

# **FY 2016 Financial Results**

# (April 2016 – March 2017)

May 11, 2017 Isao Teshirogi, Ph. D. President and CEO







- 1. Overview of FY2016 Financial Results
- 2. FY2017 Financial Forecasts
- 3. FY2017 Business Plan
- 4. Shareholder Return



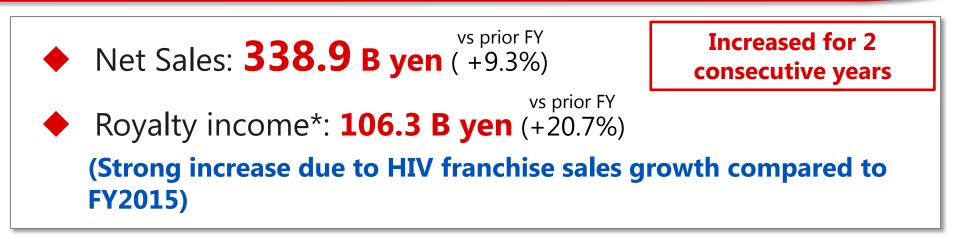


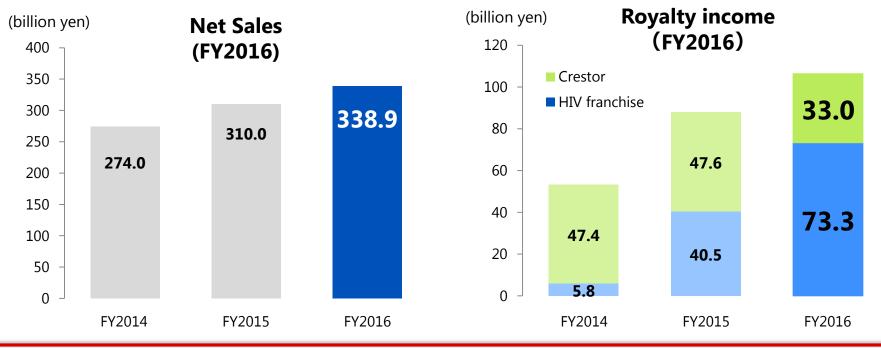
# 1. Overview of FY2016 Financial Results



# **Highlight (1) : Constant Top-line Growth**



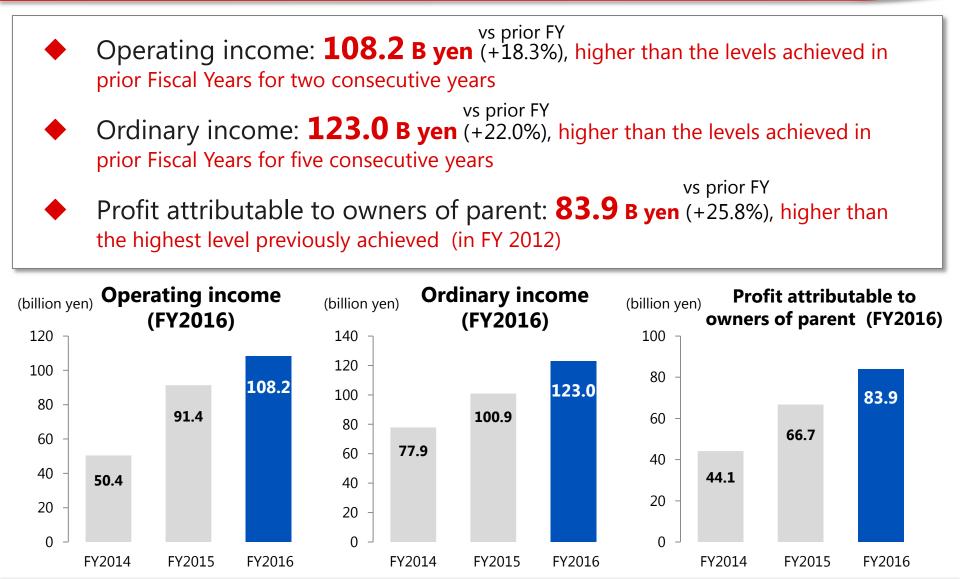




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\* Royalty income from Astra Zeneca (Crestor) and ViiV (HIV franchise) 4

#### Highlight (2) : All Income and Profit Measures Higher Than the Levels Achieved in FY2016





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# Highlight (3) : KPIs - Results in FY2016

vs prior FY

- Sales of new products\*: 43.9 B yen, +11.7% (200 B yen)
  - Ordinary Income: 123.0 B yen (150 B yen)
  - **ROIC\*\*: 13.3%** (Over 13.5%)
  - CCC\*\*\*: 6.7 months (5.5 months)
  - Original pipeline ratio: 68.2% (Over 50%)

Shareholder return

Efficiency

Growth

- ROE: 16.3% (Over 15%)
- DOE: 4.5% (Over 4.0%)

Inside of ( ) are 2020 target



# **Financial Results (Consolidated)**

(billion yen)

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	FY2016			FY2015	YonY
	Forecasts	Results	Achievement (%)	Results	change (%)
Sales	334.0	338.9	101.5%	310.0	9.3%
Operating income	97.5	108.2	111.0%	91.4	18.3%
Ordinary income	105.5	123.0	116.6%	100.9	22.0%
Profit attributable to owners of parent	76.0	83.9	110.4%	66.7	25.8%

#### Improved the accuracy of budgets

	FY2013	FY2014	FY2015	FY2016	Exchange rate (average)	FY2016 forecasts	FY2016 results
Acheivement of annual budget	<b>*</b>	Ø	Ø	O	USD (\$) – JPY (¥)	105 105	108.39
<ul> <li>Reached our budget goal for sales &amp; profit</li> <li>Reached our goal for either sales or profit</li> </ul>					GBP (£) – JPY (¥)	140	141.62
*FY2013: Profit a was not achieve	-		· · · · · · · · · · · · · · · · · · ·		EUR (€) – JPY(¥)	120	118.80



