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# Financial Results Presentation

## Q2 FY2011

(Six Months Ending September 30, 2011)

Atsumasa Makise  
Senior Managing Director  
Otsuka Holdings Co., Ltd.

- 1 Restated FY2010 Q2 Results (Due to Changes in Accounting Policies)**
- 2 FY2011 Q2 Consolidated Financial Results (Compared to Previous Year)**
- 3 FY2011 Q2 Business Segment Analysis**
- 4 FY2011 Q2 Pharmaceutical Segment Analysis**
- 5 FY2011 Q2 Abilify Sales**
- 6 FY2011 Q2 Nutraceutical Segment Analysis**
- 7 FY2011 Q2 Consolidated Financial Results (Compared to Forecast)**
- 8 FY2011 Forecast**

# 1. Restated FY2010 Q2 Results (Due to Changes in Accounting Policies)

## Changes in Accounting Policies

1) Method of translating revenue and expense accounts of foreign subsidiaries was changed from the “closing exchange rate” to the “average exchange rate”

2) Classification of upfront licensing payments received (including Abilify upfront payments) was changed from “non-operating income” to “net sales”

(100 million yen)

	FY2010 Q2 Originally reported	FY2010 Q12 Restated	Effect of changes in accounting policies	(Details)	
				1) Change in method of translation	2) Change in method of presentation
Net Sales	5,740	5,869	129	92	37
Operating income	699	729	31	-6	37
Ordinary income	740	736	-4	-4	-
Net income	532	530	-1	-1	-

R&D expenses	802	802	0	0	-
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	Closing rate	Average rate
USD	88.48	91.35
EURO	107.81	121.22

## 2. FY2011 Q2 Consolidated Financial Results (Compared to Previous Year)



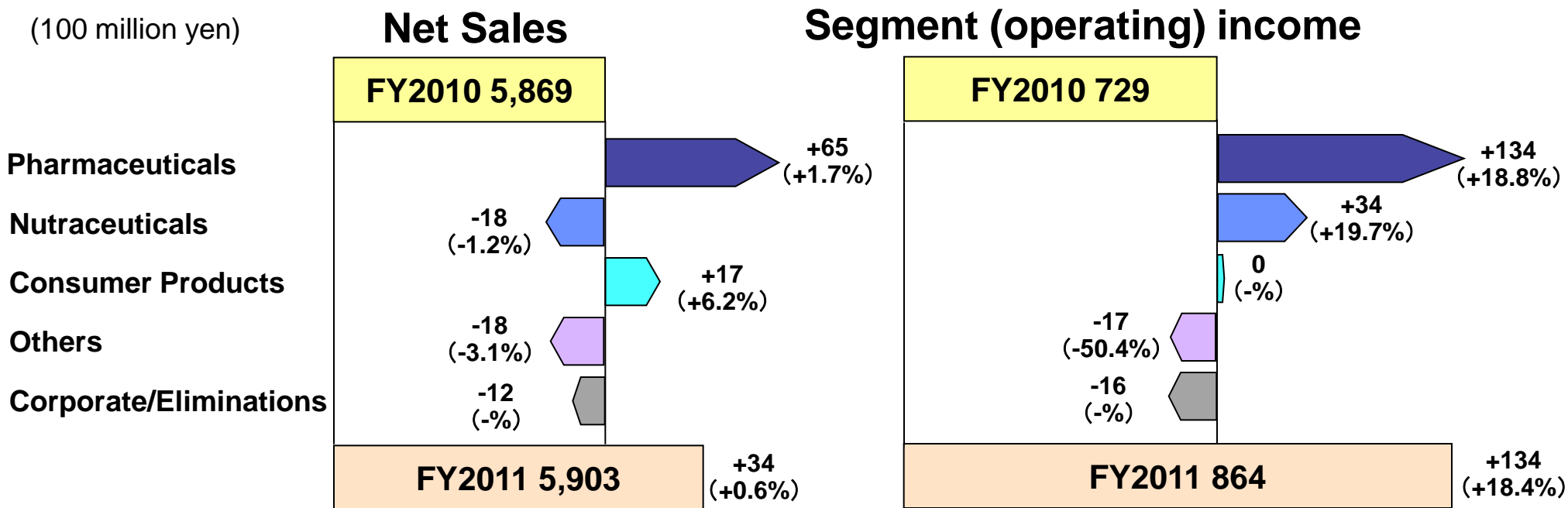
(100 million yen)

	FY2010 Q2 Restated	FY2011 Q2	Change	% Change
Net Sales	5,869	5,903	34	0.6%
Operating Income	729	864	134	18.4%
Ordinary Income	736	855	119	16.2%
Net Income	530	572	42	7.8%
R&D Expenses	802	770	-32	-4.0%

Effect of appreciation of the Yen: Net Sales -260, Operating Income -30

### 3. FY2011 Q2 Business Segment Analysis

(100 million yen)



\*Parentheses represent % increase

Net Sales	FY2010	FY2011	Change
Pharma	3,746	3,811	65
NC	1,483	1,465	-18
Consumer	268	285	17
Others	578	561	-18
Corp/Elim	-207	-219	-12
<b>Consolidated</b>	<b>5,869</b>	<b>5,903</b>	<b>34</b>

Op income	FY2010	FY2011	Change
Pharma	713	847	134
NC	172	206	34
Consumer	-2	-2	0
Others	34	17	-17
Corp/Elim	-187	-204	-16
<b>Consolidated</b>	<b>729</b>	<b>864</b>	<b>134</b>

