



**1st Quarter of Fiscal 2015
Financial Results
Conference Call**

August 3, 2015



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 1Q FY2015

- ◆ Sales and income on track
- ◆ Operating income and ordinary income are higher than the levels achieved in the Apr. to Jun. period of any prior fiscal year
- ◆ Increased Cymbalta[®] sales due to the modification of Cymbalta[®] contract with Eli Lilly Japan K.K.
- ◆ Tivicay[®] and Triumeq[®] showing strong growth globally
- ◆ Continued excellent development progress for late phase pipeline compounds

Overview of 1st Quarter FY2015 Financial Results

Strengthening
Japanese business
as a business base

Strengthening
capability to
support new global
products

Developing an
operating structure
independent of
royalty income

Financial Results (Consolidated)

(Units: B yen)

	FY2015 forecasts	FY2015		Progress vs. forecasts (%)	FY2014 Apr-Jun results	Y on Y	
		1H forecasts	Apr-Jun results			change (%)	change
Sales	296.0	138.0	63.9	46.3	62.7	1.8	1.2
Operating income	72.5	28.5	12.5	44.0	8.0	55.7	4.5
Ordinary income	79.5	28.0	14.6	52.2	13.6	7.1	1.0
Net income attributable to owners of the parent	52.0	17.0	9.7	56.8	10.3	(6.4)	(0.6)

Note: All numerical values are rounded to the nearest unit

- Operating income and ordinary income are higher than the levels achieved in the Apr. to Jun. period of any prior fiscal year

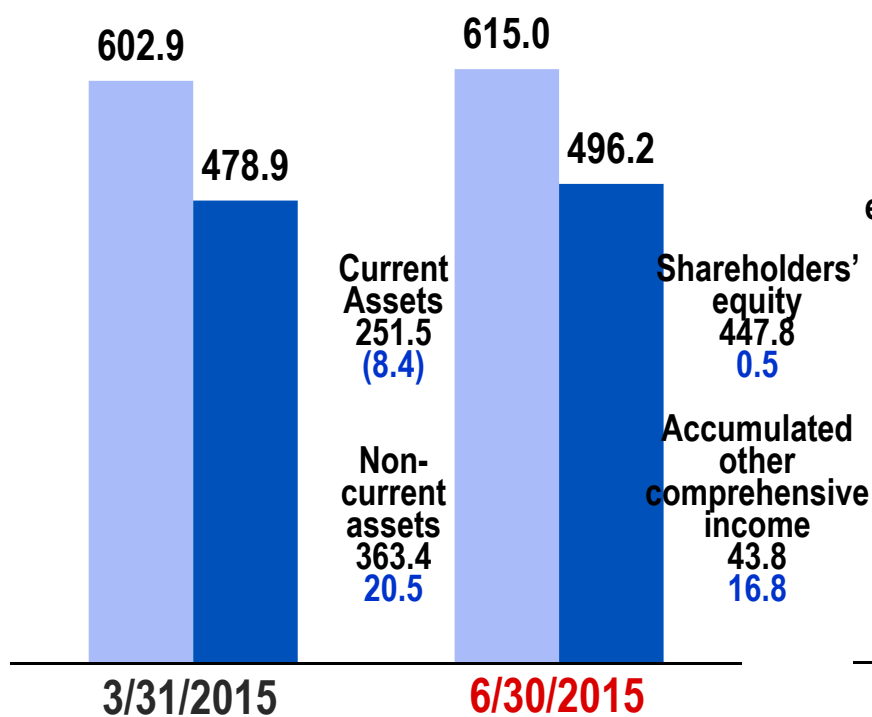
Exchange rate (average)	FY2015 forecasts	Apr-Jun results
USD (\$) – JPY (¥)	120	121.44
EUR (€) – JPY (¥)	130	134.20
GBP (£) – JPY (¥)	175	186.16

Financial Position and Cash Flow (Consolidated)