# Sales by Segments (Consolidated)

			_	(1	oillion yen)	V on V comparison
	FY2016 Forecasts	FY2016 Results	Achieve ment (%)	FY2015 Results	Y on Y Change (%)	<ul> <li>Y on Y comparison</li> <li>Prescription drugs</li> </ul>
Prescription drugs	160.2	158.0	98.6	162.1	(2.5)	<ul> <li>Decreased sales due to NHI drug price reduction and the transfer of marketing rights for 24 long-</li> </ul>
Crestor®	42.9	43.1	100.5	43.7	(1.4)	listed drugs
Cymbalta®	19.3	19.0	98.6	15.2	25.0	Growth of strategic products: Increase of the
Irbetan <sup>®</sup> franchise	15.8	15.3	96.9	15.7	(2.6)	percentage of 7 strategic products sales
Total of 3 key products	77.9	77.4	99.3	74.6	3.7	<ul> <li>Crestor<sup>®</sup>: Launched OD tablets</li> </ul>
OxyContin <sup>®</sup> franchise	9.9	9.7	97.7	10.0	(3.7)	Increased prescriptions
Finibax <sup>®</sup>	3.6	3.3	90.9	3.8	(12.8)	– Cymbalta <sup>®</sup> :
Pirespa <sup>®</sup>	6.0	5.8	97.3	6.0	(2.6)	<ul> <li>Expanded sales in depression and depressive</li> </ul>
Rapiacta®	2.3	2.9	123.9	2.0	41.4	symptoms
Total of 7 strategic products	99.8	99.1	99.3	96.5	2.7	Increased awareness in pain area
[percentage of sales]	62.3%	62.7%		59.5%		(Focused resources on maximizing the product value)
Overseas subsidiaries/export	24.8	29.2	117.8	29.7	(1.7)	Overseas subsidiaries/export
Shionogi Inc.	13.6	17.9	131.1	16.6	7.4	Shionogi Inc.
Osphena®	4.8	4.7	98.8	4.8	(2.1)	<ul> <li>Continued increase in Osphena<sup>®</sup> prescriptions</li> </ul>
Contract manufacturing	12.4	12.1	97.8	8.4	43.4	<ul> <li>Increase in royalty income from authorized generic</li> </ul>
OTC and quasi-drugs	7.0	6.8	96.7	4.9	39.5	
Royalty income	112.3	115.7	103.0	101.8	13.6	Royalty income
Royalty income for the sales of Crestor <sup>®</sup> and HIV franchise	103.0	106.3	103.2	88.1	20.7	HIV franchise: Continues to increase
Crestor®	32.8	33.0	100.8	47.6	(30.6)	Others
HIV franchise	70.2	73.3	104.4	40.5	81.1	
Others	17.2	17.1	99.1	3.0	469.7	Upfront payments for transferring the marketing
Total	334.0	338.9	101.5	310.0	9.3	rights for long-listed drugs



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# **Statements of Income (Consolidated)**

			_	(bil	lion yen)	Y on Y comparison
	FY2016 Forecasts	FY2016 Results	Achieve ment (%)	FY2015 Results	Y on Y change (%)	Cost of sales
Sales	334.0	338.9	101.5	310.0	9.3	Cost of sales ratio: Improved
[Royalty <sup>*</sup> income]	103.0	106.3	103.2	88.1	20.7	<ul> <li>Increase in sales of Cymbalta<sup>®</sup></li> <li>Cost reduction</li> </ul>
	23.4 [33.8]	23.0 [33.4]		24.1 [33.7]		<ul> <li>Increase in royalty income</li> </ul>
Cost of sales	78.0		99.7	74.8	4.0	<ul> <li>Upfront payments for transferring the marketing rights for long-listed drugs</li> </ul>
	47.5	45.1		46.4	6.0	
SG&A expenses	158.5	152.9	96.5	143.8	6.3	SG&A expenses
Selling & general expenses	<sup>29.3</sup> 98.0	<sup>27.5</sup> 93.0	94.9	<sup>30.3</sup> 94.0	(1.1)	Total cost management
R&D expenses	<sup>18.1</sup> 60.5	<sup>17.7</sup> 59.9	99.0	<sup>16.1</sup> 49.8	20.3	<ul> <li>Increase in R&amp;D expenses including investments for growth drivers such as</li> </ul>
Rad expenses	29.2	31.9		29.5		S-033188 (+20.3% vs prior FY)
Operating income	97.5	108.2	111.0	91.4	18.3	- Tight control of total costs (+6.3% vs
[Excluding royalty* income]	(5.5)	1.9	-	3.3	-	prior FY)
Non-operating income & expenses	P8.0	P14.9	185.7	P9.5	57.0	<b>Non-operating income and expenses</b> Dividends from ViiV
Ordinary in come	31.6	36.3		32.5		(+6.8 B yen vs prior FY)
Ordinary income	105.5	123.0	116.6	100.9	22.0	- Received interim dividend in addition to
						annual dividend



Note : The inside of [ ]is percentage [cost of sales]/ [sales excluding royalty income] \* Royalty income from Astra Zeneca (Crestor<sup>®</sup>) and ViiV (HIV franchise)

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# Key Actions in 2H FY2016 – towards FY2017 (1)



### Investments for growth drivers

- Accelerated the global development of S-033188: Additional R&D cost, added into the 2H revised budget, was invested in S-033188 as the first priority
- Focused investment in Intuniv<sup>®</sup> (Japan) and cefiderocol (global) highly prioritized development projects, as they are key future growth drivers

# Developing infrastructure for improving productivity

- Japan
  - > Focused on new products: Divested 24 long-listed drugs as "first mover" in the market
  - > Established six Shionogi group companies in Japan: Improving productivity and meeting societal requirements (e.g. extension of employment period, etc.)
- US
  - > Strategic alliances with Purdue Pharma L.P. and Duchesnay Inc.



- Achieved increased sales and profits exceeding original plan
- Invested in new products for sustained growth in FY2017 and beyond



### Key Actions in 2H FY2016 – towards FY2017 (2)

# Extraordinary income and loss

- Gain on sales of investment securities
  - > Cancellation of stock cross-holdings
- Business structure improvement expenses
  - > Special severance payment, etc. (US)
- Loss on impairment (Settsu Plant)
- Total income taxes, etc.
  - Reversal of deferred tax assets (US)
    - X Conservatively re-examined expected earnings given the business model change associated with new alliances with Purdue Pharma L.P. and Duchesnay Inc.

# Actions to achieve positive operating income in US business

- Strengthen the business base by maximizing the value of Symproic<sup>®</sup> and Osphena<sup>®</sup> with less management resources through strategic alliances
  - > Partnering with Purdue Pharma L.P., a leading company in the pain treatment market in US
  - Partnering with Duchesnay Inc., a specialty pharmaceutical company with a long-standing commitment to women's health
- Aim at high-productive business operation launching Shionogi-discovered products into hospital/highly-specialized markets





+2.2 B yen

(2.2 B yen)

(0.4 B yen)

(10.3 B yen)

# Achievements on Business Challenge in FY2016 (1)



### Strengthen and enhance Japanese business

- Cymbalta<sup>®</sup> and Crestor<sup>®</sup>
  - Sales expansion of strategic products due to additional indications of Cymbalta<sup>®</sup> and launch of Crestor<sup>®</sup> OD tablets, etc.

#### Drugs for ADHD

- Intuniv<sup>®</sup>: NDA approval for pediatric use

#### Oxycodone/Symproic<sup>®</sup>

- Oxycodone temper resistant formulation: NDA submission
- Additional indications of Oxycodone for chronic pain : NDA submission
- Symproic<sup>®</sup>: NDA approval for OIC

### Strengthen and enhance overseas business

- Strengthen the business base in US
  - Strategic alliances for maximizing product value
    - Symproic<sup>®</sup> (Purdue Pharma L.P.), and Osphena<sup>®</sup> (Duchesnay Inc.)

