



1st Half of Fiscal 2015 Financial Results

October 30, 2015

**Isao Teshirogi, Ph.D.
President and CEO**



SGS2020 Rolling Plan (Targets for FY2017)



Our vision: Grow as a drug discovery-based pharmaceutical company

FY2015

FY2016

FY2017

FY2018

FY2019

FY2020

Clear priorities and focused resourcing

Evolution of Core business

Growth led by FIC and LIC compounds

Shift Gears for Growth

Net sales 350.0 billion yen
Ordinary income 90.0 billion yen
ROE 12%

Net sales 500.0 billion yen
Ordinary income 125.0 billion yen
ROE 15%

Clarify annual results and business status in three-year rolling plans

FY2015 to FY2017: Advancing core businesses and positioning for further growth

- Maximize the value of Crestor® and Cymbalta® in Japan
- Increase revenues from Osphena® in the US
- Strengthen pipeline in our core therapeutic areas
- Develop an operating structure independent of royalty income

Summary of 1H FY2015

Short term

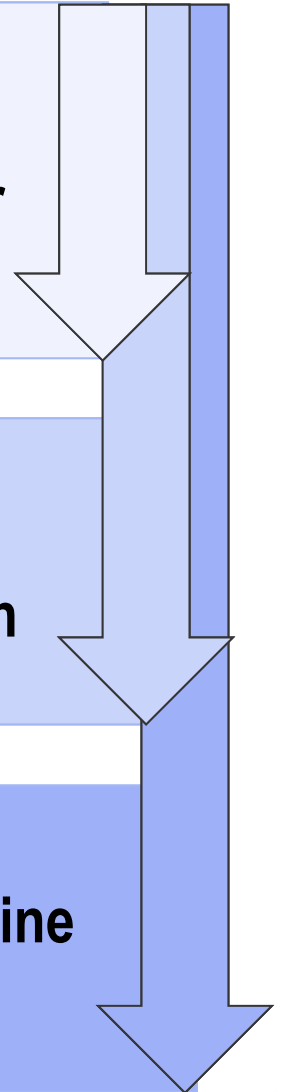
- Sales on track
- Operating income, ordinary income and net income higher than 1H forecasts, and also higher than the levels achieved in 1H of any prior fiscal year

Mid term

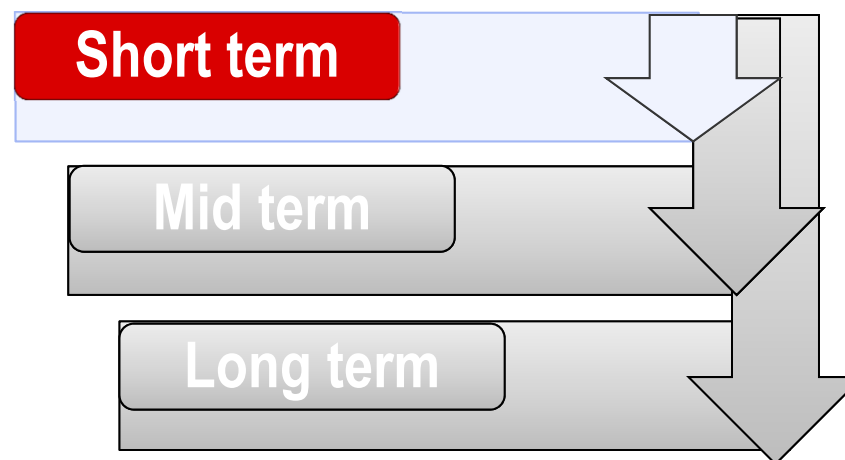
- Global growth of HIV franchise began contributing to Shionogi group as the basis for mid- to long-term growth

Long term

- Continued good progress in the development of pipeline compounds in infectious diseases and pain/CNS as future growth drivers



Overview of 1st Half FY2015 Financial Results



Financial Results (Consolidated)

(Unit: B yen)

	FY2015 forecasts	FY2015		Achievement (%)	FY2014 1H results	Y on Y	
		1H forecasts	1H results			change (%)	change
Sales	296.0	138.0	138.3	100.2	129.8	6.5	8.5
Operating income	72.5	28.5	33.9	119.1	22.7	49.4	11.2
Ordinary income	79.5	28.0	34.8	124.3	31.4	10.7	3.4
Profit attributable to owners of parent	52.0	17.0	21.4	125.8	9.7	120.2	11.7

Note: All numerical values are rounded to the nearest unit

- Operating income, ordinary income and profit attributable to owners of the parent are higher than the levels achieved in the 1H of any prior year; especially, ordinary income continued to reach record high levels in each of 4 consecutive years

Exchange rate (average)	FY2015 forecasts	FY2015 1H results
USD (\$) – JPY (¥)	120	121.9
EUR (€) – JPY (¥)	130	135.1
GBP (£) – JPY (¥)	175	187.9

Financial Position (Consolidated)

(Unit: B yen)

◆ Financial Position



Assets

Current assets

- Cash and deposits +23.4
- Accounts receivable (13.0); dividends received from ViiV (12.5)

Non-current assets

- Investment securities; rise in stock market +4.1, effect of exchange rate change +1.4, sales (1.8)



Liabilities

Current liabilities

- Income taxes payable (4.7)
- Consumption tax payable (2.9)



Net assets

- Retained earnings +12.3; net income +21.4, cash dividends paid (9.1)
- Accumulated other comprehensive income +5.5

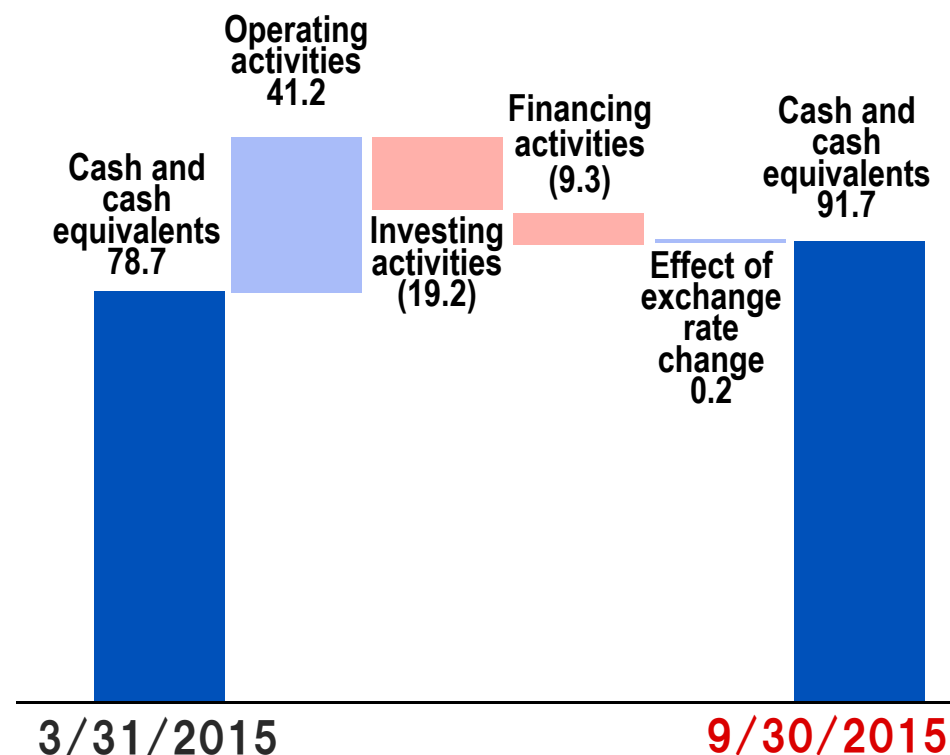
	3/31/2015	9/30/2015	change
Total assets	602.9	611.1	8.2
Current Assets	259.9	264.4	4.5
Non-current assets	343.0	346.7	3.7
Total liabilities	124.0	114.2	(9.8)
Current liabilities	67.8	57.1	(10.7)
Non-current liabilities	56.2	57.1	0.9
Net assets	478.9	496.8	17.9
Equity ratio	78.7%	80.5%	1.8%

Cash Flow (Consolidated)

(Unit: B yen)

