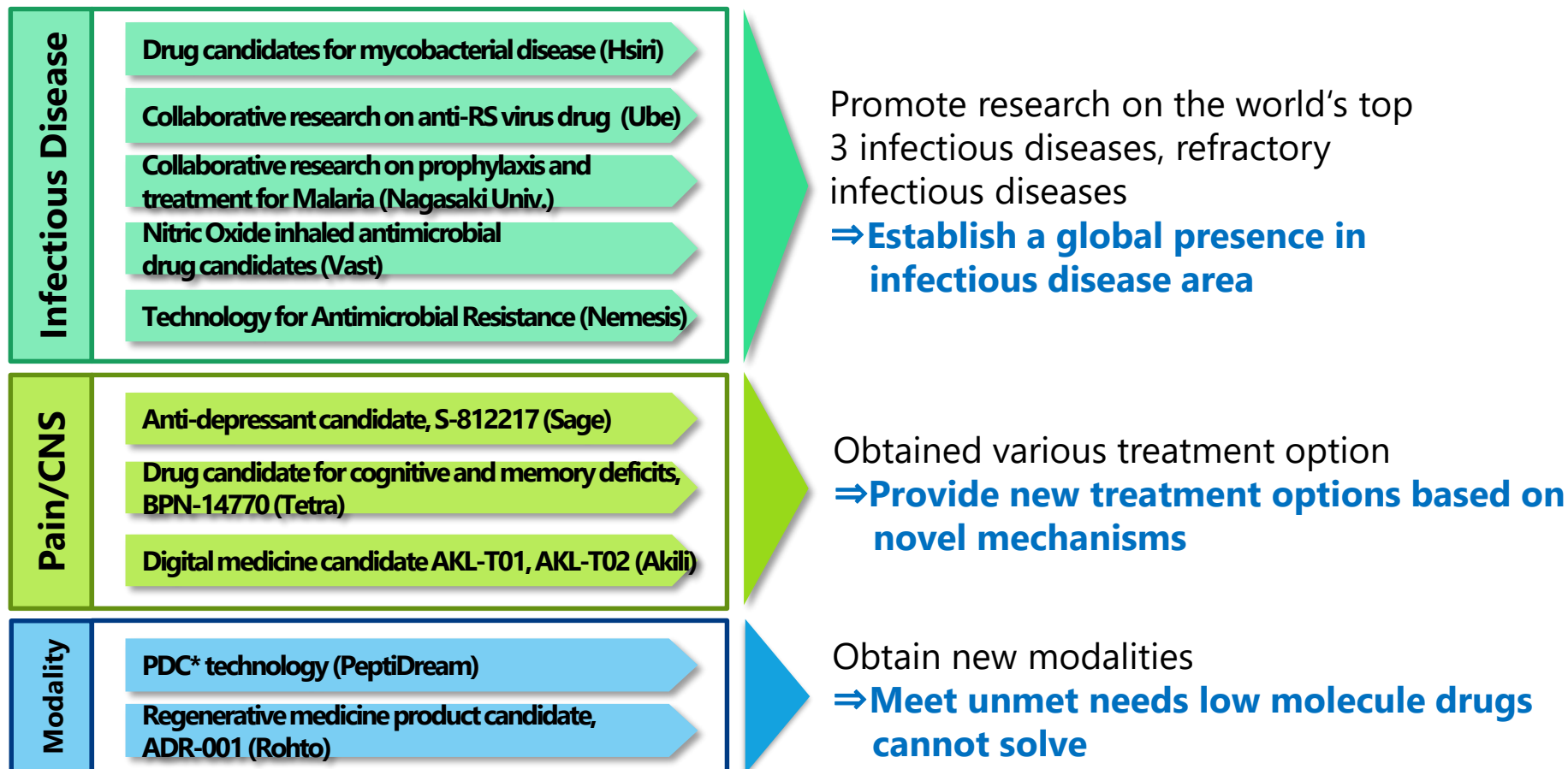


## Strategic investment (ca. 20 B yen) in R&D is planned for sustainable growth

# Strategic Investment in FY2018



## Obtained pipeline and new technology through strategic investment



## Collaborated with 10 new partners for beyond 2020

# Recognition by External Organizations (FY2018)



ディスクロージャー  
2018年度 優良企業



SAAJ 公益社団法人  
日本証券アナリスト協会  
The Securities Analysts Association of Japan

ディスクロージャー優良企業選定  
(医薬品部門1位)

**Grow  
sustainably  
with society**





# 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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