



# **1<sup>st</sup> Half of Fiscal 2013 Financial Results**

**November 1, 2013**

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# Overview of 1<sup>st</sup> Half FY2013 Financial Results

# Financial Results (Consolidated)

(Units: B yen)

	FY2013 forecasts	FY2013		Achieve- ment (%)	FY2012 1H results	Y on Y	
		1H forecasts*	1H results			change (%)	change
Sales	287.0	138.0	138.7	100.5	137.3	1.0	1.4
Operating income	60.0	24.0	28.5	118.6	26.4	7.7	2.1
Ordinary income	59.0	24.0	27.8	116.0	25.1	10.9	2.7
Net income	37.0	14.5	21.4	147.6	14.9	44.0	6.5

- All income levels from Apr. to Sep. 2013 are higher than the levels achieved in the 1H of any prior fiscal year

Note: All numerical values are rounded to the nearest unit

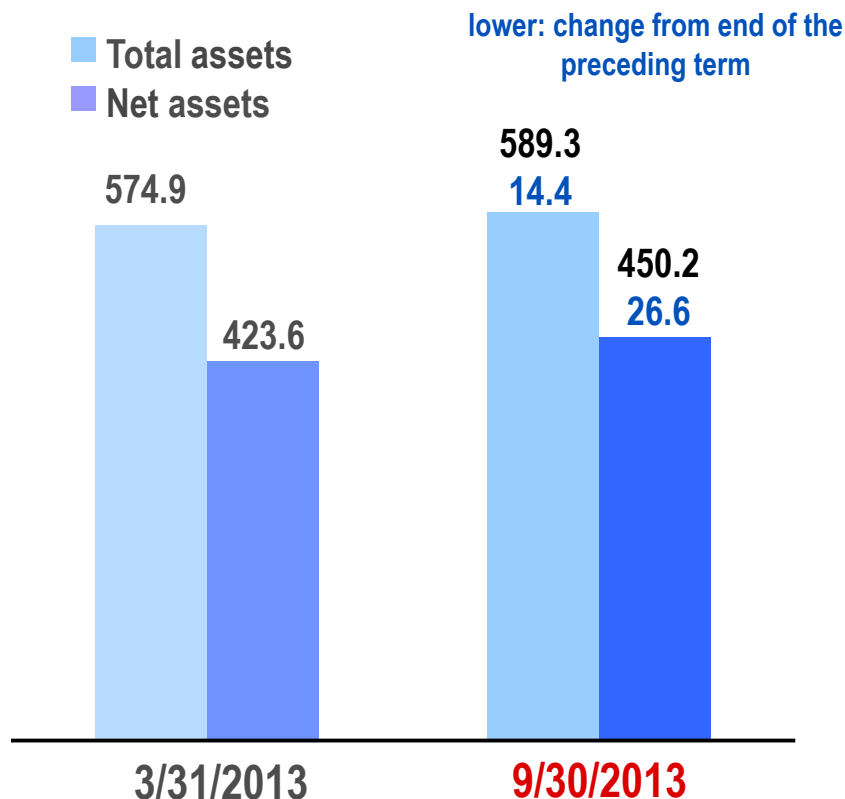
The litigation expenses have been recognized under non-operating expenses since FY2013. We have restated its consolidated statements of income for the previous fiscal year to reflect this change

Exchange rate (average)	FY2013 forecasts	FY2013 1H results
USD(\$)	95	98.85
EUR(€)	120	129.98

# Financial Position and Cash Flow (Consolidated)

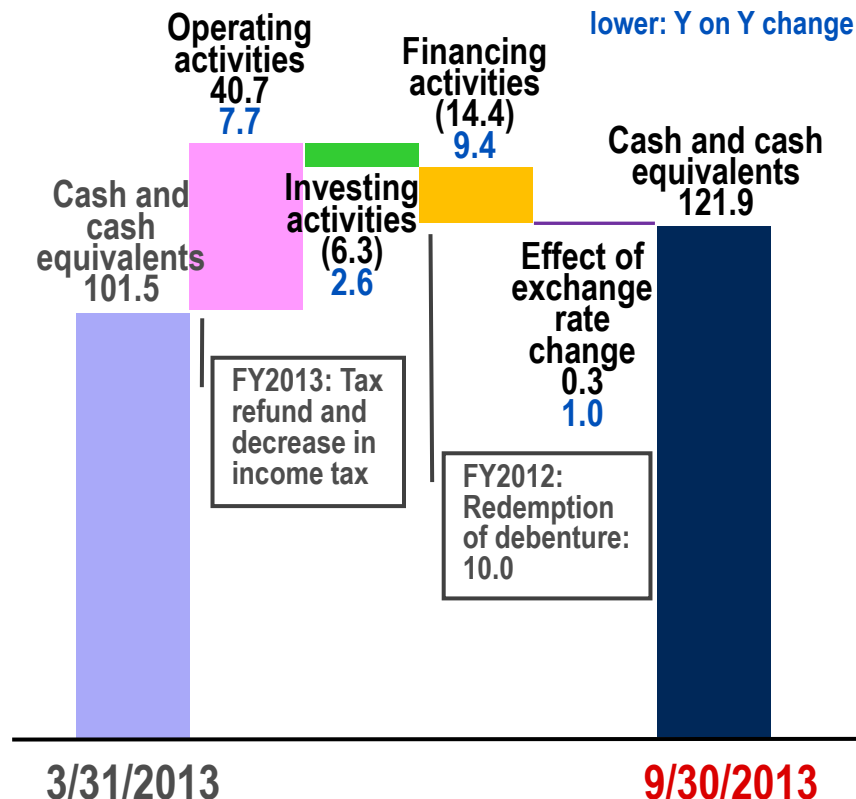
(Units: B yen)