◆ Cash Flow

- Net cash providing by operating activities
 - Income before income taxes +34.6
 - Decrease in notes and accounts receivable-trade (6.6)
 - Reduction in inventory (1.8)
 - Interest and dividends income received +14.4; accounts receivable as dividends from ViiV +13.2 including currency exchange fluctuations
- Net cash provided by investing activities
 - Payments into time deposits (11.4); surplus fund management of dividend from ViiV (11.3)
 - Investment securities; purchase (7.5), redemption +5.0
 - Proceeds from sales of investment securities +2.1
- Net cash provided by financing activities
 - Cash dividends paid (9.1)



Statement of Income (Consolidated)

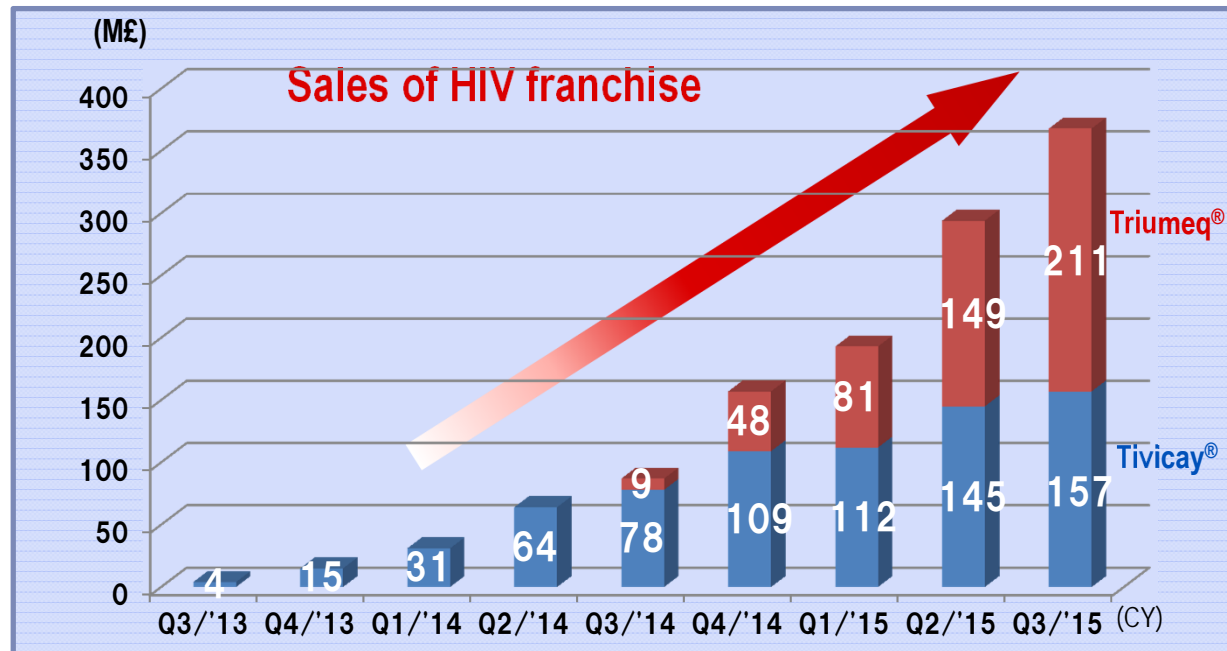
(Unit: B yen)

	FY2015		Achievement (%)	FY2014 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
Prescription drugs	79.2	78.4	99.0	77.0	1.9	1.4
Total of 3 key products	37.2	35.9	96.5	34.0	5.5	1.9
Total of 8 strategic products	49.4	47.5	96.1	45.7	3.9	1.8
Overseas subsidiaries/export*	14.8	14.7	99.5	13.8	6.7	0.9
Shionogi Inc.	9.0	8.4	93.5	7.4	13.5	1.0
Osphena®	3.0	2.6	86.0	1.7	52.9	0.9
C&O	3.4	3.3	98.3	3.3	1.9	0.0
Contract manufacturing*	3.7	3.7	99.5	6.9	(46.1)	(3.2)
OTC and quasi-drugs	2.5	2.6	102.9	2.5	4.9	0.1
Royalty income	36.5	37.5	102.6	28.3	32.4	9.2
Royalty income for the sales of Crestor® and HIV franchise	32.0	35.0	109.5	24.4	43.6	10.6
Crestor®	-	23.7	-	24.4	(3.0)	(0.7)
HIV franchise	-	11.4	-	-	-	11.4
Others	1.3	1.4	108.3	1.5	(5.9)	(0.1)
Total	138.0	138.3	100.2	129.8	6.5	8.5

Eight strategic products: Crestor®, Irbetan® franchise, Cymbalta® (3 key products), and OxyContin® franchise, Finibax®, Differin®, Pirespa®, Rapiacta®

HIV Franchise; Triumeq® and Tivicay®

Strong growth globally with its good efficacy, safety, adherence and resistance profile



- ◆ Royalties for the HIV franchise fully contributed since 2Q FY2015
- ◆ Annual dividend from ViiV for CY2015 will be recorded in 4Q FY2015
- ◆ In addition to the US NIH Guidelines' recommendation for both Triumeq® and Tivicay® plus Truvada® as the highest rating for ART-naïve patients; WHO recommended ART to be initiated in HIV patients immediately after diagnosis

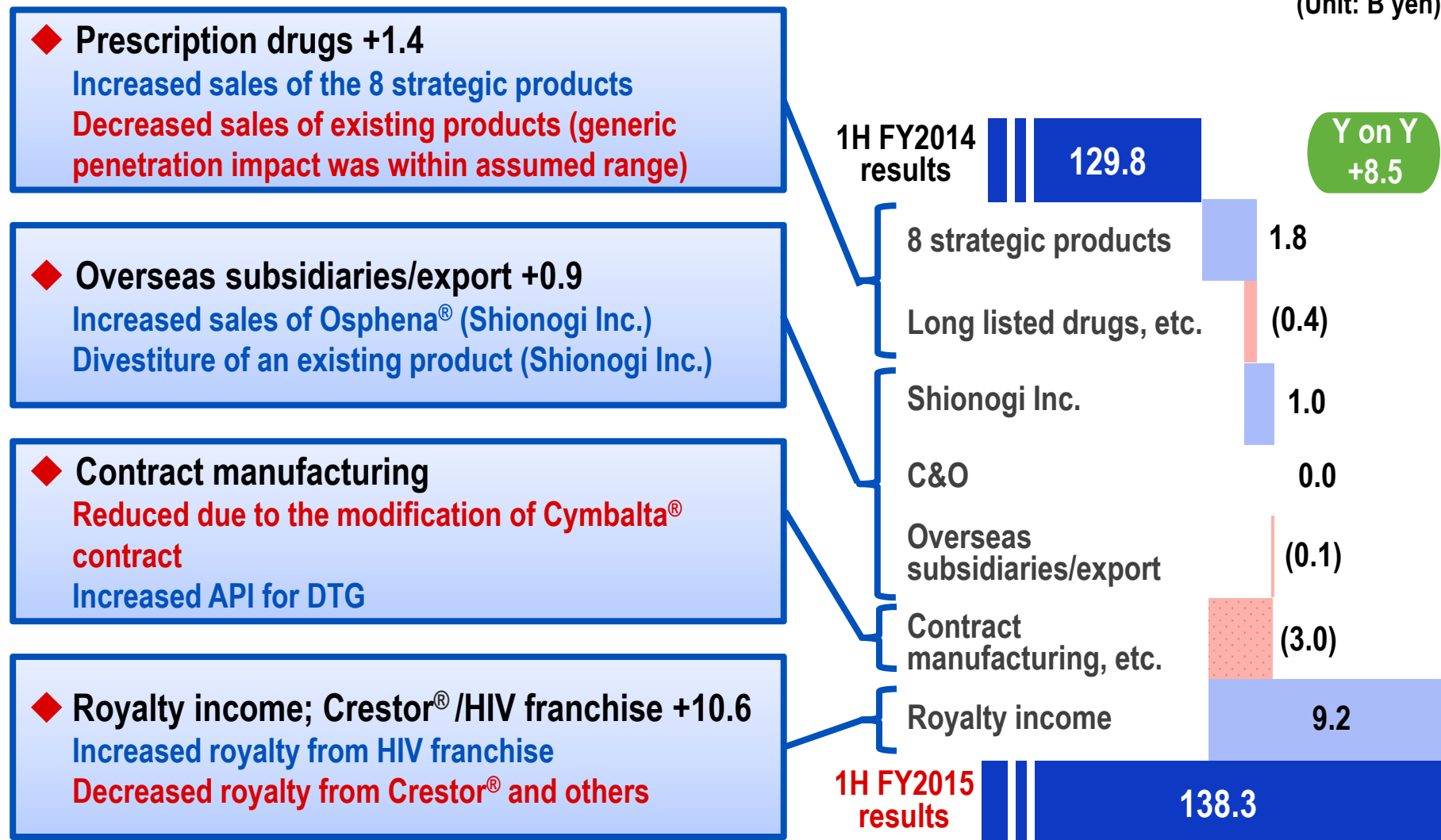
Japan: Sales of 8 Strategic Products

(Unit: B yen)

