



1st Half of Fiscal 2017 Financial Results

October 30, 2017

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President and CEO



- 1. 1st Half FY2017 Financial Results**
- 2. FY2017 Financial Forecasts**
- 3. Shareholder Return**



1. 1st Half FY2017 Financial Results

Summary of 1H FY2017: Growth in Sales by New Products

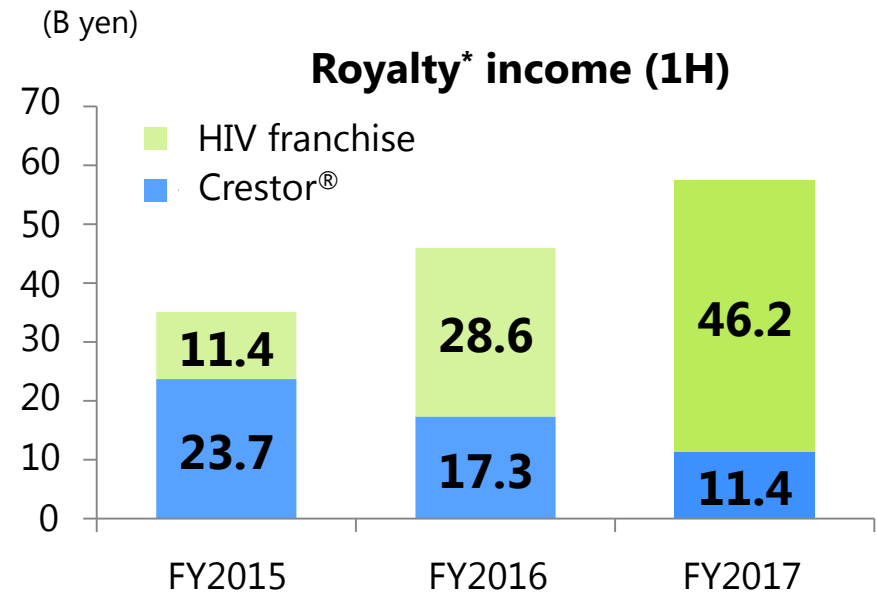
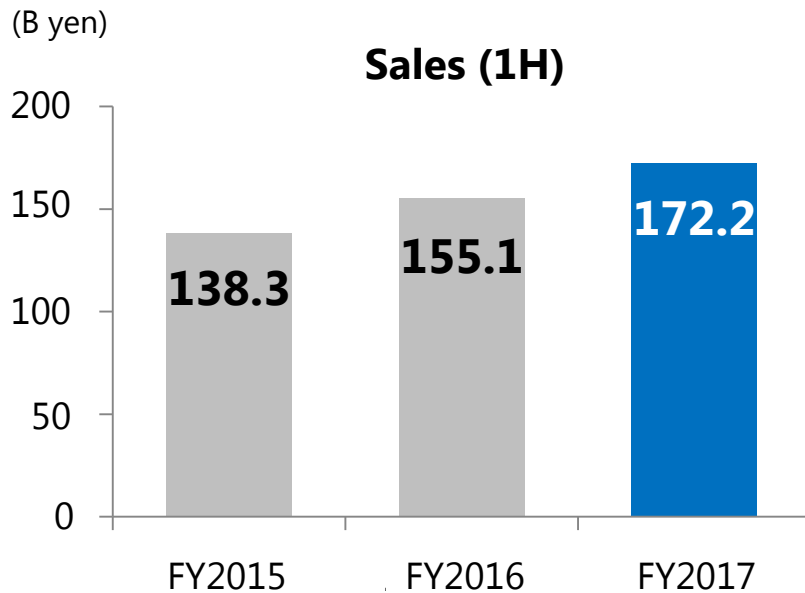


◆ Net Sales : **172.2 B yen** ^{vs 1H FY2016} (+11.0%)

**3 consecutive years
growth in sales**

◆ Royalty* income : **57.6 B yen** ^{vs 1H FY2016} (+25.2%)

(Target significantly exceeded due to HIV franchise sales expansion)



Summary of 1H FY2017: All Categories of Profit Reached Record Highs

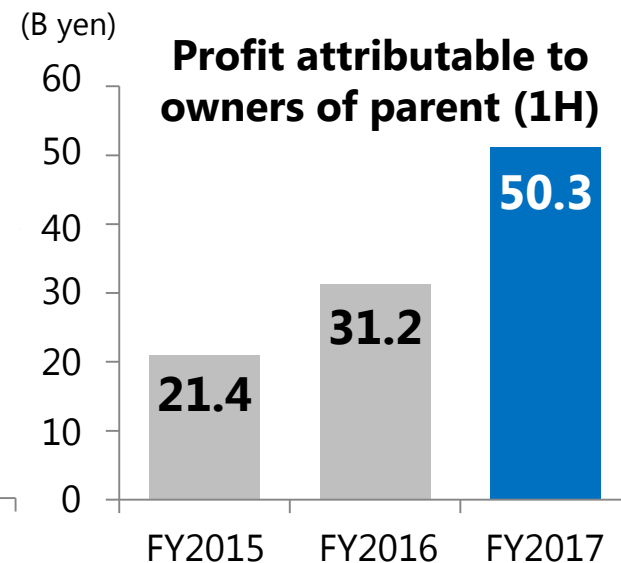
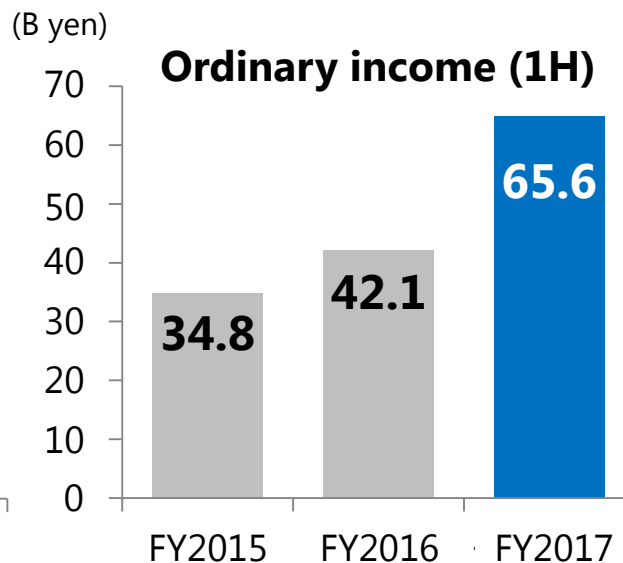
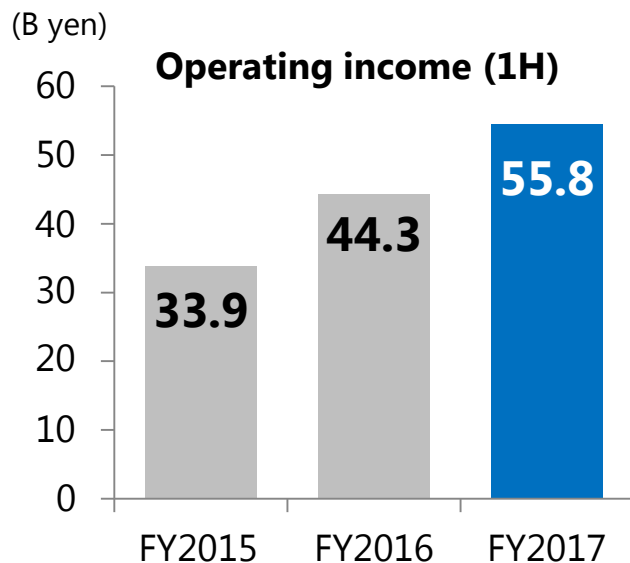