◆ Financial Position

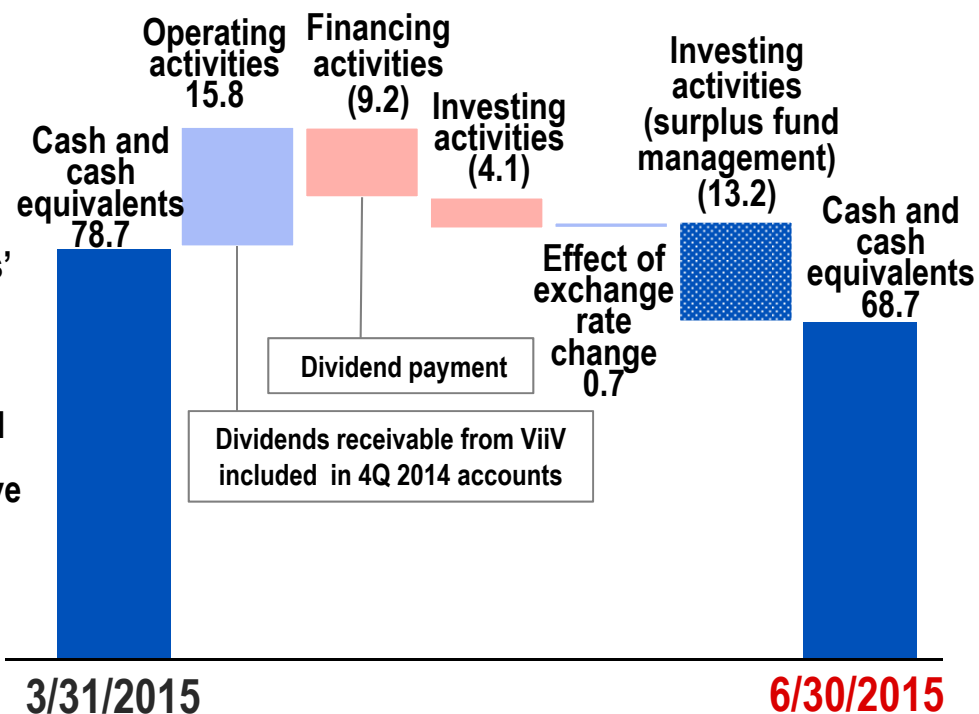
■ Total assets
■ Net assets

(Units: B yen)
lower: Y on Y change



◆ Cash Flow

(Units: B yen)



	3/31/2015	6/30/2015
Equity ratio	78.7%	79.9%

Statements of Income (Consolidated)

(Units: B yen)

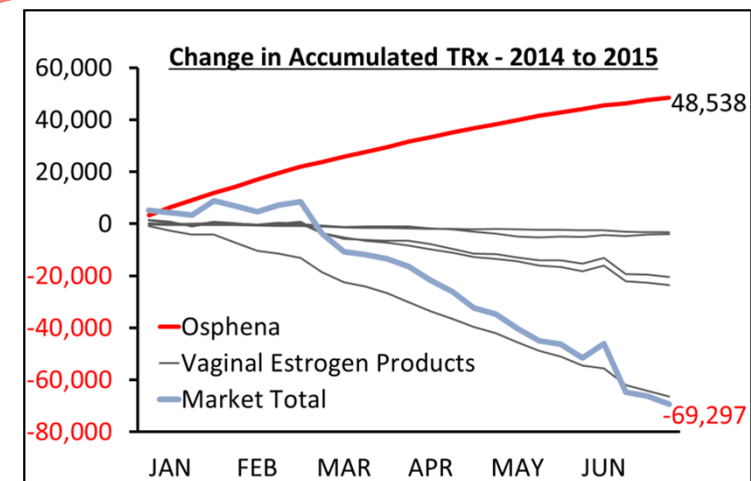
	FY2015		Progress vs. forecasts (%)	FY2014 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Prescription drugs	79.2	39.7	50.2	38.7	2.6	1.0
Total of 3 key products	37.2	18.2	48.9	17.1	6.3	1.1
Total of 8 strategic products	49.4	24.2	48.9	22.9	5.7	1.3
Overseas subsidiaries/export*	14.8	7.2	48.0	6.0	19.3	1.2
Shionogi Inc.	9.0	4.4	48.6	2.8	53.8	1.6
Osphena®	3.0	1.3	42.1	0.8	66.4	0.5
C&O	3.4	1.6	45.8	1.8	(11.9)	(0.2)
Contract manufacturing*	3.7	1.5	40.6	3.5	(57.6)	(2.0)
OTC and quasi-drugs	2.5	1.2	49.9	1.1	12.4	0.1
Royalty income	36.5	13.5	37.1	12.7	6.9	0.8
Royalty income for the sales of Crestor® and HIV franchise	32.0	12.6	39.5	11.8	7.3	0.8
Crestor®	-	11.2	-	11.8	(4.5)	(0.6)
HIV franchise	-	1.4	-	-	-	1.4
Others	1.3	0.7	56.2	0.7	(1.1)	(0.0)
Total	138.0	63.9	46.3	62.7	1.8	1.2

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

US business: Osphe[®]