#### Innovative changes to grow business in China

- Transforming C&O Pharmaceutical Technology (Holdings) Limited to be more competitive on quality and price in emerging markets



# Achievements on Business Challenge in FY2016 (2)



# **Accelerating global development**

- S-033188
  - Dosing for all patients completed on track in OwH\* study
  - HR\*\* study is going as planned

### Cefiderocol

- Preparation for NDA submission in US; CR\*\*\* study and HAP/VAP study started

#### Naldemedine

- NDA approval in US (Symproic<sup>®</sup>); NDA submission in EU

### **Cost management**

#### Total cost management

- Tightly controlled selling & general expenses
- Allocate budgets for development of S-033188 as the first priority and cefiderocol as a growth driver
- Established six group companies in Japan for improving productivity of the Shionogi group through better business operations
- Developed expertise and human resources (talent) for conducting business functions efficiently



# **Target Milestones for FY2016**



Areas	Product	As of Apr. 1, 2016	Target fo	r FY2016		
Infectious	<b>Cefiderocol</b> Multidrug-resistant Gram-negative bacterial infections	Global: Phase II, III	US: NDA submission in preparation	US: Phase III (HAP/VAP) initiated		
disease	<b>S-033188</b> Influenza virus infection	Japan: Phase II US: Phase I	Japan: Phase II completed Global: Phase III initiated, Japa	US: Phase I completed n: Phase III (pediatric) initiated		
			•			
	<b>Guanfacine</b> ADHD (pediatric)	Japan: NDA submission	Japan: A	pproval		
	<b>Cymbalta</b> <sup>®</sup> Pain associated with osteoarthritis	Japan: NDA submission	Japan: A	pproval		
Pain/CNS	Naldemedine Opioid-induced constipation	Japan/US: NDA submission	Japan/US: Approval	EU: NDA submission		
	Oxycodone Treatment of moderate to severe chronic pain	Japan: Phase III	Japan: NDA submission			
	<b>Oxycodone</b> Tamper resistant formulation	Japan: Phase I completed	Japan: NDA submission			
	<b>Lisdexamfetamine</b> ADHD (pediatric)	Japan: Phase III	Japan: Phase	III completed		
Metabolic disorder	<b>S-237648</b> Obesity	Japan: Phase II	Japan: Phase II completed	US: Phase I initiated		
Frontier	Lusutrombopag Thrombocytopenia associated with chronic liver disease	Global: Phase III	Global: I	Phase III		
Frontier	S-222611 Malignant tumor	EU: Phase I/II	EU: Phase I/I	I completed		



Red frame: Change since Feb. 1 2016 HAP: Hospital Acquired Pneumonia ADHD: Attention deficit hyperactivity disorder VAP: Ventilator Associated Pneumonia

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# Remaining Key Actions for Achieving SGS2020

#### SONG for you!

# Japanese business

 Promoting new products optimally, including Cymbalta<sup>®</sup>, Mulpleta<sup>®</sup> and Actair<sup>®</sup>

### Overseas business

 Contribute to the sales and profits of the Shionogi Group by strengthening businesses in the biggest market (US) and emerging market (China)

# Productivity

 Improving operating income, excluding royalty income, per employee

# Promptly maximizing the value of new products





# 2. FY2017 Financial Forecasts



# **Financial Forecasts (Consolidated)**

(billion yen)

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	FY2017 fo	orecasts	FY2016	Yon	Y
	full year	1H	Results	change (%)	change
Sales	340.0	162.5	338.9	0.3	1.1
Operating income	112.5	46.0	108.2	4.0	4.3
Ordinary income	123.5	51.5	123.0	0.4	0.5
Profit attributable to owners of parent	92.0	38.5	83.9	9.7	8.1

Exchange rate (average)	FY2017 forecasts	FY2016 results
USD (\$) – JPY (¥)	110.0	108.39
GBP (£) – JPY (¥)	140.0	141.62
EUR (€) – JPY(¥)	120.0	118.80



# Sales by Segments (Consolidated)

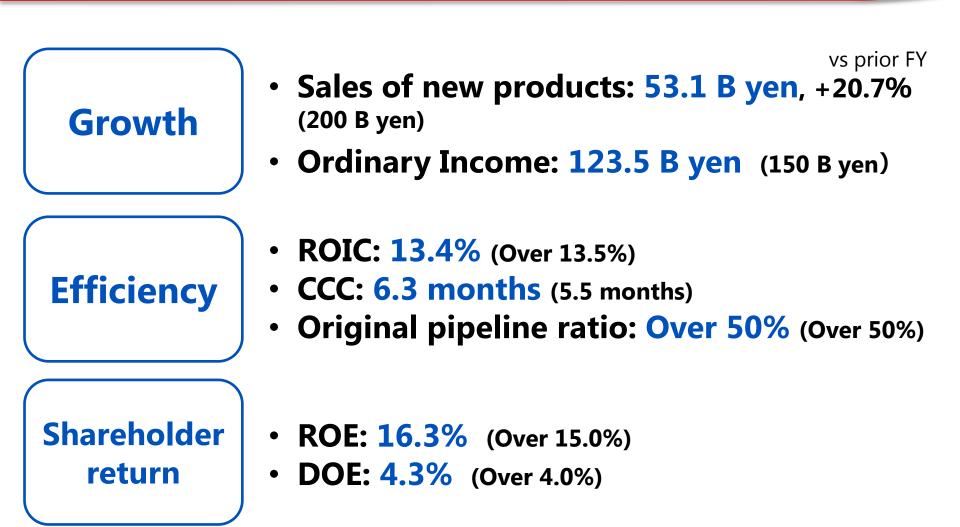
(billion yen)

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	FY2017 f	orecasts	FY2016	Yon	ſΥ
	full year	1H	Results	change (%)	change
Prescription drugs	143.9	75.2	158.0	(8.9)	(14.1)
Overseas subsidiaries/export	25.4	12.3	29.2	(13.1)	(3.8)
Shionogi Inc.	12.0	6.0	17.9	(32.8)	(5.9)
Osphena®	4.6	2.2	4.7	(3.1)	(0.1)
Contract manufacturing	15.3	7.9	12.1	26.1	3.2
OTC and quasi-drugs	7.5	3.4	6.8	10.6	0.7
Royalty income	145.0	62.3	115.7	25.4	29.4
Royalty income for the sales of Crestor <sup>®</sup> and HIV franchise	125.0	56.4	106.3	17.6	18.7
Crestor <sup>®</sup>	22.0	11.0	33.0	(33.4)	(11.0)
HIV franchise	103.0	45.4	73.3	40.5	29.7
Others	2.9	1.4	17.1	(83.1)	(14.2)
Total	340.0	162.5	338.9	0.3	1.1