- ◆ Operating income: **55.8 B yen** (+25.9%) vs 1H FY2016

Record-high levels for 3 consecutive years
- ◆ Ordinary income: **65.6 B yen** (+55.6%) vs 1H FY2016

Record-high levels for 6 consecutive years
- ◆ Profit attributable to owners of parent: **50.3 B yen** (+61.3%) vs 1H FY2016

Record-high levels for 3 consecutive years



Financial Results (Consolidated)



(Unit: B yen)

	FY2017			Progress vs 1H Forecasts (%)	FY2016	Y on Y	
	Full year Forecasts	1H Forecasts*	1H Results		1H Results	Change (%)	Change (B yen)
Sales	340.0	162.5	172.2	106.0	155.1	11.0	17.1
Operating income	112.5	46.0	55.8	121.2	44.3	25.9	11.5
Ordinary income	123.5	51.5	65.6	127.4	42.1	55.6	23.4
Profit attributable to owners of parent	92.0	38.5	50.3	130.7	31.2	61.3	19.1

Exchange Rate (average)	FY2017 Forecasts	FY2017 1H Results
USD (\$) – JPY (¥)	110.0	111.06
GBP (£) – JPY (¥)	140.0	143.59
EUR (€) – JPY (¥)	120.0	126.34

Statements of Income (Consolidated)



(Unit: B yen)

	FY2017			Progress vs 1H Forecasts (%)	FY2016	Y on Y	
	Full year Forecasts	1H Forecasts**	1H Results		1H Results	Change (%)	Change (B yen)
Sales	340.0	162.5	172.2	106.0	155.1	11.0	17.1
(Royalty* income)	125.0	56.4	57.6	102.1	46.0	25.2	11.6
	22.5 [35.6]	24.9 [38.2]	23.0 [34.6]		25.0 [35.5]		
Cost of sales	76.5	40.5	39.7	98.0	38.7	2.5	1.0
Gross profit	263.5	122.0	132.5	108.6	116.4	13.8	16.1
	44.4	46.8	44.6		46.5		
SG&A expenses	151.0	76.0	76.7	101.0	72.1	6.4	4.6
Selling & administrative expenses	29.1 99.0	29.8 48.5	27.1 46.6	96.2	29.3 45.4	2.6	1.2
R&D expenses	15.3 52.0	16.9 27.5	17.5 30.1	109.5	17.2 26.7	12.9	3.4
	33.1	28.3	32.4		28.6		
Operating income	112.5	46.0	55.8	121.2	44.3	25.9	11.5
Non-operating income & expenses	P11.0	P5.5	P9.8	178.8	L2.1	-	12.0
	36.3	31.7	38.1		27.2		
Ordinary income	123.5	51.5	65.6	127.4	42.1	55.6	23.4

Note: Small numbers in red are percent of sales, and numbers inside of [] are percent of sales excluding royalties

* Royalty income from ViiV (HIV franchise) and AstraZeneca (Crestor®)

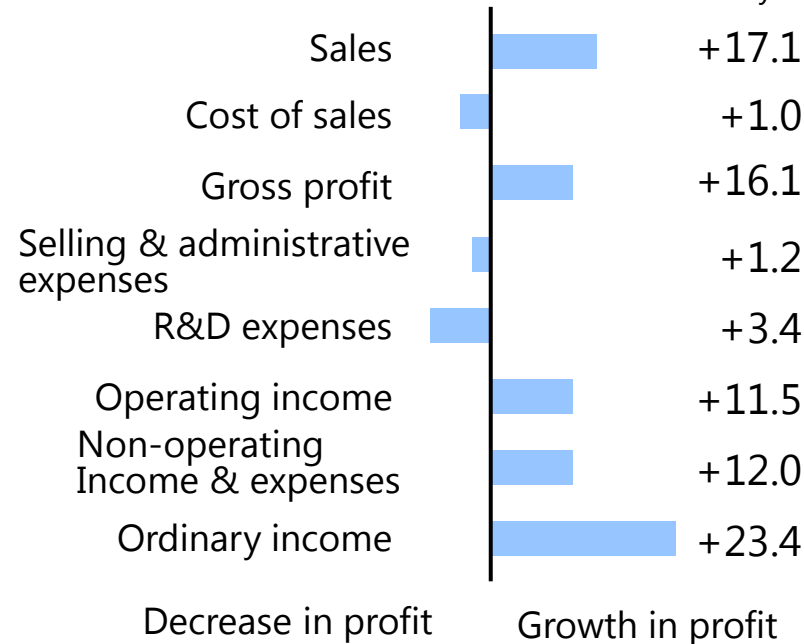
** The consolidated earnings forecasts announced on May 10, 2017 were written here, and the revisions were announced on Oct. 23, 2017.