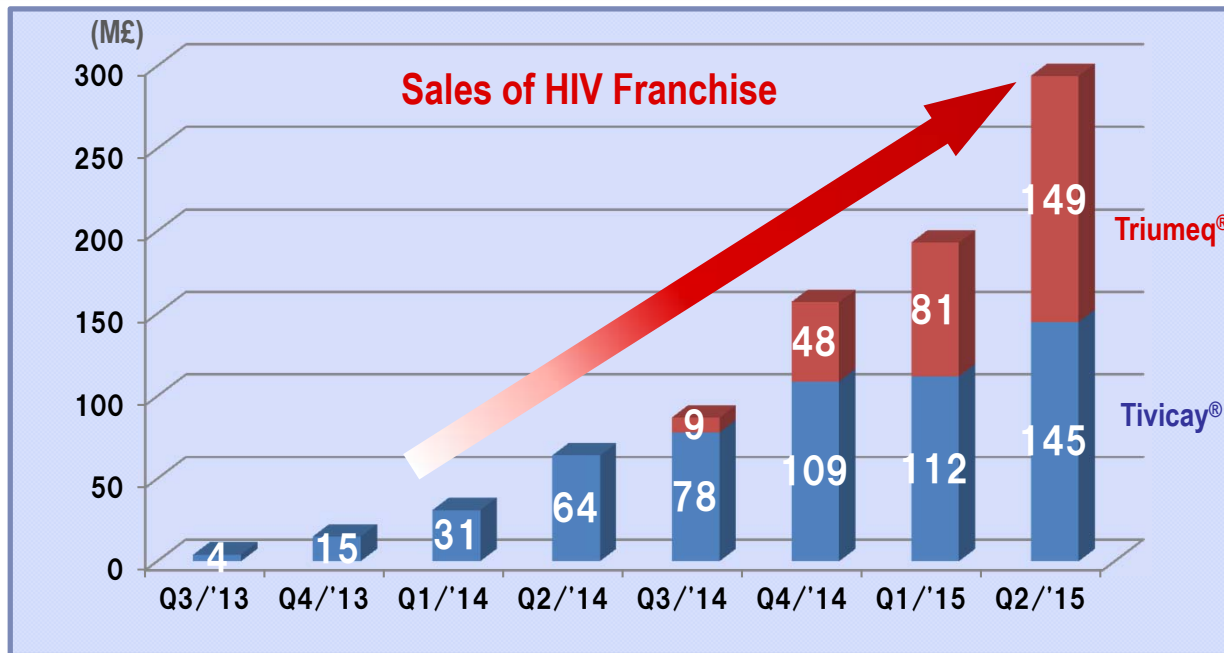
- ◆ Optimized promotional activities with greater precision and clarity in HCP audience focus and messaging
 - Increased patient adherence and accessibility by launching 90 count bottle and simplifying copay card offers, provided in both traditional and electronic formats
 - Standardized weekly review process with new KPIs

- ◆ Osphe normalized TRx is increasing and trending above market throughout 2015
- ◆ Grew market share to nearly 5% in a declining VVA market



Accelerating Osphe[®] growth with new DTC campaign (start 2Q FY2015) and future additional indication for vaginal dryness (start Phase III study 3Q FY2015)

HIV Franchise



- ◆ Sales of the HIV franchise continue to grow strongly worldwide
- ◆ Sales are also rapidly expanding in the Japanese market (Triumeq® was launched in Apr. 2015)
- ◆ Began receiving royalties for the HIV franchise in 1Q (previously expected in 2Q)
- ◆ Annual dividend from ViiV for CY2015 will be recorded in 4Q FY2015

Japan: Sales of 8 Strategic Products

(Units: B yen)

	FY2015		Progress vs. forecasts (%)	FY2014 Apr- Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Prescription drugs	79.2	39.7	50.2	38.7	2.6	1.0
Crestor [®]	21.3	10.6	49.9	10.8	(1.8)	(0.2)
Irbetan [®] franchise	8.2	4.1	49.9	3.7	9.4	0.4
Cymbalta ^{®*}	7.7	3.5	45.0	2.5	36.2	1.0
Total of 3 key products	37.2	18.2	48.9	17.1	6.3	1.1
OxyContin [®] franchise	5.3	2.6	48.7	2.7	(4.2)	(0.1)
Finibax [®]	1.9	1.0	51.3	0.9	11.7	0.1
Differin [®]	1.9	0.9	45.2	0.9	(2.6)	(0.0)
Pirespa [®]	3.0	1.6	52.2	1.3	24.1	0.3
Rapiacta [®]	0.1	(0.0)	-	0.1	-	(0.1)
Total of 8 strategic products	49.4	24.2	48.9	22.9	5.7	1.3
[percent of sales]	[62.4]	[60.8]	-	[59.1]	-	-