## ◆ Financial Position



	3/31/2013	9/30/2013
Equity ratio	73.1%	75.8%

## ◆ Cash Flow



# Statements of Income (Consolidated)

(Units: B yen)

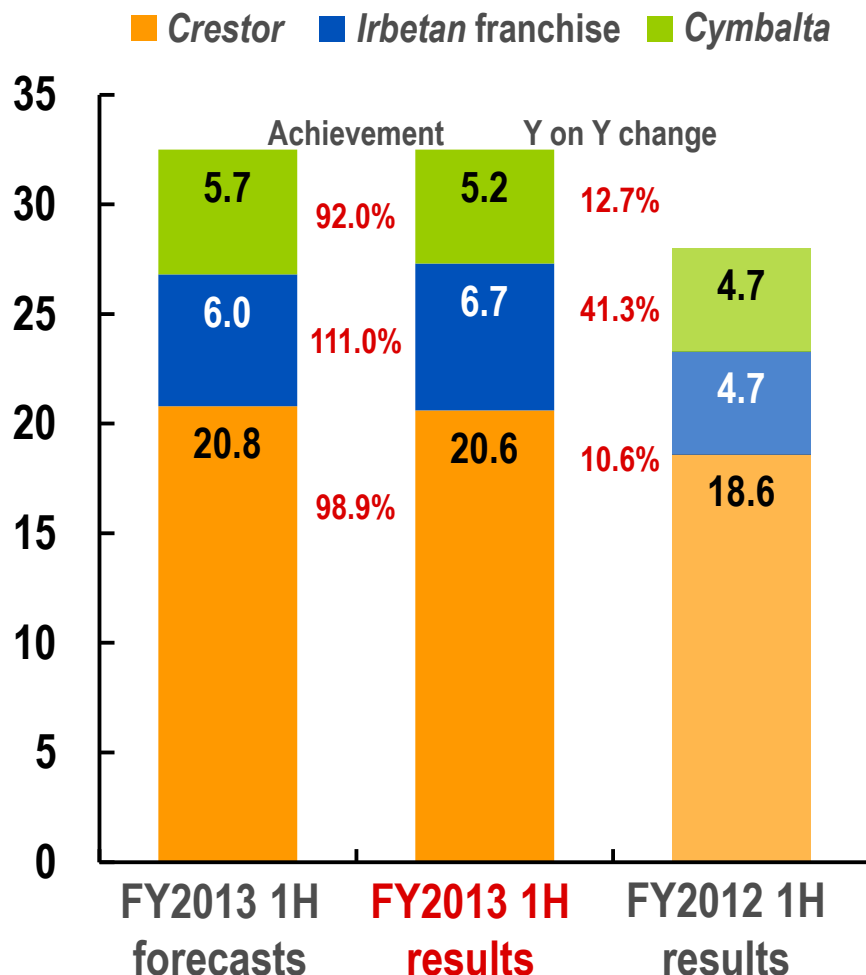
	FY2013		Achievement (%)	FY2012 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
Prescription drugs	83.1	80.9	97.4	79.7	1.5	1.2
Total of 3 key products	32.5	32.5	99.9	28.0	16.1	4.5
Total of 8 strategic products	45.0	44.4	98.8	39.8	11.7	4.6
Overseas subsidiaries/export	14.4	15.4	106.7	a) 14.8	3.7	0.6
Shionogi Inc.	9.0	9.5	105.8	7.5	27.5	2.0
<i>Osphena</i>	0.8	b) 0.1	12.4	-	-	0.1
C&O	2.9	2.9	100.2	2.9	(0.7)	(0.0)
Contract manufacturing	5.2	5.0	96.3	4.5	12.4	0.5
OTC and quasi-drugs	2.7	2.3	85.9	2.8	(17.0)	(0.5)
Diagnostics	0.6	0.8	131.5	1.1	(28.4)	(0.3)
Royalty income	31.0	33.4	107.8	33.4	0.0	0.0
<i>Crestor</i>	29.5	31.2	105.7	30.7	1.6	0.5
Others	1.0	0.9	92.7	1.0	(11.7)	(0.1)
<b>Total</b>	<b>138.0</b>	<b>138.7</b>	<b>100.5</b>	<b>137.3</b>	<b>1.0</b>	<b>1.4</b>