	FY2015		achievement (%)	FY2014 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
Prescription drugs	79.2	78.4	99.0	77.0	1.9	1.4
Crestor [®]	21.3	20.4	95.8	21.1	(3.1)	(0.7)
Irbetan [®] franchise	8.2	8.3	101.5	7.5	10.5	0.8
Cymbalta ^{®*}	7.7	7.2	93.4	5.5	31.5	1.7
Total of 3 key products	37.2	35.9	96.5	34.0	5.5	1.9
OxyContin [®] franchise	5.3	5.2	97.2	5.3	(2.4)	(0.1)
Finibax [®]	1.9	2.1	110.7	1.9	8.9	0.2
Differin [®]	1.9	1.6	81.8	1.8	(13.5)	(0.2)
Pirespa [®]	3.0	2.8	92.0	2.6	5.8	0.2
Rapiacta [®]	0.1	(0.0)	-	0.1	-	(0.1)
Total of 8 strategic products	49.4	47.5	96.1	45.7	3.9	1.8
[percent of sales]	[62.4]	[60.5]	-	[59.4]	-	-

Change in Sales vs. Previous Year

(Unit: B yen)



Statements of Income (Consolidated)

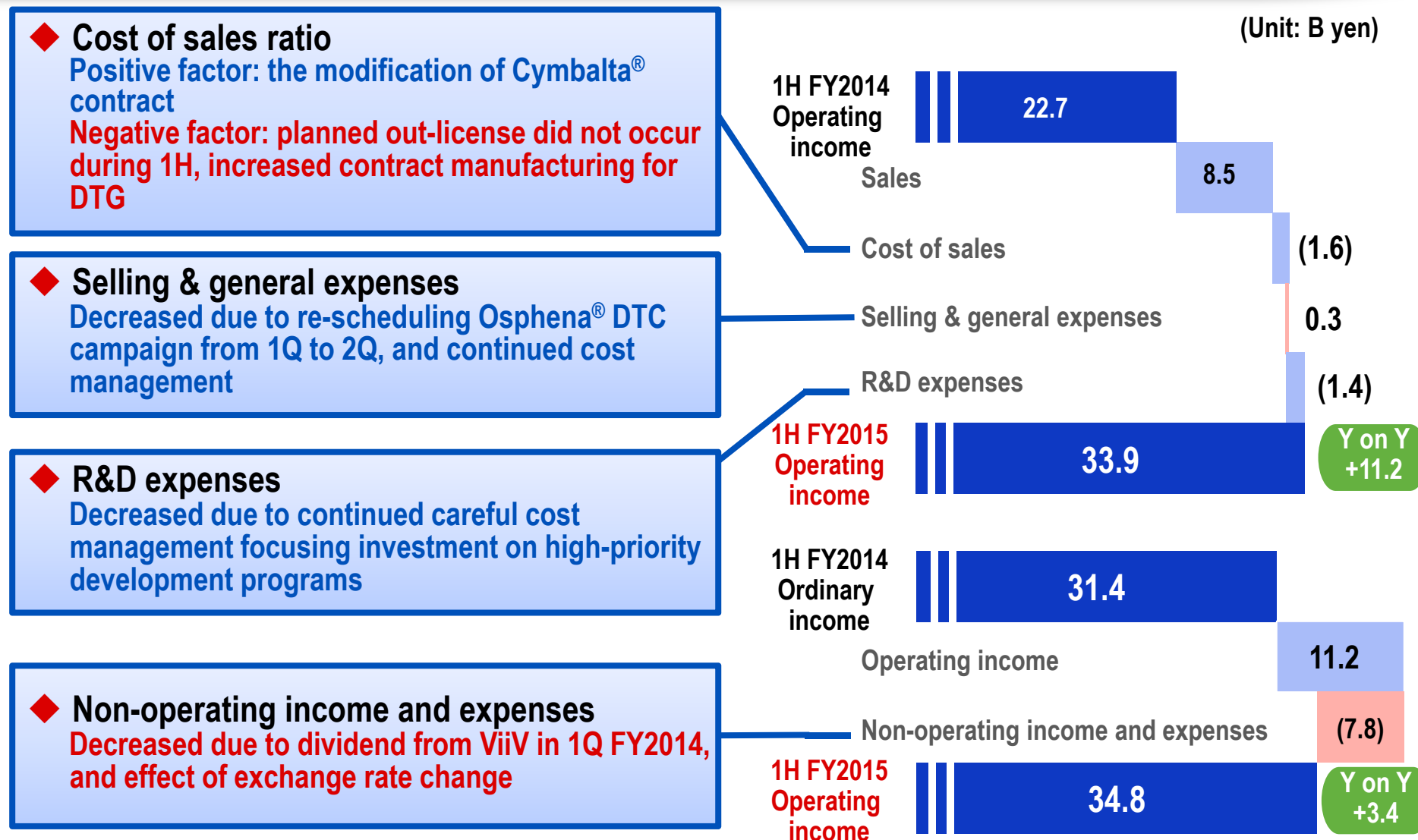
	FY2015		vs. forecasts		FY2014 1H results	Y on Y	
	1H forecasts	1H results	achievement (%)	Difference		change (%)	change
Sales	138.0	138.3	100.2	0.3	129.8	6.5	8.5
[Royalty* income]	32.0	35.0	109.5	3.0	24.4	43.6	10.6
	25.6 [33.3]	26.4 [35.3]			29.4 [36.2]		
Cost of sales	35.3	36.5	103.3	1.2	38.1	(4.4)	(1.6)
Gross profit	102.7	101.8	99.1	(0.9)	91.7	11.0	10.1
	53.8	49.1			53.1		
SG&A expenses	74.2	67.9	91.5	(6.3)	69.0	(1.6)	(1.1)
Selling & general expenses	50.2	46.1	91.7	(4.1)	45.8	0.6	0.3
R&D expenses	24.0	21.8	91.0	(2.2)	23.2	(5.9)	(1.4)
	20.7	24.5			17.5		
Operating income	28.5	33.9	119.1	5.4	22.7	49.4	11.2
[Excluding royalty* income]	(3.5)	(1.1)	-	2.4	(1.7)	-	0.6
Non-operating income and expenses	L0.5	P0.9	-	1.4	P8.7	-	(7.8)
	20.3	25.2			24.2		
Ordinary income	28.0	34.8	124.3	6.8	31.4	10.7	3.4
Extraordinary income and loss	-	L0.1	-	(0.1)	P0.2	-	(0.3)
Income before income taxes	28.0	34.6	123.7	6.6	31.7	9.4	2.9
Total income taxes, etc.	11.0	13.3	120.6	2.3	22.0	(39.6)	(8.7)
Profit attributable to owners of parent	17.0	21.4	125.8	4.4	9.7	120.2	11.7

Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties

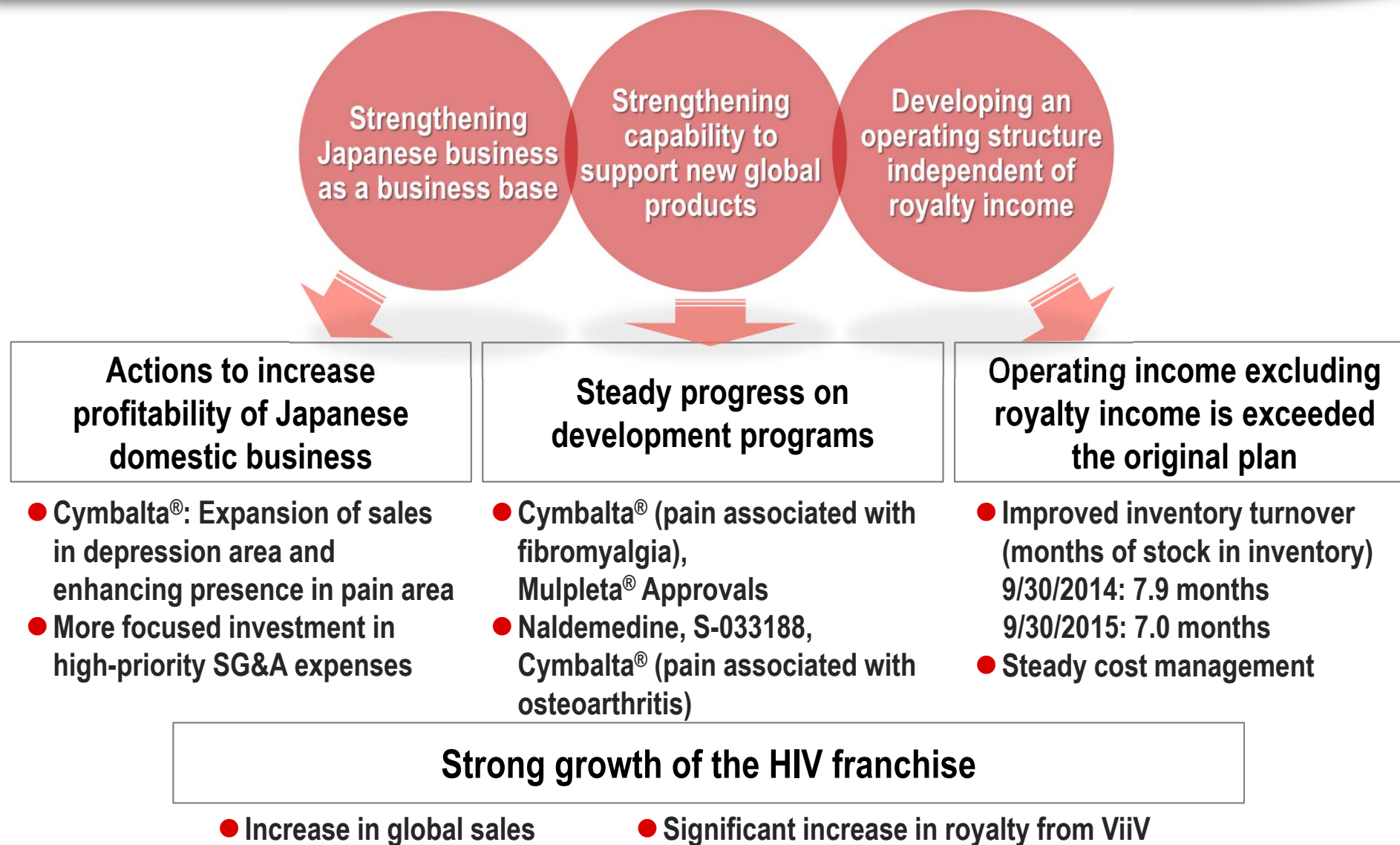
* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

Change in Earning Structure vs. Previous Year

(Unit: B yen)



Achievements in 1H FY2015



Modification of Cymbalta® Contract Contributed to Consolidated Performance

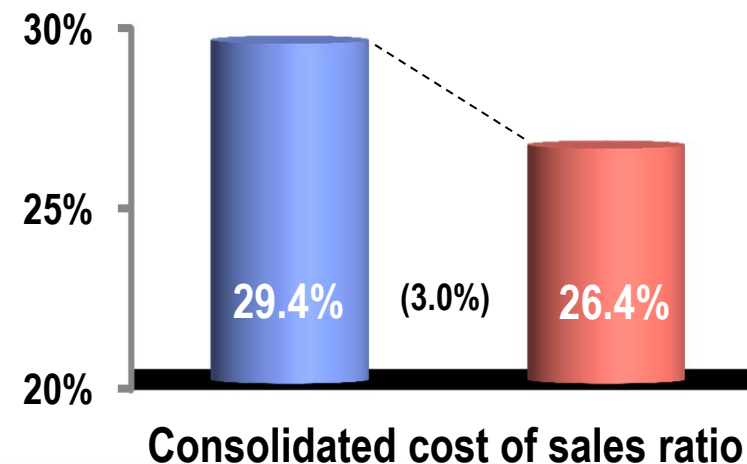
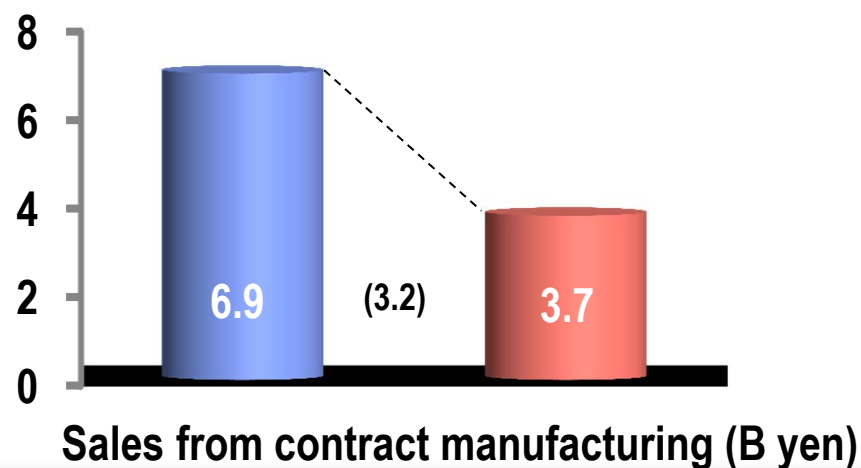
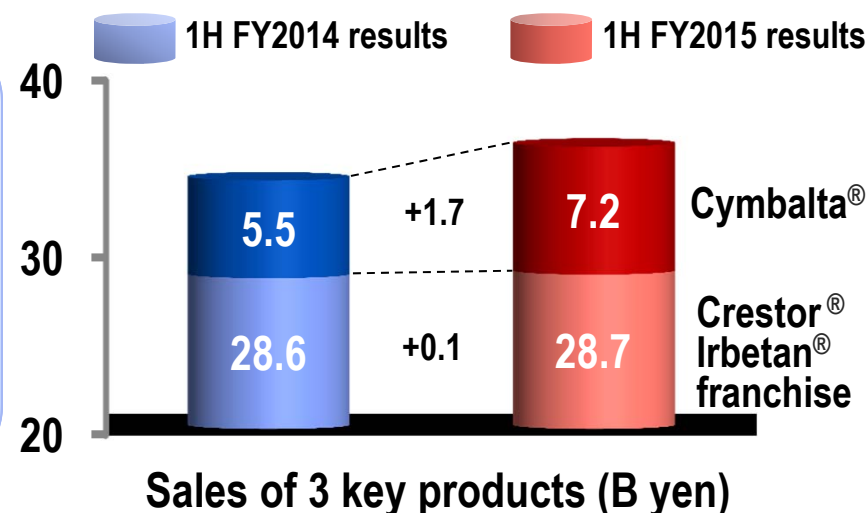
Both Shionogi and Eli Lilly Japan K.K. strengthened their promotional activities
Sales of Cymbalta® brand showed strong growth

◆ Shionogi received remuneration for its promotional activity

- Increase in sales of ethical pharmaceutical products

◆ Revised API price based on the modified contract

- Decreased sales from contract manufacturing but improved cost of goods ratio



Key Actions for 2H FY2015 Based on Achievements in 1H

**Strengthening
Japanese business
as a business base**

- Accelerate expansion of sales of Cymbalta®
- Rapid market penetration of Mulpleta® and Actair®
- New business scope of the Human Health Care Division
- Activities for NDA submission and launch of S-877503

**Strengthening
capability to
support new global
products**

- Maximize the value of Osphena®
- Expand of sales of Rabeprazole in China
- Establish platform for NDA submission and launch of naldemedine

**Developing an
operating structure
independent of
royalty income**

- Achieve the target cost of sales ratio
- Improve inventory turnover
- Sustain and further increase tight control over operating costs

FY2015 Financial Forecasts

Revision of FY2015 Financial Forecasts (Consolidated)

(Unit: B yen)