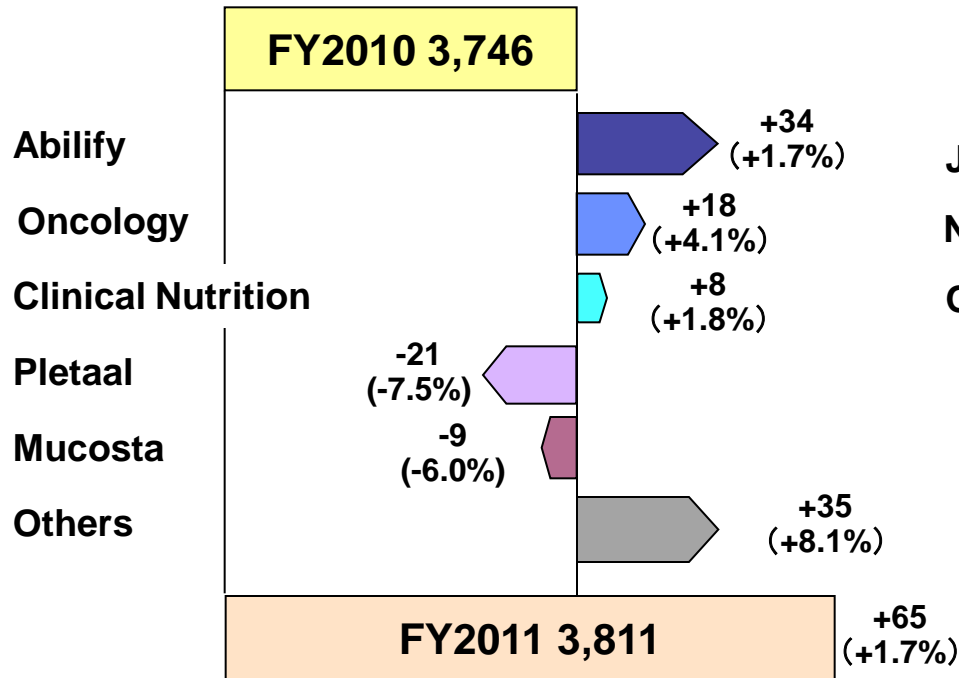
< Operating margin (%) >

	FY2010	FY2011
Pharma	19.0	22.2
NC	11.6	14.0
Consumer	-0.6	-0.7
Others	5.8	3.0
Corp/Elim	-	-
<b>Consolidated</b>	<b>12.4</b>	<b>14.6</b>

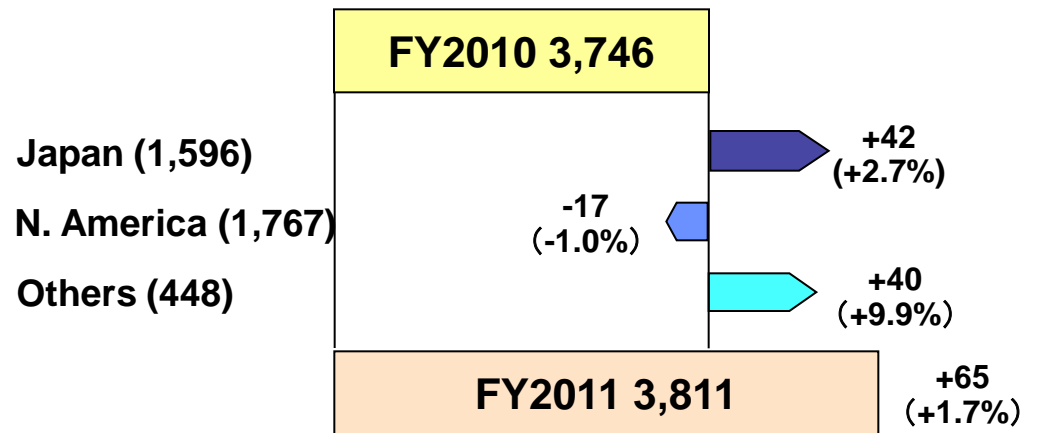
# 4. FY2011 Q2 Pharmaceutical Segment Analysis



## (100 million yen) Net Sales

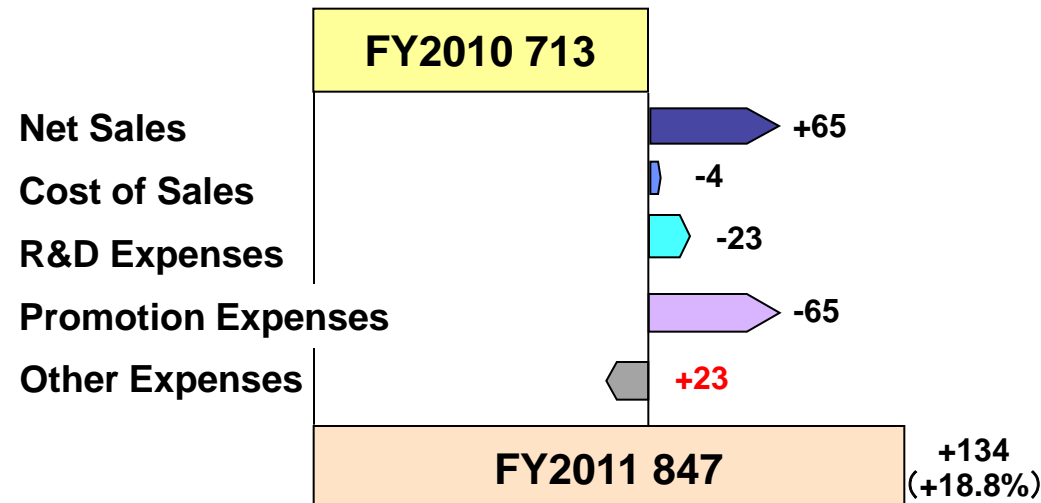


## Net Sales by Market



Products	2010 2Q	2011 2Q	Change	% Change
Abilify	1,988	2,022	34	1.7%
Oncology	432	449	18	4.1%
Clinical Nutrition	466	475	8	1.8%
Pletaal	272	252	-21	-7.5%
Mucosta	155	146	-9	-6.0%
Others	433	468	35	8.1%
<b>Pharma Total</b>	<b>3,746</b>	<b>3,811</b>	<b>65</b>	<b>1.7%</b>