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

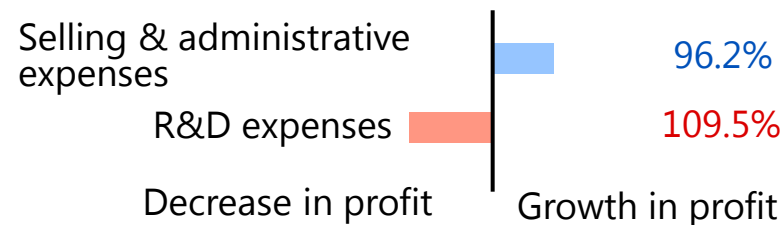


Y on Y comparison

(Unit: B yen)



Progress vs 1H Forecasts**



Main Variation Factors (Y on Y)

- Sales
 - Strong sales growth of strategic products
 - Increase of royalty income of HIV franchise from ViiV
 - Received payments* from Roche regarding S-033188
- SG&A expenses :
 - Selling & administrative expenses : +1.2 B yen
 - › Advance investment for new products
 - R&D expenses : +3.4 B yen
 - › Investment for global development of S-033188
- Non-operating income & expenses
 - Received dividend: Global sales growth of HIV franchise and dividend payment in accordance with the revised contract with ViiV

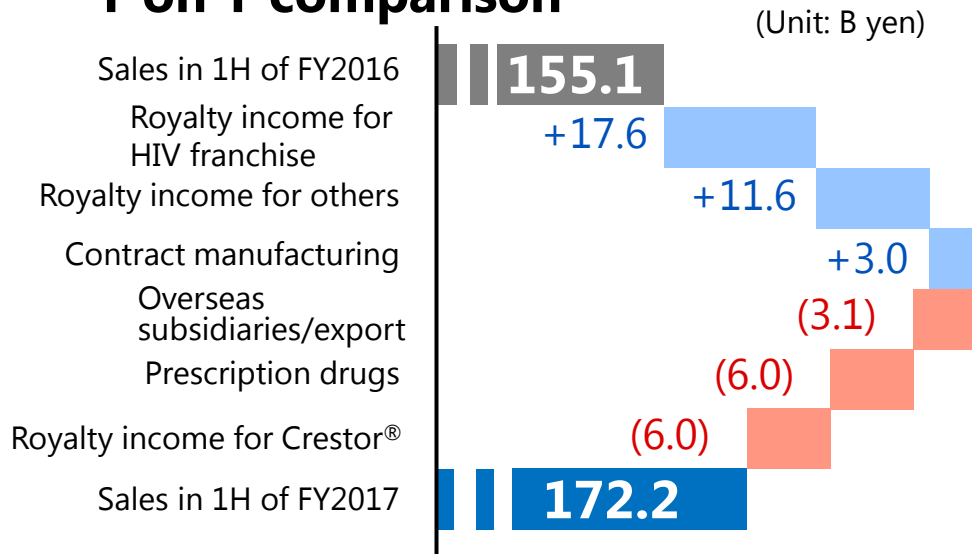
Main Variation Factors (vs 1H Forecasts**)

- Cost of sales
 - Cost of sales ratio
 - › Improved by 1.9%: Increase in royalty income
 - Cost of sales ratio excluding royalty income***
 - › Improved by 3.6%: Received payments* from Roche regarding S-033188
- SG&A expenses: Total cost management
 - Selling & administrative expenses : (1.9) B yen
 - R&D expenses : +2.6 B yen
 - › Investment for global development of S-033188

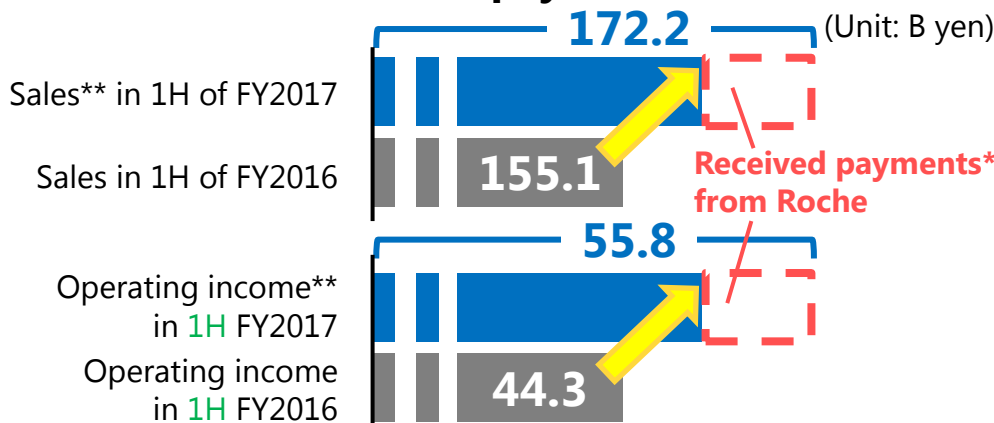
Y on Y Comparison and Main Variation Factors (Sales by Segments)



Y on Y comparison



Y on Y comparison - Effect of received payments* from Roche -



Main Variation Factors (Y on Y change: + 17.1 B yen, +11.0 %)

- Prescription drugs
 - Sales growth of strategic products
 - Decrease sales due to transfer of marketing rights of long-listed drugs
- Overseas subsidiaries/export
 - Decrease in royalty for authorized generic in the US
- Contract manufacturing
 - Increase in API for dolutegravir
- Royalty income
 - Global sales growth of HIV franchise
 - Received payments* from Roche regarding S-033188 (ca. 10.0 billion yen)

In case of excluding received payments* from Roche

- Sales and Operating income excluding received payments* from Roche
 - Achieved increase in sales and profits vs. 1H FY2016



Negotiated with Roche after obtaining positive results of OwH* study

Revised the original financial scheme to a new one, with a milestone structure that includes payments both for development progression events and for obtaining successful results

More stable financial scheme for both companies which comprehensively takes into consideration the impacts to the fiscal period of each company

- **In this 1H, Shionogi received the first payment (ca. 10.0 B yen) from Roche ahead of schedule**

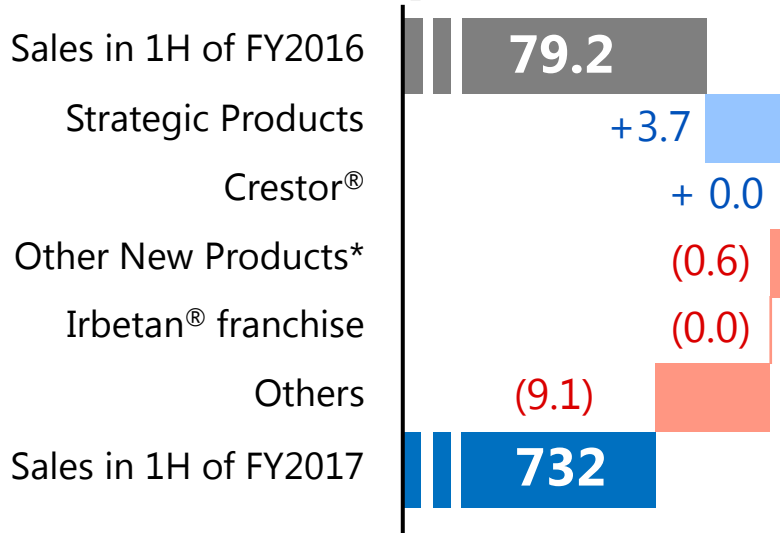


Maximizing the value of S-033188 globally through a stronger collaboration with Roche

