1st Quarter of Fiscal 2015 Financial Results Conference Call

August 3, 2015

SHIONOGI

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

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

Growth led by FIC and LIC compounds

Shift Gears for Growth

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

Financial Results (Consolidated)

(Units: B yen)

	FY2015 forecasts	FY2015 1H forecasts	FY2015 Apr-Jun results	Progress vs. forecasts (%)	FY2014 Apr-Jun results	Y on Y change (%)	Y on Y 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

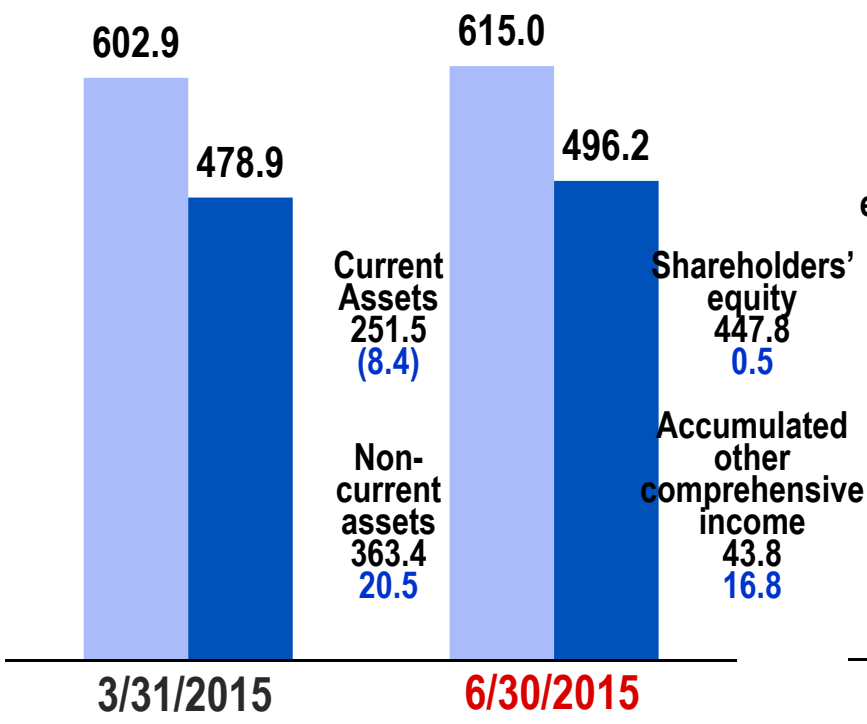
- **Operating income and ordinary income are higher than the levels achieved in the Apr. to Jun. period of any prior fiscal year**