## Segment (operating) income

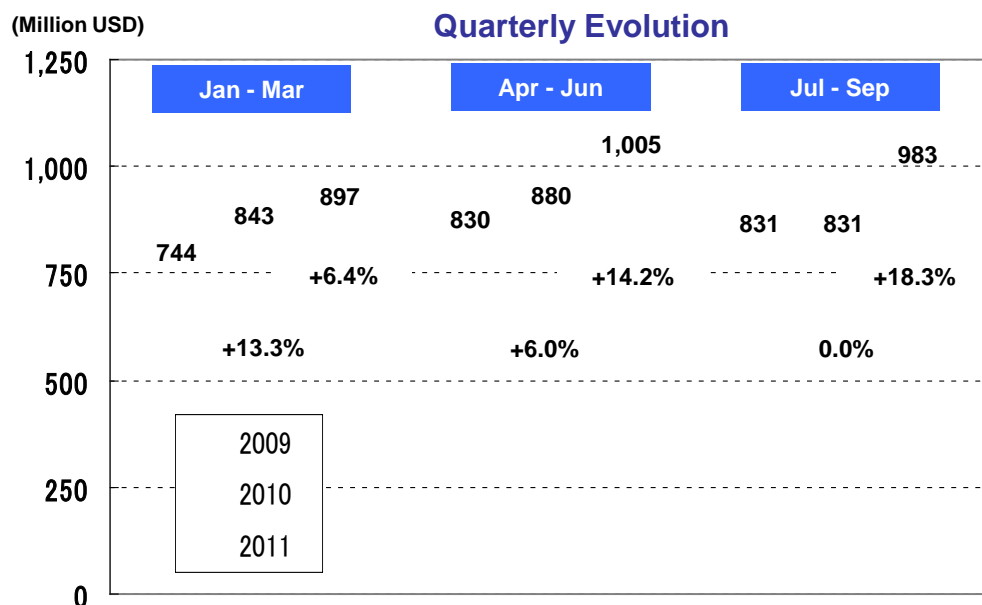


## 5. FY2011 Q2 Abilify Sales

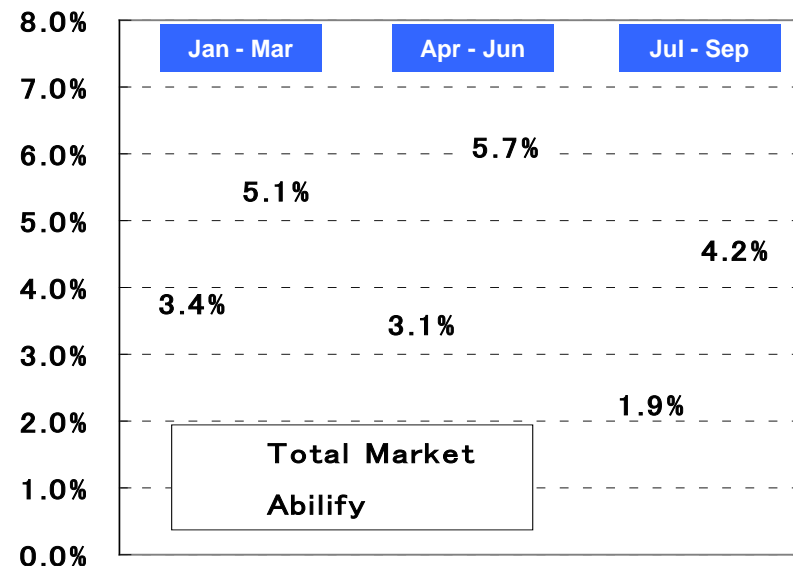
(100 million yen)

	FY2010 Q2	FY2011 Q2	Change	% Change
Abilify	1,988	2,022	34	1.7%
US	1,574	1,559	-15	-0.9%
<Million USD>	<1,723>	<1,901>	<179>	10.4%
Japan	110	120	10	8.9%
Other	304	343	39	12.8%

### Abilify in the US Market



### Atypical antipsychotic prescription market

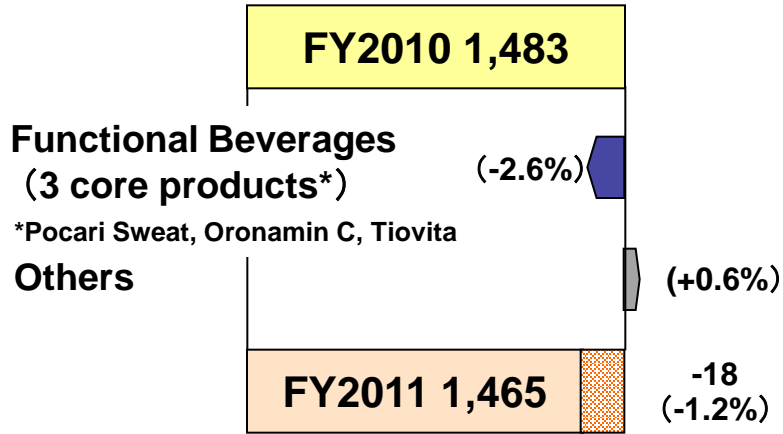


Source: Wolter Kluwer, pharmacy data (September 2011)