# KPIs - Target for FY2017 -



Inside of ( ) are 2020 target



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# 3. FY2017 Business Plan



# Shionogi's Business Environment Change in FY2017



# Sales in Japan

- Launches of generic versions of Crestor<sup>®</sup> and Irbetan<sup>®</sup>
- Some reduction in sales since the marketing rights for long-listed drugs have been transferred

# Cost of sales

No immediate advantage from reduction in sales of long-listed drugs

# Royalty income

Reduced royalty income from Crestor<sup>®</sup> from AstraZeneca

# Total Cost

Increase in pre-launch and marketing costs related to launch of multiple new products



# **Basic Strategy in FY2017**



#### **Basic strategy in FY2017**

- While flexibly responding to a challenging business environment, achieve revenue and profit targets by *strengthening and enhancing the growth trajectory of new products*
- Continue to make strong progress in global R&D to advance new growth drivers and maintain sustainable growth

### **Qualitative objectives**

- Increase sales and profit
  - Organization-wide collaboration on marketing activities
  - Leveraging alliances
- Clear priorities and focused resourcing
  - Focus management resources to support key growth drivers

# FY2017: Taking the next step to achieve Updated SGS2020



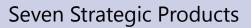
# Changed Definition of Strategic Products in Japan



#### **Previous strategic products**

Three highest priority Strategic Products

- Crestor<sup>®</sup>
- Cymbalta<sup>®</sup>
- Irbetan<sup>®</sup> franchise



- Three highest priority Strategic Products
- OxyContin<sup>®</sup> franchise, Finibax<sup>®</sup>, Pirespa<sup>®</sup>, and Rapiacta<sup>®</sup>



New strategic products							
Strategic products	New products						
<ul> <li>Cymbalta<sup>®</sup></li> <li>Intuniv<sup>®</sup></li> <li>Symproic<sup>®</sup>, oxycodone tamper resistant formulation, and oxycodone for chronic pain</li> </ul>	<ul> <li>Strategic Products</li> <li>Actair<sup>®</sup>, Mulpleta<sup>®</sup>, Pirespa<sup>®</sup>, OxyContin<sup>®</sup> franchise, Rapiacta<sup>®</sup>, Brightpoc<sup>®</sup> Flu, and Glashvista<sup>®</sup></li> </ul>						

# Revised the list of strategic products designated to receive preferential investment given changes in new product line-up



# **Challenges and Actions in FY2017**



#### **Responding to changes in our business environment**

	Challenges	Actions
Sales	Japan • Launch of generic drugs • Reduced sales due to transfer of marketing rights	<ul> <li>Japan: Growth led by Cymbalta<sup>®</sup>'s additional indications in the pain area, Intuniv<sup>®</sup>, Symproic<sup>®</sup>, and oxycodone tamper resistant formulation</li> <li>US: Maximizing the value of Symproic<sup>®</sup> and Osphena<sup>®</sup> through smooth transition into strategic alliances</li> </ul>
Royalty income	• Decreasing royalty income of Crestor®	<ul> <li>Increasing royalty income due to expanding global sales of HIV franchise</li> </ul>
Total cost	<ul> <li>Increasing costs due to launch of new products</li> </ul>	<ul> <li>Improving productivity based on total cost management including R&amp;D expenses, cost of sales, etc.</li> </ul>



# **Continued revenue and profit growth in FY2017**



# **Statements of Income (Consolidated)**

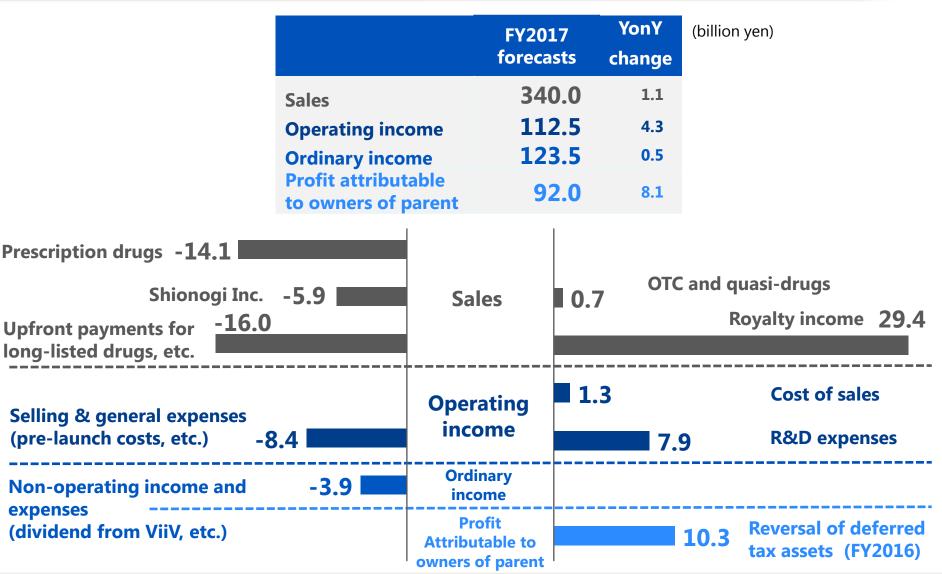
	FY2017	forecast	FY2016	Y on	Y	(billion yen)
	Full year	1H	Result	change(%)	change	
Sales	340.0	162.5	338.9	0.3	1.1	
[Royalty <sup>*</sup> income]	125.0	56.0	106.3	17.6	18.7	
Cost of sales	22.5 [35.6]	24.9 [38.0]	23.0 [33.4]			
Cost of sales	76.5	40.5	77.8	(1.6)	(1.3)	
Gross profit	263.5	122.0	261.1	0.9	2.4	
	44.4	46.8	45.1			
SG&A expenses	151.0	76.0	152.9	(1.3)	(1.9)	
Selling & general expenses	99.0	48.5	93.0	6.4	6.0	
R&D expenses	52.0	27.5	59.9	(13.2)	(7.9)	
	33.1	28.3	31.9			
Operating income	112.5	46.0	108.2	4.0	4.3	
[Excluding royalty <sup>*</sup> income]	(12.5)	(10.0)	1.9	-	(14.4)	
Non-operating income & expenses	P11.0	P5.5	P14.9	(25.9)	(3.9)	
	36.3	31.7	36.3			
Ordinary income	123.5	51.5	123.0	0.4	0.5	
Profit attributable to owners of parent	92.0	38.5	83.9	9.7	8.1	



Note : The inside of [ ]is percentage of cost of sales to sales excluding royalty income \* Royalty income from Astra Zeneca (Crestor) and Viiv (HIV franchise)

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# Details of Revenue and Profit Growth in FY2017 (Main Variation Factors)