	FY2015							FY2014	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change	results	
Sales	296.0	301.5	5.5	138.3	158.0	163.2	5.2	274.0	10.0
Operating income	72.5	78.0	5.5	33.9	44.0	44.1	0.1	50.4	54.9
Ordinary income	79.5	88.0	8.5	34.8	51.5	53.2	1.7	77.9	13.0
Profit attributable to owners of parent	52.0	59.0	7.0	21.4	35.0	37.6	2.6	44.1	33.9

Exchange rate (average)	FY2015 forecasts (original)	FY2015 forecasts (revised)	change
USD (\$) – JPY (¥)	120	120	-
EUR (€) – JPY (¥)	130	130	-
GBP (£) – JPY (¥)	175	180	5

Revision of Sales by Segments (Consolidated)

(Unit: B yen)

	FY2015							FY2014	Y on Y change (%)
	Full year			1H	2H				
	original	revised	change	results	original	revised	change		
Prescription drugs	167.0	167.0	-	78.4	87.8	88.6	0.8	161.4	3.5
Crestor®	44.4	44.4	-	20.4	23.1	24.0	0.9	43.6	1.8
Irbetan® franchise	17.0	17.0	-	8.3	8.8	8.7	(0.1)	15.1	12.4
Cymbalta®*1	17.4	17.4	-	7.2	9.7	10.2	0.5	10.9	59.0
Total of 3 key products	78.8	78.8	-	35.9	41.6	42.9	1.3	69.7	13.1
OxyContin® franchise	10.7	10.7	-	5.2	5.4	5.5	0.1	10.3	4.3
Finibax®	3.8	3.8	-	2.1	1.9	1.7	(0.2)	4.0	(4.5)
Differin®	3.8	3.8	-	1.6	1.9	2.2	0.3	3.9	(1.9)
Pirespa®	5.4	5.4	-	2.8	2.4	2.6	0.2	5.4	0.6
Rapiacta®	2.8	2.8	-	(0.0)	2.7	2.8	0.1	2.6	5.8
Total of 8 strategic products	105.3	105.3	-	47.5	55.9	57.8	1.9	95.8	9.9
Overseas subsidiaries/export*2	30.4	30.4	-	14.7	15.6	15.7	0.1	28.7	6.0
Shionogi Inc.	17.4	17.4	-	8.4	8.4	9.0	0.6	15.9	9.1
Osphena®	7.4	7.4	-	2.6	4.4	4.8	0.4	4.6	61.9
C&O	8.0	8.0	-	3.3	4.6	4.7	0.1	6.9	15.6
Contract manufacturing*2	7.6	7.6	-	3.7	3.9	3.9	0.0	15.6	(51.3)
OTC and quasi-drugs	4.7	4.7	-	2.6	2.2	2.1	(0.1)	4.6	3.0
Royalty income	83.3	88.8	5.5	37.5	46.8	51.3	4.5	60.7	46.3
Crestor®	74.5	80.0	5.5	23.7	42.5	45.0	2.5	47.4	50.2
HIV franchise				11.4				5.8	
Others	3.0	3.0	-	1.4	1.7	1.6	(0.1)	3.1	(2.2)
Total	296.0	301.5	5.5	138.3	158.0	163.2	5.2	274.0	10.0

Revision of Statement of Income (Consolidated)

(Unit: B yen)

	FY2015							FY2014	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change	results	
Sales	296.0	301.5	5.5	138.3	158.0	163.2	5.2	274.0	10.0
[Royalty* income]	74.5	80.0	5.5	35.0	42.5	45.0	2.5	53.2	50.2
Cost of sales	24.8 [33.2] 73.5	24.4 [33.2] 73.5	-	26.4 [35.3] 36.5	24.2 [33.1] 38.2	22.7 [31.3] 37.0	(1.2)	30.0 [37.2] 82.2	(10.6)
Gross profit	222.5	228.0	5.5	101.8	119.8	126.2	6.4	191.8	18.9
SG&A expenses	50.7 150.0	49.8 150.0	-	49.1 67.9	48.0 75.8	50.3 82.1	6.3	51.6 141.4	6.1
Selling & general expenses	101.0	101.0	-	46.1	50.8	54.9	4.1	92.6	9.1
R&D expenses	49.0	49.0	-	21.8	25.0	27.2	2.2	48.9	0.3
Operating income	24.5 72.5	25.9 78.0	5.5	24.5 33.9	27.8 44.0	27.0 44.1	0.1	18.4 50.4	54.9
[Excluding royalty* income]	(2.0)	(2.0)	-	(1.1)	1.5	(0.9)	(2.4)	(2.9)	-
Non-operating income and expenses	P7.0	P10.0	3.0	P0.9	P7.5	P9.1	1.6	P27.5	-
Ordinary income	26.9 79.5	29.2 88.0	8.5	25.2 34.8	32.6 51.5	32.6 53.2	1.7	28.4 77.9	13.0

Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties

* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

Dividend Forecasts

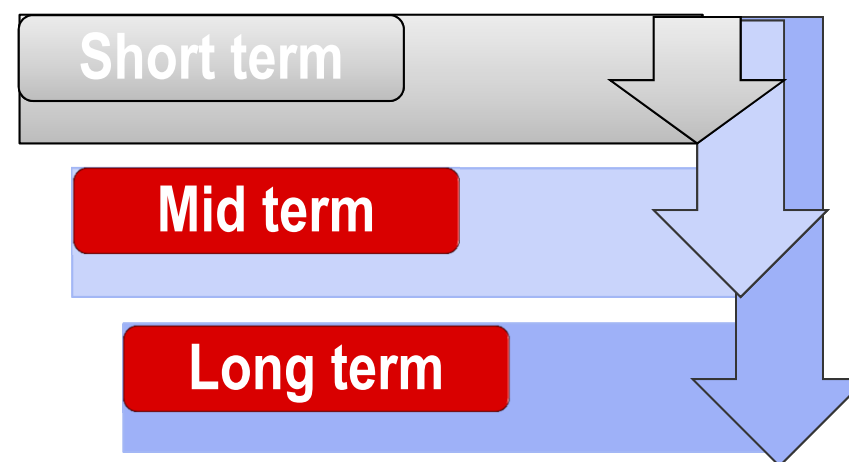
- ◆ Maximize enterprise value by balancing three key factors; return to shareholders, investment for further growth and strategic opportunities
- ◆ Sharing our mid- to long-term profit growth with our shareholders by increasing returns as appropriate
- ◆ Dividend forecast for FY2015: 60 yen

	Dividend per share			DOE	ROE
	half-year	year-end	annual		
FY2014	24.00	28.00	52.00	3.7%	9.4%
Original FY2015	28.00	(forecast) 28.00	(forecast) 56.00	—	(planned) 10.6%
Revised FY2015	28.00	(forecast) 32.00	(forecast) 60.00	—	(forecast) 11.9%

Promote Constructive Dialogue with Shareholders

- ◆ In response to publication of Japan's Corporate Governance Code, Shionogi disclosed its Corporate Governance Report to the Tokyo Stock Exchange, and also posted the **“Basic Views and Guidelines on Corporate Governance”** documents on our website on **October 29, 2015**
- ◆ Shionogi's basic stance on corporate governance
 - Emphasize its independent attitude and manner
 - Consider current issues while preparing for future environmental changes
 - Clearly explain and disclose corporate information as well as consistently engage in constructive dialogue with shareholders

Next Actions to Achieve the Vision of SGS2020



External Environment of Pharmaceutical Industry

Rapidly-aging global society

- ◆ Increasing, but increasingly segmented, medical needs
- ◆ Increased expectations for efficacy and safety of new drugs
- ◆ Growing expectations healthy life expectancy
- ◆ Increasing trends toward self medication

Expanding range of therapeutic agents to include new drug discovery paradigms

- ◆ Applying innovative technologies such as iPS cells to enable regenerative medicine and new drug discovery
- ◆ Shifting to precision medicine*, targeting therapy based on individual factors such as genetic background, environment and lifestyle

Changes in the Japanese and global pharmaceutical markets

- ◆ Developed countries: Financial pressure on health insurance, controversy around high drug prices, both adding to pricing pressure
- ◆ Emerging countries: Slowdown in economic growth, political risk to drug pricing, intellectual property risk

Enhanced expectations for the pharmaceutical industry in Japan

- ◆ Contribution to economic growth as a high value-added industry
- ◆ Strategic industry supported by the government

