



# *1<sup>st</sup> Quarter of Fiscal 2010 Conference Call*

*August 2, 2010*

 **SHIONOGI & CO., LTD.**



## *Forward-Looking Statements*

- 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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# *Overview of 1<sup>st</sup> Quarter FY2010 Results*

## 1<sup>st</sup> Quarter FY2010 Results

### *Financial Results (Consolidated & Non-Consolidated)*



(Units: billion yen)

<Consolidated>	Apr.1-Jun.30 FY2010	Apr.1-Jun.30 FY2009	Y on Y Change (%)
Sales	75.2	64.0	17.5
Operating income	7.9	6.0	31.1
Ordinary income	7.2	5.8	23.6
Net income	4.8	4.6	4.9

(Units: billion yen)

<Non-consolidated>	Apr.1-Jun.30 FY2010	Apr.1-Jun.30 FY2009	Y on Y Change (%)
Sales	59.0	52.2	13.0
Operating income	13.8	5.4	154.3
Ordinary income	14.0	6.1	130.9
Net income	9.7	4.4	121.6

Due to change in the accounting periods, 1<sup>st</sup> quarter results of FY2010 include 6 months from Jan.1 to Jun.30 for the US subsidiaries.

## 1<sup>st</sup> Quarter FY2010 Results



### *Financial Position and Cash Flows (Consolidated)*

(Units: billion yen)

<Financial position>	Jun. 30, 2010	Mar. 31, 2010	Change
Total assets	537.8	540.7	(2.9)
Net assets	331.6	341.9	(10.3)
Equity ratio (%)	61.6	63.2	(1.6)
Net assets per share (yen)	989	1,019	(30)

(Units: billion yen)

<Cash flows>	Apr. 1-Jun. 30 FY2010	Apr. 1-Jun. 30 FY2009	Change
Net cash provided by operating activities	10.9	8.8	2.1
Net cash provided by investing activities	(11.8)	0.8	(12.6)
Net cash provided by financing activities	(6.6)	14.4	(21.0)
Net increase (decrease)	(8.6)	24.6	(33.2)
Cash and cash equivalents at end of period	88.9	76.1	-

# 1<sup>st</sup> Quarter FY2010 Results



## *Sales by Segments (Consolidated)*

(Units: billion yen)

	1 <sup>st</sup> half FY2010 Forecasts	Apr. 1-Jun. 30 FY2010 Results	% Progress vs. 1 <sup>st</sup> half	Apr. 1-Jun. 30 FY2009 Results	Y on Y Change (%)	Y on Y Change
<b>Prescription drugs</b>	<b>73.9</b>	<b>38.0</b>	<b>51.4</b>	<b>37.2</b>	<b>2.1</b>	<b>0.8</b>
Crestor	14.5	6.6	45.2	5.5	19.9	1.1
Irbetan	3.8	1.6	42.6	0.4	347.9	1.2
Cymbalta	0.5	0.4	73.2	-	-	0.4
<b>Total of 3 strategic products</b>	<b>18.8</b>	<b>8.5</b>	<b>45.4</b>	<b>5.8</b>	<b>46.6</b>	<b>2.7</b>
OxyContin	4.7	2.5	52.8	2.2	13.7	0.3
Finibax	2.1	0.9	41.6	0.8	5.2	0.1
Differin	1.9	0.6	33.4	0.5	32.2	0.1
Pirespa	1.4	0.7	46.5	0.3	150.1	0.4
Rapiacta	0.5	0.0	-	-	-	0.0
<b>Total of 8 new products</b>	<b>29.4</b>	<b>13.2</b>	<b>44.8</b>	<b>9.6</b>	<b>37.6</b>	<b>3.6</b>
Flomox	9.0	5.3	59.3	5.8	(8.6)	(0.5)
Rinderon	4.8	2.5	52.8	2.6	(1.1)	(0.1)
Flumarin	3.6	1.8	50.3	2.2	(16.5)	(0.4)
Claritin	3.4	1.6	47.9	1.8	(8.0)	(0.2)
Vancomycin	2.2	1.2	55.5	1.7	(29.4)	(0.5)
<b>Export/Overseas subsidiaries</b>	<b>34.0</b>	<b>17.1</b>	<b>50.3</b>	<b>11.9</b>	<b>42.6</b>	<b>5.2</b>
Shionogi Inc.	29.7	15.2	51.0	9.5	58.8	5.7
Doripenem	1.8	0.5	28.9	1.2	(57.3)	(0.7)
<b>Contract manufacturing</b>	<b>0.9</b>	<b>1.0</b>	<b>106.5</b>	<b>1.4</b>	<b>(35.7)</b>	<b>(0.4)</b>
<b>OTC and quasi-drugs</b>	<b>2.9</b>	<b>1.4</b>	<b>47.0</b>	<b>1.4</b>	<b>(3.9)</b>	<b>0.0</b>
<b>Diagnostics</b>	<b>1.3</b>	<b>0.7</b>	<b>57.2</b>	<b>0.8</b>	<b>(9.7)</b>	<b>(0.1)</b>
<b>Royalty income</b>	<b>32.0</b>	<b>16.4</b>	<b>51.5</b>	<b>10.5</b>	<b>56.6</b>	<b>5.9</b>
Crestor	305	15.4	50.3	10.0	53.6	5.4
<b>Others</b>	<b>1.0</b>	<b>0.6</b>	<b>57.2</b>	<b>0.5</b>	<b>2.8</b>	<b>0.1</b>
<b>Total</b>	<b>146.0</b>	<b>75.2</b>	<b>51.5</b>	<b>64.0</b>	<b>17.5</b>	<b>11.2</b>