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

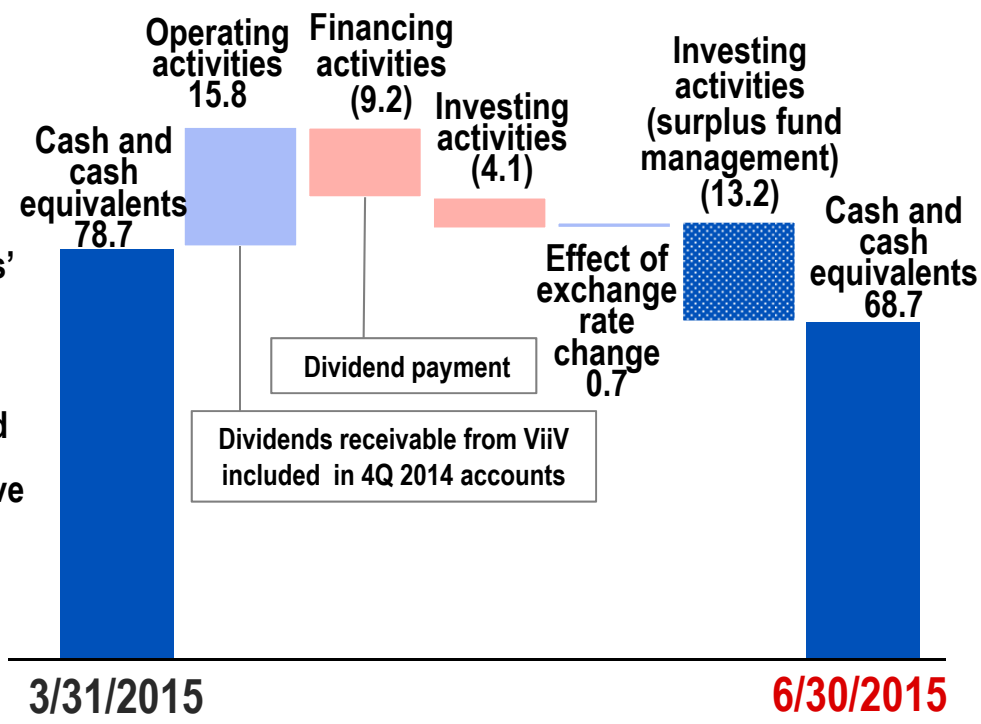
(Units: B yen)
lower: Y on Y change



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

Cash Flow

(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
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

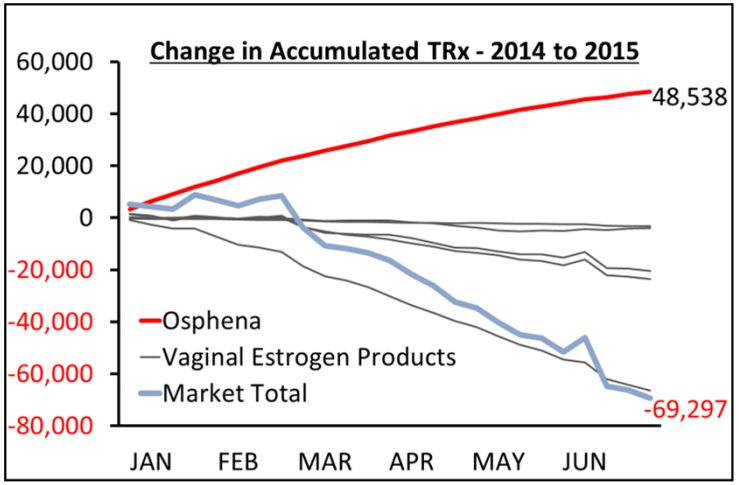
Eight strategic products: Crestor®, Irbetan® franchise, Cymbalta® (3 key products), and OxyContin® franchise, Finibax®, Differin®, Pirespa®, Rapiacta®

* The accounting policy for API for dolutegravir was changed from export to contract manufacturing in FY2014