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



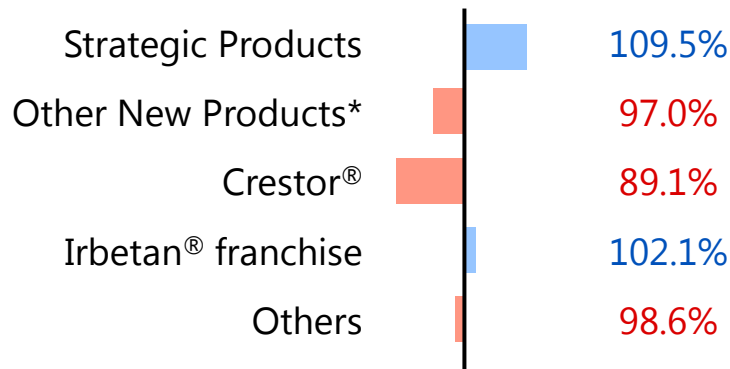
Y on Y comparison (Unit: B yen)



Main Variation Factors (Y on Y change: (6.0) B yen, (7.6)%)

- Strategic Products
 - Cymbalta®: Sales growth mainly in the pain area
 - Smooth launch of new products such as Intuniv® and Symproic®
 - Intuniv®: Already achieved the sales forecast for full year
- Others
 - Decreased sales due to transfer of marketing rights of long-listed drugs

Progress vs. 1H forecast**



Main Variation Factors (Y on Y change: (2.0) B yen, (2.7)%)

- Strategic Products
 - Cymbalta®: Exceeded the sales forecast for 1H
 - Intuniv®: Already achieved the sales forecast for full year
 - Symproic®: Exceeded the sales forecast for 1H
- Crestor®
 - Uptake of the authorized generic of Crestor® earlier than expected

2. FY2017 Financial Forecasts

Upward Revision of FY2017 Financial Forecasts (Consolidated)



(Unit: B yen)

	FY2017			FY2016	Y on Y	
	Original Forecast	Revised Forecast	Change	Full year Results	Change (%)	Change (B yen)
Sales	340.0	345.0	5.0	338.9	1.8	6.1
Operating income	112.5	113.5	1.0	108.2	4.9	5.3
Ordinary income	123.5	132.0	8.5	123.0	7.3	9.0
Profit attributable to owners of parent	92.0	101.0	9.0	83.9	20.4	17.1

- Upward revisions for all categories of income and profit
- First time for Shionogi to exceed the profit attributable to owners of parent of 100.0 billion yen

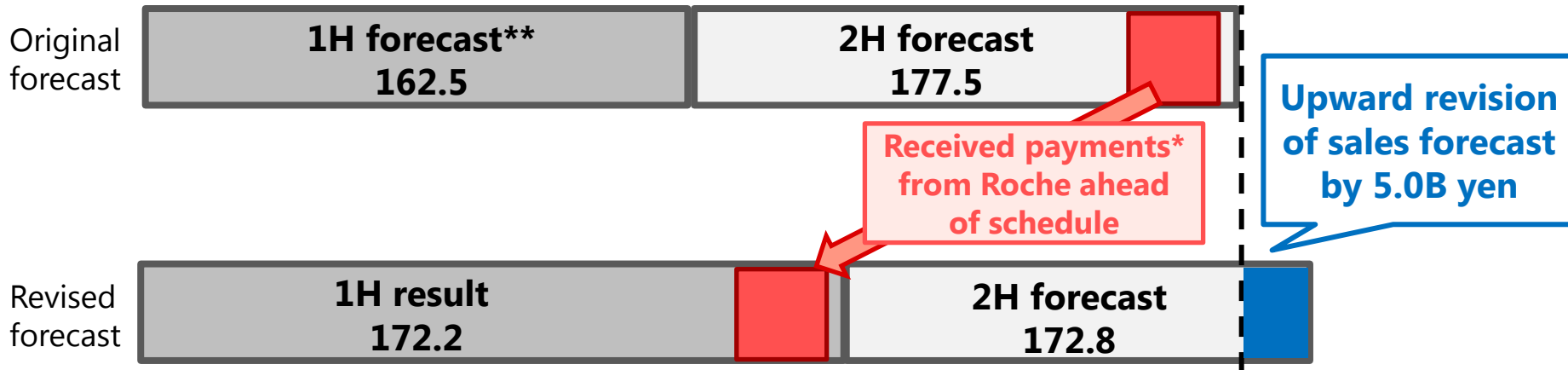
Exchange Rate (average)	FY2017 Forecasts	FY2016 Results
USD (\$) – JPY (¥)	110.0	108.39
GBP (£) – JPY (¥)	140.0	141.62
EUR (€) – JPY (¥)	120.0	118.80

1H Results and Revised Full Year Forecasts of FY2017



• Sales (340.0→345.0)

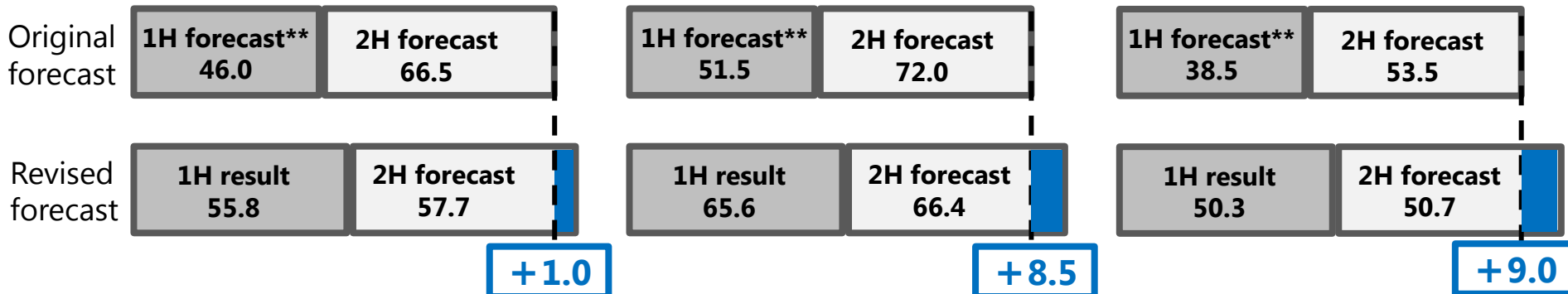
(Unit: B yen)