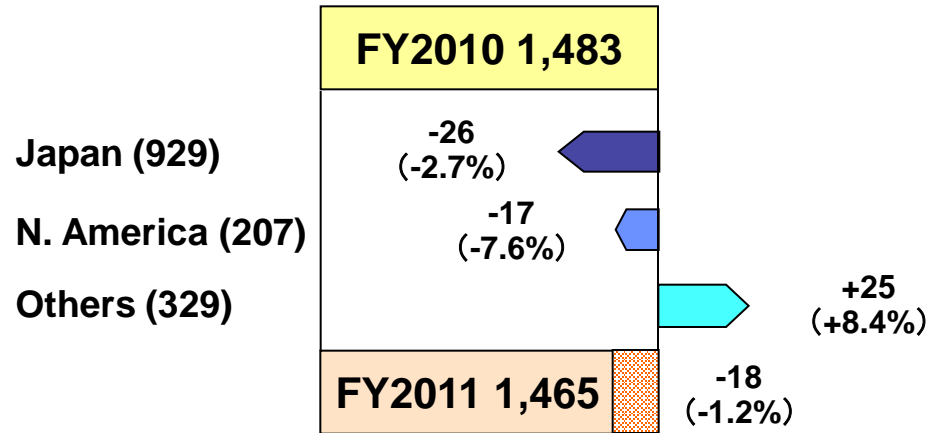
# 6. FY2011 Q2 Nutraceutical Segment Analysis

(100 million yen)

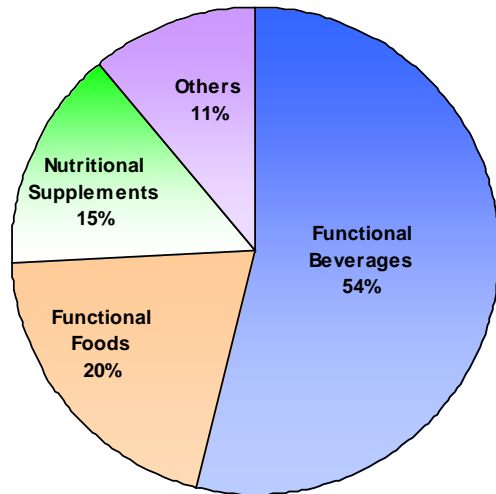
## Net Sales



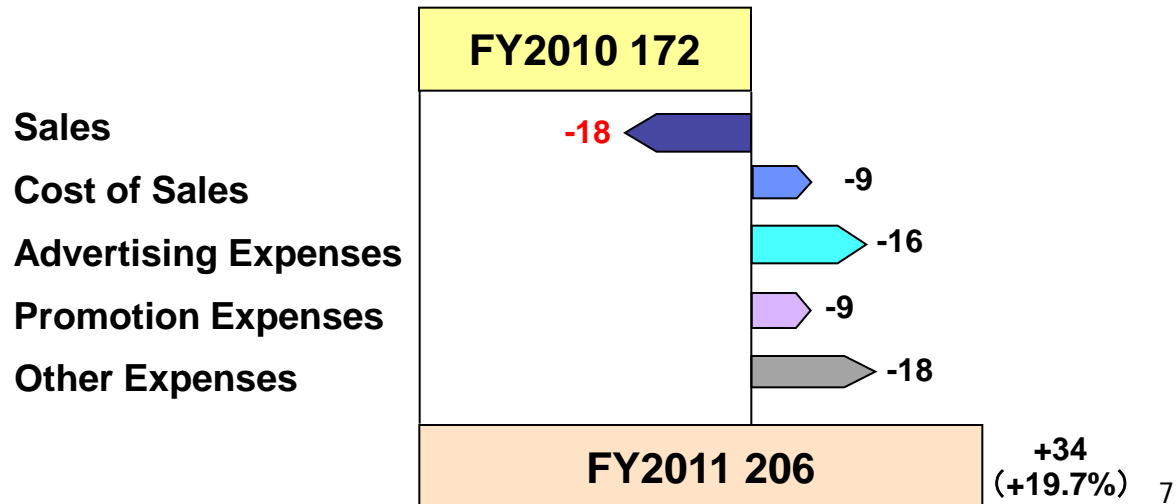
## Net Sales by Market



## Sales by Category



## Segment (operating) income





## 7. FY2011 Q2 Consolidated Financial Results (Compared to Forecast)



(100 million yen)

	FY2011 Half-Year Forecast	FY2011 Half-Year Actual	Variance	Main factors Red letter represents unfavorable factors
Net Sales	5,980	5,903	-77	Impact of JPY appreciation ▲80
Operating Income	630	864	234	R&D expenses ▲170
Ordinary Income	670	855	185	Foreign exchange loss
Net Income	450	572	122	Increase in income taxes
R&D Expenses	940	770	-170	
Exchange Rate (USD)	85.00	82.00	-3.00	
Exchange Rate (EUR)	115.00	115.03	0.03	

## 8. FY2011 Forecast

(100 million yen)

	FY2010 Actual	FY2011 Full-Year Forecast			Change from FY2010	
		Previous	Amount changed	Revised	Change	% Change
Net Sales	11,276	11,700	-200	11,500	224	2.0%
Operating Income	1,263	1,200	250	1,450	187	14.8%
Ordinary Income	1,284	1,270	180	1,450	166	12.9%
Net Income	824	820	120	940	116	14.1%
R&D Expenses	1,647	1,890	-240	1,650	3	0.2%
Earnings Per Share (Yen)	164.51	146.99	21.51	168.50		
Dividends Per Share (Yen)	28.00	45.00	-	45.00		
Exchange Rate (USD)	87.79	85.00	-5.00	80.00		
Exchange Rate (EUR)	116.27	115.00	-5.00	110.00		

\*Estimated exchange rates for Q3 and Q4 are 78yen (USD) and 103yen (EUR).