US business: Osphena®

- **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

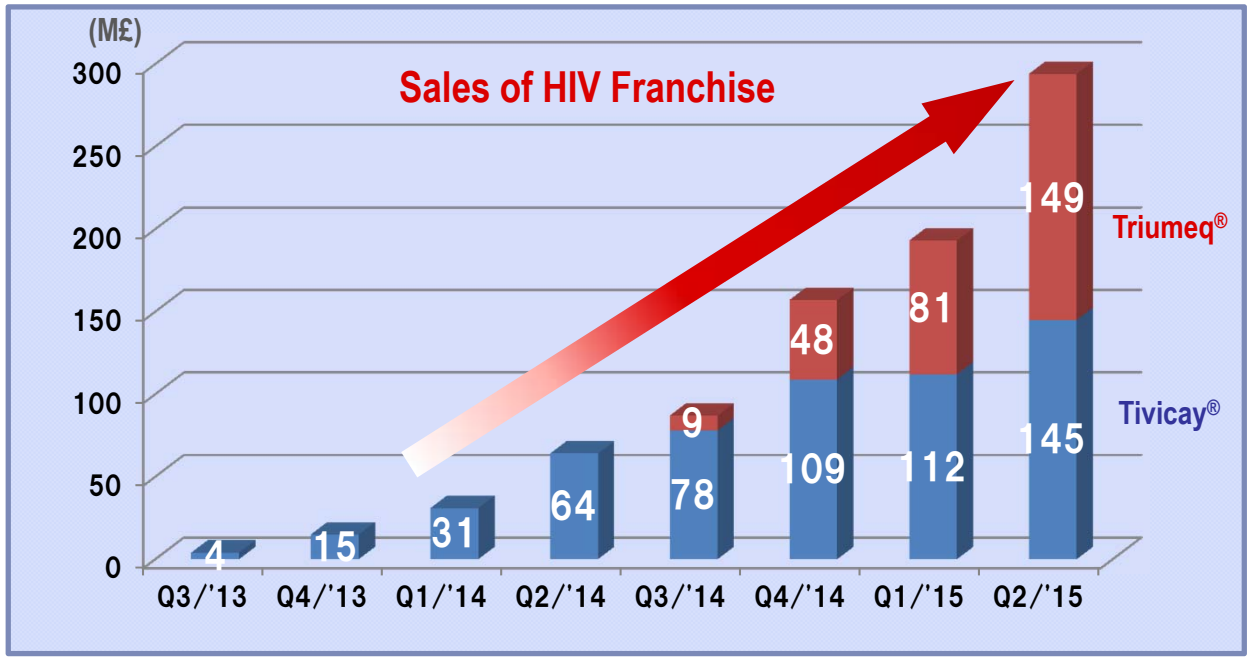
- **Osphena normalized TRx is increasing and trending above market throughout 2015**
- **Grew market share to nearly 5% in a declining VVA market**



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

Normalized TRx: Recalculated the prescription of 90 count bottle to 30 count bottle
Vaginal dryness: Symptom caused by reduced estrogen levels in vaginal tissue

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]	-	-

* Remuneration for promotional activity from FY2015

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

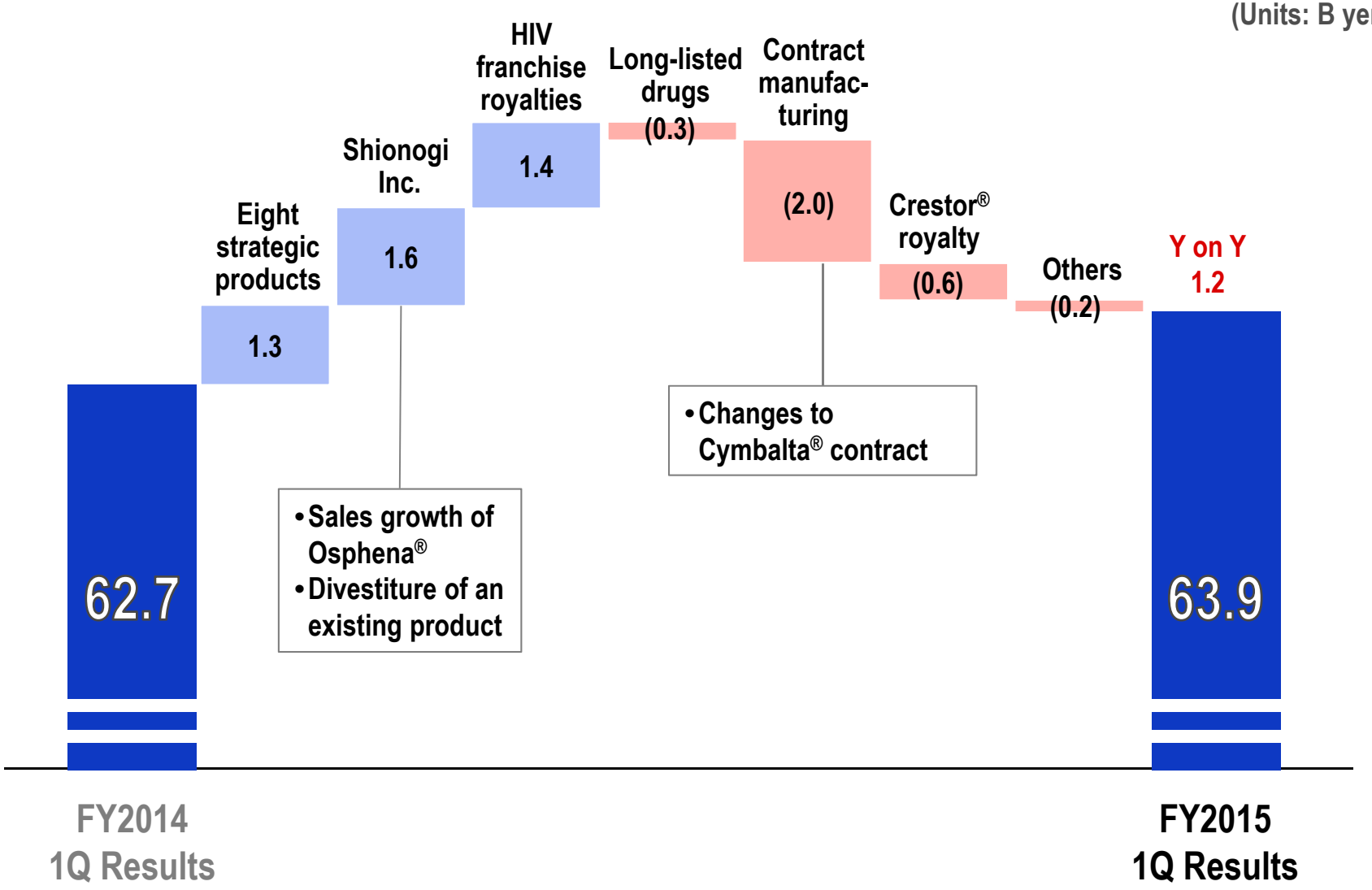
  ⇒Modification of the Cymbalta® contract is resulting in increased sales and reduced cost-of-goods
- **Additional indication for pain associated with fibromyalgia (May 2015)**

