



S-O-N-G
for you!

1st Quarter of Fiscal 2009

Conference Call

August 3, 2009



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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- 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 FY09 Results



Financial Results (Consolidated & Non-Consolidated)

(Units: billion yen)

<Consolidated>

	Apr.1-Jun.30 FY2009	Apr.1-Jun.30 FY2008	Y on Y change (%)
Sales	64.0	51.7	23.8
Operating income	6.0	8.0	(24.8)
Ordinary income	5.8	8.3	(30.3)
Net income	4.6	5.3	(14.6)

<Non-consolidated>

	Apr.1-Jun.30 FY2009	Apr.1-Jun.30 FY2008	Y on Y change (%)
Sales	52.2	49.5	5.3
Operating income	5.4	7.2	(24.9)
Ordinary income	6.1	8.2	(26.3)
Net income	4.4	5.5	(20.2)



Financial Position and Cash Flows (Consolidated)

(Units: billion yen)

<Financial position>	As of Jun.30 2009	As of Mar.31 2009	Change
Total assets	530.8	501.8	29.0
Net assets	322.4	310.0	12.4
Equity ratio (%)	60.7	61.7	(1.0)
Net assets per share (yen)	961	924	37
<Cash flows>	Apr.1-Jun.30 FY2009	Apr.1-Jun.30 FY2008	Change
Net cash provided by operating activities	8.8	8.6	0.2
Net cash provided in investing activities	0.8	(3.8)	4.6
Net cash provided by (used in) financing activities	14.4	(4.2)	18.6
Total	24.6	0.1	24.5
Cash & cash equivalents at the end of period	76.1	67.8	-

1st Quarter FY2009 Results



Sales by Segments (Consolidated)

(Units: billion yen)

	1st half FY2009 Forecast	Apr.1-Jun.30 FY2009 Results	% Progress vs. 1st half	Apr.1-Jun.30 FY2008 Results	Y on Y Change (%)	Y on Y Change
Prescription drugs	74.3	37.2	50.1	38.0	(2.2)	(0.8)
Flomox	11.0	5.8	53.1	6.1	(4.6)	(0.3)
Crestor	10.5	5.5	52.0	3.8	44.1	1.7
Rinderon	5.0	2.6	51.2	2.6	(1.2)	0.0
OxyContin	4.2	2.2	51.9	2.0	6.5	0.2
Flumarin	4.5	2.2	48.2	2.5	(12.9)	(0.3)
Claritin	3.5	1.8	50.6	1.8	1.1	0.0
Vancomycin	3.4	1.7	50.9	2.3	(26.3)	(0.6)
Imunace	1.8	1.3	74.4	2.0	(34.3)	(0.7)
Finibax	1.9	0.8	43.7	0.6	35.0	0.2
Differin	1.4	0.5	34.3	-	-	0.5
Irbetan	1.4	0.4	25.8	0.8	(53.5)	(0.4)
Avelox	0.8	0.3	38.3	0.4	(26.7)	(0.1)
Pirespa	0.8	0.3	32.5	-	-	0.3
Export/Overseas operating	26.4	11.9	45.4	1.9	521.0	10.0
Sciele Pharma, Inc.	21.1	9.5	45.2	-	-	9.5
Doripenem	2.5	1.2	48.8	0.5	157.5	0.7
Contract manufacturing	2.8	1.4	53.2	1.2	22.8	0.2
OTC and quasi-drugs	2.6	1.4	54.6	1.4	(0.8)	0.0
Diagnostics	1.6	0.8	51.5	0.9	(10.7)	(0.1)
Royalty income	23.4	10.5	45.0	7.5	39.4	3.0
Crestor	22.0	10.0	45.4	7.2	38.2	2.8
Real estate & others	1.9	0.5	29.3	0.6	(9.1)	(0.1)
Total	133.0	64.0	48.1	51.7	23.8	12.3



Statements of Operating Income (Consolidated)

(Units: billion yen)	1st half FY2009 Forecast	Apr.1-Jun.30 FY2009 Results	% Progress vs. 1st half	Apr.1-Jun.30 FY2008 Results	Y on Y Change (%)	Y on Y Change
Sales	133.0	64.0	48.1	51.7	23.8	12.3
[Royalty]	[23.4]	[10.5]	[45.0]	[7.5]	[39.4]	[3.0]
	27.8	26.9		32.0		
	[33.8]	[32.2]		[37.4]		
Cost of sales	37.0	17.2	46.5	16.5	4.1	0.7
Gross profit	96.0	46.8	48.8	35.1	33.1	11.7
	57.9	63.6		52.4		
SG&A	77.0	40.7	52.9	27.1	50.3	13.6
Selling&general expenses	49.0	24.6	50.3	16.6	48.4	8.0
R&D expenses	28.0	16.1	57.5	10.4	53.4	5.7
	14.3	9.5		15.6		
Operating income	19.0	6.0	32.0	8.0	(24.8)	(2.0)