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

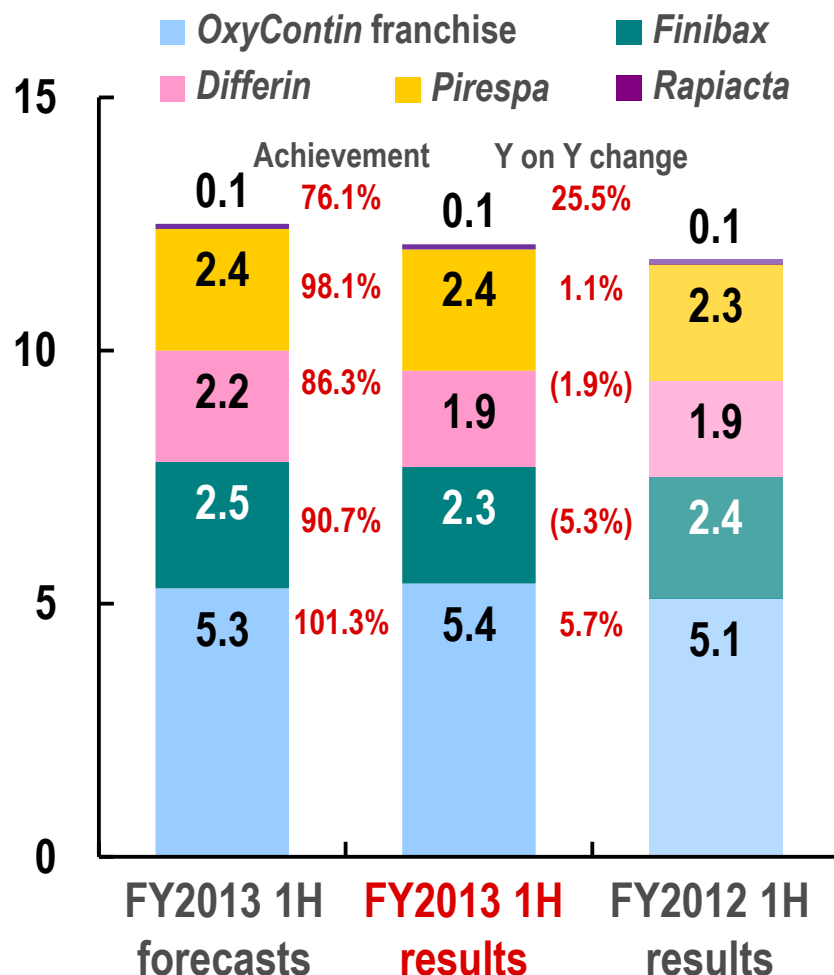
# Domestic: Sales of 8 Strategic Products

(Units: B yen)

## ◆ 3 Key Products



## ◆ 5 Strategic Products



# Statements of Income (Consolidated)

(Units: B yen)

	FY2013		Achievement (%)	FY2012 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
<b>Sales</b>	<b>138.0</b>	<b>138.7</b>	100.5	<b>137.3</b>	1.0	1.4
【Royalty income】	31.0	33.4	107.8	33.4	0.0	0.0
	28.3 [36.4]	26.9 [35.4]		29.3 [38.7]		
<b>Cost of sales</b>	<b>39.0</b>	<b>37.2</b>	95.5	<b>40.2</b>	(7.4)	(3.0)
<b>Gross profit</b>	<b>99.0</b>	<b>101.5</b>	102.5	<b>97.1</b>	4.5	4.4
	54.3	52.6		51.5		
<b>SG&amp;A expenses</b>	<b>75.0</b>	<b>73.0</b>	97.3	<b>70.7</b>	3.3	2.3
Selling & general expenses	48.0	47.4	98.8	45.7	3.8	1.7
R&D expenses	27.0	25.6	94.8	25.0	2.4	0.6
	17.4	20.5		19.2		
<b>Operating income</b>	<b>24.0</b>	<b>28.5</b>	118.6	<b>26.4</b>	7.7	2.1
【Excluding royalty income】	(7.0)	(4.9)	-	(7.0)	-	2.1

# Review of 1<sup>st</sup> Half FY2013 (1)

## ◆ Japanese Domestic Sales

- Increase in sales of eight strategic products of 11.7% Y on Y
- Total sales increased 1.5% Y on Y by maintaining sales of long listed products
- Substantially improved profitability through zero-based review of fixed cost base

## ◆ Shionogi Inc.

- *Osphena*: Launched on Jun. 3, 2013
  - Steady increase in healthcare provider awareness
  - Good access for sales professionals, high level of interest from healthcare providers
  - Managed care access for > 80% of covered lives
  - TRx growth more gradual than anticipated
- Positive operating income in underlying business (excluding launch investment in *Osphena*)
  - Increased OPI over 2H FY2012, without *Osphena*