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)

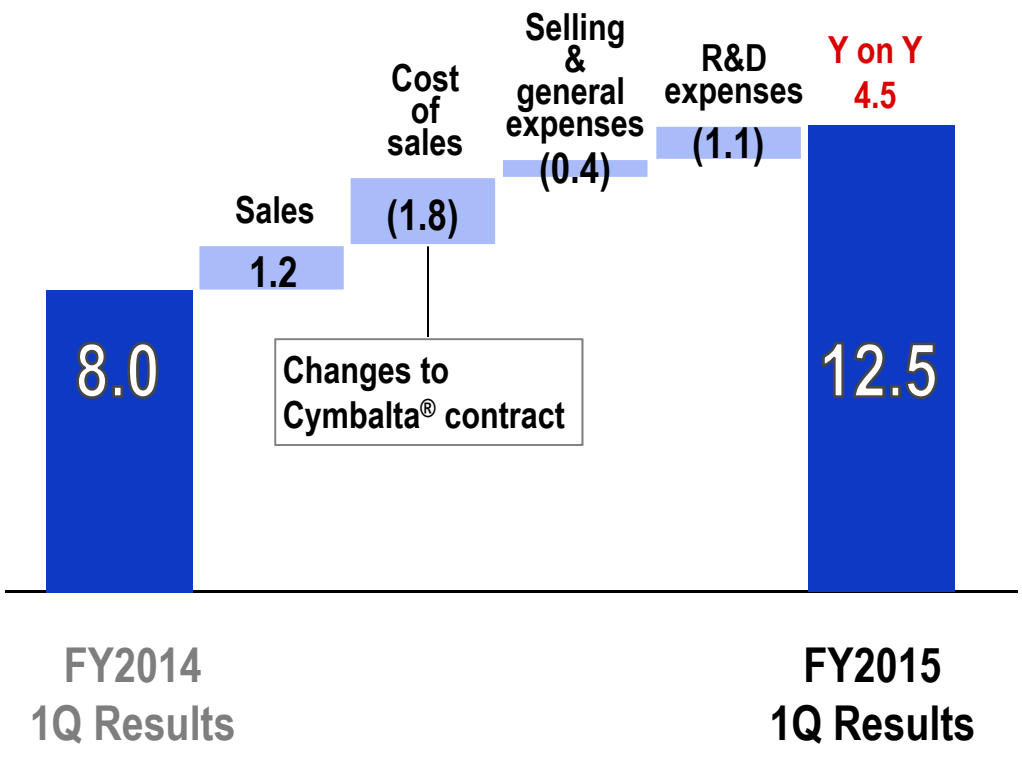
	FY2015		Progress vs. forecasts (%)	FY2014 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Sales	138.0	63.9	46.3	62.7	1.8	1.2
[Royalty* income]	32.0	12.6	39.5	11.8	7.3	0.8
Cost of sales	25.6 [33.3] 35.3	28.3 [35.2] 18.0	51.1	31.6 [38.9] 19.8	(9.0)	(1.8)
Gross profit	102.7	45.8	44.6	42.9	6.8	2.9
SG&A expenses	53.8 74.2	52.1 33.3	44.9	55.6 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)
Operating income	20.7 28.5	19.6 12.5	44.0	12.8 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)
Ordinary income	20.3 28.0	22.9 14.6	52.2	21.7 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