Japan: One of the Key Products - Cymbalta®

- ◆ **Sales structure was changed to 1brand-1channel**
 - Both Shionogi and Eli Lilly Japan K.K. strengthened their promotional activities
 - Sales of Cymbalta® brand are growing strongly
- ◆ **Impact of the modification of Cymbalta® contract**
 - Shionogi receives remuneration for promotion based on Cymbalta® sales
 - Decrease in cost of sales

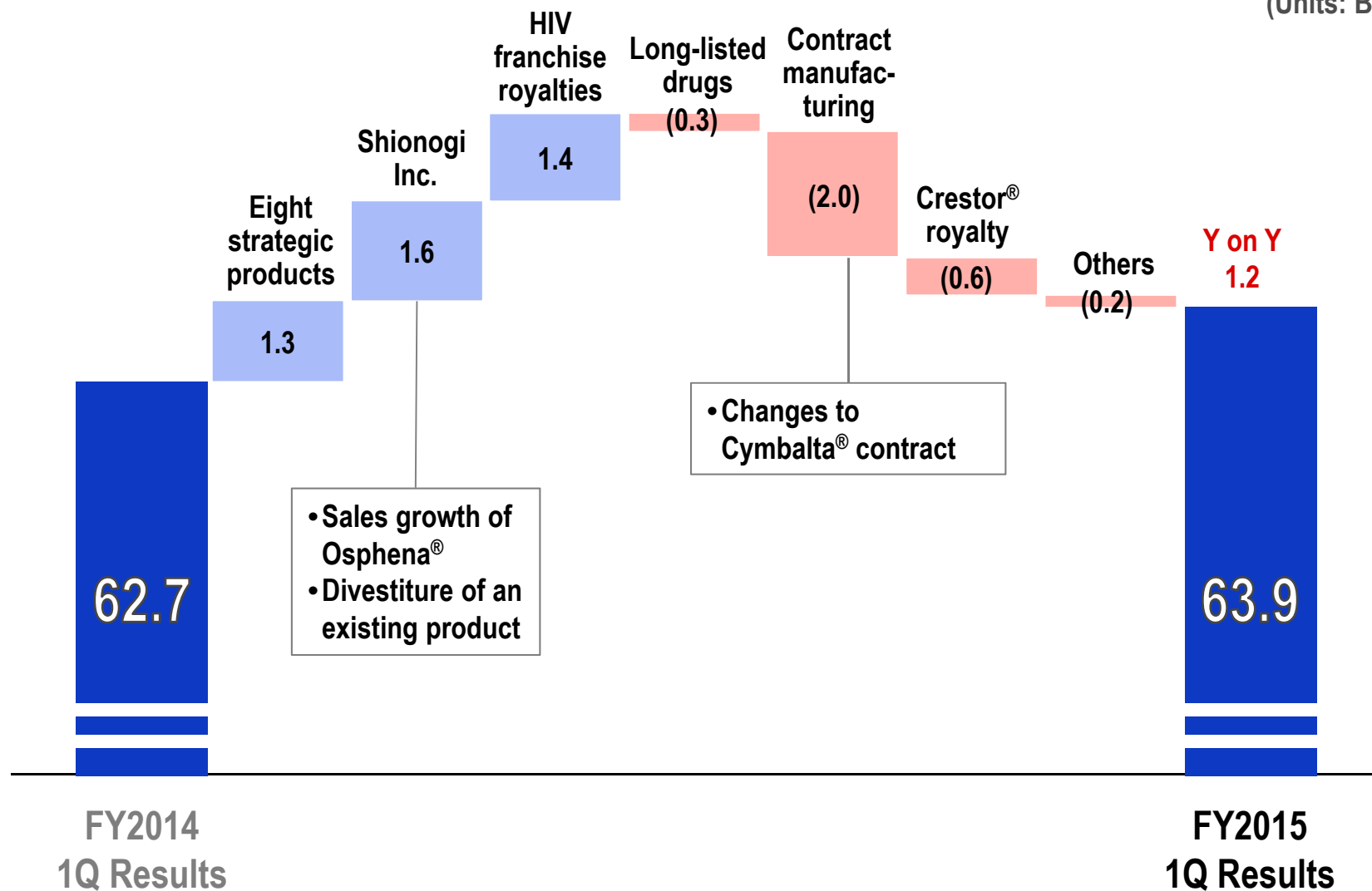
⇒ Modification of the Cymbalta® contract is resulting in increased sales and reduced cost-of-goods
- ◆ **Additional indication for pain associated with fibromyalgia (May 2015)**