# Pharmaceutical Development Update

**Kuniaki Natsume, Ph.D.**  
**Senior Operating Officer**  
**Business Development and Planning**  
**Otsuka Holdings Co., Ltd**

- 1 Major development projects**
- 2 Development Update in 2Q/FY2011 (as of September 30)**
  - Launches
  - Approvals
  - Advance to Phase III
  - Advance to the next stage
- 3 Topics**
  - Mucosta<sup>®</sup> ophthalmic suspension Unit Dose 2%
  - OPC-34712
- 4 Current status of projects entering into P-III & scheduled NDA submissions**

# 1. Major development projects (as of Sep. 30, 2011)



Phase	P-1	P-2	P-3	NDA
CNS	OPC-34712 Schiz./JP	OPC-34712 ADHD/US	IM Depot Schiz./US,EU,JP ABILIFY® MDD/JP ABILIFY® Tourette's/US E KEPPRA® Epilepsy (Partial seizures in children/ Generalized seizures) JP E KEPPRA® Partial seizures (Injection) JP Neupro® PD/RLS/JP OPC-34712 MDD/US OPC-34712 Schiz./US,EU	ABILIFY® Bipolar/JP ABILIFY® Tic/Asia
	TSU-68 NSCLC/JP OPB-31121 Anti-cancer/JP,Asia OPB-51602 Anti-cancer/US,JP,Asia OCV-105 Pancreatic/JP ET-743 STS/JP OPB-111001 Prostate/JP	TS-1 Prostate,renal/JP ABI-007 Gastric/JP TSU-68 Breast/JP,Asia TSU-68 Gastric/JP TSU-68 Colorectal/Asia OTS102 Biliary/JP OCV-101 Pancreatic/JP TAS-102 Colorectal/JP SPRYCEL® Pancreatic/US,EU	TS-1 Gastric/US TS-1 Uterocervical/JP,Asia TS-1 HCC/JP ABI-007 NSCLC/JP OVF Cancer pain/JP TSU-68 HCC/JP,Asia SATIVEX® Cancer pain/US	
Oncology		TAS-106 Solid cancer/US	OTS102 Pancreatic/JP	
Cardiovascular			SAMSCA® PKD/JP,US,EU SAMSCA® Hepatic edema/JP,Asia	SAMSCA® Hyponatremia/Asia,Canada *; Approved
Others/ Diagnostics		Mucosta® ophthalmic suspension Dry eye/US OPC-67683 Tuberculosis/EU,JP,US ACU-4429 AMD/US TAC-201 Cedar pollen allergy/JP NST-141 Pruritus/JP OPC-6535 COPD/JP,US,Asia	YP-18 Peritonitis,others/JP CIMZIA® RA/JP ONGLYZA™ Diabetes/JP	Mucosta® ophthalmic suspension Dry eye/JP *; Approved ODK-0902 H.influenzae/JP
		OPA-6566 Glaucoma/US OPB-2045G Anti-infective/JP	OPC-6535 Crohn's/JP,Asia	

Blue column indicates the changes in 2Q

## 2-1. Key Development Progress

- One product launched in Japan

Product/Generic name	Country/Area	Details
ZOLINZA <sup>®</sup> (Vorinostat)	Japan	Approved for cutaneous T-cell lymphoma (CTCL) on July 1. Promotion and distribution started on Sep. 14 based of the distribution agreement signed between MSD and Taiho.

- Two new products approved

Product name	Country/Area	Details
Mucosta <sup>®</sup> ophthalmic suspension UD2%	Japan	Approved for manufacturing and marketing on Sept. 26.
SAMSCA <sup>®</sup>	China, South Korea, Canada	Approved for hyponatremia.

## 2-2. Key Development Progress

- Four projects advanced to P-III

Development code	Country/Area	Indication
OPC-34712	USA	Major Depressive Disorder
OPC-34712	USA, EU	Schizophrenia
Aripiprazole	USA	Tourette's syndrome
E KEPPRA® Injection	Japan	Partial seizures

- Other projects advanced to the next stage

Development code/ Product name	Phase	Country/Area	Indication
SPRYCEL®	P II	USA,EU	Pancreatic cancer
OPA-6566	P I / II	USA	Glaucoma
OPB-2045G	P I / II	Japan	Disinfectant
OPB-111001	P I	Japan	Prostate cancer

# 3-1. Mucosta® Eye Drops: Treatment of dry eye syndrome

Eye drop formulation of an anti-gastric ulcer agent rebamipide (Mucosta®) : Effective in both corneal and conjunctival disturbances