# 1<sup>st</sup> Quarter FY2010 Results

## *Financial Results of US Operations*

(Units: upper/million dollar,  
lower/billion yen)



	1 <sup>st</sup> half FY2010 Forecasts*	Jan. 1-Mar. 31 FY2010 Results	Apr. 1-Jun. 30 FY2010 Results	Jan.1-Jun.30 FY2010 Results	% Progress vs. 1 <sup>st</sup> half
Sales	330 29.7	110 10.1	56 5.1	166 15.2	50.3
Cost of sales	42 3.7	18 1.6	23 2.1	41 3.7	97.6
SG&A expenses	233 21.0	76 7.0	83 7.6	159 14.6	68.2
Operating income	55 5.0	16 1.5	(50) (4.6)	(34) (3.1)	-
Extraordinary loss	- -	- -	L 25 L 2.2	L 25 L 2.2	-

\*: 9 months from Jan. 1 to Sep. 30

### <Reasons for business under performance from Apr.1 to Jun.30 FY2010>

- Deteriorating market environment by intense sales competition including generic products
- Reduction of wholesaler's stocks resulting by reviewing the sales contract with wholesalers
- Increase of the returned goods by launch of competitive generic products against the branded products
- Increase of rebate
- Deteriorating cost rate due to disposal of returned goods, reduction of stock valuation and effect of products mixture
- Business structure improvement expenses by the integration of US operations

## 1<sup>st</sup> Quarter FY2010 Results



### *Next Actions and Forecasts of US Operations*

#### <Actions>

Actions below will be carried out for efficient and stable US operations, and for robust income structure

- Complete the integration of US operations to achieve efficient operations
- Reinforce developmental structure and make quick decisions for rapid launch of pipelines
- Reduce the number of sales products and construct efficient sales structure
- Reduction of SG&A expenses containing labor cost
- Quality control and cost reduction in manufacturing and so on

(Units: upper/million dollar,  
lower/billion yen)

	1 <sup>st</sup> half FY2010 Forecasts*	1 <sup>st</sup> half FY2010 Revised Forecasts*	Change from Original		Full year FY2010 Forecasts	Full year FY2010 Revised Forecasts	Change from Original
Sales	330 29.7	248 22.6	(82) (7.1)		570 51.3	460 41.8	(110) (9.5)
Cost of sales	42 3.7	53 4.8	11 1.1		66 5.8	80 7.3	14 1.5
SG&A expenses	233 21.0	222 20.3	(11) (0.7)		394 35.5	352 32.0	(42) (3.5)
Operating income	55 5.0	(27) (2.5)	(82) (7.5)		110 10.0	28 2.5	(82) (7.5)
Extraordinary loss	- -	L 25 L 2.2	L 25 L 2.2		- -	L 25 L 2.2	L 25 L 2.2

\*: 9 months from Jan. 1 to Sep. 30



## 1<sup>st</sup> Quarter FY2010 Results



### *Sales in Each Therapeutic Area of US Operations*

(Units: million dollar)

Therapeutic Areas	1 <sup>st</sup> half FY2010 Original Forecasts	Jan. 1-Jun. 30 FY2010 Results	Jan. 1-Jun. 30 FY2009 Results	1 <sup>st</sup> half FY2010 Revised Forecasts	Change from Original
Cardio/Diabetes	177	103	113	147	(30)
Women's Health	58	25	39	31	(27)
Pediatrics	95	37	40	70	(25)
Total	330	165	192	248	(82)

Therapeutic Areas	FY2010 Original Forecasts	FY2010 Revised Forecasts	Change from Original	Overview of Revision
Cardio/Diabetes	300	243	(57)	Decreased sales of Fenoglide Reduced sales of Sular due to the launch of generics Supply of Sular authorized generic
Women's Health	106	67	(39)	Decreased sales of Prenate DHA by competitors Expansion of Prenate Essential to offset the loss of Prenate DHA sales
Pediatrics	164	150	(14)	Decreased sales of Twinject Sales expansion of Ulesfia
Total	570	460	(110)	

## 1<sup>st</sup> Quarter FY2010 Results



### *Revision of FY2010 Financial Forecasts (Consolidated)*

(Units: billion yen)

<1 <sup>st</sup> half FY2010>	Original Forecasts	Y on Y Change (%)	Revised Forecasts	Y on Y Change (%)	Change from Original
Sales	146.0	10.1	142.8	7.7	(3.2)
Operating income	23.0	28.9	19.7	10.4	(3.3)
Ordinary income	22.0	34.2	18.7	14.0	(3.3)
Net income	14.5	25.1	11.0	(5.1)	(3.5)

(Units: billion yen)

<FY2010>	Original Forecasts	Y on Y Change (%)	Revised Forecasts	Y on Y Change (%)	Change from Original
Sales	295.0	5.9	290.0	4.1	(5.0)
Operating income	61.0	16.3	57.0	8.7	(4.0)
Ordinary income	59.0	16.8	55.0	8.9	(4.0)
Net income	39.0	1.0	36.0	(6.8)	(3.0)