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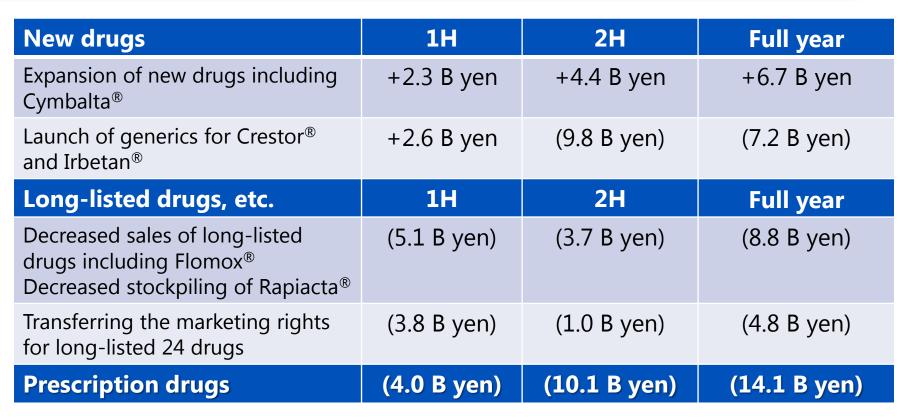
### Sales Forecasts for Prescription Drugs in Japan



	FY2017 f	orecast	FY2016	Y on	Y	(billior
	Full year	1H	Results	change (%)	change	
Cymbalta <sup>®</sup>	25.3	11.1	19.0	33.2	6.3	
Intuniv <sup>®</sup>	0.6	0.3	0	-	0.6	
Symproic <sup>®</sup>	0.4	0.1	0	-	0.4	
<b>Total of Strategic Products</b>	26.3	11.5	19.0	38.4	7.3	
Actair <sup>®</sup>	0.1	0.0	0.1	66.8	0.1	-
Mulpleta <sup>®</sup>	0.2	0.1	0.1	32.1	0	
Pirespa <sup>®</sup>	6.0	3.1	5.8	2.1	0.1	
OxyContin <sup>®</sup> franchise	8.9	4.6	9.7	(8.2)	(0.8)	
Rapiacta <sup>®</sup>	2.8	0.1	2.9	(3.4)	(0.1)	
Brightpoc <sup>®</sup> Flu	0.9	0.1	1.0	(5.9)	(0.1)	
Glashvista®	0.7	0.3	0.6	24.8	0.1	
<b>Total of New Products</b>	45.8	19.9	39.1	17.1	6.7	
Crestor®	36.4	24.7	43.1	(15.6)	(6.7)	
Irbetan <sup>®</sup> franchise	14.8	7.6	15.3	(3.1)	(0.5)	
Others	46.9	23.0	60.5	(22.5)	(13.6)	
Prescription drugs	143.9	75.2	158.0	(8.9)	(14.1)	



# Main Variation Factors in Sales of Prescription Drugs in Japan



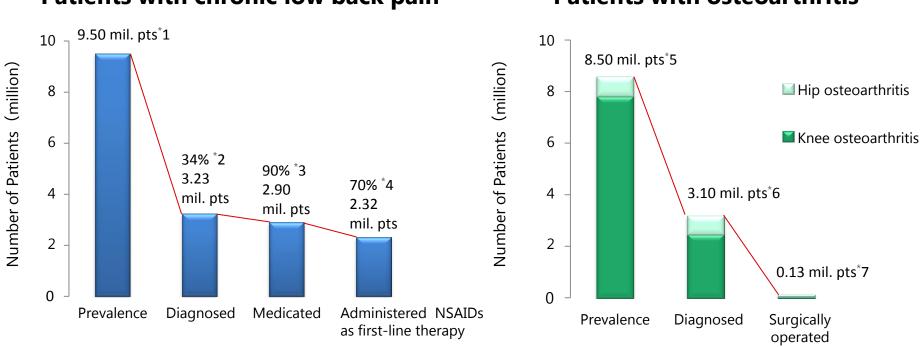
- Decreased sales of Crestor<sup>®</sup> and Irbetan<sup>®</sup> due to the launch of generic drugs will be compensated for through growth of new drugs including Cymbalta<sup>®</sup>, Intuniv<sup>®</sup>, Symproic<sup>®</sup>, etc.
- Focusing on new drugs without depending on the long-listed drugs



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# **Growth of New Products (1) : Cymbalta®**

#### Market potential in chronic low back pain and osteoarthritis



Patients with chronic low back pain

#### Patients with osteoarthritis

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**Expand the share of Cymbalta<sup>®</sup> in the existing market Increase the number of patients visiting healthcare providers** 

### for diagnosis or treatment

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\*1 Epi data \*2 Report on national survey regarding chronic low back pain 2003 (S. Fukuhara, et al.) \*3 In-house data \*4 Tracking research (conducted on Dec., 2015) \*5 ROAD Study N. Yoshimura. et al; J Bone Miner Metab (2009) 27:620-628 29 \*6 In-house data \*7 YANO Research; kansetsu-life HP



# **Maximizing the Value of Cymbalta**<sup>®</sup>

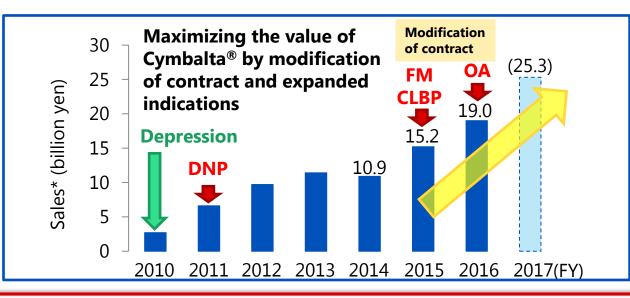


### Action plan for sales expansion in the pain area

- Promoting collaboration with Eli Lilly Japan K.K.
- Focusing sales forces on the orthopedics or internal medicine department
- Utilizing the product as a key drug for patients with lower ADL or QOL caused by chronic pain, such as DNP, FM, CLBP and OA, due to its long-term safety profile



