

# 1st Quarter of Fiscal 2011 Conference Call

August 1, 2011





### 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.
- The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.





## Overview of 1st Quarter FY2011 Results





### Financial Results (Consolidated)

(Units: billion yen)

	Apr.1-Jun.30 FY2011	Apr.1-Jun.30 FY2010	Y on Y Change (%)
Sales	63.7	75.2	(15.3)
<b>Operating income</b>	11.4	7.9	43.7
Ordinary income	11.6	7.2	62.1
Net income	3.7	4.8	(21.7)

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

### Financial Position and Cash Flows (Consolidated)

(Units: billion yen)

<financial position=""></financial>	Jun. 30, 2011	Mar. 31, 2011	Change
Total assets	502.5	523.2	(20.7)
Net assets	322.5	328.0	(5.5)
Equity ratio (%)	64.2%	62.7%	1.5%

(Units: billion yen)

<cash flows=""></cash>	Apr. 1-Jun. 30 FY2011	Apr. 1-Jun. 30 FY2010	Change
Net cash provided by operating activities	12.3	10.9	1.4
Net cash provided by investing activities	(4.8)	(11.8)	7.0
Net cash provided by financing activities	(7.2)	(6.6)	(0.6)
Net increase (decrease)	(0.6)	(8.6)	8.0
Cash and cash equivalents at end of period	110.0	88.9	_

### Breakdown of Sales (Consolidated)



(Units: billion yen)

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	1 <sup>st</sup> half FY2011 Forecasts	Apr. 1-Jun. 30 FY2011 Results	% Progress vs. 1 <sup>st</sup> half	Apr. 1-Jun. 30 FY2010 Results	Y on Y Change (%)	Y on Y Change	
<b>Prescription drugs</b>	80.4	39.3	49.0	38.0	3.6	1.3	
Crestor	17.6	8.3	47.4	6.6	27.4	1.7	
Irbetan	4.8	2.1	44.2	1.6	31.0	0.5	
Cymbalta	2.5	1.3	52.8	0.4	261.0	0.9	
Total of 3 strategic products	24.9	11.8	47.3	8.5	38.1	3.3	
OxyContin	5.1	2.2	43.5	2.5	(10.5)	(0.3)	
Finibax	2.0	1.0	48.8	0.9	11.8	0.1	
Differin	1.9	0.8	42.4	0.6	27.0	0.2	
Pirespa	1.6	0.8	49.5	0.7	21.7	0.1	
Rapiacta	0.1	0.0	31.4	(0.0)	_	0.0	
Total of 8 new products	35.6	16.6	46.7	13.2	26.1	3.4	
Flomox	9.0	5.1	57.0	5.3	(3.9)	(0.2)	
Rinderon	4.5	2.4	52.7	2.5	(6.4)	(0.1)	
Claritin	3.5	1.8	50.4	1.6	8.3	0.2	
Flumarin	3.3	1.7	52.9	1.8	(3.5)	(0.1)	
<b>Export/Overseas subsidiaries</b>	15.8	4.3	27.2	17.1	(74.8)	(12.8)	
Shionogi Inc.	10.2	2.5	25.4	15.2	(82.9)	(12.7)	
Doripenem	2.4	0.5	21.8	0.5	0.5	0.0	
Contract manufacturing	2.6	1.6	64.5	1.0	74.9	0.6	
OTC and quasi-drugs	2.5	1.2	50.8	1.4	(6.9)	(0.2)	
Diagnostics	1.2	0.7	60.4	0.7	(2.5)	(0.0)	
Royalty income	34.0	15.9	46.8	16.4	(3.6)	(0.5)	
Crestor	32.0	15.2	47.6	15.4	(0.8)	(0.2)	
Others	1.0	0.4	46.3	0.6	(19.1)	(0.2)	
Total	137.5	63.7	46.3	75.2	(15.3)	(11.5)	

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



### Statements of Income (Consolidated)

(Units: billion yen)