Highlights of Consolidated Financial Results

- **Sales: +23.8%**
 - Domestic sales of prescription drugs decreased by 0.8 billion yen (-2.2%) year on year.
 - Existing products like antibiotics and Imunace[®] were decreased.
 - Crestor[®] has increased the market share at a good pace.
 - Newly-launched products such as Differin[®] and Pirespa[®] has contributed to sales steadily.
 - Consolidated sales increased by 12.3 billion yen (23.8%) year on year.
 - Crestor[®] royalty has expanded as a result of global sales expansion.
 - Doripenem export increased.
 - Sciele contributed to sales as a consolidated subsidiary.

- **Operating income: -24.8%**
 - Operating income decreased because certain R&D expenses were concentrated in 1st quarter.
 - R&D expenses: +53.4% y/y.
 - Full year operating income is expected to increase to 60 billion yen (+87.4% y/y) as planned.



Revision of FY2009 Financial Forecast (Consolidated)

(Units: billion yen)

<1st half FY2009>

	Original Forecast	Y on Y Change (%)	Revised Forecast	Y on Y Change (%)	Change from Original
Sales	133.0	26.6	130.0	23.7	(3.0)
Operating income	19.0	2.9	17.0	(7.9)	(2.0)
Ordinary income	18.0	(5.1)	16.0	(15.7)	(2.0)
Net income	11.0	(7.1)	10.0	(15.5)	(1.0)

	Original Forecast	Y on Y Change (%)	Revised Forecast	Y on Y Change (%)	Change from Original
<FY2009 full-year>					
Sales	284.0	24.8	280.0	23.1	(4.0)
Operating income	60.0	87.4	60.0	87.4	0.0
Ordinary income	58.0	81.2	58.0	81.2	0.0
Net income	35.0	123.5	35.0	123.5	0.0



Revision of FY2009 Financial Forecast (Non-consolidated)

(Units: billion yen) <1 st half FY2009>	Original Forecast	Y on Y Change (%)	Revised Forecast	Y on Y Change (%)	Change from Original
Sales	106.5	6.5	106.5	6.5	0.0
Operating income	17.0	4.4	17.0	4.4	0.0
Ordinary income	17.0	(5.2)	17.0	(5.2)	0.0
Net income	10.5	(8.3)	10.5	(8.3)	0.0
<FY2009 full-year>	Original Forecast	Y on Y Change (%)	Revised Forecast	Y on Y Change (%)	Change from Original
Sales	225.5	9.1	225.5	9.1	0.0
Operating income	49.5	36.6	51.5	42.1	2.0
Ordinary income	49.5	30.5	51.5	35.8	2.0
Net income	31.0	29.9	32.0	34.1	1.0



Sciele FY2009 Forecast

(Units: \$M)

(Units: billion yen)

Original	1 st half	2 nd half	FY2009
Sales	222	278	500
Operating income	43	97	140
Revised			
Sales	191	267	458
Operating income	22	97	119
Change			
Sales	(31)	(11)	(42)
Operating income	(21)	0	(21)

1 st half	2 nd half	FY2009
21.1	26.6	47.7
4.1	9.2	13.3
Revised		
18.1	25.6	43.7
2.1	9.2	11.3
Change		
(3.0)	(1.0)	(4.0)
(2.0)	0.0	(2.0)



Difference between Forecast and Results of Sciele FY2009

● Sales (Units: \$M)

- Terminated Victory acquisition (1st half: -10, full-year: -42)
- Delay in sales plans of existing products (1st half: -21, full-year: 0)
 - Delay in 1st half sales plan due to reduction of wholesaler's stocks resulting from economic recession
 - Focus on expanding newly-launched products and leveraging current product growth drivers in 2nd half to achieve sales forecast of full-year

● Operating income (Units: \$M)

- Terminated Victory acquisition (1st half: -4, full-year: -17)
- Delay in sales plans for existing products and incremental M&A and integration expenses (1st half: -17, full-year: -4)

A background image of a laboratory setting. In the foreground, a pipette is positioned above a multi-well plate. The plate contains several wells, each with a small amount of blue liquid. The pipette is tilted, and a drop of liquid is visible at its tip. The background is a soft, out-of-focus blue and white, suggesting a clean, professional environment.