# 1<sup>st</sup> Quarter FY2010 Results

## *Revision of FY2010 Financial Forecasts (Sales by Segments)*



	Original Forecasts (May 10)			Revised Forecasts (Aug. 2)			Change from Original		
	1 <sup>st</sup> half	2 <sup>nd</sup> half	FY2010	1 <sup>st</sup> half	2 <sup>nd</sup> half	FY2010	1 <sup>st</sup> half	2 <sup>nd</sup> half	FY2010
<b>Prescription drugs</b>	<b>73.9</b>	<b>79.7</b>	<b>153.6</b>	<b>74.9</b>	<b>80.3</b>	<b>155.2</b>	<b>1.0</b>	<b>0.6</b>	<b>1.6</b>
Crestor	14.5	15.5	30.0	14.5	15.5	30.0	-	-	-
Irbetan	3.8	4.5	8.3	3.8	4.5	8.3	-	-	-
Cymbalta	0.5	0.5	1.0	0.8	1.0	1.8	0.3	0.5	0.8
Total of 3 strategic products	18.8	20.5	39.3	19.1	21.0	40.1	0.3	0.5	0.8
OxyContin	4.7	4.8	9.5	4.7	4.8	9.5	-	-	-
Finibax	2.1	2.2	4.3	2.1	2.2	4.3	-	-	-
Differin	1.9	2.0	3.9	1.9	2.0	3.9	-	-	-
Pirespa	1.4	2.0	3.4	1.4	2.0	3.4	-	-	-
Rapiacta	0.5	3.5	4.0	0.0	3.0	3.0	(0.5)	(0.5)	(1.0)
Total of 8 new products	29.4	35.0	64.4	29.2	35.0	64.2	(0.2)	-	(0.2)
Flomox	9.0	10.0	19.0	9.0	10.0	19.0	-	-	-
Rinderon	4.8	4.1	8.9	4.8	4.1	8.9	-	-	-
Flumarin	3.6	3.0	6.6	3.6	3.0	6.6	-	-	-
Claritin	3.4	4.7	8.1	3.4	4.7	8.1	-	-	-
Vancomycin	2.2	1.7	3.9	2.2	1.7	3.9	-	-	-
<b>Export/Overseas subsidiaries</b>	<b>34.0</b>	<b>27.6</b>	<b>61.6</b>	<b>26.9</b>	<b>25.2</b>	<b>52.1</b>	<b>(7.1)</b>	<b>(2.4)</b>	<b>(9.5)</b>
Shionogi Inc.	29.7	21.6	51.3	22.6	19.2	41.8	(7.1)	(2.4)	(9.5)
Doripenem	1.8	3.6	5.4	1.8	3.6	5.4	-	-	-
<b>Contract manufacturing</b>	<b>0.9</b>	<b>1.6</b>	<b>2.5</b>	<b>1.5</b>	<b>1.6</b>	<b>3.1</b>	<b>0.6</b>	<b>-</b>	<b>0.6</b>
<b>OTC and quasi-drugs</b>	<b>2.9</b>	<b>2.6</b>	<b>5.5</b>	<b>2.9</b>	<b>2.6</b>	<b>5.5</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Diagnostics</b>	<b>1.3</b>	<b>1.5</b>	<b>2.8</b>	<b>1.3</b>	<b>1.5</b>	<b>2.8</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Royalty income</b>	<b>32.0</b>	<b>34.0</b>	<b>66.0</b>	<b>34.3</b>	<b>34.0</b>	<b>68.3</b>	<b>2.3</b>	<b>-</b>	<b>2.3</b>
Crestor	30.5	33.0	63.5	32.5	33.0	65.5	2.0	-	2.0
<b>Others</b>	<b>1.0</b>	<b>2.0</b>	<b>3.0</b>	<b>1.0</b>	<b>2.0</b>	<b>3.0</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total</b>	<b>146.0</b>	<b>149.0</b>	<b>295.0</b>	<b>142.8</b>	<b>147.2</b>	<b>290.0</b>	<b>(3.2)</b>	<b>(1.8)</b>	<b>(5.0)</b>

# *Pipeline*



### *Progress of Developmental Compounds (since May 2010)*

#### ◆ *Change of Phases in Clinical Studies*

- CUVPOSA™ (Glycopyrrolate, Anticholinergic, Oral solution): Chronic severe drooling in pediatric patients
  - USA: Approved (Shionogi Pharma, Inc.)
- S-811717 (Oxycodone hydrochloride, Injection): For the treatment of moderate to severe pain in patients with cancer pain
  - Japan: NDA filed in preparation
- Out-licensed/S-3013 (Secretory Phospholipase A2 inhibitor, Oral): Acute coronary syndrome, Mixed dyslipidemia
  - USA/EU: Phase III

#### ◆ *Newly added developmental compound*

- S-488410 (Peptide cancer vaccine, injection): Esophageal cancer
  - Japan: Phase I/II in preparation