## Review of 1<sup>st</sup> Half FY2013 (2)

### ◆ Crestor Royalty

- Exceeded the forecast due to strong global sales of *Crestor* by AstraZeneca in 1H 2013 and yen depreciation

### ◆ Cost Control

- Improve COGS to sales ratio excluding royalties by 1% compared to 1H forecast due to stable sales of Shionogi Inc. and continuous reduction of cost of sales
- Invest on *Osphena*'s early success while maintaining cost control

### ◆ R&D

- Accelerate the development programs within the budget while effectively leveraging internal resources
- Dolutegravir (*Tivicay*)
  - Approved by US FDA on Aug. 12, 2013
  - Indication: Combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection
  - FLAMINGO study results (Sep. 2013, presented at ICAAC 2013):  
Once-daily dolutegravir is superior to darunavir/ritonavir in ART-naïve adults

# FY2013 Financial Forecasts

# Revision of FY2013 Financial Forecasts (Consolidated)

(Units: B yen)

	FY2013							FY2012	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change	results	
Sales	287.0	284.8	(2.2)	138.7	149.0	146.1	(2.9)	282.9	0.7
Operating income	60.0	62.0	2.0	28.5	36.0	33.5	(2.5)	59.6	4.1
Ordinary income	59.0	61.0	2.0	27.8	35.0	33.2	(1.8)	58.9	3.5
Net income	37.0	43.0	6.0	21.4	22.5	21.6	(0.9)	66.7	(35.6)

Note: Decrease in tax-related expenses due to deductible losses on valuation of stocks of subsidiaries and affiliates included as extraordinary losses in non-consolidated financial results

# Revision of Sales by Segments (Consolidated)

(Units: B yen)

	FY2013							FY2012	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change	results	
Prescription drugs	170.6	168.4	(2.2)	80.9	87.5	87.5	-	165.7	1.6
Crestor	42.4	42.4	-	20.6	21.6	21.8	0.2	38.1	11.3
Irbetan franchise	12.0	13.0	1.0	6.7	6.0	6.3	0.3	10.7	21.3
Cymbalta	11.5	11.0	(0.5)	5.2	5.8	5.8	-	9.7	13.7
Total of 3 key products	65.9	66.4	0.5	32.5	33.4	33.9	0.5	58.5	13.5
OxyContin franchise	10.4	10.4	-	5.4	5.1	5.0	(0.1)	10.2	2.3
Finibax	5.2	4.8	(0.4)	2.3	2.7	2.5	(0.2)	5.0	(4.5)
Differin	4.5	4.2	(0.3)	1.9	2.3	2.3	-	4.0	4.6
Pirespa	4.6	4.6	-	2.4	2.2	2.2	-	4.5	2.0
Rapiacta	2.5	2.5	-	0.1	2.4	2.4	-	2.0	24.3
Total of 8 strategic products	93.1	92.9	(0.2)	44.4	48.1	48.5	0.4	84.2	10.3
Overseas subsidiaries/export	31.8	33.1	1.3	15.4	17.4	17.7	0.3	30.6	8.1
Shionogi Inc.	20.2	20.7	0.5	9.5	11.2	11.2	-	17.0	22.0
Osphena	5.5	5.5	-	0.1	4.7	5.4	0.7	-	-
C&O	6.0	6.0	-	2.9	3.1	3.1	-	5.8	3.2
Contract manufacturing	10.8	8.7	(2.1)	5.0	5.6	3.7	(1.9)	7.3	20.0
OTC and quasi-drugs	5.1	4.7	(0.4)	2.3	2.4	2.4	-	5.2	(9.0)
Diagnostics	1.7	1.9	0.2	0.8	1.1	1.1	-	2.2	(14.0)
Royalty income	65.0	66.0	1.0	33.4	34.0	32.6	(1.4)	69.8	(5.5)
Crestor	62.0	63.0	1.0	31.2	32.5	31.8	(0.7)	63.0	0.1
Others	2.0	2.0	-	0.9	1.0	1.1	0.1	2.1	(3.3)
Total	287.0	284.8	(2.2)	138.7	149.0	146.1	(2.9)	282.9	0.7

# Revision of Statement of Income (Consolidated)

(Units: B yen)