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)			

Maximize the value of Cymbalta® by additional indications in pain area

Change in Sales vs. Previous Year

(Units: B yen)



Statements of Income (Consolidated)

(Units: B yen)

	FY2015		Progress vs. forecasts (%)	FY2014 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Sales	138.0	63.9	46.3	62.7	1.8	1.2
[Royalty* income]	32.0	12.6	39.5	11.8	7.3	0.8
	25.6 [33.3]	28.3 [35.2]		31.6 [38.9]		
Cost of sales	35.3	18.0	51.1	19.8	(9.0)	(1.8)
Gross profit	102.7	45.8	44.6	42.9	6.8	2.9
	53.8	52.1		55.6		
SG&A expenses	74.2	33.3	44.9	34.9	(4.5)	(1.6)
Selling & general expenses	50.2	22.7	45.1	23.1	(1.9)	(0.4)
R&D expenses	24.0	10.6	44.3	11.7	(9.5)	(1.1)
	20.7	19.6		12.8		
Operating income	28.5	12.5	44.0	8.0	55.7	4.5
[Excluding royalty* income]	(3.5)	(0.1)	-	(3.7)	-	3.6
Non-operating income and expenses	L0.5	P2.1	-	P5.6	-	(3.5)
	20.3	22.9		21.7		
Ordinary income	28.0	14.6	52.2	13.6	7.1	1.0

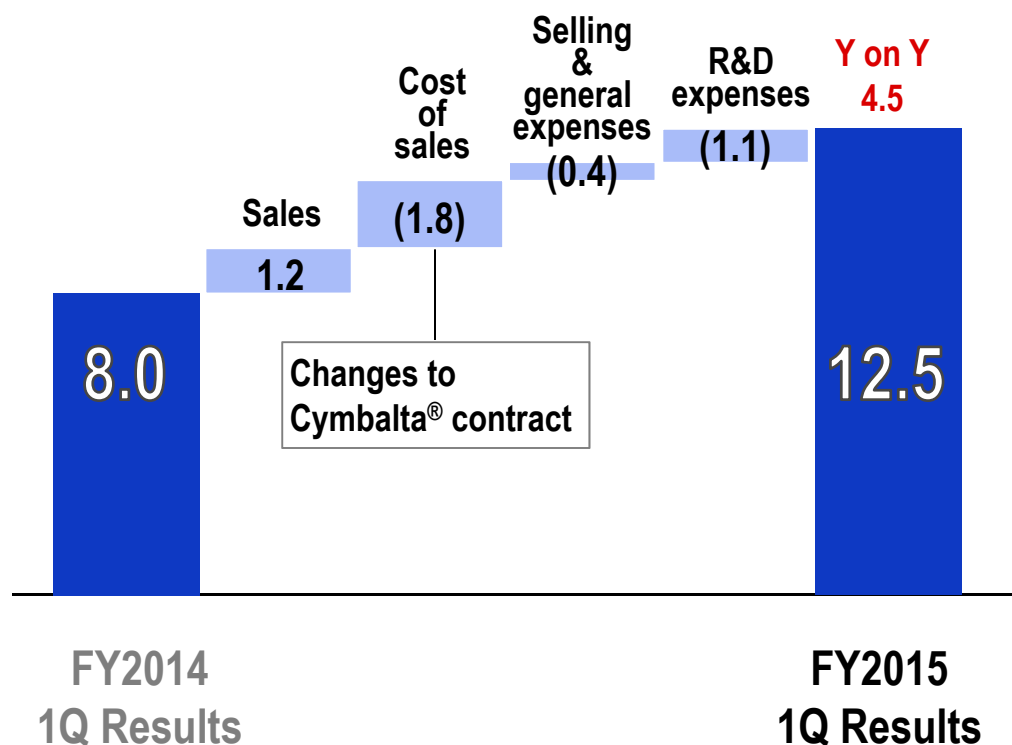
Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties

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

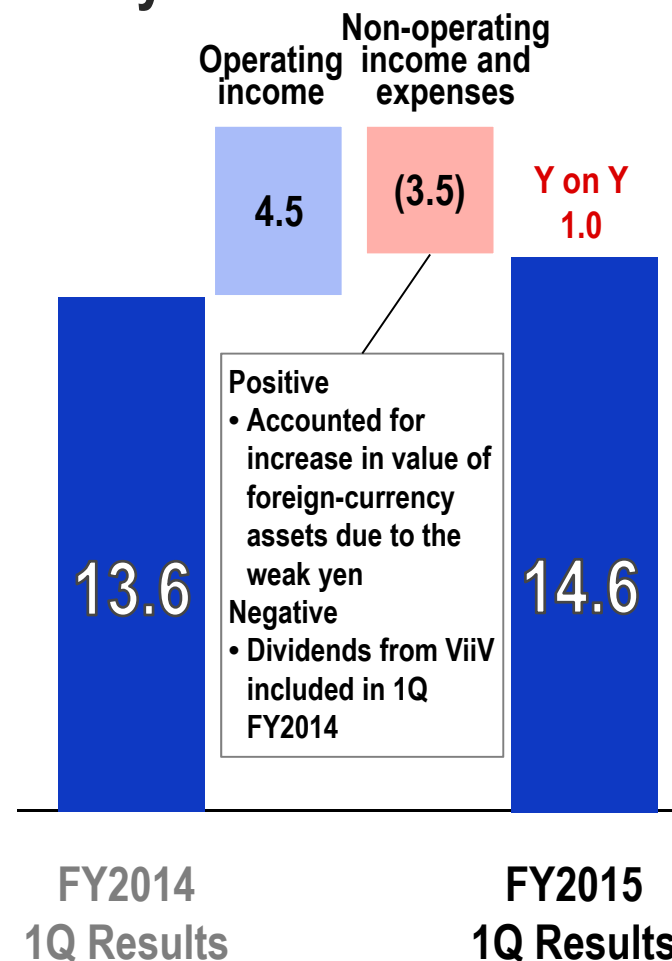
Change in Earnings Structure vs. Previous Year

(Units: B yen)

◆ Operating income



◆ Ordinary income



Research & Development

FIC

First-in-Class

Innovative medicines with particularly high novelty and efficacy that can significantly change the existing therapeutic paradigm.

LIC

Last-in-Class

Unrivaled medicines with clear superiority over others that have the same mechanism of action.

Target Milestones for FY2015 and Progress

Areas	Code No.	Indication	Target milestone for FY2015	As of 6/30/2015
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	Phase I
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	Japan: Phase III completed	NDA submission (in preparation)
	S-297995 (naldemedine)	Alleviation of opioid-induced adverse effects	US/Japan: NDA submission	Phase III
	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	Japan: Approval	NDA submission (Dec. 2014)

Infectious Diseases: HIV Integrase Inhibitor Franchise

Phase I	Phase II	Phase III	NDA	Approval	Launch
Tivicay® (dolutegravir)					
Triumeq® (dolutegravir/abacavir/lamivudine)					
Dolutegravir + rilpivirine			Out-licensed to ViiV		
Cabotegravir LA + rilpivirine LA			Co-development of ViiV and Janssen		

- ◆ **Development of oral fixed dose combination tablet of dolutegravir (DTG) and rilpivirine (RPV)**
 - Phase I studies are now underway in healthy subjects for various test formulations of DTG+RPV to select the best fixed dose tablet
 - Phase III study initiated in May 2015 to evaluate the antiviral activity, safety, and tolerability of switching to DTG (50mg) + RPV (25mg) compared to current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed (non-inferiority endpoint)
- ◆ **Development of long-acting injectable cabotegravir (S/GSK1265744)**
 - Phase IIb study to evaluate a long-acting intramuscular regimen (once a month, or once every 2 months) for maintenance of virologic suppression (following induction with an oral regimen of S/GSK1265744 and abacavir/lamivudine) in HIV-1 infected, antiretroviral therapy naïve subjects
 - Phase IIa study for pre-exposure prophylaxis (once every 3 months injection, intramuscular); ÉCLAIR study in HIV uninfected men and HPTN077 study in uninfected men and women, to evaluate the safety, tolerability, and acceptability

Pain/CNS: Opioid Analgesics

Phase I	Phase II	Phase III	NDA	Approval	Launch
OxyContin [®] *, OxiNorm [®] , OxiFast [®] (Cancer pain): Japan					
Naldemedine (Alleviation of opioid-induced adverse effects): Global				☐ In-house	
OxyContin [®] * (Non-cancer pain): Japan				☐ In-licensed	
S-718632 (Chronic pain, abuse-deterrent extended release hydrocodone): US				* Planning to switch to abuse-deterrent formulation in Japan	