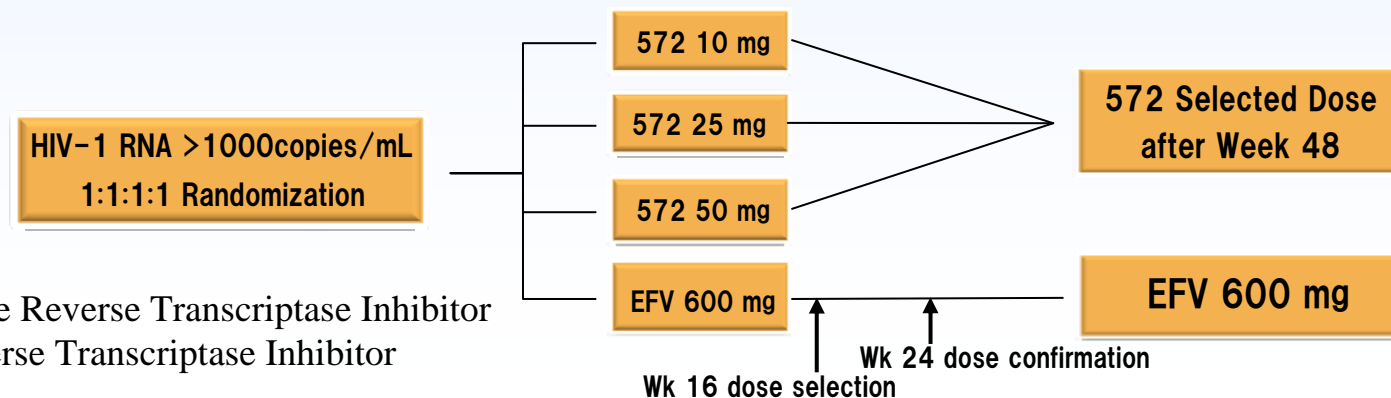
### *S/GSK1349572: SPRING-1 Study (Phase IIb)*

#### ◆ *S/GSK1349572 ('572, Integrase inhibitor, HIV)*

- Developed by Shionogi-ViiV Healthcare LLC.
- Once daily, without PK booster, low dose
- Highly potent antiviral activity
- Good resistance profile (*in vitro*)

#### ◆ *SPRING-1 Study Design (Interim 16-week analysis)*

- 205 therapy-naïve patients
- '572 10, 25, 50 mg/Efavirenz ('EFV, NNRTI) 600 mg + backbone drugs (2 NRTIs)
- Primary endpoint: % <50 copies/mL at 16 weeks



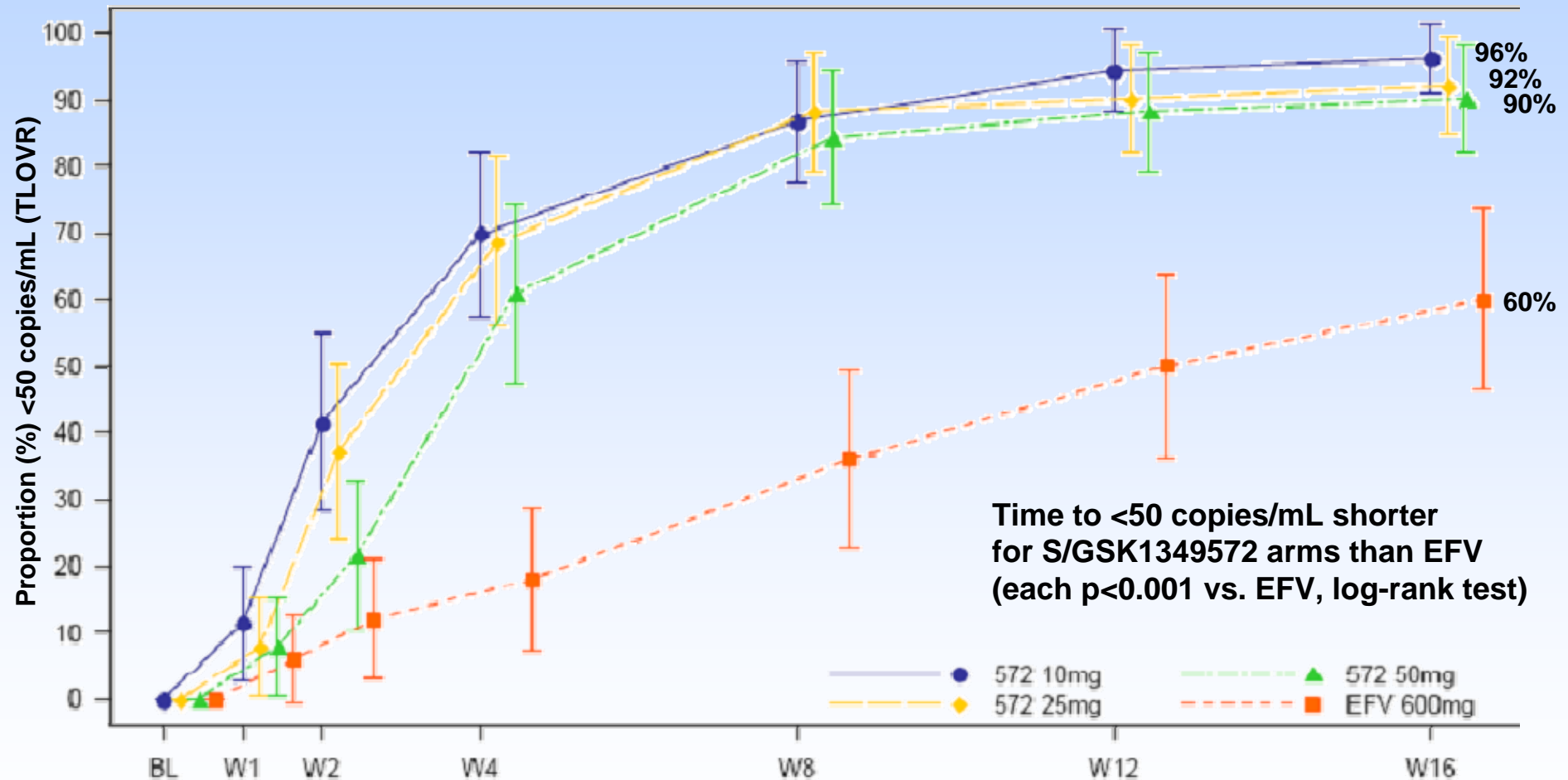
NNRTI: Non-nucleoside Reverse Transcriptase Inhibitor  
NRTI: Nucleoside Reverse Transcriptase Inhibitor