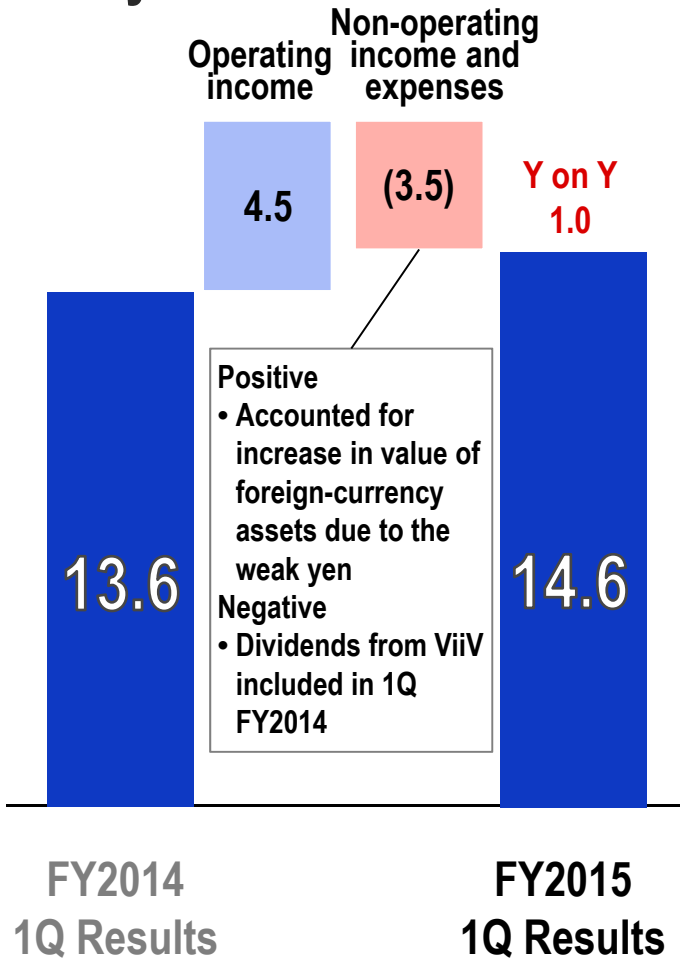
Change in Earnings Structure vs. Previous Year

(Units: B yen)