◆ Development of naldemedine, alleviation of opioid-induced adverse effects (COMPOSE program)

- Phase III studies are on-going: chronic non-cancer pain patients in the US and cancer and chronic non-cancer pain patients in Japan
- Code-break of COMPOSE I, II, IV: Met the primary endpoints in all pivotal studies
- NDA submission in the US and Japan in Q4 FY2015

◆ Development of OxyContin[®] (non-cancer pain)

- Obtained new indication requested for development by MHLW in Dec. 2010
- Phase III study ongoing: the treatment of moderate to severe chronic pain

◆ Development of abuse-deterrent, tamper-resistant formulation of opioid

- Clinical studies of abuse-deterrent, tamper-resistant oxycodone tablets for cancer pain and non-cancer pain are on-going
- Entered into a global alliance for abuse-deterrent hydrocodone with Egalet (US: Phase I study)

Pain/CNS: Top Line Results of COMPOSE Program

	COMPOSE I and II	COMPOSE IV
Area	Global	Japan
Drug	Naldemedine (0.2 mg tablet, once daily, 12W)	Naldemedine (0.2 mg tablet, once daily, 2W)
Target patients	Chronic non-cancer pain patients	Cancer patients
Efficacy profile		
<u>Primary endpoint:</u> Proportion of responders	The treatment difference in responder rate between naldemedine and placebo was statistically significant	
<u>Secondary endpoints:</u> Frequency of SBM*s, CSBM**s, SBMs without strainings	The treatment differences in all secondary endpoints between naldemedine and placebo were statistically significant	
Safety profile		
Tolerability	Generally well tolerated	
TEAE***s (>= 5%)	Abdominal pain and diarrhea	Diarrhea
Attenuation of opioid analgesic effects and withdrawal symptom	No significant changes were seen in the pain intensity NRS**** scores and COWS***** scores	

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
Cymbalta® (Pain associated with chronic low back pain)					NDA submission: Dec. 2014
S-888711 (Thrombocytopenia)					NDA submission: Dec. 2014
S-877503 (ADHD)					NDA submission (in preparation)
Cymbalta® (Pain associated with osteoarthritis)					NDA submission (in preparation)
S-297995 (Alleviation of opioid-induced adverse effects)					
S-877489 (ADHD)					
OxyContin® (Moderate to severe chronic pain; tamper resistant formulation)					
S-649266 (Severe gram-negative infections)					
S-033188 (Influenza virus infection)					

**Steady
series of
launches
in the
Japanese
market**

Next Actions to Achieve the Targets for FY2015 Business Plan Building on the Results of 1Q FY2015

Strengthening
Japanese business
as a business base

Strengthening
capability to
support new global
products

Developing an
operating structure
independent of
royalty income

Results of 1Q FY2015

Good progress of Cymbalta® after the contract modification

- Both Shionogi and Eli Lilly strengthened their promotional activities
- Increase in sales
- Improvement in the cost of sales

Sales growth of Osphena® in the US

- New HCP messaging and focus
- Improvements in adherence and access
- Increased TRx (normalized to 30-count) and market share

Growth of the HIV franchise

- Global sales growth
- Solid increase in royalty from ViiV

Steady progress on development program

- Continued excellent progress in naldemedine Phase III program
- Additional indications for Cymbalta®

Challenges to Achieve FY2015 Business Plan Targets

**Strengthening
Japanese business
as a business base**

- Further expansion of sales for Cymbalta®
- Achieve the sales targets of 8 strategic products
- Progress of pipeline to overcome the cliff in the Japanese market

**Strengthening
capability to
support new global
products**

- Further expansion of sales of Osphena® in the US
- Continue to accelerate global development of our original pipeline compounds