## Pipeline



### *S/GSK1349572: Results of SPRING-1 Study (Efficacy)*

◆ Proportion (%) of subjects with <50 copies/mL (undetectable) at 16 weeks



Note: 95% confidence intervals are derived using the normal approximation.

➤ In all of '572 arms vs. 'EFV, more potent antiviral activity was shown and time to undetectable viral load was significantly shorter.

## *S/GSK1349572: Results of SPRING-1 Study (Safety)*

### ◆ Adverse Events on investigational products

	<b>572 10 mg (N=53)</b>	<b>572 25 mg (N=51)</b>	<b>572 50 mg (N=51)</b>	<b>572 Subtotal (N=155)</b>	<b>EFV 600 mg (N=50)</b>
<b>Grade 2-4 Drug Related (all)</b>	<b>3 (6%)</b>	<b>2 (4%)</b>	<b>4 (8%)</b>	<b>9 (6%)</b>	<b>9 (18%)</b>
Gastrointestinal	1 (2%)	1 (2%)	1 (2%)	3 (2%)	2 (4%)
Psychiatric disorders	0	0	0	0	3 (6%)
Skin disorders	0	0	0	0	2 (4%)
General disorders	1 (2%)	0	1 (2%)	2 (1%)	1 (2%)
<b>Serious Adverse Events (all)</b>	<b>3 (6%)</b>	<b>1 (2%)</b>	<b>2 (4%)</b>	<b>6 (4%)</b>	<b>3 (6%)</b>
<b>AEs Leading to WD/IP Discontinuation</b>	<b>0</b>	<b>1 (2%)</b>	<b>0</b>	<b>1 (&lt;1%)</b>	<b>4 (8%)</b>

AE: Adverse event, WD/IP: Withdrawal investigational product

➤ ‘572 was generally well tolerated. Drug-related adverse events of moderate or higher intensity were reported in more subjects receiving ‘EFV than ‘572.