	1 <sup>st</sup> half FY2011 Forecasts	Apr. 1-Jun. 30 FY2011 Results	% Progress vs. 1 <sup>st</sup> half	Apr. 1-Jun. 30 FY2010 Results	Y on Y Change (%)	Y on Y Change
Sales	137.5	63.7	46.3	75.2	(15.3)	(11.5)
[Royalty income]	[34.0]	[15.9]	[46.8]	[16.4]	[(3.6)]	[(0.5)]
	27.3 [36.2]	28.3 [37.7]		27.7 [35.5]		
Cost of sales	37.5	18.0	48.1	20.8	(13.5)	2.8
Gross profit	100.0	45.6	45.7	54.3	(16.0)	(8.7)
	54.9	53.7		61.7	, ,	, ,
SG&A expenses	75.5	34.2	45.3	46.4	(26.3)	(12.2)
Selling & general expenses	47.0	21.1	45.0	33.3	(36.6)	(12.2)
R&D expenses	28.5	13.0	45.8	13.0	0.3	0.0
	17.8	18.0		10.6		
<b>Operating income</b>	24.5	11.4	46.8	7.9	43.7	3.5
Extraordinary income and loss	_	L6.2	-	L2.1	_	-

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

Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.



### Breakdown of Extraordinary Income and Loss

(Units: billion yen)

#### Extraordinary income and loss: L6.2 billion yen

Extraordinary income:

- + 0.3
- > Sales of idle real estate and investment securities
- Extraordinary loss:
  - ➤ Loss on valuation of investment securities (2.7) Valuation loss on the current price of listing share
  - ➤ Impairment loss (1.6) Discontinuance of ADX415 development

(6.6)

- ➤ Impact of the Great Eastern Japan (1.0) Fixed cost in non-operational period and the impact of aftershocks
- Loss on penalty (0.9) Settlement related to contract dispute in Shionogi Inc.
- ➤ Business structure improvement expenses (0.2) Consolidation of US operations in New Jersey

Note: As the described numerical value is cut, the total value might not agree with the sum of individual numerical values.



### Financial Results of US Operations (Shionogi Inc.)

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

	1 <sup>st</sup> half	Apr. 1-Jun. 30	0/ Duoguega			FY2010		
	FY2011 Forecasts	FY2011 Results	% Progress vs. 1 <sup>st</sup> half	Jan-Mar 2010	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar 2011
Sales	128 10.2	31 2.5	24.7*	110 10.1	56 5.1	69 5.8	68 5.6	9 0.4
Cost of sales	16 1.2	6 0.5	40.7	18 1.6	23 2.1	15 1.3	12 1.0	10 0.8
SG&A expenses	122 9.7	43 3.5	35.3	76 7.0	83 7.6	54 4.6	55 4.5	44 3.5
<b>Operating</b> income	(10) (0.8)	(17) (1.4)	_	16 1.5	(51) (4.6)	(1) (0.0)	1 0.1	(46) (3.9)

<sup>\*:</sup> As the numerical value is calculated on the basis of dollar, the value is not agree with the value described in slide No.5 (yen currency).

#### <Particulars about the results from Apr.1 to Jun.30 FY2011>

- Sales: Decrease due to underperformance of new products and generic competition for Sular etc.
- Revenue deductions: Increase in returned goods of expired products
- Cost of sales: Cost percentage increased due to lower sales and higher deductions





**Therapeutic** 

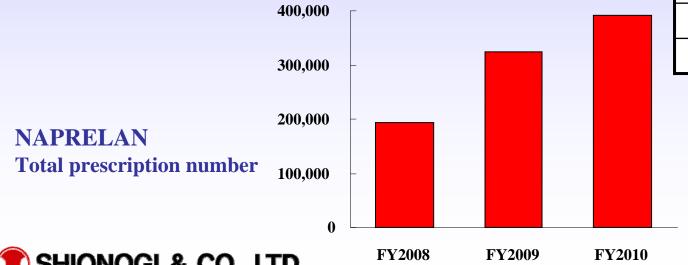
area

### Product Acquisition from Victory Pharma

- **Products: 7 for pain and 2 for infectious diseases**
- **Licenser: Victory Pharma, Inc.**
- Payment: \$118M (additional milestone up to \$9M)
- **Sales promotion** 
  - Dedicate to NAPRELAN, Rybix and Moxatag
  - Leverage commercial infrastructure of Shionogi Inc. with no increase in number of sales reps

NAPRELAN	
Rybix	
XODOL	
Fexmid	Pain
<b>Dolgic Plus</b>	
Zebutal	
Magnacet	
Moxatag	Infectious
Keflex	diseases