Pipeline

Change of Phases in Clinical Studies

- **S-021812 (Peramivir)**
(Neuraminidase inhibitor, Influenza infection)
 - Asian multinational Phase III completed, NDA filing in preparation
- **S-349572 (Integrase inhibitor, HIV)**
 - Phase IIa completed in the U.S., Phase IIb initiated in the U.S. and Europe
- **LY248686 (Duloxetine) (SNRI, Diabetic neuropathic pain)**
 - Phase III completed in Japan, NDA filing in preparation
- **S-2367 (NPY Y5 receptor antagonist, Obesity)**
 - Phase I study initiated in Japan
- **S-555739 (PGD2 receptor antagonist, Allergic disease)**
 - Phase I study in Japan and POM study in Europe completed, Phase IIa initiated in Japan

Discontinued development

- **S-777469 (Selective CB2 receptor agonist, Atopic dermatitis; Oral)**
 - Reason: Not shown pharmacological effect in Ph IIa studies both in Japan and in the U.S.
 - Study design of the U.S. Ph IIa (N = 209): 400mg, 800mg BID and placebo groups
 - Shift the resources into S-444823 (CB receptor agonist (topical)) development

SNRI: Serotonin noradrenalin reuptake inhibitor, NPY: Neuropeptide Y, PGD2: Prostaglandin D2, POM: Proof of Mechanism, CB: Cannabinoid

S-021812 (Peramivir): Phase III Study Results

● Single dose study

➤ Patients and Study Design

- Influenza virus infected patients (N = 1099)
- Double-blind, oseltamivir phosphate (Tamiflu®)-controlled, Asian multinational study (Japan, Korea and Taiwan)
- 300mg/600mg intravenous administration (Tamiflu: 75mg BID, 5-day oral dosing)

Median TTAS

Group	Time (hr)	
	Single	Repeated
300mg	78.0	114.4
600mg	81.0	42.3
Tamiflu	81.8	-
Evaluable patients (300mg or 600mg)	-	68.6

● Repeated dose study for high-risk patients

➤ Patients and Study Design

- Influenza virus infected patients with high-risk (N = 42)
- Double-blind, multi-center study

● Time to alleviation of influenza symptoms (TTAS)

- Single dose: Shown non-inferiority compared to Tamiflu group
- Repeated dose: Improved in shorter period in high-risk patients, TTAS could be prolonged