#### Maximizing the value of Cymbalta<sup>®</sup> with four additional indications in pain area

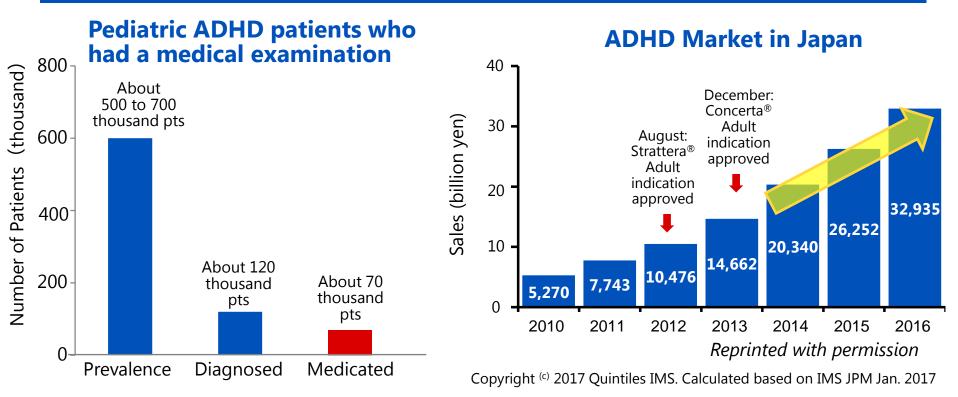


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ADL: activities of daily living DNP: diabetic neuropathy FM: fibromyalgia CLBP: chronic low back pain OA: osteoarthritis \*Sales: Remuneration for promotional activity from Eli Lilly Japan K.K. since FY2015

# **Growth of New Products (2) : Intuniv<sup>®</sup>**





[Reference information] Overseas sales of product by Shire

- Intuniv<sup>®</sup> (by Shire) : \$335M (in FY2013; Generic drugs was launched in Dec. 2014)
- Vyvanse<sup>®</sup>: \$2,014M (in FY2016; +17% vs prior FY)

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# Maximizing the Value of Intuniv<sup>®</sup>



### Action plan for smooth launch and sales growth

- Allocation of sales forces with high level of expertise in each region
- Providing product information of Intuniv<sup>®</sup> to healthcare providers utilizing all sales forces of Shionogi
- Marketing collaboration with Shire Japan K.K.

#### Maximizing the value of two products, non-stimulant Intuniv<sup>®</sup>, which has a new mechanism of action, and stimulant lisdexamfetamine in this new therapeutic area for Shionogi

#### **Projected launch timings**





# Growth of New Products (3) : Opioids and OIC treatment

### Marketability

- Opioid market in Japan: About 35 B yen (about 1.1 million patients)
- Patients treated with strong opioids in Japan (non-cancer pain): Only about 1% (about 4 B yen)
  - Substantial unmet medical need remains
- Patients suffering from OIC: 40-50%

Source: Calculated based on IMS Health MIDAS MAT-2Q12, etc.

#### Contribution to a more vigorous society

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Current formulation Can be easily crushed

- Preventing the abuse of opioids for medical use
- Promoting pain management based on the proper use



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Tamper resistant formulation\* Difficult to manipulate for misuse and abuse



# Maximizing the Value of Opioids and Product for the Treatment of OIC



### Action plan for maximizing the value (FY2017)

#### Launch of Methapain<sup>®</sup>

Strengthen our product lineup for cancer pain management

#### Launch of Symproic<sup>®</sup>

Achieve the total care for pain using only orally administered drugs by alleviating opioidinduced side effects

#### Oxycodone

- Launch of tamper resistant formulation
- Additional indication: moderate to severe chronic pain
- Prevent the abuse of opioids
- Reach more patients with medical need for opioid pain therapy

Synergistic effect of multiple products in the pain area: Cymbalta<sup>®</sup> ⇔ Oxycodone tamper resistant formulation ⇔ Symproic<sup>®</sup>





### Strengthen Overseas Business: Accelerating Global Development



#### **Infectious diseases**

- S-033188: Two Phase III studies are ongoing

   (1) OwH study (completion of administration for all patients)
   (2) HR study

   Cefiderocol: Two Phase III studies are ongoing
  - (1) Carbapenem-resistant study 2 HAP/VAP study

### Pain/CNS

S-120083: Phase II study is ongoing in US
S-117957: Phase I study is ongoing

### Frontier

• **Lusutrombopag**: Phase III study is ongoing (Last Patient In)



HAP: Hospital Acquired Pneumonia VAP: Ventilator Associated Pneumonia

## Strengthen Overseas Business: New Business Strategy



### Shionogi Inc. (US): New business strategy

- Strategic alliances
  - → Maximize product value with lean, focused use of our own resources
  - Achieve a smooth launch of Symproic<sup>®</sup> in alliance with Purdue Pharm L.P., a leading company in the pain treatment market in US
  - Maximize the value of Osphena<sup>®</sup> by partnering with Duchesnay Inc., a specialty pharmaceutical company with a long-standing commitment to women's health
- Launching Shionogi-discovered products into hospital/highlyspecialized markets
  - → High-productivity business area
  - Cefiderocol (Multidrug-resistant Gram-negative bacterial infections)
    - > NDA submission in 1<sup>st</sup> Half of FY2017 (QIDP\*)
  - Lusutrombopag (Thrombocytopenia associated with chronic liver disease)
    - > NDA submission in 2<sup>nd</sup> Half of FY2017 (fast-track product)



# **Target Milestones for FY2017**



Areas	Product	As of Apr. 1, 2017		Target for FY2017	
Infectious	<b>Cefiderocol</b> Multidrug-resistant Gram-negative bacterial infections	Global: Preparation for NDA submission		US: NDA submission	
disease	<b>S-033188</b> Influenza virus infection	Global: Phase III	Japan: Phase III (pediatric)	Japan: NDA submission	
	<b>Intuniv<sup>®</sup></b> ADHD (pediatric)	Japan: NDA	submission	Japan: Launch	
	Symproic <sup>®</sup> Opioid-induced constipation Japan: Approval		Approval	Japan: Launch	
Pain/CNS	<b>Symproic</b> <sup>®</sup> Opioid-induced constipation	US: Approval		US: Launch	
	<b>Oxycodone</b> Treatment of moderate to severe chronic pain	Japan: NDA submission		Japan: Approval	
	<b>Oxycodone</b> Tamper resistant formulation	Japan: NDA submission		Japan: Approval	
	<b>Lisdexamfetamine</b> ADHD (pediatric)	Japan: Preparation for NDA submission		Japan: NDA submission	
	<b>S-600918</b> Neuropathic pain	Japan: Phase I		Phase II (regions to be determined)	
Frontier	<b>Lusutrombopag</b> Thrombocytopenia associated with chronic liver disease	Global: Phase III		US and EU: NDA submission	
	<b>Actair®</b> (Pediatric allergic rhinitis caused by house-dust mite allergen	Japan: NDA submission		Japan: Approval	