Achieve Growth by Leveraging the Strengths of Shionogi

Needs of a rapidly-aging society
(extension of HALE, support return to productive activities)

Sales area

- Japanese market
- US market

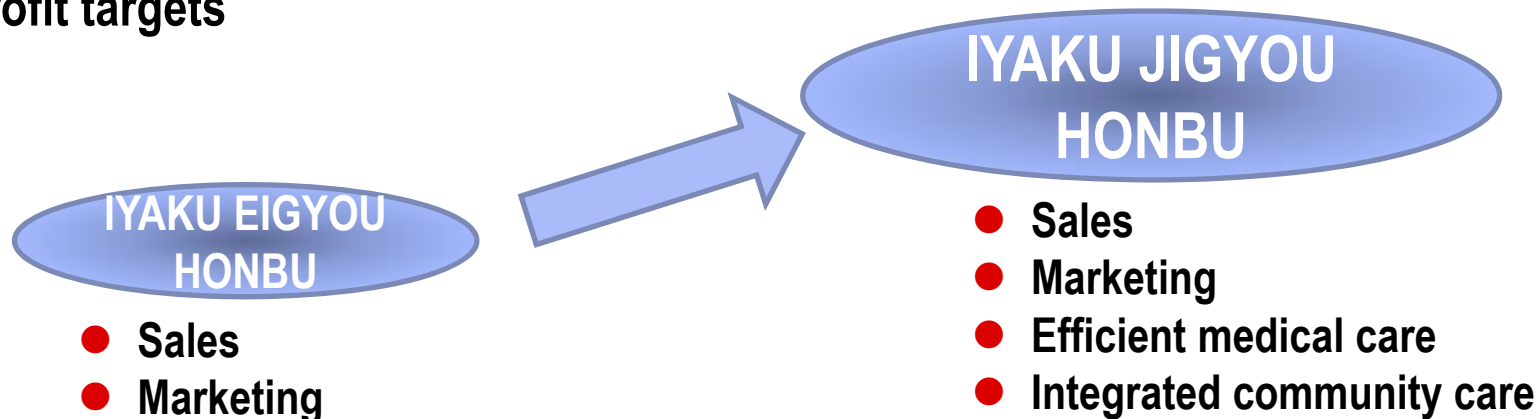
Therapeutic area (pipeline)

- Small molecule drug discovery
- Infectious disease
- Pain/CNS

**Sales and therapeutic areas chosen based on our
strengths and the needs of society**

Strengthening Japanese Domestic Business

- ◆ Many changes occurring in the health and medical care environment, such as the construction of integrated community care systems
- ◆ Renamed the Japanese name of the Human Health Care Division from “IYAKU EIGYOU HONBU” to “**IYAKU JIGYOU HONBU**”, and established “**Medical Relations Unit**”
- ◆ Transform domestic commercial business from one specialized in sales and marketing into a new business which will be able to contribute to medical services from a broader perspective
- ◆ IYAKU JIGYOU HONBU remains dedicated to achieving the domestic business profit targets



Pipeline for Future Growth in the Japanese Domestic Market

Phase I	Phase II	Phase III	NDA	Approval	Launch
Cymbalta® (Pain associated with fibromyalgia)			Approved: May 2015		
S-524101 (Allergic rhinitis caused by house-dust mite allergen)			Approved: Mar. 2015		
Mulpleta® (lusutrombopag) (Thrombocytopenia)			Approved: Sep. 2015		
Cymbalta® (Pain associated with chronic low back pain)			NDA submission: Dec. 2014		
S-877503 (ADHD)			NDA submission (in preparation)		
Cymbalta® (Pain associated with osteoarthritis)			NDA submission (in preparation)		
Naldemedine (S-297995) (Alleviation of opioid-induced adverse effects)			NDA submission (in preparation)		
S-877489 (ADHD)					
OxyContin® (Moderate to severe chronic pain; tamper resistant formulation)					
S-649266 (Severe gram-negative infections)					
S-033188 (Influenza virus infection)					
S-237648 (Obesity)					

Steady series of launches in the Japanese market



US Business: Strengthening Our Capability to Support New Global Products



◆ Osphena®

- Sharing the actual story of patients' experience with Osphena® through a new DTC campaign launched in mid-Sep.
- New initiatives to support patient access and affordability
- Continuing focus on ROI and effective resource allocation
- Initiating clinical study in vaginal dryness to expand indication and maximize the value of Osphena®

◆ For the launch of global pipeline products

- Laying groundwork for entry into Shionogi's therapeutic focus areas of pain and infectious disease

Establishment of Shionogi Healthcare Co., Ltd.

**Rapidly-aging
global society**

**Increasingly difficult
financial condition of
medical insurance system**

**Increasing importance
of self-medication**

**Establishment of Shionogi Healthcare Co., Ltd.
a new wholly-owned subsidiary, which will operate
consumer healthcare business in Japan**

Future schedule (plan)

- After the establishment of Shionogi Healthcare, Shionogi will transfer its consumer healthcare business to the new subsidiary in Jan. 2016
- The new subsidiary will initiate its business from Apr. 2016

Increased focus and quick decision making

**Enhance business activities by contributing to extending the
healthy life expectancy of customers by providing them with high-
quality healthcare products**

Pipeline

Target Milestones and Progress in FY2015

Areas	Code No.	Indication	Target milestone for FY2015	As of Oct. 2015
Infectious disease	S-649266	Severe gram-negative infections	Global: Phase III initiated	Phase II
	S-033188	Influenza virus infection	Japan: Phase I completed Go/No Go decision	<u>Phase II</u>
Pain/CNS	Cymbalta®	Pain associated with fibromyalgia	Japan: Approved (May 2015)	
		Pain associated with chronic low back pain	Japan: Approval	NDA submission (Dec. 2014)
		Pain associated with osteoarthritis	<u>Japan: Phase III completed</u>	<u>NDA submission (in preparation)</u>
	S-297995 (naldemedine)	Alleviation of opioid-induced adverse effects	US/Japan: NDA submission	<u>NDA submission (in preparation)</u>
	OxyContin®	Cancer/Non-cancer pain (Abuse deterrent)	Japan: Phase I initiated	
	S-718632	Chronic pain (Abuse deterrent)	US: Decision on final formulation	Phase I
	S-877503	ADHD	Japan: NDA submission	NDA submission (in preparation)
Frontier	S-888711	Thrombocytopenia	<u>Japan: Approval (Sep. 2015)</u>	

Infectious Diseases: HIV Integrase Inhibitor Franchise

Phase I	Phase II	Phase III	NDA	Approval	Launch
Dolutegravir + rilpivirine					
Cabotegravir LA + rilpivirine LA					

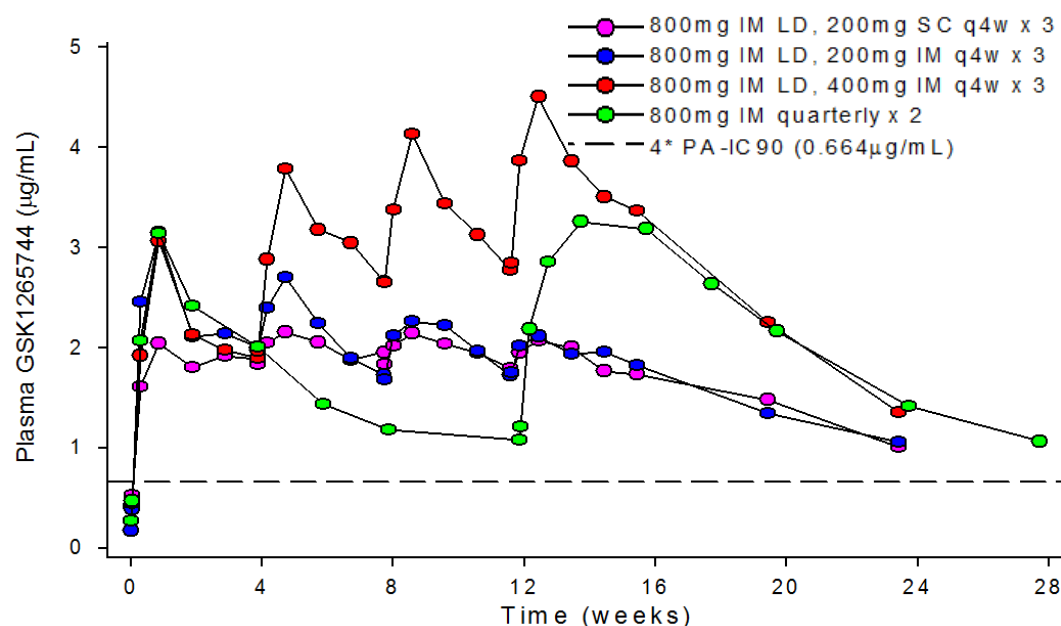
Co-development of ViiV and Janssen

◆ Development of oral fixed dose combination tablet of dolutegravir (DTG) and rilpivirine (RPV)