**Product name** 





### Revision of FY2011 Financial Forecasts (US Operations)

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

	1 <sup>st</sup> half FY2011 Original Forecasts	1 <sup>st</sup> half FY2011 Revised Forecasts	Change from Original	Full year FY2011 Original Forecasts	Full year FY2011 Revised Forecasts	Change from Original
Sales	128	91	(37)	280	260	(20)
	10.2	7.2	(3.0)	22.4	20.8	(1.6)
Cost of sales	16	14	(2)	34	43	9
	1.2	1.1	(0.1)	2.7	3.4	0.7
SG&A expenses	122	97	(25)	244	217	(27)
	9.7	7.7	(2.0)	19.5	17.4	(2.1)
<b>Operating income</b>	(10) (0.8)	(20) (1.6)	(10) (0.8)	1 0.1	0.0	(1) (0.1)

#### <Actions for the improvement of US operations in FY2011>

- Sales: Increase sales of promoted products and reduce loss of sales after generic entry by launching authorized generics, in addition to the contribution of Victory's products
- Revenue deductions: Control by measures such as improved contracting
- Cost of sales: Improve the cost by cooperating with CMOs
- SG&A expenses: Decrease general ad. expense by closing of Shionogi Ireland, Ltd.

### Revision of FY2011 Financial Forecasts (Consolidated)

(Units: billion yen)

<1st half>	Original Forecasts	Y on Y Change (%)	Revised Forecasts	Y on Y Change (%)	Change from Original
Sales	137.5	(4.1)	134.5	(6.2)	(3.0)
<b>Operating income</b>	24.5	27.4	24.5	27.4	_
Ordinary income	23.5	32.8	23.5	32.8	_
Net income	15.5	125.9	15.5	125.9	_

<full year=""></full>	Forecasts	Y on Y Change (%)
Sales	286.0	1.3
<b>Operating income</b>	58.0	23.7
Ordinary income	56.0	24.0
Net income	37.0	84.8

### Revision of FY2011 Sales Forecasts (Breakdown/Consolidated)

(Units: billion yen)

	Original Forecasts				
	1 <sup>st</sup> half	2 <sup>nd</sup> half	Full year		
Prescription drugs	80.4	86.4	166.8		
Crestor	17.6	19.4	37.0		
Irbetan	4.8	5.7	10.5		
Cymbalta	2.5	3.0	5.5		
Total of 3 strategic products	24.9	28.1	53.0		
OxyContin	5.1	5.4	10.5		
Finibax	2.0	2.2	4.2		
Differin	1.9	2.2	4.1		
Pirespa	1.6	1.8	3.4		
Rapiacta	0.1	1.4	1.5		
Total of 8 new products	35.6	41.1	76.7		
Flomox	9.0	10.0	19.0		
Rinderon	4.5	4.7	9.2		
Claritin	3.5	4.0	7.5		
Flumarin	3.3	2.9	6.2		
Export/Overseas subsidiaries	15.8	17.7	33.5		
Shionogi Inc.	10.2	12.2	22.4		
Doripenem	2.4	2.6	5.0		
Contract manufacturing	2.6	3.3	5.9		
OTC and quasi-drugs	2.5	2.6	5.1		
Diagnostics	1.2	1.5	2.7		
Royalty income	34.0	36.0	70.0		
Crestor	32.0	35.0	67.0		
Others	1.0	1.0	2.0		
Total	137.5	148.5	286.0		

<b>Revised Forecasts</b>					
1 <sup>st</sup> half	2 <sup>nd</sup> half	Full year			
80.4	87.1	167.5			
17.6	19.4	37.0			
4.8	5.7	10.5			
2.5	3.0	5.5			
24.9	28.1	53.0			
5.1	5.4	10.5			
2.0	2.2	4.2			
1.9	2.2	4.1			
1.6	1.8	3.4			
0.1	1.4	1.5			
35.6	41.1	76.7			
9.0	10.0	19.0			
4.5	4.7	9.2			
3.5	4.0	7.5			
3.3	2.9	6.2			
12.3	19.6	31.9			
7.2	13.6	20.8			
1.9	3.1	5.0			
3.1	3.7	6.8			
2.5	2.6	5.1			
1.2	1.5	2.7			
34.0	36.0	70.0			
32.0	35.0	67.0			
1.0	1.0	2.0			
134.5	151.5	286.0			