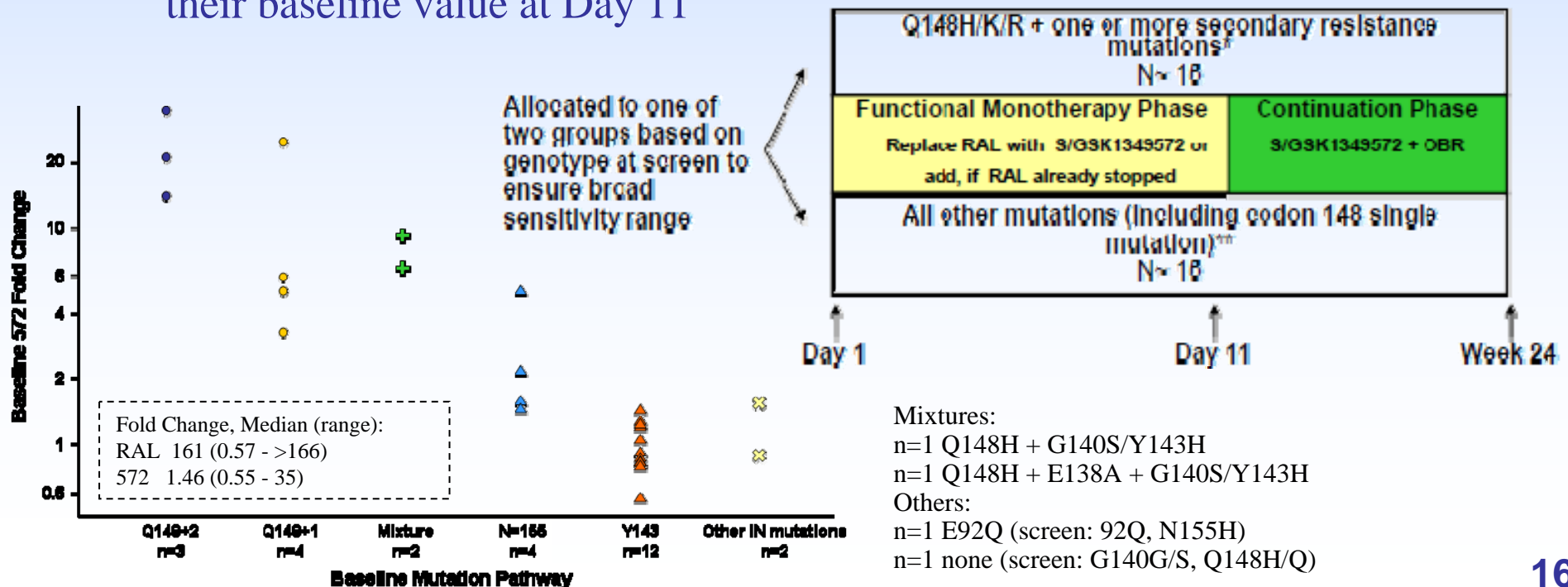
## Pipeline



### *S/GSK1349572: VIKING Study (Phase IIb)*

#### ◆ *VIKING Study Design (Initial results at Day 11)*

- 27 Subjects: Current or historic Raltegravir ('RAL)-failures with evidence of 'RAL-resistance. At least 3 anti-HIV drug classes resistant (including integrase inhibitor).
- To Day10: '572 50 mg + failing background regimen  
From Day11: '572 50 mg + optimized background therapies
- Primary endpoint: % <400 copies/mL or at least 0.7 log<sub>10</sub> copies/mL below their baseline value at Day 11



## Pipeline



# *S/GSK1349572: Results of VIKING Study*

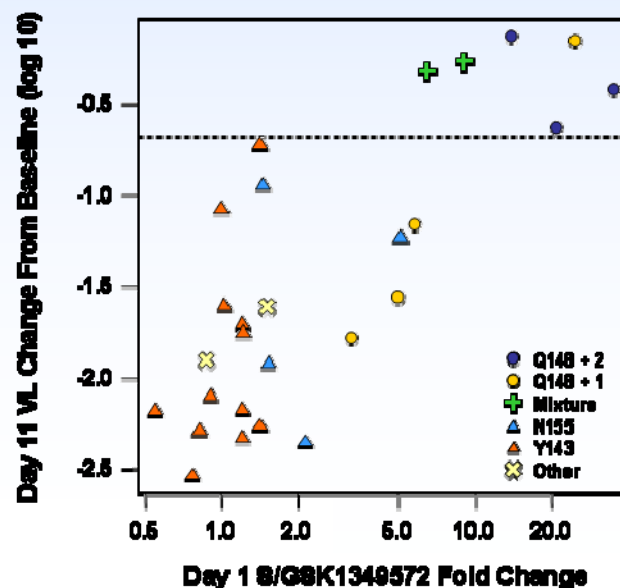
## ◆ Plasma HIV-RNA response

Primary End-point  
<400copies/mL or  
≥0.7 log<sub>10</sub>copies/mL decline  
n/N (%)

Secondary End-point  
log<sub>10</sub>copies/mL change  
from baseline  
Mean (SD)

All subjects	21/27 (78%)	-1.45 (SD 0.76)
Group A: Q148H/K/R + ≥1 Q148 associated mutations at L74, E138 or G140 (n=9)	3/9 (33%)	-0.72 (SD 0.63)
Group B: All other genotypes from N155H and Y143H pathways or Q148H/K/R single mutants (n=18)	18/18 (100%)	-1.82 (SD 0.53)

## ◆ Virologic response at Day 11: Correlation with baseline Fold Change (FC) in susceptibility to S/GSK1349572



➤ Despite the high level resistance to 'RAL, the majority of subjects showed good antiviral responses through Day 11.

➤ Few additional 'RAL associated mutations were seen and minimal changes were noted in '572 FC.

Mixtures:

N=1 Q148H + G140S/Y143H

N=1 Q148H + E138A + G140S/Y143H

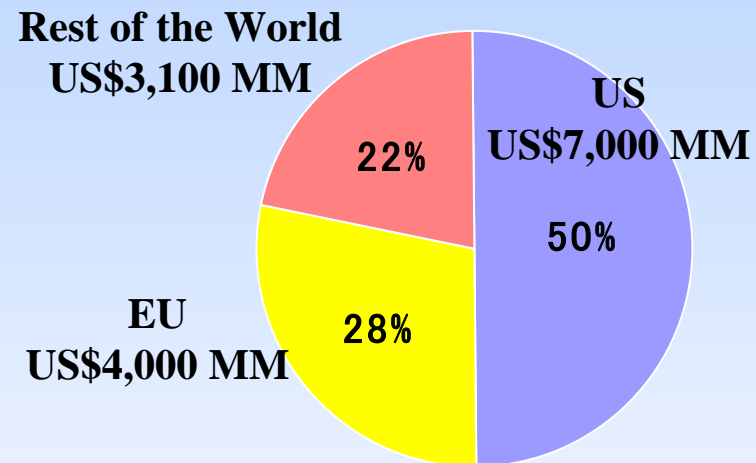
Others:

N=1 E92Q (screen: E92Q, N155H)