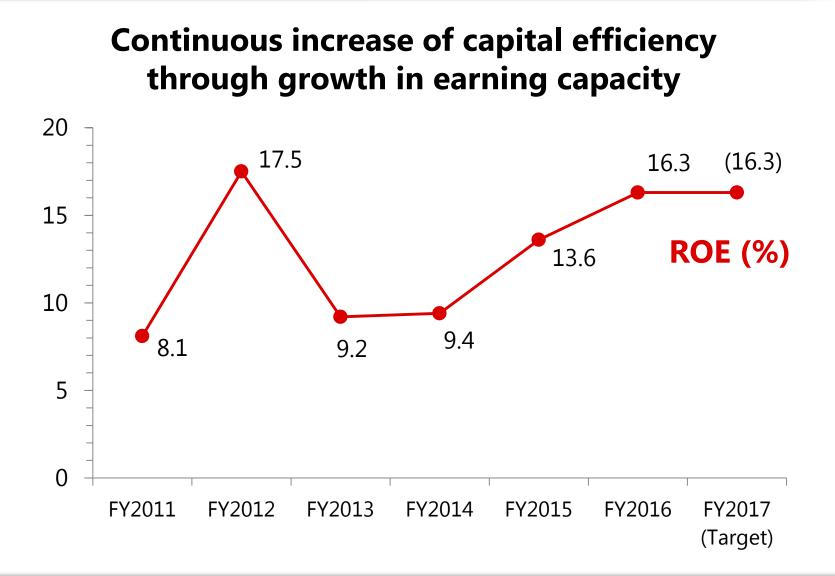
Red frame: Change since Apr. 1 2017 ADHD: Attention deficit hyperactivity disorder



# 4. Shareholder Return



### **Increase in Capital Efficiency (ROE Trend)**



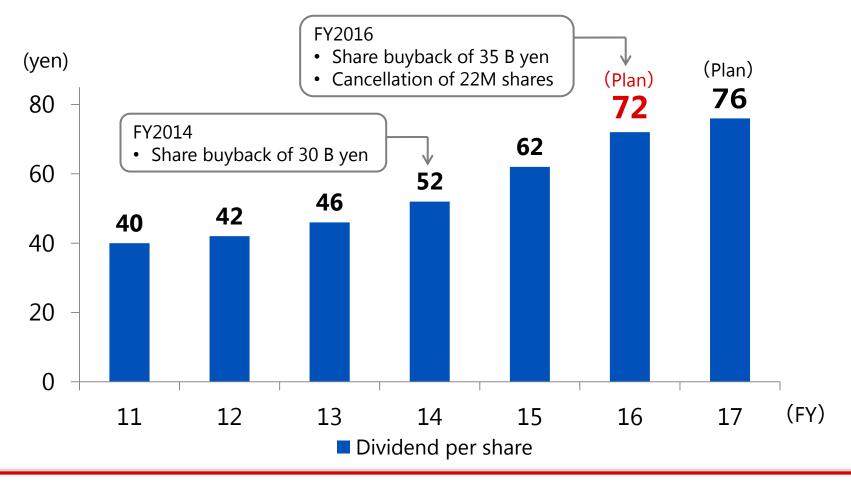


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#### **Shareholder Return - Sharing the Growth**

#### **Continuous dividend increases and flexible share buybacks**

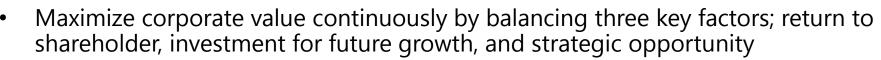
Planning to increase dividend for five consecutive years





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# Fundamental Policy on the Appropriation of Retained Earnings



- Sharing our mid- to long-term profit growth with our shareholders by increasing returns as appropriate, including share buyback
- Revision to year-end dividend forecasts in FY2016: 34 yen → 38 yen
   Planning to increase dividends for five consecutive years (Total return ratio: 69.1%)
- Dividend forecasts in FY2017: 76 yen per share

FY	[	DOE	ROE		
	Half-year	Year-end	Annual	DOL	<b>NOL</b>
2015	yen 28.00	yen 34.00	yen 62.00	4.1%	13.6%
2016	34.00	(Plan) <b>38.00</b>	(Plan) <b>72.00</b>	4.5%	16.3%
2017	(Plan) 38.00	(Plan) 38.00	(Plan) 76.00	(Estimate) <b>4.3%</b>	(Estimate) 16.3%



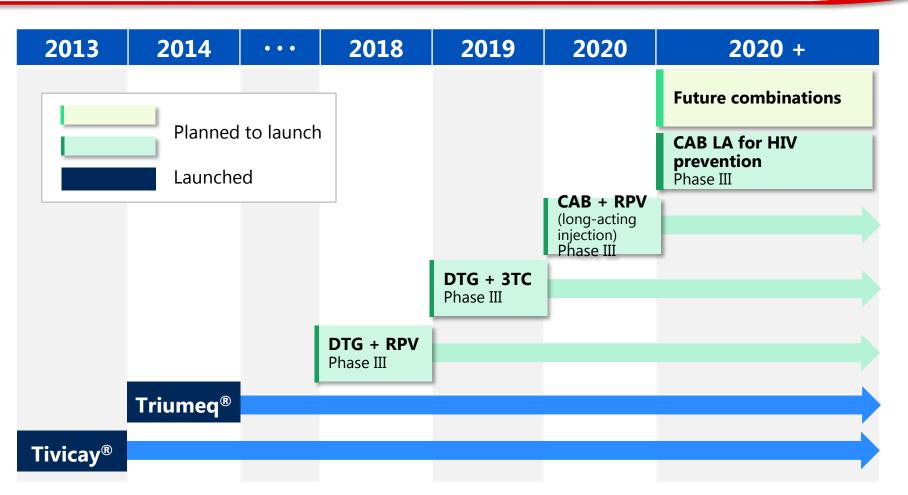
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### **Appendix** - Progress in Our Pipeline -



### **HIV Integrase Inhibitor Franchise**



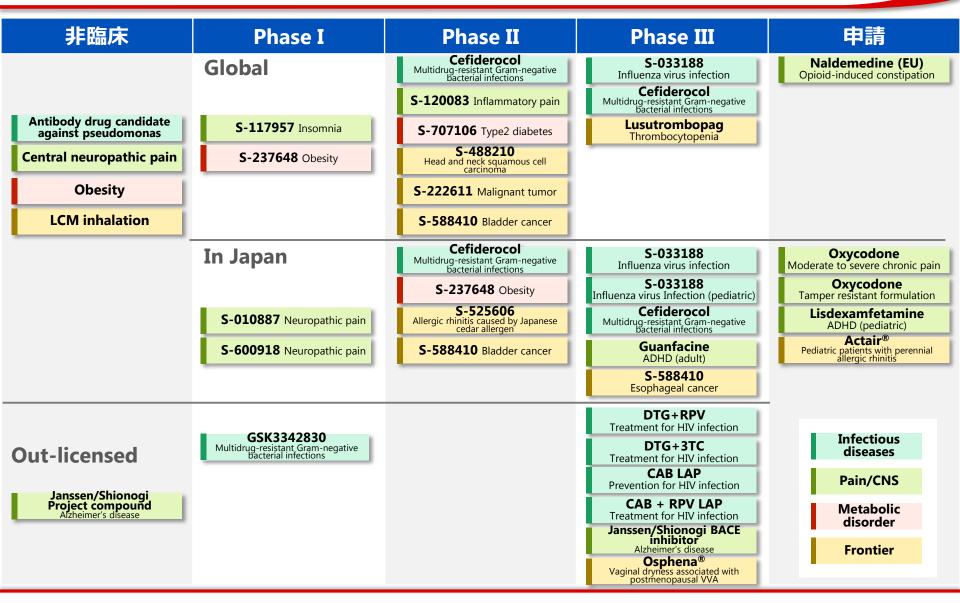
#### ViiV's strategy to develop new treatment regimens to address the needs of people living with HIV places our HIV integrase inhibitors at the core of therapy