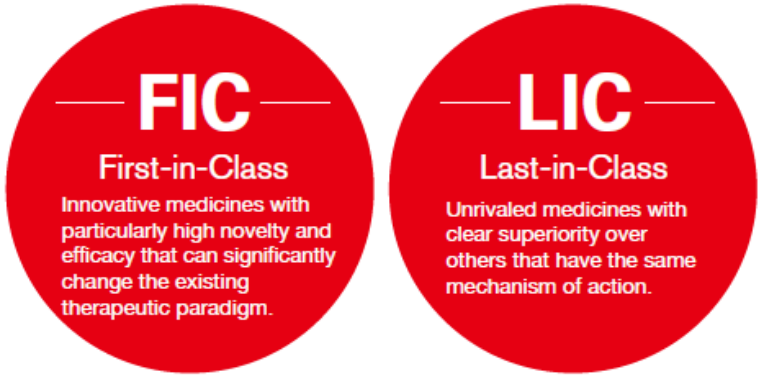
◆ Operating income



◆ Ordinary income



Research & Development

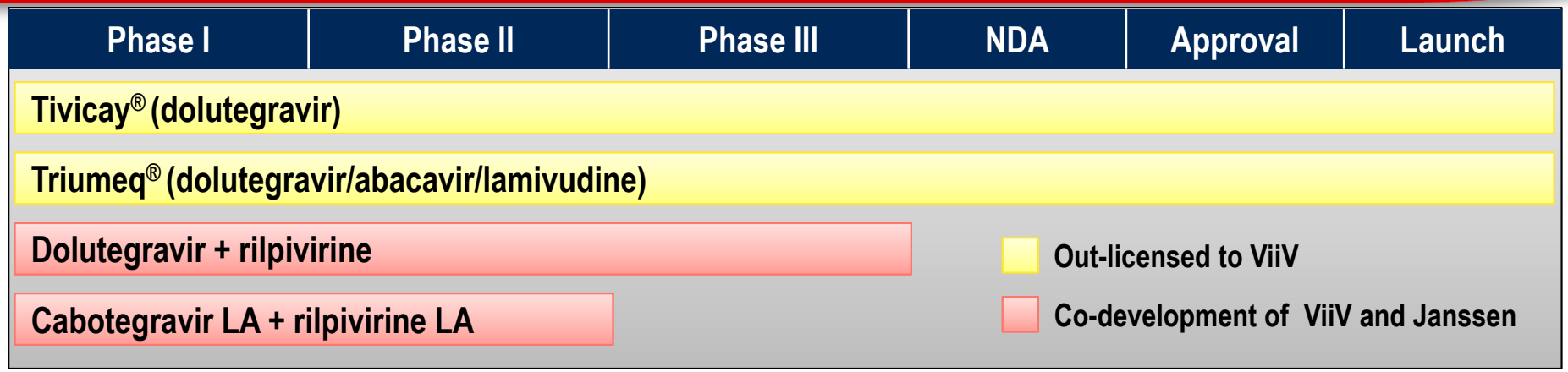


R&D

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



- **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

LA: Long acting parenteral formulation

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					
OxyContin®* (Non-cancer pain): Japan					
S-718632 (Chronic pain, abuse-deterrent extended release hydrocodone): US					

In-house

In-licensed

* 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		
Primary endpoint: Proportion of responders	The treatment difference in responder rate between naldemedine and placebo was statistically significant	
Secondary endpoints: 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	

*SBM: Spontaneous Bowel Movement, **CSBM: Complete Spontaneous Bowel Movement, ***TEAEs: Treatment-Emergent Adverse Event, ****NRS: Numerical Rating Scale, *****COWS: Clinical Opiate Withdrawal Scale

R&D

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

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Infectious disease Pain/CNS Frontier