(Cints: Dinion yen)		
Change from Original		
1 <sup>st</sup> half	2 <sup>nd</sup> half	Full year
0	0.7	0.7
_	_	_
_	-	-
_	_	_
_	_	_
_	_	-
_	_	_
_	_	_
_	_	_
_	_	_
_	_	_
	_	_
_	_	_
_	_	_
(2.5)	1.0	(1.0)
(3.5)	1.9	(1.6)
(3.0)	1.4	(1.6)
(0.5)	0.5	0
0.5	0.4	0.9
_	_	_
_	_	_
_	_	_
_	_	_
_	_	_
(3.0)	3.0	0
(2.2)		



# **Pipeline**



#### **Pipeline**

## S-O-N-G for youl

### Change of Phases (since May 2011)

- Change of Phases
  - Finibax® (Carbapenem antibiotic, Injection):
    - > Pediatric infection: NDA in preparation in Japan
    - ➤ Serious infection (Additional new dosage regimen): Addition of 0.5 g-specification to previous one (0.25 g) in Japan
  - S-297995 (Peripheral opioid receptor antagonist, Oral): Alleviation of opioid-induced gastrointestinal symptoms (nausea, vomiting and constipation)
    - > Started Phase IIb in USA (Anti-constipation)
  - S-555739 (PGD2 receptor antagonist, Oral): Allergic rhinitis
    - > IND in preparation in USA
    - Phase IIb in preparation in Japan

NDA: New drug application PGD2: Prostaglandin D2

IND: Investigational new drug

- **Discontinued development** 
  - ADX415 (Selective α2 receptor agonist, Oral): Hypertension



#### **Pipeline**

### S-349572 (Dolutegravir: DTG): VIKING-3 Study

- **♦** Brief summary of VIKING-3 study
  - Fourth Phase III study next to SPRING-2, SAILING and SINGLE studies (Open-label study)
  - Patients (n=150):
     Antiretroviral therapy-experienced adults with current or historical failure on an INI containing regimen (patients with resistance to INI)
  - Study designs:
    - > DTG 50 mg twice daily with the current failing regimen for 7 days
    - > From Day 8, DTG 50 mg twice daily with an OBR
  - Primary endpoints:
    - ➤ Mean change from baseline in HIV-1 RNA at Day 8
    - ➤ Population of subjects with HIV-1 RNA < 50 copies/mL at week 24
    - ➤ Number of subjects with clinical or laboratory adverse events and their severity over time



#### Pipeline (as of August 2011) Phase I Phase II Phase III Filing **Approved** S-474474 (Hypertension) Japan: Phase III S-2367 (Obesity) Japan: Phase II Metabolic **Syndrome** S-707106 (Type2 diabetes) USA: Phase IIa S-234462 (Obesity) USA: Phase I Finibax® (Infection, Pediatric) Japan: NDA in preparation **Infectious** S-349572 (HIV infection) Global: Phase III **Diseases** S-265744 LAP (HIV infection) USA: Phase I Cymbalta® (DNP) Japan: Filed September 2009

S-811717 (Cancer pain) Japan: Filed September 2010

S-297995 (Alleviation of opioid-induced adverse effect)



Pain

**USA: Phase IIb** 

Japan: Phase IIb

#### Pipeline (as of August 2011)

Phase I Phase II

Phase III

**Filing** 

**Approved** 

Women's Health PSD502 (Premature ejaculation) USA/EU: Phase III

Ospemifene (Post-menopausal vaginal atrophy) USA: Phase III

S-555739 (Allergic disease)

EU: Proof of Mechanism, USA: IND in preparation

Japan: Phase IIb in preparation

S-888711 (Thrombocytopenia)

USA/EU: Phase II Japan: Phase IIa

**Others** 

S-288310 (Peptide cancer vaccine, Bladder cancer) Japan: Phase I/II

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

S-222611 (Malignant tumor) EU: Phase Ib

S-524101 (Allergic rhinitis caused by house-dust mite allergen) Japan: Phase I

#### <Out-licensed>

Doripenem (Respiratory tract infection) USA: Filed

S-3013 (Acute coronary syndrome) USA/EU: Phase III

S-0373 (Spinocerebellar ataxia) Japan: Phase II



# End of File