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## Pipeline (as of May 2017)







#### Target Milestones for Launch of New Products



FY2017	FY2018	FY2019	
Japanese business			
Symproic <sup>®</sup> Intuniv <sup>®</sup> ADHD (pediatric) Oxycodone Tamper resistant formulation Moderate to severe chronic pain Actair <sup>®</sup> Pediatric patients with perennial allergic rhinitis	S-033188 Lisdexamfetamine	Guanfacine ADHD (adult)	
Overseas business			
Symproic <sup>®</sup> (US)	Cefiderocol Osphena <sup>®</sup> Vaginal dryness associated with postmenopausal VVA Lusutrombopag Naldemedine (EU)		
Global out-licensed products			
	DTG + RPV	DTG + 3TC	





# Appendix

- Actions to Achieve FY2016 Business Plan -
- Definition of New Products -
- KPIs for SGS2020 -



#### Actions to Achieve FY2016 Business Plan (cited from Financial Results in 1H FY2016)

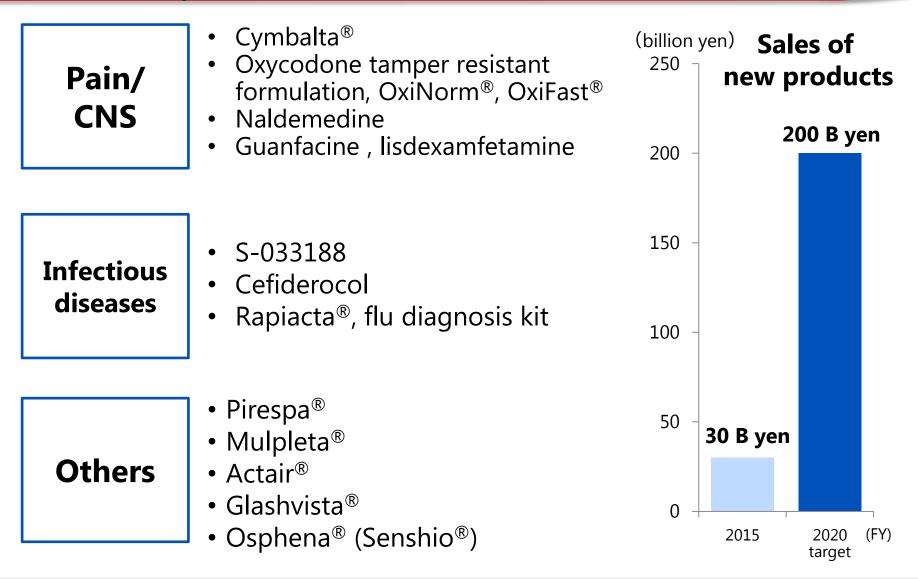


Strengthen and enhance Japanese business	Strengthen and enhance overseas business	
<ul> <li>Cymbalta<sup>®</sup> <ul> <li>Plan to expand indications: Pain associated with osteoarthritis</li> </ul> </li> <li>ADHD         <ul> <li>Plan to receive NDA approval for guanfacine</li> <li>Establish platform for the launch</li> </ul> </li> </ul>	<ul> <li>Naldemedine         <ul> <li>Continue to explore partnering options</li> <li>Establish platform for the launch</li> </ul> </li> <li>Osphena<sup>®</sup> <ul> <li>Expand market share</li> <li>Continue Phase III clinical study for vaginal dryness</li> </ul> </li> </ul>	
Global development	Cost management	
<ul> <li>S-033188         <ul> <li>Initiate global Phase III trials</li> </ul> </li> <li>Cefiderocol         <ul> <li>Strong commitment to AMR issue</li> </ul> </li> </ul>	<ul> <li>Focus resources on high priority business activities</li> <li>Implement the new cost management scheme which combines general expenses and R&amp;D expenses into one unified expense budget</li> </ul>	



# **Definition of New Products**

(cited from Updated SGS2020)





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#### KPIs for SGS2020 (cited from Updated SGS2020)

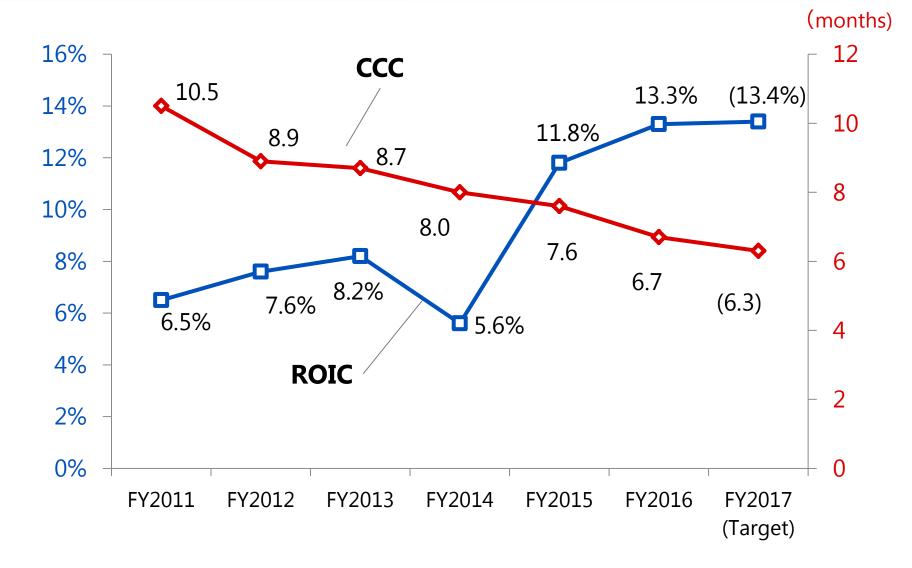


Growth	<ul> <li>Sales of new products: 200 B yen</li> <li>Ordinary income: 150 B yen</li> </ul>
Efficiency	<ul> <li>ROIC: Over 13.5%</li> <li>CCC: 5.5 months</li> <li>Original pipeline ratio: Over 50%</li> </ul>
Shareholder return	<ul> <li>ROE: Over 15.0%</li> <li>DOE: Over 4.0%</li> </ul>



### Trend in ROIC and CCC







### **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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