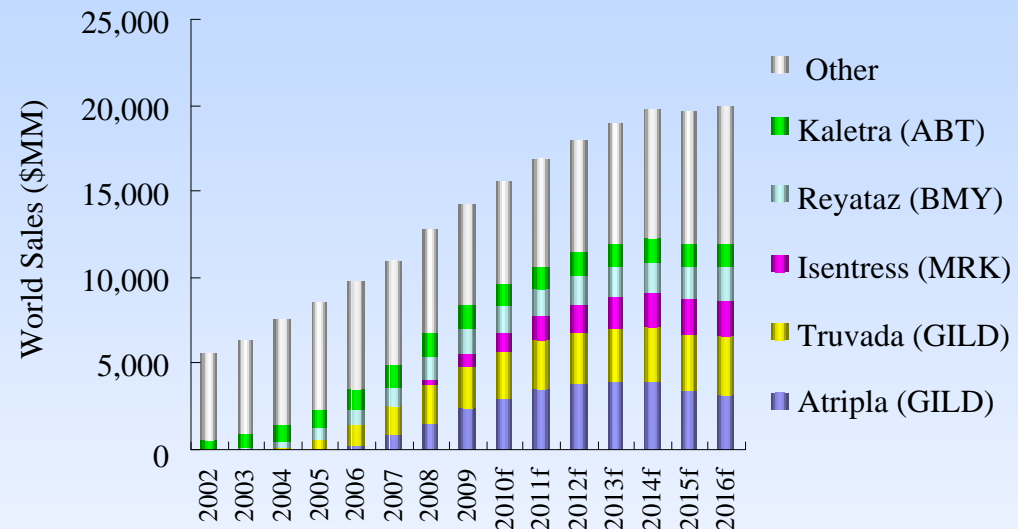
N=1 none (screen: G140G/S, Q148H/Q)

## *Anti-HIV Drug Market*

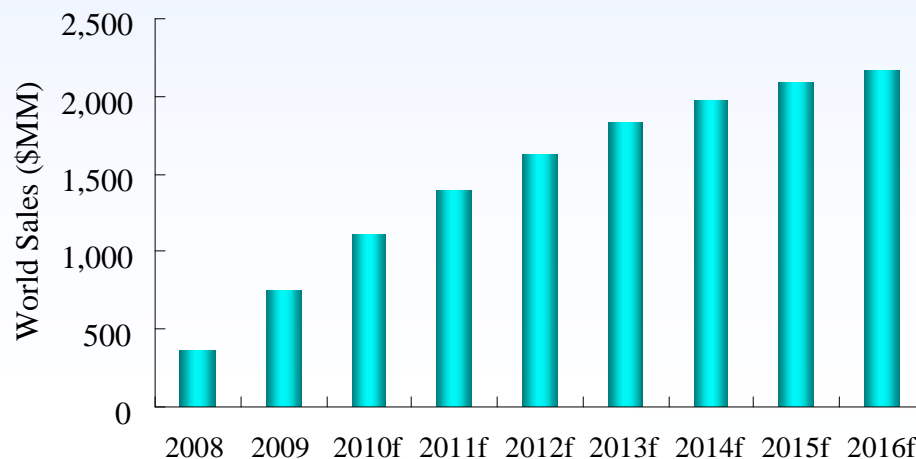
### Sales by region (2009)