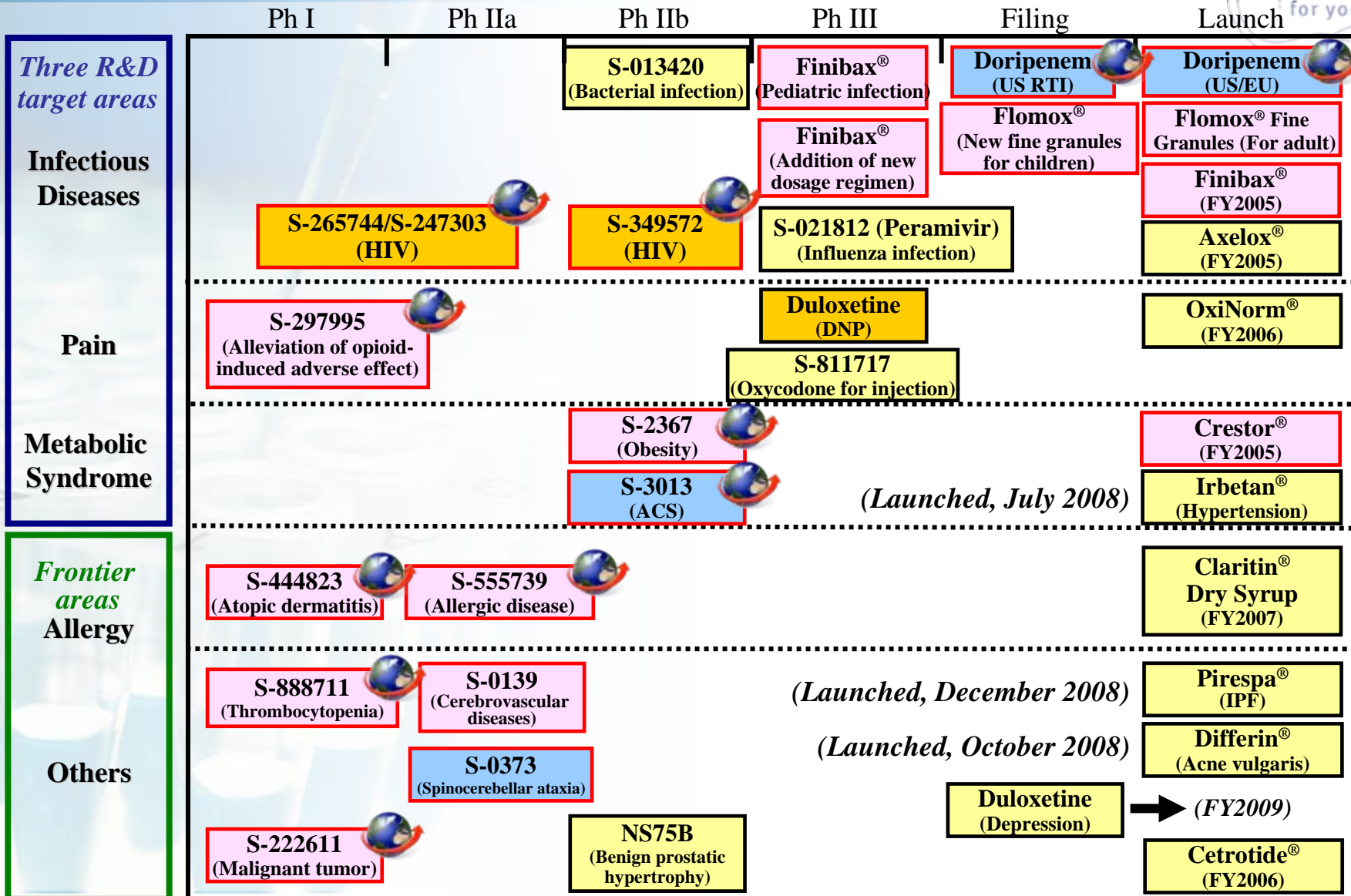
● Safety

- Single dose: Significantly lower adverse effect in 300mg group compared to Tamiflu group

S-349572: Phase IIa and Additional Study Results at IAS2009

- **Developed by Shionogi-GlaxoSmithKline Pharmaceuticals, LLC**
- **Phase IIa study overview**
 - **Patients and study design**
 - INI-naive HIV-1 infected patients (N = 35)
 - Double-blind, placebo-controlled, multi-center study
 - 2mg - 50mg QD, monotherapy over 10 days
 - **Pharmacological effect**
 - Observed plasma concentrations and pharmacological effects in a dose-dependent manner
 - Decrease of 1.5 - 2.5 log₁₀ copies/mL in plasma HIV-1 RNA levels from baseline compared placebo group on day 11
 - Undetected plasma HIV-1 RNA levels (<50 copies/mL) in 70% of 50 mg group
 - **Safety**
 - Well tolerated (no deaths or serious adverse events and no subjects withdrew from the study due to an adverse event)
- ***In vitro* study**
 - **Superior drug resistance profile**
 - Unprecedented activity against INI-resistant clinical isolates
 - Show fewer mutations emerged under S-349572 exposure

Pipeline (As of August, 2009)



In-house Co-development Out-licensed In-licensed

Developing in-house products globally

IPF: Idiopathic pulmonary fibrosis, DNP: Diabetic Neuropathic Pain, RTI: Respiratory Tract Infection, ACS: Acute coronary syndromes



Update on Sciele's Pipeline

- **Ulesfia™** (Benzyl alcohol 5% topical lotion, Head lice)
 - Launched July 2009
- **Clonidine XR** (Clonidine hydrochloride: Centrally acting alpha adrenergic agonist, Hypertension)
 - The U.S.: Phase III trial completed, U.S. filing expected 2nd Half 2009
- **Glycopyrrolate** (Glycopyrrolate: Anticholinergic, Chronic Drooling)
 - The U.S.: Phase III trial completed, U.S. filing expected 2nd Half 2009
- **Clonicef** (Clonidine hydrochloride: Centrally acting alpha adrenergic agonist, ADHD)
 - The U.S.: Phase III (monotherapy trial & combination therapy) completed, U.S. filing expected 2nd Half 2009
- **PSD502** (Lidocaine/prilocaine: Eutectic mixture of anesthetics, PE)
 - Positive results of Phase III trials in the U.S., Canada and Europe
 - Statistically and clinically significant increase in all co-primary endpoints
 - Well tolerated and devoid of systemic side effects
 - Regulatory filings expected 1st Half 2010



Sciele R&D

PRODUCT/ INDICATION	Ph I	Ph II	Ph III	Filing	Launched
PrandiMet[®] Type II Diabetes	(Repaglinide/Metformin)				(January 2009)
Prenate DHA[®] Prenatal Vitamin	(Vitamins, Minerals, DHA, Metafolin)				(April 2009)
Ulesfia[™] Head lice	(Benzyl Alcohol)				(July 2009)
Clonidine XR Hypertension	(Clonidine Extended Release)				
Glycopyrrolate Chronic Drooling	(Glycopyrrolate Liquid)				
Epinephrine Anaphylaxis	(Single Dose Epinephrine Auto Injector)				
CloniceL ADHD	(Clonidine)				
PSD502 Premature Ejaculation	(Lidocaine/Prilocaine)				
PravaFen Mixed Dyslipidemia	(Pravastatin/Fenofibrate)				
ADX415 Hypertension	(2a specific adrenergic agonist)				

Cardio

Diabetes

Pediatrics

**Women's Health/
Sexual Dysfunction**