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

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

Growth of the HIV franchise

- Global sales growth
- Solid increase in royalty from ViiV

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

Steady progress on development program

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

Challenges to Achieve FY2015 Business Plan Targets

- 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

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

- Maintain tight controls over operating costs

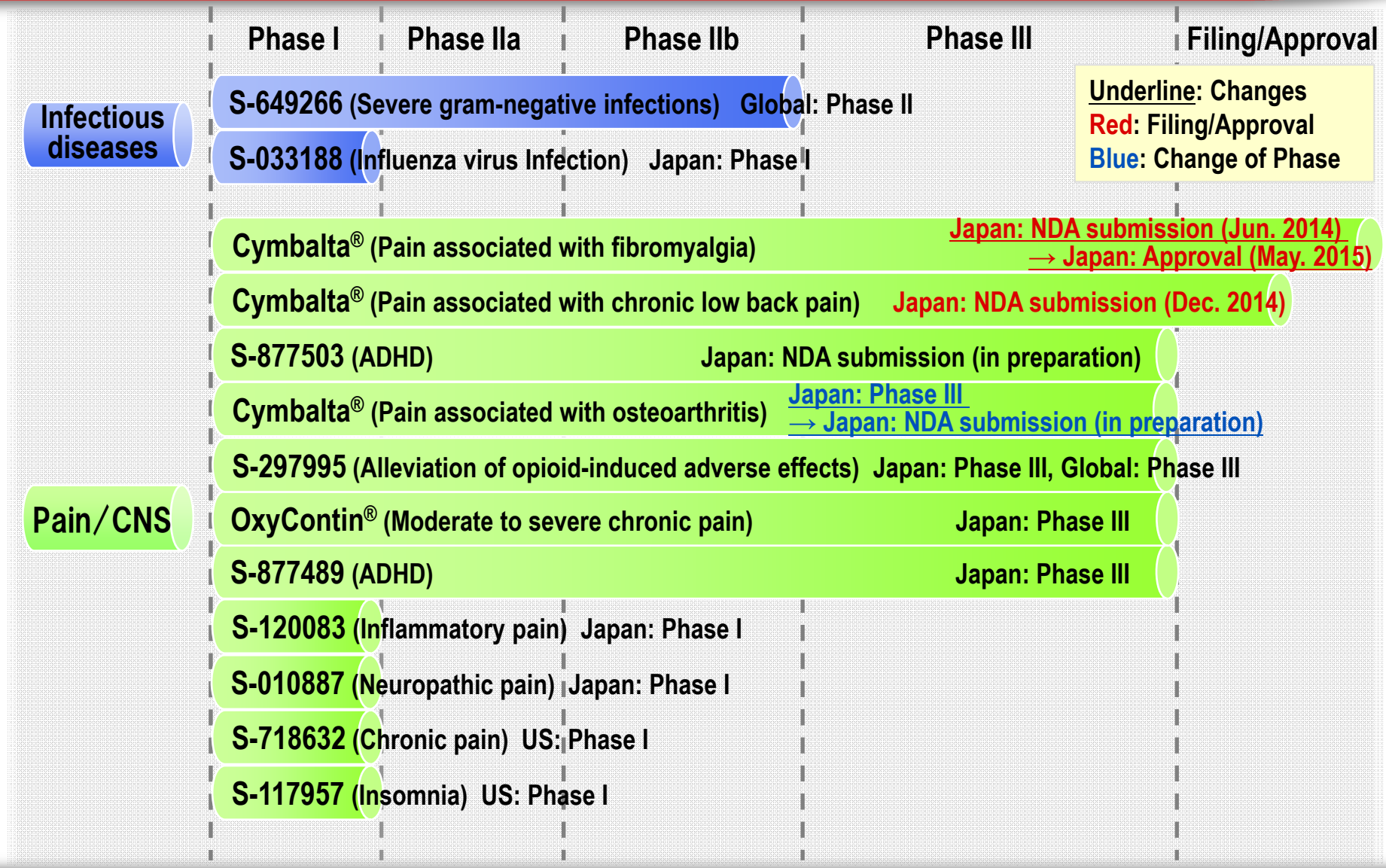
Appendix
- Pipeline -

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

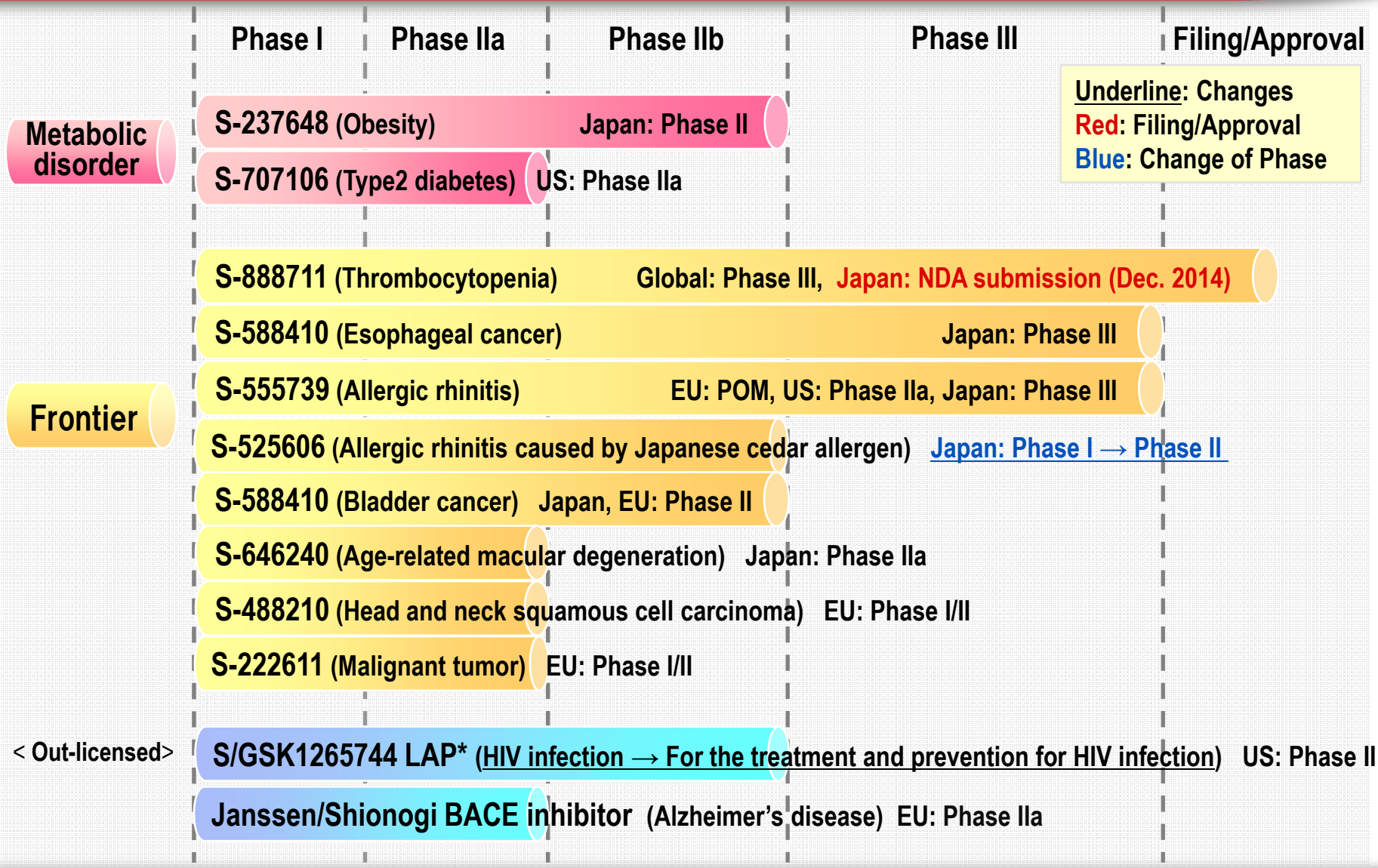
* Licensed out to ViiV Healthcare

Pipeline (as of Aug. 2015)



ADHD: Attention deficit hyperactivity disorder

Pipeline (as of Aug. 2015)



* Licensed out to ViiV Healthcare

POM: Proof of mechanism
LAP: Long acting parenteral formulation

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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