	FY2013							FY2012	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change	results	
Sales	287.0	284.8	(2.2)	138.7	149.0	146.1	(2.9)	282.9	0.7
【 Royalty income 】	65.0	66.0	1.0	33.4	34.0	32.6	(1.4)	69.8	(5.5)
Cost of sales	28.2 [36.5]	27.3 [35.6]		26.9 [35.4]	28.2 [36.5]	27.8 [35.7]		27.8 [36.9]	
	81.0	77.8	(3.2)	37.2	42.0	40.6	(1.4)	78.6	(1.0)
Gross profit	206.0	207.0	1.0	101.5	107.0	105.5	(1.5)	204.3	1.3
SG&A expenses	50.9	50.9		52.6	47.7	49.3		51.2	
	146.0	145.0	(1.0)	73.0	71.0	72.0	1.0	144.8	0.2
Selling & general expenses	93.0	92.0	(1.0)	47.4	45.0	44.6	(0.4)	91.7	0.3
R&D expenses	53.0	53.0	-	25.6	26.0	27.4	1.4	53.0	(0.0)
Operating income	20.9	21.8		20.5	24.2	23.0		21.1	
	60.0	62.0	2.0	28.5	36.0	33.5	(2.5)	59.6	4.1
【 Excluding royalty income 】	(5.0)	(4.0)	1.0	(4.9)	2.0	0.9	(1.1)	(10.3)	-

# Key Points in the 2H of FY2013: *Osphena*

## ◆ Key Points to Achieve the FY2013 Targets

- Increase consumer awareness in addition to the number of prescribers



### Increase the Number of Prescribers:

- Implement new national and local marketing programs  
⇒ Support paradigm/behavior shift from local estrogen treatment to oral *Osphena*

### Increase Consumer Awareness:

- Consumer advertisement
  - Launched print direct to consumer campaign in several magazines in October
- ⇒ Consumers become directly knowledgeable about *Osphena* as a treatment option and empowered to speak with their physicians

# Key Points in the 2H of FY2013: Japanese Domestic Sales

## ◆ Expand Sales of Eight Strategic Products

### ● *Cymbalta*

- Started direct to consumer education on pain caused by depression
- Increase doctor and consumer awareness about diabetic neuropathic pain to support to communicate about cause of pain and treatment

### ● *Rapiacta*

- Co-promotion with Nipro Corporation to strengthen an important pediatric area in the anti-influenza market
- Start direct to consumer education to appeal necessary treatment for shortening infection periods that can be administered through a single-dose intravenous drip infusion via media
- Sales professionals provide information on the quick influenza testing kit *Brightpoc Flu* to make a broad contribution in the field ranging from diagnosis to treatment

### ● *Differin*

- Restart advertising campaign to encourage acne patients to seek dermatological treatment

# Dolutegravir (*Tivicay*)

## ◆ Covering Broad Population of HIV-infected Patients

- *Tivicay* can be used in treatment-naïve and treatment-experienced patients including children ages 12 years and older weighing at least 40kg (regarding children, excluding those who have previously taken other integrase inhibitors)



## ◆ *Tivicay*, with its Strong Efficacy and Safety Profile, is an Important New Option for All Lines of HIV Treatment

- Launched by a highly experienced team at ViiV, a global specialist HIV company

## ◆ Development of Integrase Inhibitor Franchise Products by ViiV

- NDA/MAA submission of a STR combining *Tivicay* and *Epzicom*
  - US: Oct. 22, 2013, EU: Oct. 25, 2013
- S/GSK1265744 LAP is currently going through early clinical evaluation



# Dividend Forecasts



	Dividends per Share		
	half-year	year-end	annual
	Yen	Yen (forecast)	Yen (forecast)
FY2013	22 . 00	22 . 00	44 . 00
FY2012	20 . 00	22 . 00	42 . 00