- Two drug combination therapy leveraging dolutegravir's efficacy, safety and resistance profile
- Phase III study ongoing

◆ Development of long-acting injectable cabotegravir (S/GSK1265744)

- Long-acting injectable formulation is expected to reduce the mental burden on patients who otherwise would take their anti HIV agent everyday
- Phase II study ongoing



Plasma concentration-time curve of cabotegravir*

Infectious Diseases: S-649266, S-033188

Phase I	Phase II	Phase III	NDA	Approval
[Severe gram-negative infections, Global] S-649266				
[Influenza virus infection, Japan] S-033188				

◆ S-649266 (Severe gram-negative infections, injection)

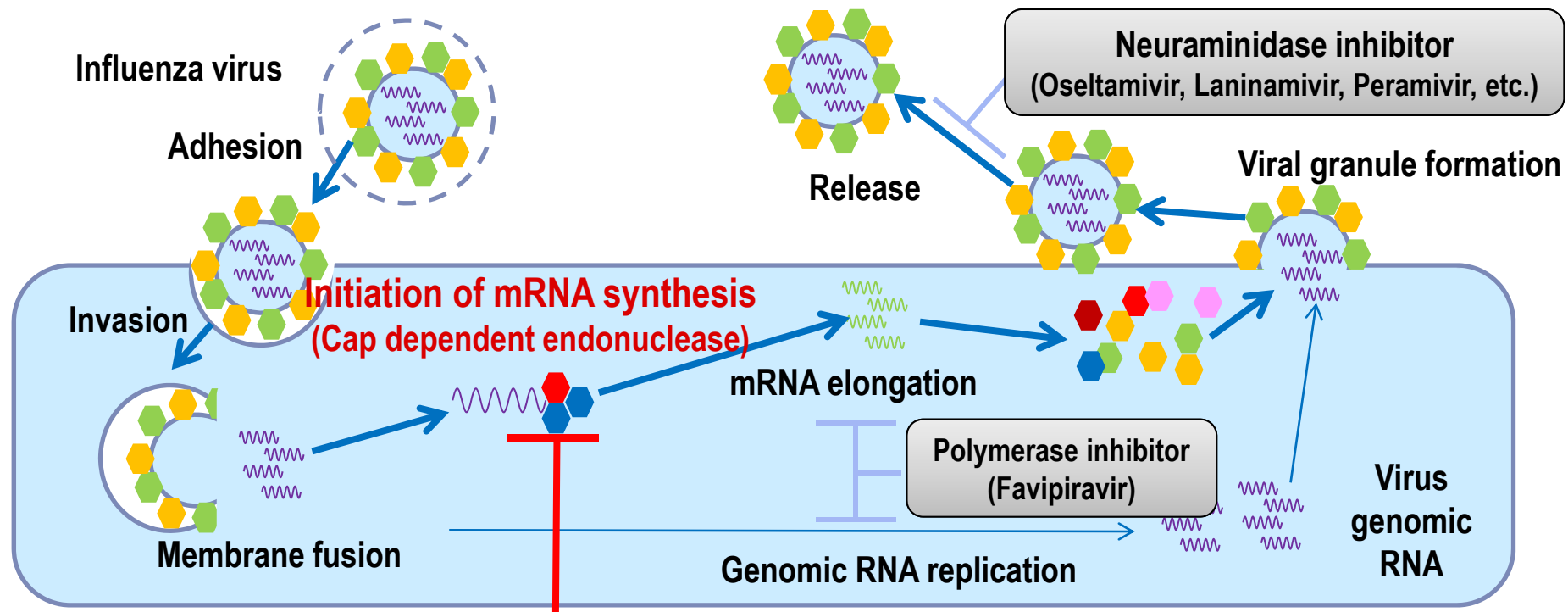
- Novel antibiotic for severe gram-negative infections which shows a unique transport mechanism for uptake into bacterial cells
- Global: Plan to initiate Phase III in 2015 [Severe gram-negative infections]

◆ S-033188 (Influenza virus infection, oral)

- Novel mechanism of action (distinct from neuraminidase inhibitors)
- Showed potent *in vitro* inhibitory activity against both influenza A virus, including highly pathogenic bird influenza strains, and influenza B virus
- Target of one time, one dose therapy
- Safety and PK profile confirmed in Phase I study
- Designated for “**priority review system**” on Oct. 27th by the MHLW.
 - The review period will be shortened and it will also be given priority for NHI drug price assessment.
- NDA submission in Japan in FY2017, as early as possible

Infectious Diseases: S-033188

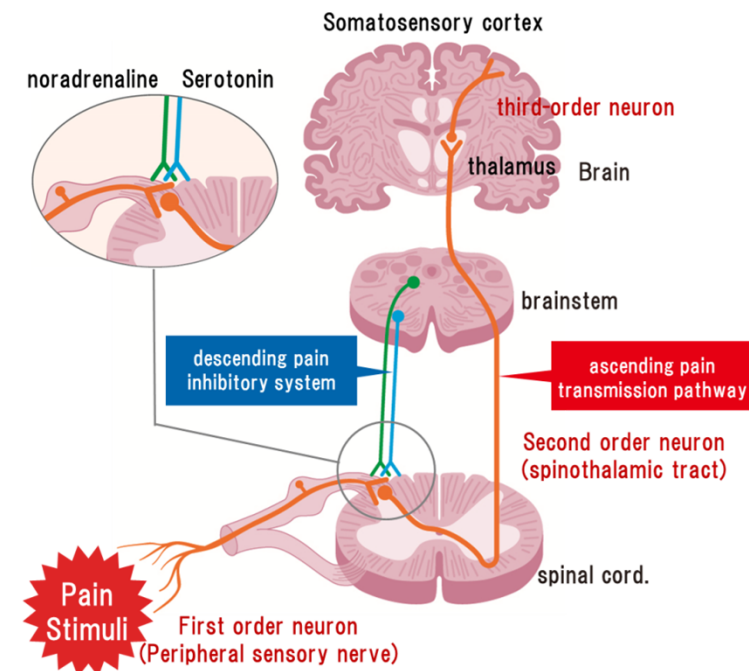
- ◆ New drug candidate for Influenza virus infection with novel mechanism of action
 - **Inhibit initiation of mRNA synthesis** which is the first proliferation step after entry of the influenza virus into the cell → "Cap dependent endonuclease inhibitor"
 - Inability to produce proteins essential for virus proliferation inhibits viral granule formation



Pain/CNS: Additional Indication for Cymbalta®

Phase III	NDA	Approval	Launch
Depression and depressive state (launched in Apr. 2010)			
Pain associated with diabetic neuropathy (additional indication in Feb. 2012)			
Pain associated with fibromyalgia (additional indication in May 2015)			
Pain associated with chronic low back pain (NDA in Dec. 2014)			
Pain associated with osteoarthritis (NDA submission in preparation)			

- ◆ Analgesic action of Cymbalta®, independent from antidepressant action, is thought to activate descending pathways that modulate pain
- ◆ An additional indication for pain associated with fibromyalgia was approved (May 2015)
- ◆ Favorable results were confirmed in Phase III study for pain associated with osteoarthritis
→ Plan to submit NDA in FY2015