• Operating income (112.5→113.5)

• Ordinary income (123.5→132.0)

• Profit attributable to owners of parent (92.0→101.0)



Revision of Statement of Income (Consolidated)



(Unit: B yen)

	FY2017			FY2016	Y on Y	
	Original Forecast	Revised Forecast	Change	Full year Results	Change (%)	Change (B yen)
Sales	340.0	345.0	5.0	338.9	1.8	6.1
(Royalty* income)	125.0	125.8	0.8	106.3	18.3	19.5
	22.5 [35.6]	22.2 [34.9]		23.0 [33.4]		
Cost of sales	76.5	76.5	-	77.8	(1.6)	(1.3)
Gross profit	263.5	268.5	5.0	261.1	2.8	7.4
SG&A expenses	44.4	44.9		45.1		
	151.0	155.0	4.0	152.9	1.4	2.1
Selling & administrative expenses	29.1	29.0		27.5		
	99.0	100.0	1.0	93.0	7.5	7.0
R&D expenses	15.3	15.9		17.7		
	52.0	55.0	3.0	59.9	(8.2)	(4.9)
Operating income	33.1	32.9		31.9		
	112.5	113.5	1.0	108.2	4.9	5.3
Non-operating income & expenses	P11.0	P18.5	7.5	P14.9	24.6	3.6
Ordinary income	36.3	38.3		36.3		
	123.5	132.0	8.5	123.0	7.3	9.0

Main reasons

1. Selling & administrative expenses +1.0 B yen: Increase of expenses regarding C&O and SI
2. R&D expenses +3.0 B yen: Increase of expenses in the global Phase III study of S-033188
3. Increased dividend from ViiV +7.5 B yen: Global sales growth of HIV franchise

Revision of Sales by Segments (Consolidated)



(Unit: B yen)

	FY2017			FY2016	Y on Y	
	Original Forecast	Revised Forecast	Change	Full year Results	Change (%)	Change (B yen)
Prescription drugs	143.9	144.1	0.2	158.0	(8.8)	(13.9)
Overseas	25.4	25.5	0.1	29.2	(12.7)	(3.7)
Shionogi Inc.	12.0	11.2	(0.8)	17.9	(37.3)	(6.7)
Osphena [®]	4.6	3.9	(0.7)	4.7	(17.8)	(0.8)
Contract manufacturing	15.3	15.4	0.1	12.1	27.0	3.3
OTC and quasi-drugs	7.5	7.0	(0.5)	6.8	3.1	0.2
Royalty income	145.0	150.3	5.3	115.7	30.0	34.7
Royalty income for the sales of HIV franchise and Crestor [®]	125.0	125.8	0.8	106.3	18.3	19.5
HIV franchise	103.0	103.3	0.3	73.3	40.9	30.0
Crestor [®]	22.0	22.5	0.5	33.0	(31.8)	(10.5)
Others	2.9	2.7	(0.2)	17.1	(84.4)	(14.4)
Total	340.0	345.0	5.0	338.9	1.8	6.1

Revision of Sales of Prescription Drugs in Japan



(Unit: B yen)

	FY2017			FY2016	Y on Y	
	Original Forecast	Revised Forecast	Change	Full year Results	Change (%)	Change (B yen)
Cymbalta [®]	25.3	26.0	0.6	19.0	36.5	6.9
Intuniv [®]	0.62	2.0	1.4	-	-	2.0
Symproic [®]	0.38	0.60	0.22	-	-	0.6
Total of Strategic products	26.3	28.6	2.3	19.0	50.3	9.6
Actair [®]	0.13	0.13	(0.0)	0.08	66.7	0.1
Mulpleta [®]	0.17	0.17	0.0	0.13	32.2	0.0
Pirespa [®]	6.0	6.0	(0.0)	5.8	2.0	0.1
OxyContin [®] franchise	8.9	8.9	0.0	9.7	(8.1)	(0.8)
Rapiacta [®]	2.8	2.8	0.0	2.9	(3.2)	(0.1)
Brightpoc [®] Flu	0.93	0.92	(0.0)	1.0	(6.6)	(0.1)
Glashvista [®]	0.69	0.31	(0.4)	0.55	(43.9)	(0.2)
Total of New Products	45.8	47.7	1.9	39.1	22.0	8.6
Crestor [®]	36.4	34.4	(2.0)	43.1	(20.2)	(8.7)
Irbetan [®] franchise	14.8	14.8	0.0	15.3	(3.1)	(0.5)
Others	46.9	47.2	0.3	60.5	(22.0)	(13.3)
Prescription drugs	143.9	144.1	0.2	158.0	(8.8)	(13.9)

Sales of Prescription Drugs in Japan (Revised)



Main variation factors in sales of prescription drugs in Japan

New drugs	1H Results	2H Revised Forecast	Full year Revised Forecast
Growth of new drugs including Cymbalta®	+3.1	+5.5	+8.6
Launch of generics for Crestor® and Irbetan®	(0.0)	△9.2	△9.2
Long-listed drugs, etc.	1H Results	2H Revised Forecast	Full year Revised Forecast
Decreased sales of long-listed drugs including Flomox® Decreased stockpiling of Rapiacta®	△5.3	△3.1	△8.4
Transferring the marketing rights for 24 long-listed drugs	△3.8	△1.2	△4.9
Prescription drugs	△6.0	△7.9	△13.9

(Unit: B yen)

- **Decreased sales of Crestor® and Irbetan® due to the launch of generic drugs will be compensated for by the growth of new drugs including Cymbalta®, Intuniv®, Symproic®, etc.**
- **Continue to focus on new drugs, not depending on the long-listed drugs**