# Pipeline

# Accelerate Global Clinical Development of Late-phase Drugs

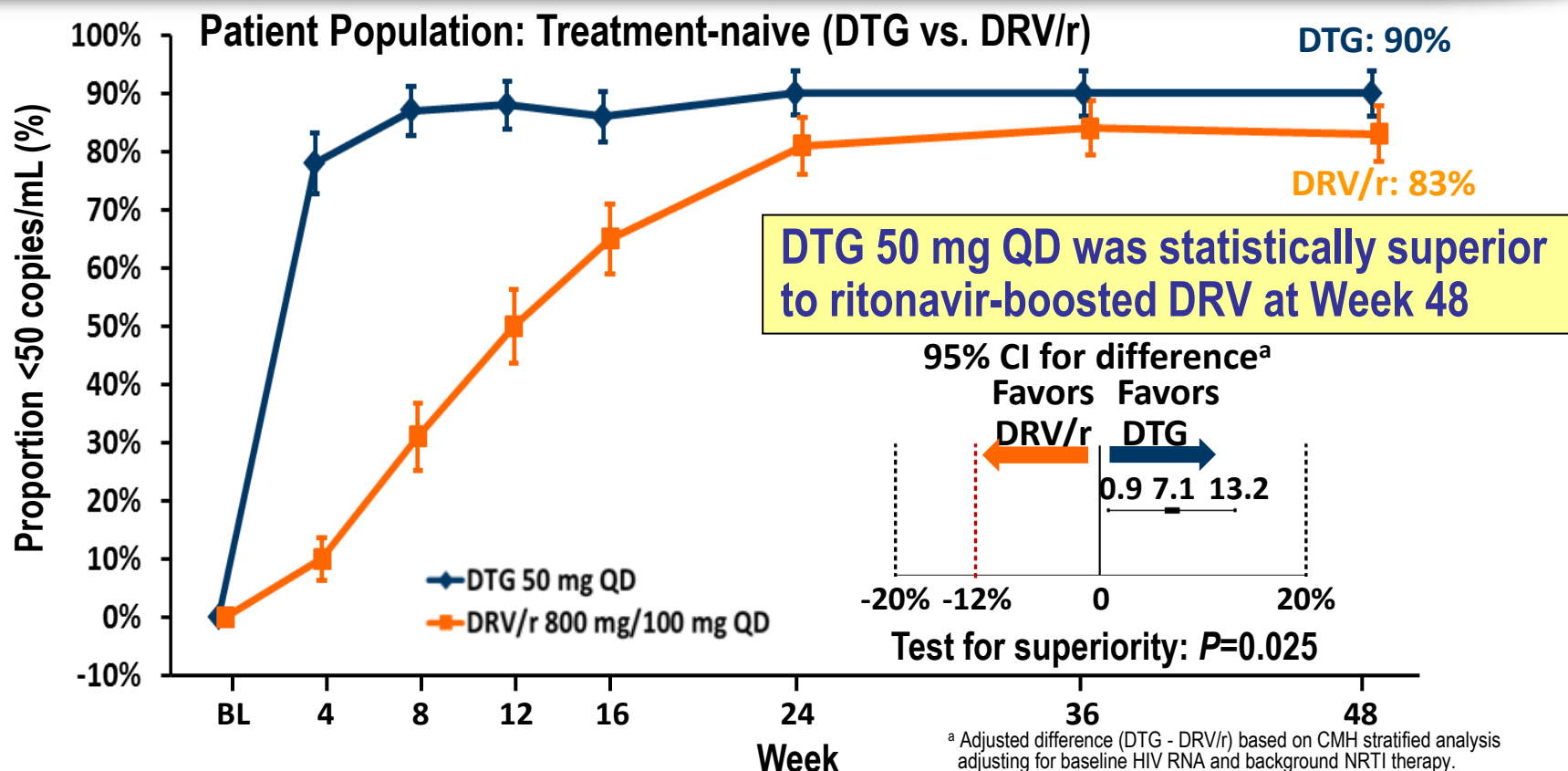
## ◆ Concentrate the Investment on Three High-priority Compounds

- S-297995 (Naldemedine)
  - Global: Initiated Phase III for opioid-induced constipation mainly in the US
  - Japan: Initiated Phase III for opioid-induced constipation
- S-555739
  - Japan: Initiated Phase III for perennial allergic rhinitis while also planning to initiate another Phase III for seasonal allergic rhinitis in spring 2013
- S-888711 (Lusutrombopag)
  - Japan: Initiated Phase III based on positive results of Phase IIb study for thrombocytopenia with chronic liver diseases
  - US/EU: Assess indication, market, and development plan

## ◆ Targeted Milestones for FY2013






- S-524101 (Allergic rhinitis caused by house-dust mite allergen)
  - Japan: Phase II/III code-break
- S-646240 (Age-related macular degeneration)
  - Japan: Phase IIa code-break, go/no-go decision

# Dolutegravir: FLAMINGO Study



- Non-inferiority was demonstrated between the DTG and DRV/r based regimens, with statistical superiority for the DTG arm
  - A lower number of withdrawals due to AEs and other reasons, and fewer virologic non-responders among individuals with baseline HIV-1 RNA > 100,000 c/mL in the DTG arm
- No emergent INI, PI or NRTI mutations were seen in either arm
- DTG provides a potent and well-tolerated alternative to DRV/r for this naïve population