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

- Maintain tight controls over operating costs

Appendix

- Pipeline -

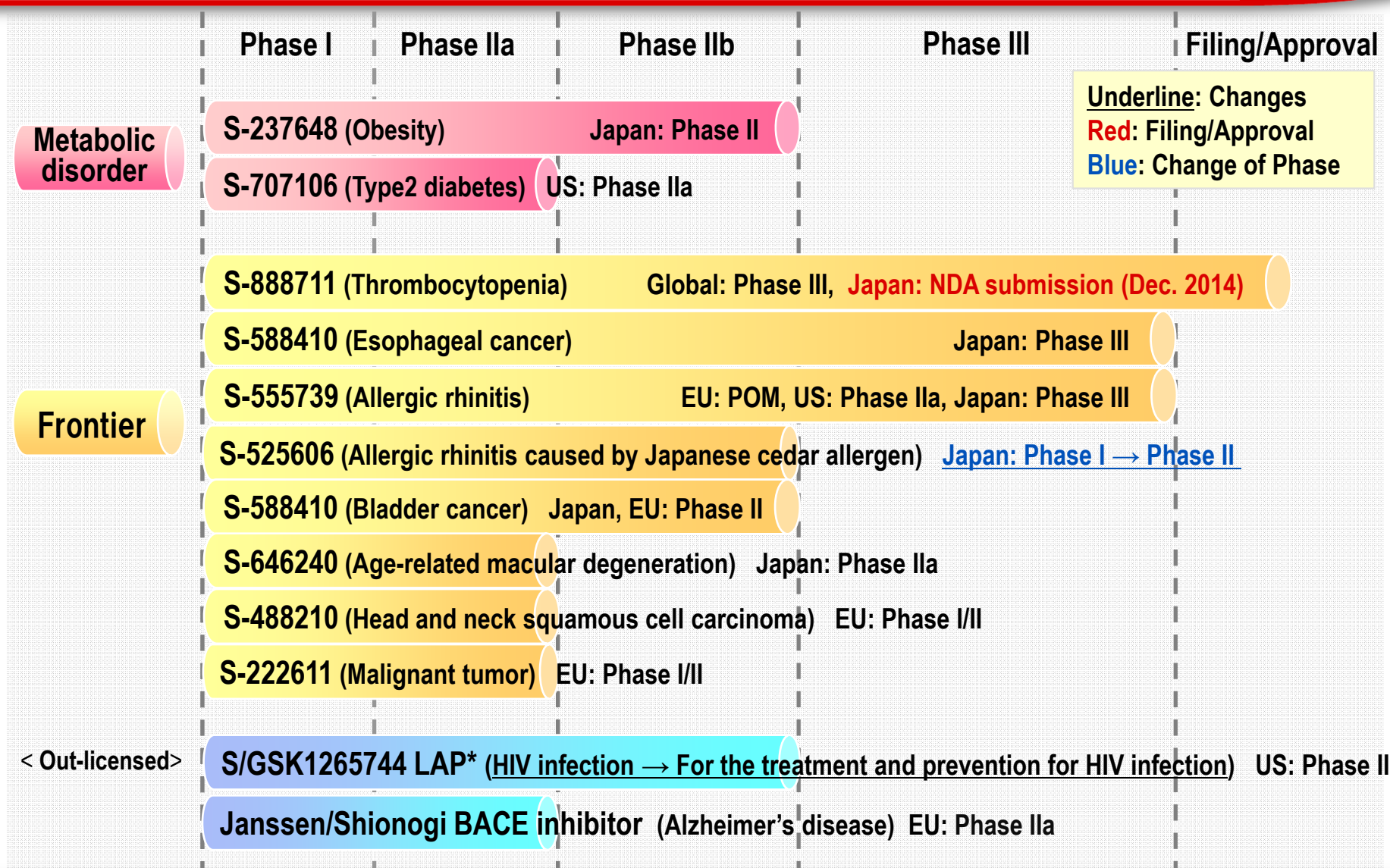
Changes in Pipeline (since May 2015)

Code No. / Product name	Indication	Phase	Area	Changes
Approval				
Cymbalta®	Pain associated with fibromyalgia	Approval	Japan	NDA submission (Jun. 2014) → Approval (May 2015)
Endoxan®	Malignant lymphoma	Approval	Japan	NDA submission based on public knowledge (Feb. 2015) → Approval (Jun. 2015)
Predonine®	Malignant lymphoma	Approval	Japan	NDA submission based on public knowledge (Feb. 2015) → Approval (Jun. 2015)
Change of phase				
Cymbalta®	Pain associated with osteoarthritis	NDA submission (in preparation)	Japan	Phase III → NDA submission (in preparation)
S-525606	Allergic rhinitis caused by Japanese cedar allergen	Phase II	Japan	Phase I → Phase II
Change of indication				
S/GSK1265744 LAP*	For the treatment and prevention for HIV infection	Phase II	US	HIV infection → For the treatment and prevention for HIV infection

Pipeline (as of Aug. 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: Phase I	
Pain/CNS	Cymbalta® (Pain associated with fibromyalgia)			Japan: NDA submission (Jun. 2014) → Japan: Approval (May. 2015)	
	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: Phase III → Japan: NDA submission (in preparation)	
	S-297995 (Alleviation of opioid-induced adverse effects)			Japan: Phase III, Global: Phase III	
	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 Aug. 2015)



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

Forward-Looking Statements



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