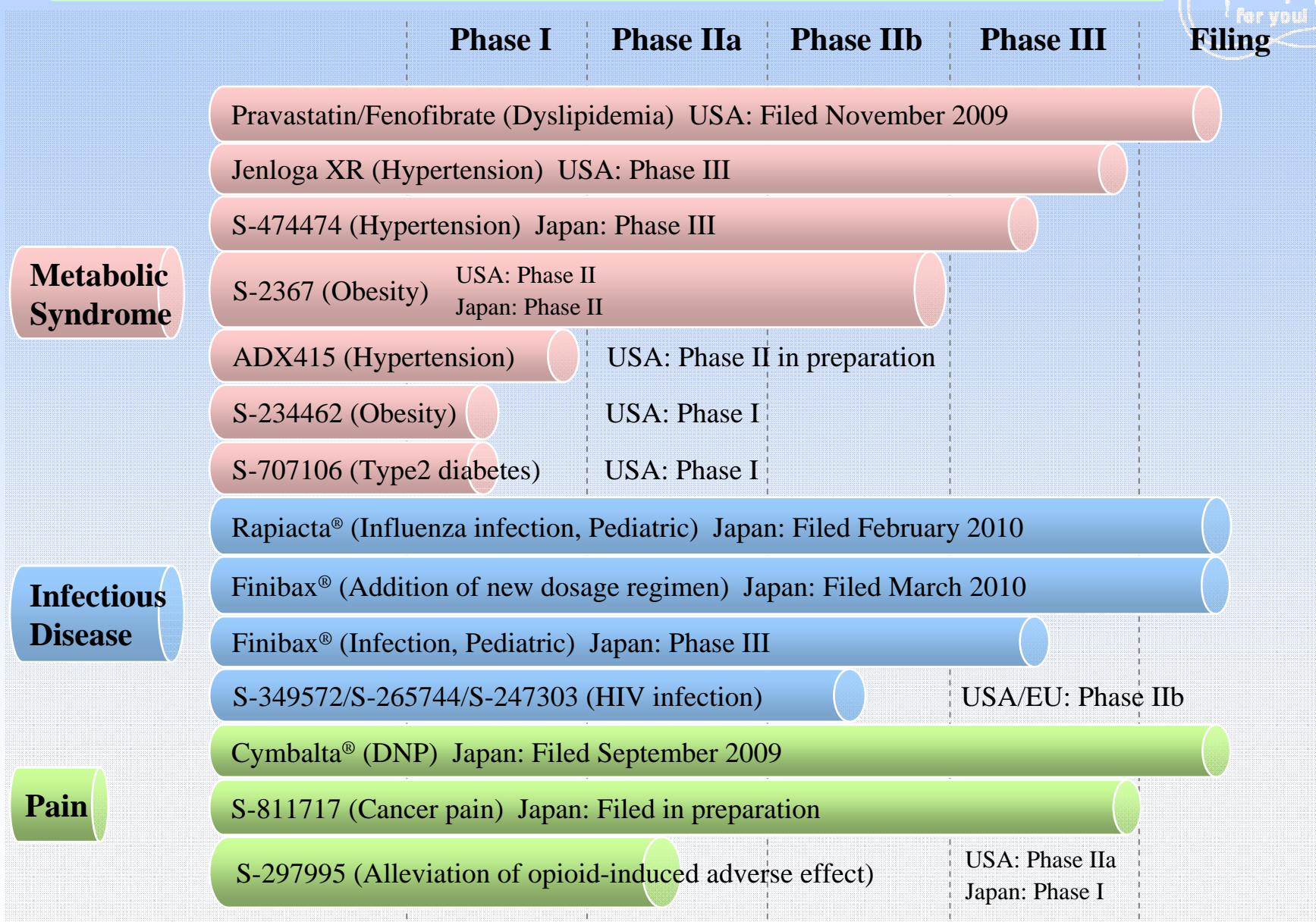
### Sales forecasts by class



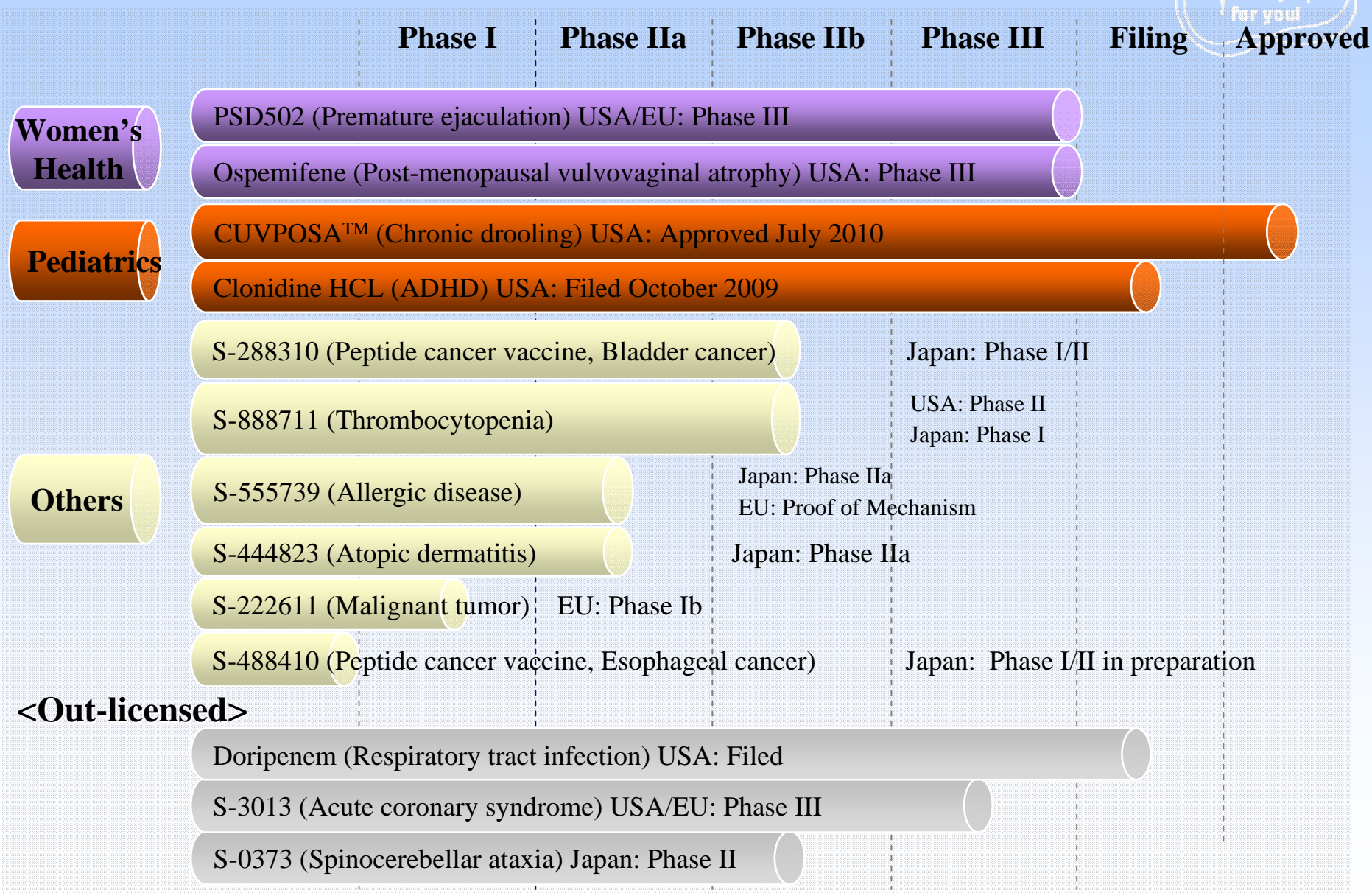
### Raltegravir (Isentress®) sales forecasts



## Development Pipeline (As of August 2010)



## Development Pipeline (As of August 2010)







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