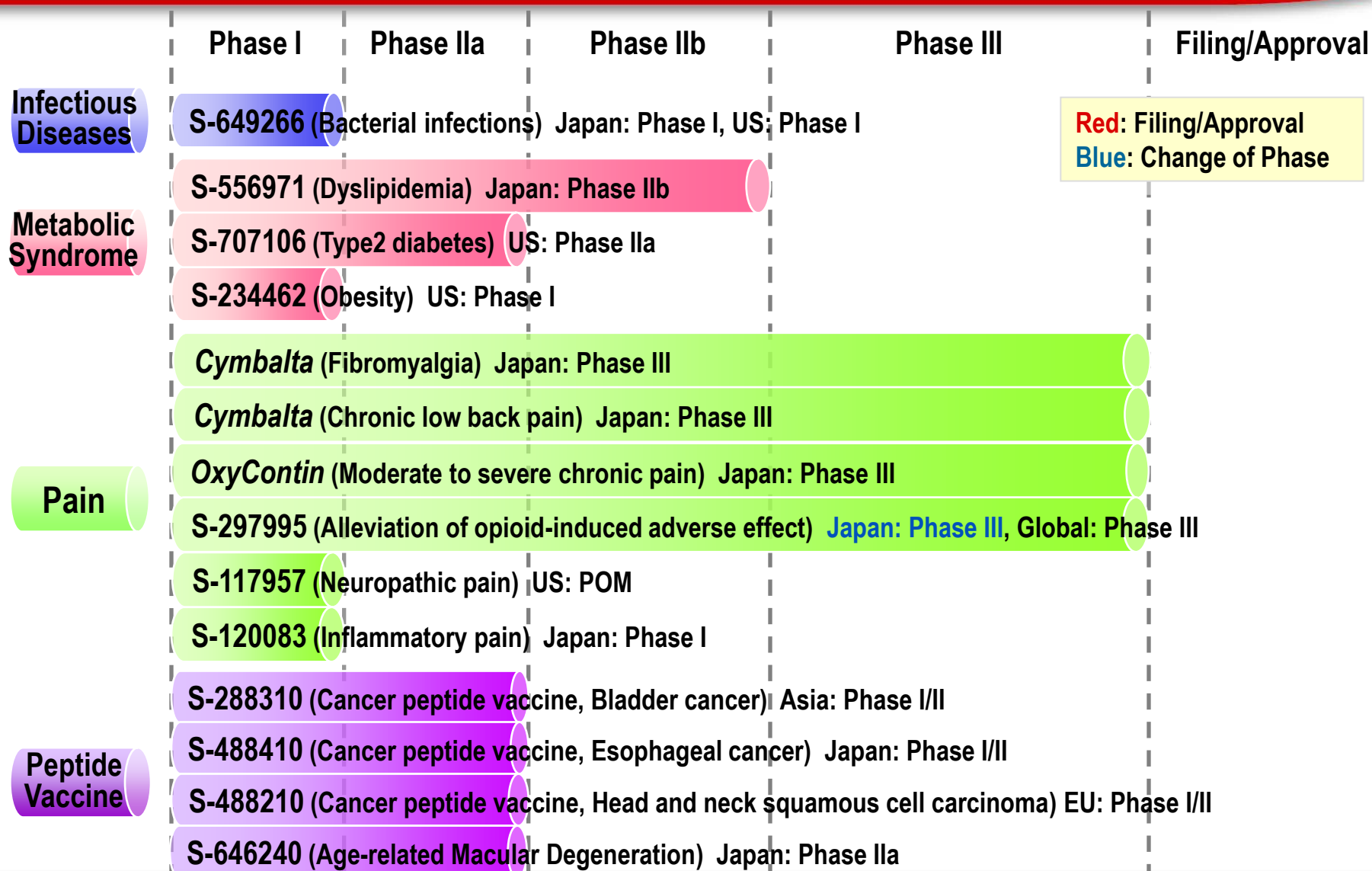
# Dolutegravir: Summary of Phase III/IV Results

Study No.	Patient Population	Study Design	Results
<b>ING113086</b> 	Treatment-naïve	ART-naïve pts (n=822) DTG 50mg QD vs. RAL 400mg BID (+ ABC/3TC or TDF/FTC) non-inferiority design	Week 48 <b>Non-inferior</b> (AIDS 2012)
<b>ING114467</b> 		ART-naïve pts (n=833) DTG 50 mg/ABC/3TC QD vs. Atripla QD non-inferiority design	Week 48 <b>Superior</b> (ICAAC 2012)
<b>ING112574</b> 	INI-resistance patients	INI-resistant pts (n=183) Single cohort, DTG 50mg BID + OBR	Week 24 63% patients showed HIV RNA <50c/mL (HIV 11 2012)
<b>ING111762</b> 	Treatment-experienced but INI-naïve	ART-experienced, INI-naïve pts (n=719) DTG 50mg QD vs. RAL 400mg BID (+ BR) non-inferiority design	Week 24 (CROI 2013) Week 48 (IAS 2013) <b>Superior</b>
<b>ING114915</b> 	Treatment-naïve	ART-naïve pts (n=468) DTG 50mg QD vs. DRV/r 800/100mg QD (+ ABC/3TC or TDF/FTC) non-inferiority design (open label)	Week 48 <b>Superior</b> (ICAAC 2013)