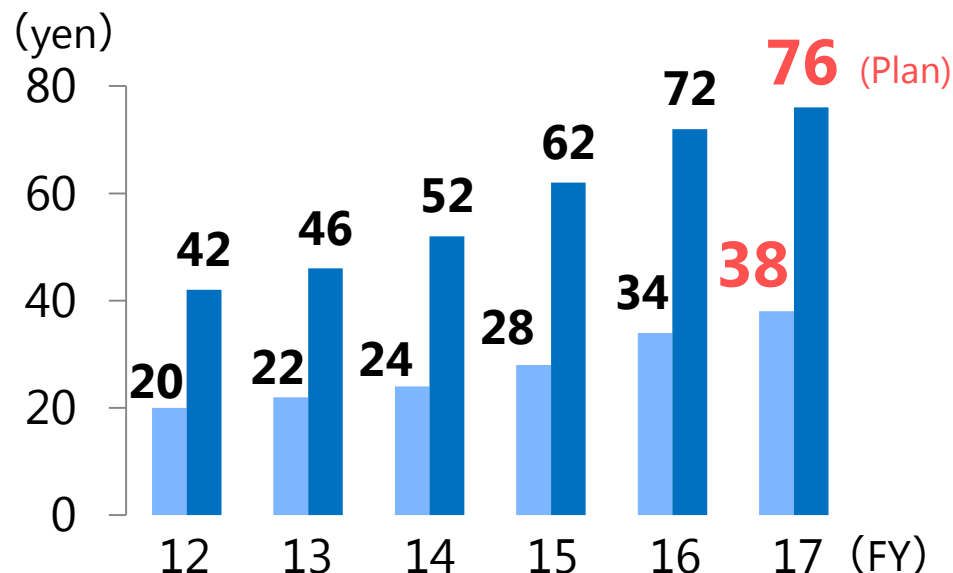
3. Shareholder Return

Dividend Forecasts



	Dividend per share			DOE	ROE
	half-year	year-end	annual		
FY2016	34.00	38.00	72.00	4.5%	16.3%
FY2017	38.00	38.00 (Plan)	76.00 (Plan)	4.3% (Estimate)	17.8% (Estimate)

Planning continuous increases in both half-year dividends and annual dividends





Appendix

Sales by Segments (Consolidated)



(Unit: B yen)

	FY2017				FY2016	Y on Y	
	Full year Forecasts	1H Forecasts*	1H Results	Progress vs. 1H forecasts (%)	1H Results	Change (%)	Change (B yen)
Prescription drugs	143.9	75.2	73.2	97.3	79.2	(7.6)	(6.0)
Overseas	25.4	12.3	12.2	99.0	15.3	(20.2)	(3.1)
Shionogi Inc.	12.0	6.0	6.0	101.3	9.1	(33.6)	(3.1)
Osphena®	4.6	2.2	2.0	89.3	2.0	(0.7)	(0.0)
Contract manufacturing	15.3	7.9	8.4	107.0	5.4	56.1	3.0
OTC and quasi-drugs	7.5	3.4	3.4	98.1	3.4	(1.5)	(0.1)
Royalty income	145.0	62.3	73.8	118.5	50.6	45.7	23.2
Royalty income for the sales of HIV franchise and Crestor®	125.0	56.4	57.6	102.1	46.0	25.2	11.6
HIV franchise	103.0	45.4	46.2	101.8	28.6	61.3	17.6
Crestor®	22.0	11.0	11.4	103.3	17.3	(34.4)	(6.0)
Others	2.9	1.4	1.2	86.4	1.2	1.2	0.0
Total	340.0	162.5	172.2	106.0	155.1	11.0	17.1

Sales of Prescription Drugs in Japan



(Unit: B yen)

	FY2017			Progress vs. 1H forecasts (%)	FY2016	Y on Y	
	Full year Forecasts	1H Forecasts*	1H Results		1H Results	Change (%)	Change (B yen)
Cymbalta [®]	25.3	11.1	11.7	105.5	8.9	31.8	2.8
Intuniv [®]	0.62	0.29	0.69	238.2	-	-	0.69
Symproic [®]	0.38	0.08	0.16	203.6	-	-	0.16
Total of Strategic products	26.3	11.5	12.6	109.5	8.9	41.4	3.7
Actair [®]	0.13	0.05	0.05	111.8	0.03	82.4	0.02
Mulpleta [®]	0.17	0.08	0.08	99.7	0.06	38.1	0.02
Pirespa [®]	6.0	3.1	3.1	101.7	3.0	3.3	0.10
OxyContin [®] franchise	8.9	4.6	4.6	98.0	5.0	(9.3)	(0.47)
Rapiacta [®]	2.8	0.14	0.07	52.5	0.12	(39.2)	(0.05)
Brightpoc [®] Flu	0.93	0.09	0.14	145.6	0.09	44.3	0.04
Glashvista [®]	0.69	0.34	0.15	42.7	0.41	(64.8)	(0.27)
Total of New Products	45.8	19.9	20.7	104.2	17.6	17.5	3.1
Crestor [®]	36.4	24.7	22.0	89.1	21.9	0.2	0.04
Irbetan [®] franchise	14.8	7.6	7.8	102.1	7.8	(0.6)	(0.05)
Others	46.9	23.0	22.7	98.6	31.8	(28.6)	(9.1)
Prescription drugs	143.9	75.2	73.2	97.3	79.2	(7.6)	(6.0)

Sales Expansion of New Drugs and Negative Impact of First Generic Entries for our Main Products



(Unit: B yen)

New drugs	Full year Forecast	1H Forecast*	1H Results
Growth of new drugs including Cymbalta®	+6.7	+2.2	+3.1
Launch of generics for Crestor® and Irbetan®	(7.2)	+2.5	(0.0)
Long-listed drugs, etc.	Full year Forecast	1H Forecast*	1H Results
Decreased sales of long-listed drugs including Flomox® Decreased stockpiling of Rapiacta®	(8.7)	(5.0)	(5.3)
Transferring the marketing rights for long-listed 24 drugs	(4.9)	(3.8)	(3.8)
Prescription drugs	(14.1)	(4.0)	(6.0)

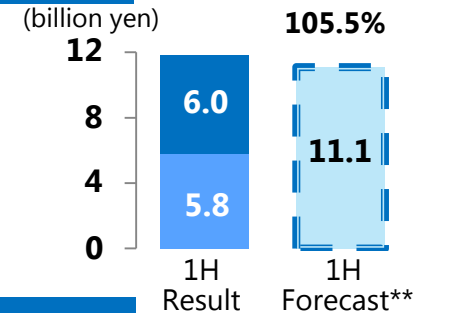
- **New Products: Sales growth led by strategic products**
- **Crestor®: Lower than our forecast due to early uptake of Crestor® AG**
- **Long-listed drugs: On track**