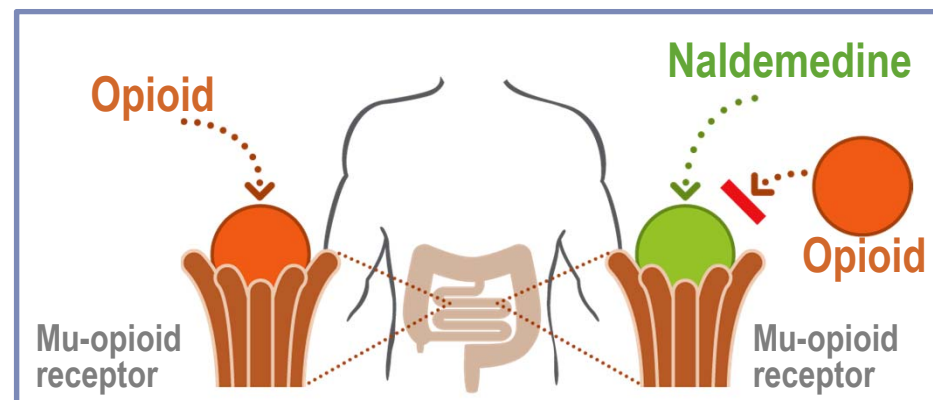
Pain/CNS: Naldemedine

Phase I	Phase II	Phase III	NDA	Approval	Launch
Naldemedine (Alleviation of opioid-induced adverse effects): Global NDA submission (in preparation)					

◆ Mechanism of action of naldemedine on opioid induced constipation (OIC)

Opioids provide analgesia as well as act on peripheral opioid receptors. The latter action in the GI tract causes dysmotility and constipation

Naldemedine is a PAMORA that targets peripheral mu-opioid receptors. In the GI tract, this directly blocks opioid effects on the bowel




OIC: Opioid Induced Constipation

PAMORA: Peripherally-Acting Mu-Opioid Receptor Antagonists

◆ Naldemedine market

- Global opioid market*: US\$14.8B
- Chronic opioid patients 70M (US, UK, Germany, France and Canada)
- 40~90%** of chronic opioid patients experience OIC, and <50% of patients taking laxative report satisfactory results

In-licensing of SR-0379

- ◆ **Acquired exclusive global rights to an antimicrobial peptide that accelerates wound healing, SR-0379, from FunPep Co., Ltd., a biotechnology venture company spin-out from academia**
 - **Synthetic functional peptide consisting of 20 amino acids**
 - **Topical administration of SR-0379 is expected to be a new therapeutic option for the treatment of intractable cutaneous ulcers, such as decubitus ulcers**
- 
- A large, solid red arrow pointing downwards, centered horizontally between the two main bullet points.
- ◆ **Shionogi could address this critical medical need in the nursing, hospital, and hospice care settings**

Appendix

- Pipeline -

Changes in Pipeline (since Aug. 2015)

Code No. / Product name	Indication	Phase	Area	Changes
Approval				
Mulpleta®	Thrombocytopenia	Approval	Japan	NDA submission (Dec. 2014) → Approval (Sep. 2015)
Change of phase				
S-033188	Influenza virus infection	Phase II	Japan	Phase I → Phase II
Naldemedine (S-297995)	Alleviation of opioid-induced adverse effects	NDA submission	Global	Phase III → NDA submission
Compound added to the list				
S-525101	Pediatric patients with perennial allergic rhinitis	Phase III	Japan	

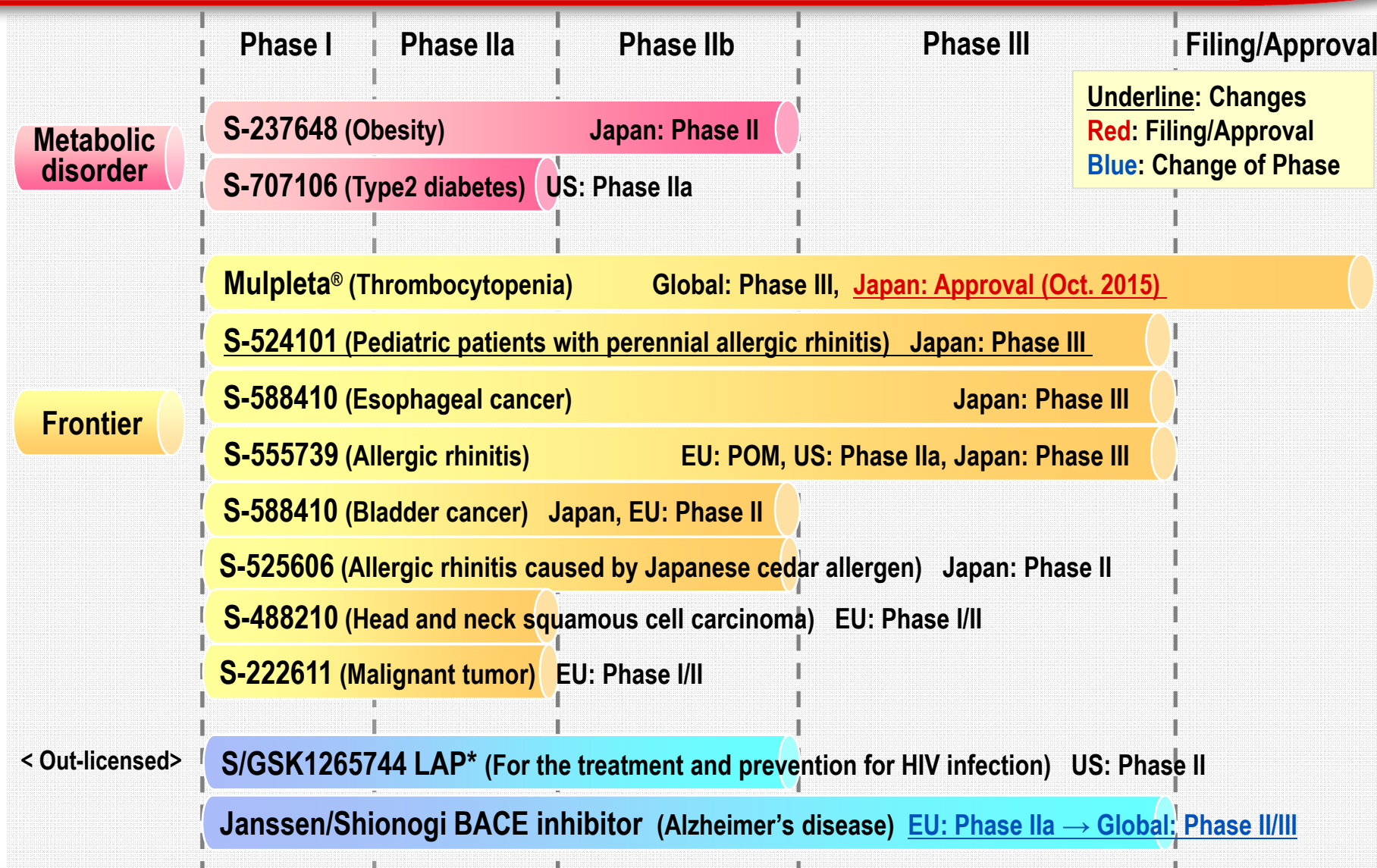
[Out-Licensing Activity]

Change of phase				
Janssen/Shionogi BACE inhibitor	Alzheimer's disease	Phase II/III	Global	Phase IIa → Phase II/III EU → Global

Pipeline (as of Oct. 2015)

	Phase I	Phase IIa	Phase IIb	Phase III	Filing/Approval
Infectious diseases	S-649266 (Severe gram-negative infections)			Global: Phase II	<u>Underline: Changes</u> Red: Filing/Approval Blue: Change of Phase
	S-033188 (Influenza virus Infection)			Japan: <u>Phase I → Phase II</u>	
Pain/CNS	Cymbalta® (Pain associated with chronic low back pain)			Japan: NDA submission (Dec. 2014)	
	S-877503 (ADHD)			Japan: NDA submission (in preparation)	
	Cymbalta® (Pain associated with osteoarthritis)			Japan: NDA submission (in preparation)	
	Naldemedine (Alleviation of opioid-induced adverse effects)			Japan, Global: <u>Phase III → NDA submission (in preparation)</u>	
	OxyContin® (Moderate to severe chronic pain)			Japan: Phase III	
	S-877489 (ADHD)			Japan: Phase III	
	S-120083 (Inflammatory pain)			Japan: Phase I	
	S-010887 (Neuropathic pain)			Japan: Phase I	
	S-718632 (Chronic pain)			US: Phase I	
	S-117957 (Insomnia)			US: Phase I	

Pipeline (as of Oct. 2015)



Underline: Changes
Red: Filing/Approval
Blue: Change of Phase

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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