## Generic name (Product name) - Indication

- **Rebamipide (Mucosta® ophthalmic suspension UD2%)**
- **Dry eye syndrome**

## Mechanism of action - Features

- **Different from existing fluid retaining agents with mucin-secreting action**
  - ✓ **Directly acts on corneal and conjunctival epithelia, and increases the amount of secretory and membrane-bound mucin**
- **Effective in both corneal and conjunctival disturbances**
- **Improve subjective symptoms (foreign body sensation and eye-ache)**
- **Main side effects: bitterness, blurred vision**

## Newly-developed eye drops from an anti-gastric ulcer agent, rebamipide (Mucosta®)

**1990**  
Launched as Mucosta® indicated for gastritis and gastric ulcer

**Mucosta® tablets 100**



**Mucosta® granules 20%**



◆ **Gastric mucus (mucin)-secreting action**

**2011**  
To be launched as Mucosta® ophthalmic suspension UD2%

**Dry eye syndrome**  
Mucosta® ophthalmic suspension Unit Dose 2%



◆ **Improved subjective symptoms & keratoconjunctival disturbance shown in clinical trials**

## Comments

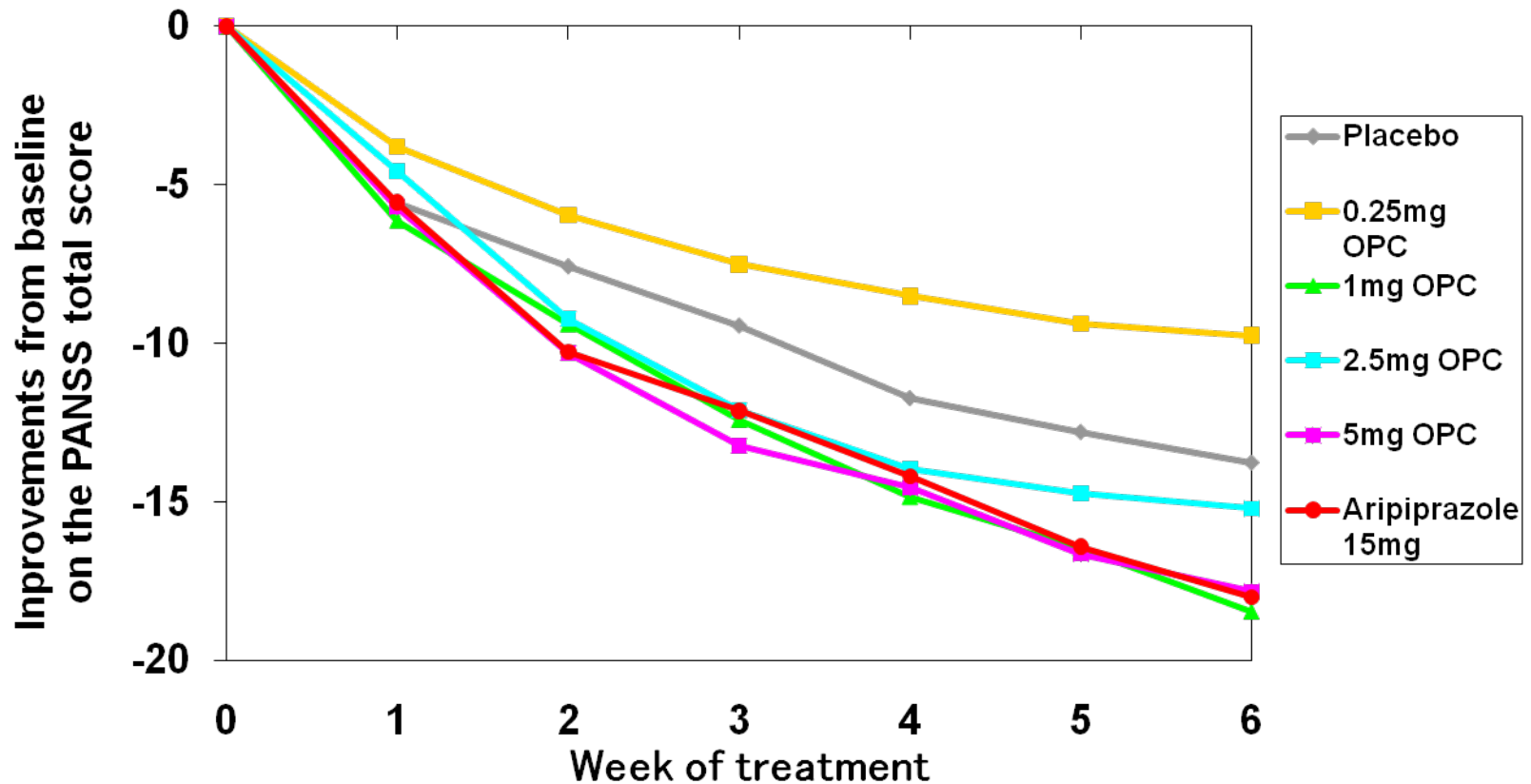
- **Approved for manufacturing and marketing on Sep. 26, 2011 (Japan)**
- **Phase II (USA)**