Sales Growth of New Products



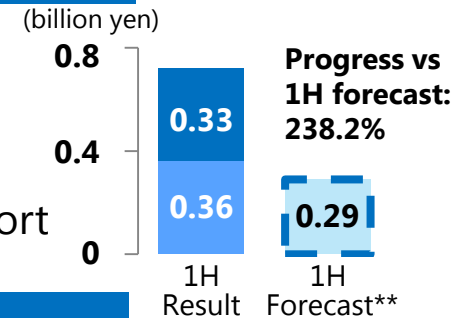
Sales* growth of Cymbalta® in the pain area

- Sales growth in the pain area from the orthopedics and internal medicine departments
 - Positive perception by orthopedists especially in OA
 - Sales growth in CLBP from both the orthopedics and internal medicine departments



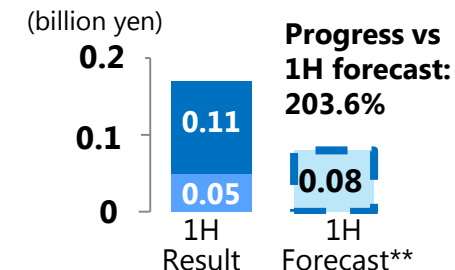
Smooth launch and sales growth of Intuniv® (launched on May 26, 2017) → Already achieved the full year sales forecast

- Strong sales growth as a new treatment option for ADHD
 - Allocation of sales forces with high level of expertise in each region
 - Co-promotion with our partner Shire Japan
- Maximizing overall beneficial impact with complementary social support

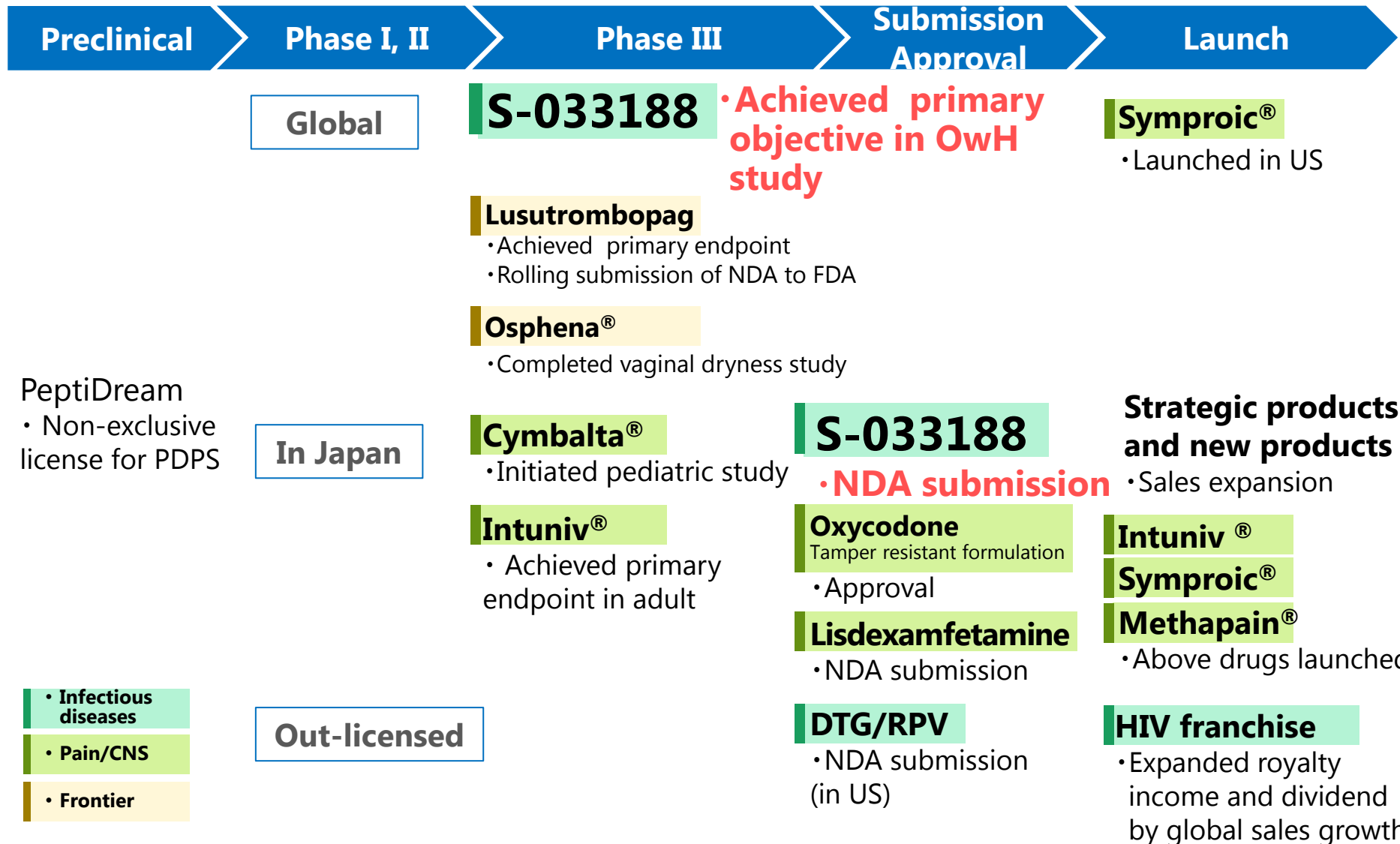


Strengthen our product lineup in the Oxycontin® Family

- Launched Methapain® (Apr. 11, 2017) and Symproic® (Jun. 7, 2017) on schedule
- Symproic® is adopted by nearly 80% of the designated hospitals for cancer in Japan
- Approval of oxycodone tamper resistant formulation



Progress in 1H FY2017*



Objectives for 2H FY2017*



Global

S-600918

- Initiate phase II study

S-120083

- Completion of administration for all patients in phase II study

In Japan

Oxycodone

- Initiate phase I study (BE** study)