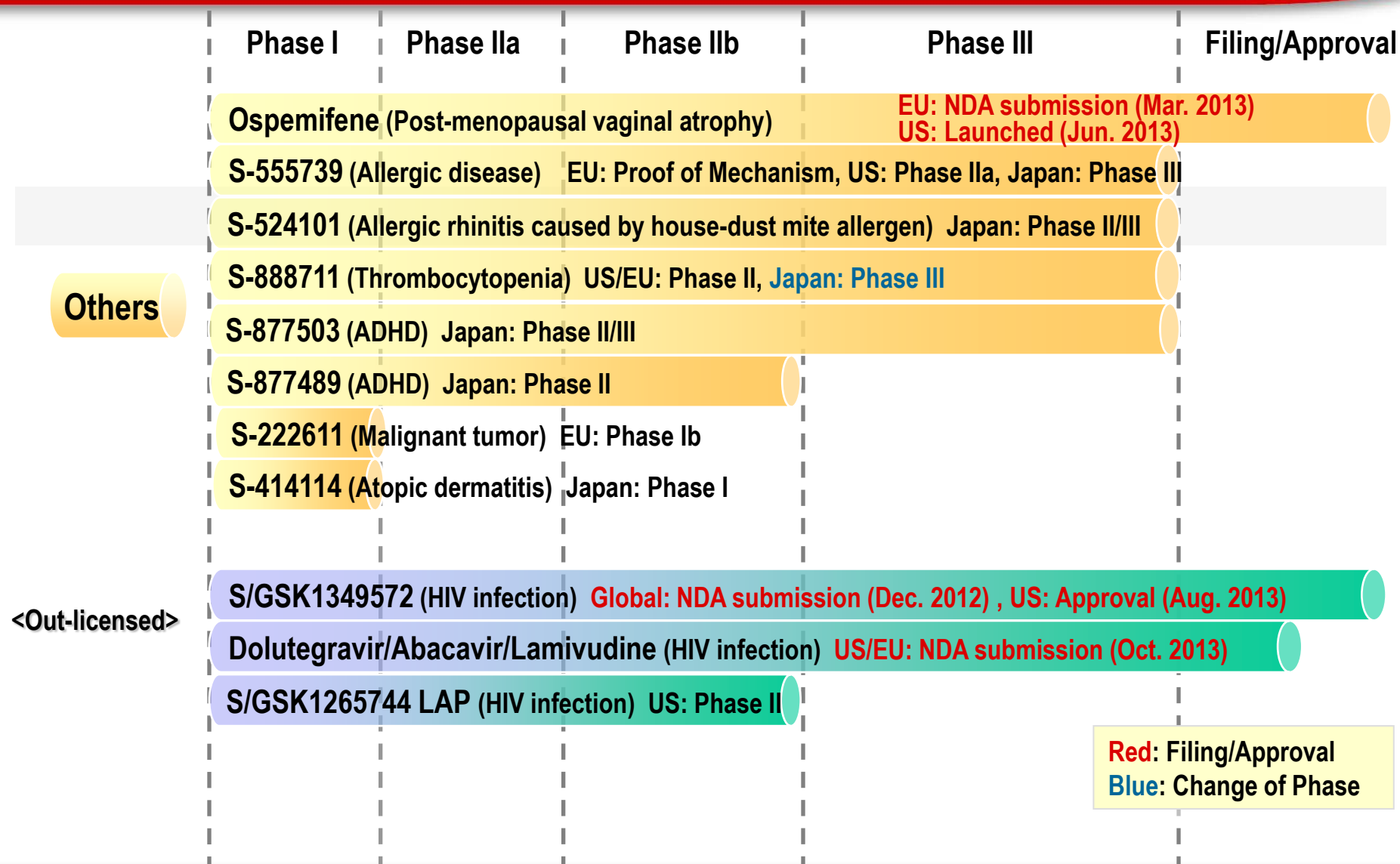
# Change of Phase (since August 2013)

Code No. (Generic name) 【 Product name 】	Category (Administration)	Indication	Change of Phase
S-297995 (Naldemedine)	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid-induced adverse effects	Japan: Phase III in preparation ⇒Phase III
S-888711 (Lusutrombopag)	Small molecule TPO mimetic (Oral)	Thrombocytopenia	Japan: Phase III in preparation ⇒Phase III
S/GSK1349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: NDA submission (Dec. 2012) ⇒US: Approval (Aug. 2013)
Dolutegravir/Abacavir/ Lamivudine	Integrase inhibitor/ Nucleoside reverse transcriptase inhibitor (Oral)	HIV infection	US/EU: NDA submission (Oct. 2013)
Vancomycin hydrochloride 【 Vancomycin 】	Glycopeptide antibiotic (Drip infusion)	Gram-positive bacteria-associated bloodstream infection, Febrile neutropenia, Alternative agent in penicillin-allergic adults and children	Japan: To be determined ⇒NDA submission in preparation
Prednisolone 【 Predonine 】	Synthetic corticosteroid (Oral)	Duchenne muscular dystrophy	Japan: NDA submission (Feb. 2013) ⇒Approval (Sep. 2013)
	Synthetic corticosteroid (Injection/Oral)	Kawasaki disease (Acute stage)	Japan: NDA submission (Sep. 2012) ⇒Approval (Sep. 2013)
Interferon gamma-1a 【 Immunomax-γ 】	Interferon gamma-1a (Genetical recombination) (Injection)	Mycosis fungoides/Sezary syndrome	Japan: Phase II ⇒NDA submission (Aug. 2013)

# Pipeline (as of October 2013)



# Pipeline (as of October 2013)





- This presentation contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements.
- Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.
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