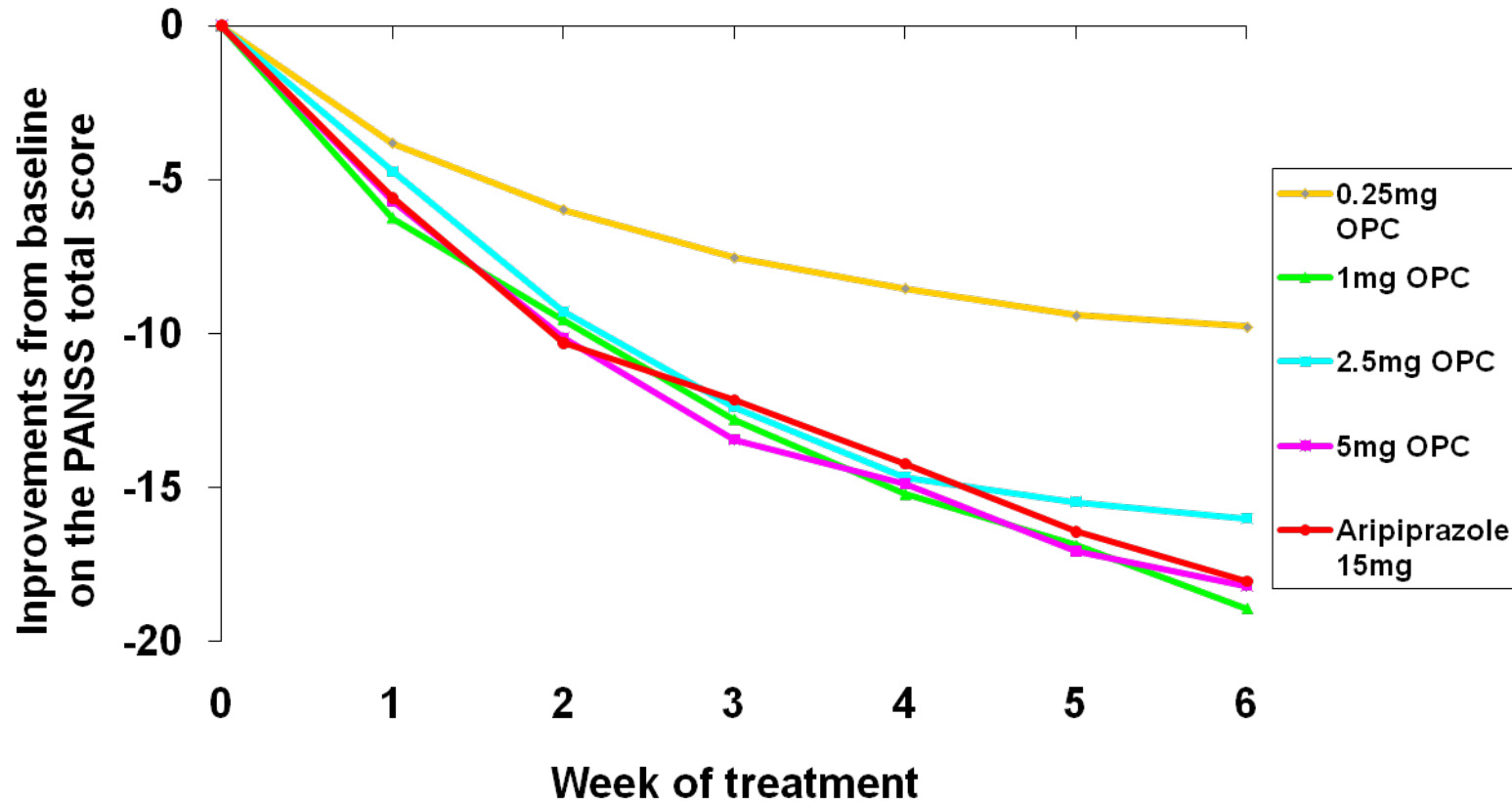
## 3-2. OPC-34712

<b>Development code</b>	<b>OPC-34712</b>	
<b>Indication</b>	<b>Schizophrenia</b>	
<b>Phase</b>	<b>P2</b>	
<b>Country/Area</b>	<b>USA</b>	
<b>Conference</b>	<b>US. Psychiatric &amp; Mental Health Congress 2011.11.7-10</b>	
<b>Details</b>	■ <b>Indication</b>	<b>Schizophrenia</b>
	■ <b>Total patients No.</b>	<b>459 (randomized)</b>
	■ <b>Comparison group</b>	<b>Placebo, aripiprazole</b>
	■ <b>Dose</b>	<b>0.25mg, 1.0±0.5mg, 2.5±0.5mg, 5.0±1.0mg</b>
	■ <b>Schedule</b>	<b>6 weeks</b>
	■ <b>Primary end point</b>	<b>Mean change from baseline to endpoint in PANSS Total score</b>
	■ <b>Results</b>	<ul style="list-style-type: none"> <li>■ <b>Despite the high placebo response rate, the original study objective has been met.</b> <ul style="list-style-type: none"> <li>✓ <b>Efficacy of OPC-34712 is comparable to that of aripiprazole.</b></li> <li>✓ <b>OPC-34712 tends to be superior in improving negative symptoms and cognition.</b></li> <li>✓ <b>non-effective dose= 0.25 mg/day</b></li> <li>✓ <b>effective dose range : 1.0 – 5.0 mg/day</b></li> </ul> </li> </ul>