S-033188

- **Initiate pediatric study (granules)**

Cefiderocol

- NDA submission in US

Lusutrombopag

- NDA submission in US, EU

S-033188

- **Approval**

Symproic®

- Smooth launch

Oxycodone

- Tamper resistant formulation
- Launch

Actair®

- Approval and launch

- Infectious diseases

- Pain/CNS

- Frontier

Out-licensed

DTG/RPV

- Approval in US

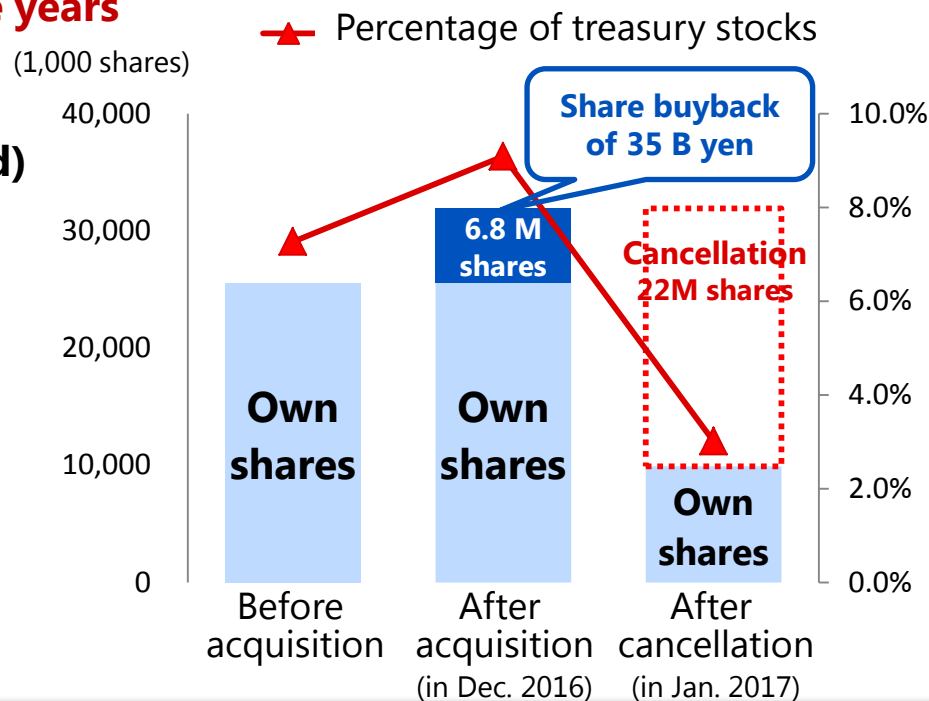
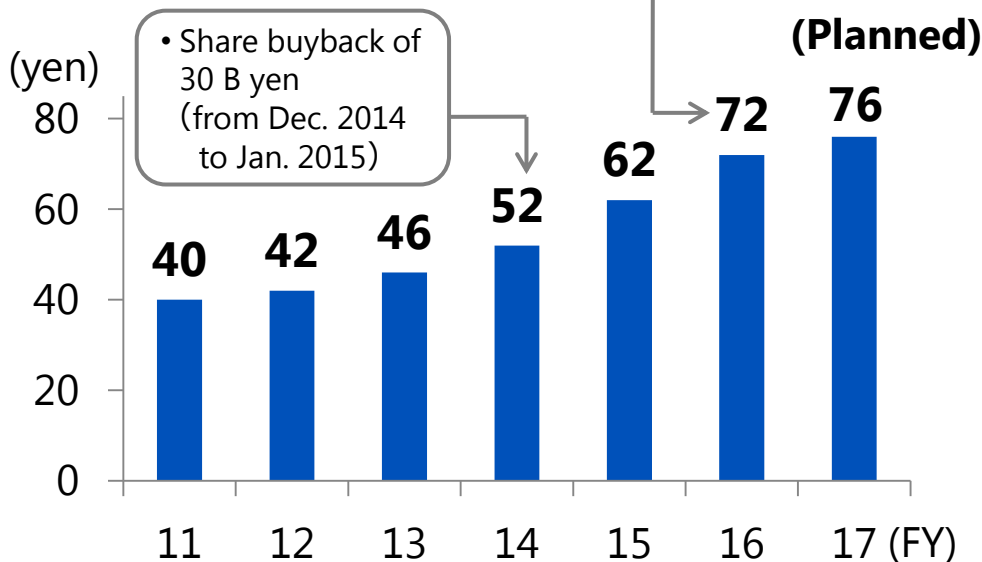
Shareholder Return Policy of Shionogi



- Maximize enterprise value by balancing three key factors: return to shareholders, investment for further growth and strategic opportunities
- Sharing our mid- to long-term profit growth with our shareholders by increasing returns as appropriate by share buyback, cancellation of treasury stocks, and elimination of cross-share holdings

Planning to increase dividend for six consecutive years

- Share buyback of 35 B yen (from Nov. to Dec. 2016)
- Cancellation of 22M shares (in Jan. 2017)



Target Milestones for FY2017 (as of Oct. 2017)



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

Pipeline (as of Oct. 2017)



Preclinical	Phase I	Phase II	Phase III	Filed
	Global	Cefiderocol Multidrug-resistant Gram-negative bacterial infections S-120083 Inflammatory pain S-707106 Type2 diabetes S-488210 Head and neck squamous cell carcinoma epertinib Malignant tumor S-588410 Bladder cancer	S-033188 (baloxavir marboxil) Influenza virus infection Cefiderocol Multidrug-resistant Gram-negative bacterial infections Lusutrombopag Thrombocytopenia	Naldemedine (EU) Opioid-induced constipation
Antibody drug candidate against pseudomonas Central neuropathic pain Obesity LCM inhalation	S-117957 Insomnia S-237648 Obesity			
	In Japan	Cefiderocol Multidrug-resistant Gram-negative bacterial infections S-237648 Obesity S-525606 Allergic rhinitis caused by Japanese cedar allergen S-588410 Bladder cancer	Cefiderocol Multidrug-resistant Gram-negative bacterial infections Intuniv® ADHD (adult) Cymbalta® Depression (pediatric) S-588410 Esophageal cancer	S-033188 (baloxavir marboxil) Influenza virus infection S-033188 (baloxavir marboxil) Influenza virus Infection (pediatric) Oxycodone Moderate to severe chronic pain Oxycodone Tamper resistant formulation Lisdexamfetamine ADHD (pediatric) Actair® Pediatric patients with perennial allergic rhinitis
Out-licensed Janssen/Shionogi Project compound Alzheimer's disease	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		DTG+3TC Treatment for HIV infection CAB LAP Prevention for HIV infection CAB + RPV LAP Treatment for HIV infection Janssen/Shionogi BACE inhibitor Alzheimer's disease Osphena® Vaginal dryness associated with postmenopausal VVA	DTG/RPV Treatment for HIV infection <ul style="list-style-type: none"> Infectious diseases Pain/CNS Metabolic disorder Frontier

Target Milestones for Launch of New Products



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

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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- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.
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