### 3-3. Mean change in PANSS Total score by study week (LOCF), efficacy sample ( I )

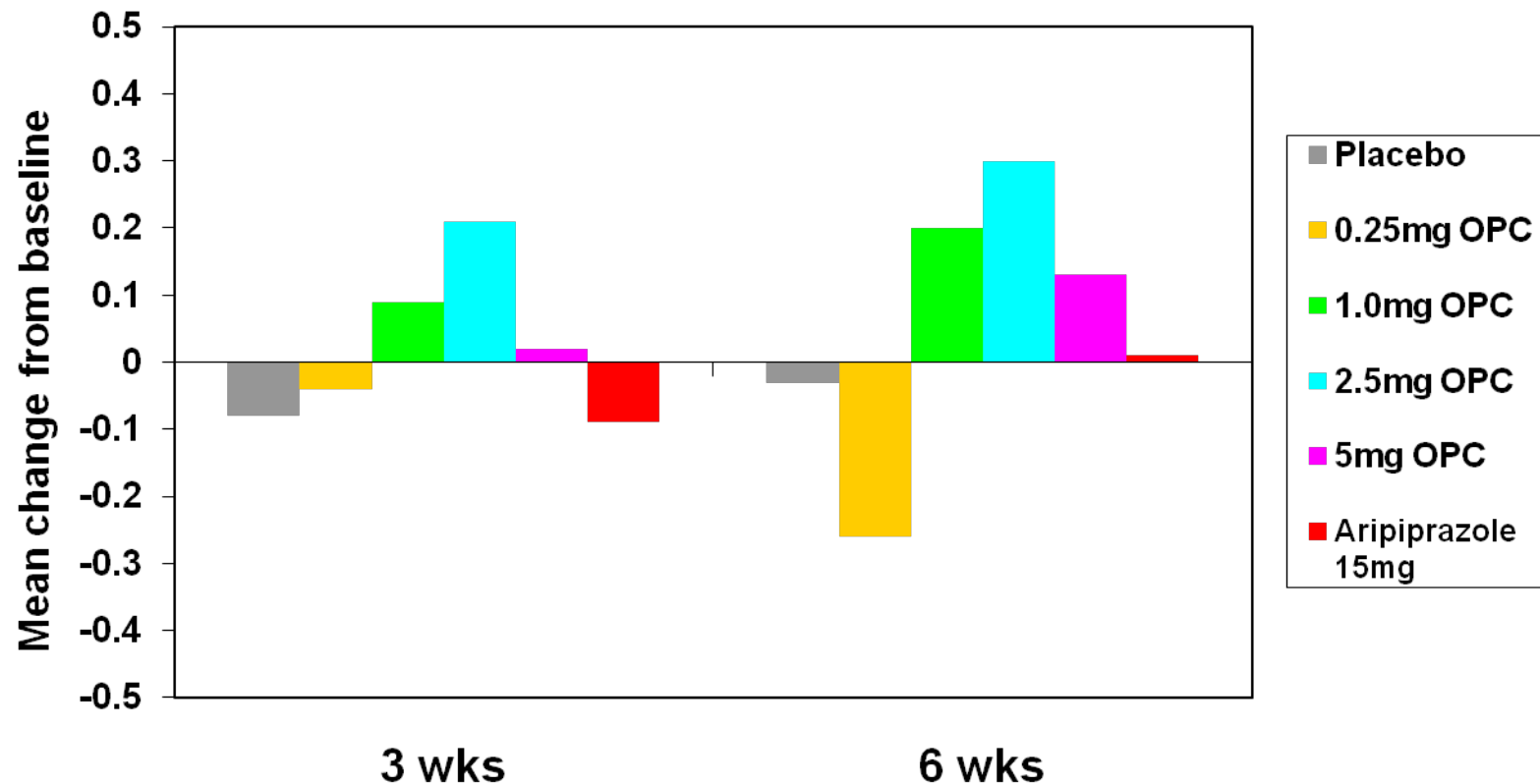


### 3-4. Mean change in PANSS Total score by study week (LOCF), efficacy sample (II -reference)



## 3-5. Mean change in CogState Composite Score

OPC-34712 showed greater improvements than aripiprazole.



## 3-6. Conclusions

- **Effective dose range: 1.0mg/day - 5.0 mg/day**
- **Non-effective dose: 0.25mg/day**
- **Efficacy and safety are comparable to those observed with aripiprazole.**
- **Improvements in scores of negative symptoms and cognition tend to be superior to those of aripiprazole .**

**Although the placebo group exhibited higher than expected improvements, the initial study objective has been met.**

## 4-1. Major P<sup>III</sup> projects expected to start in FY2011

Four development projects, mainly in CNS, are scheduled to proceed to phase<sup>III</sup> in FY2011. (Initial plan) ⇒ Four projects advanced to Phase<sup>III</sup>.

Advancement to P<sup>III</sup>

No.	Areas	Generic Name / Development Code	Country/ Area	Indication
1	CNS	OPC-34712	US	Major Depressive Disorder
2		OPC-34712	US	Schizophrenia
3		Aripiprazole (Novel Oral Formulation)	US	Tourette's Syndrome
4	Others	THN-01	Japan	Tissue Adhesion Prophylaxis

☆E KEPPRA<sup>®</sup> (Injection) in patients with partial seizures advanced to Phase<sup>III</sup> in Japan.

## 4-2. NDA submissions scheduled in FY2011

Ten development projects, mainly in CNS, are scheduled to proceed to filing stage in FY2011. ⇒ One project has completed NDA submission.

Submitted projects

No.	Areas	Generic name/ Development code	Country/ Area	Indication
1	CNS	Aripiprazole IM Depot	US	Schizophrenia
2		Aripiprazole	Korea	Tics
3		Rotigotine	Japan	Parkinson's Disease
4			Japan	Restless Legs Syndrome
5	Oncology	Nanoparticle Albumin-bound Paclitaxel (injectable suspension)	Japan	Gastric Cancer
6			Japan	NSCLC
7	Others	Saxagliptin	Japan	Type II Diabetes Mellitus
8		Certolizumab Pegol	Japan	Rheumatoid Arthritis
9		YP-18	Japan	Intra-abdominal Abscess
10		P0201 (Semisolid nutrient)	Japan	Nutritional Support