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# Financial Results Presentation

## Q1 FY2012

(Three Months Ending June 30, 2012)

August 9, 2012

Otsuka Holdings Co., Ltd.

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- 1 FY2012 Q1 Consolidated Financial Results**
- 2 FY2012 Q1 Business Segment Analysis**
- 3 FY2012 Q1 Pharmaceutical Segment Analysis**
- 4 FY2012 Q1 Abilify Sales**
- 5 FY2012 Q1 Nutraceutical Segment Analysis**
- 6 FY2012 Estimate**

# 1. FY2012 Q1 Consolidated Financial Results

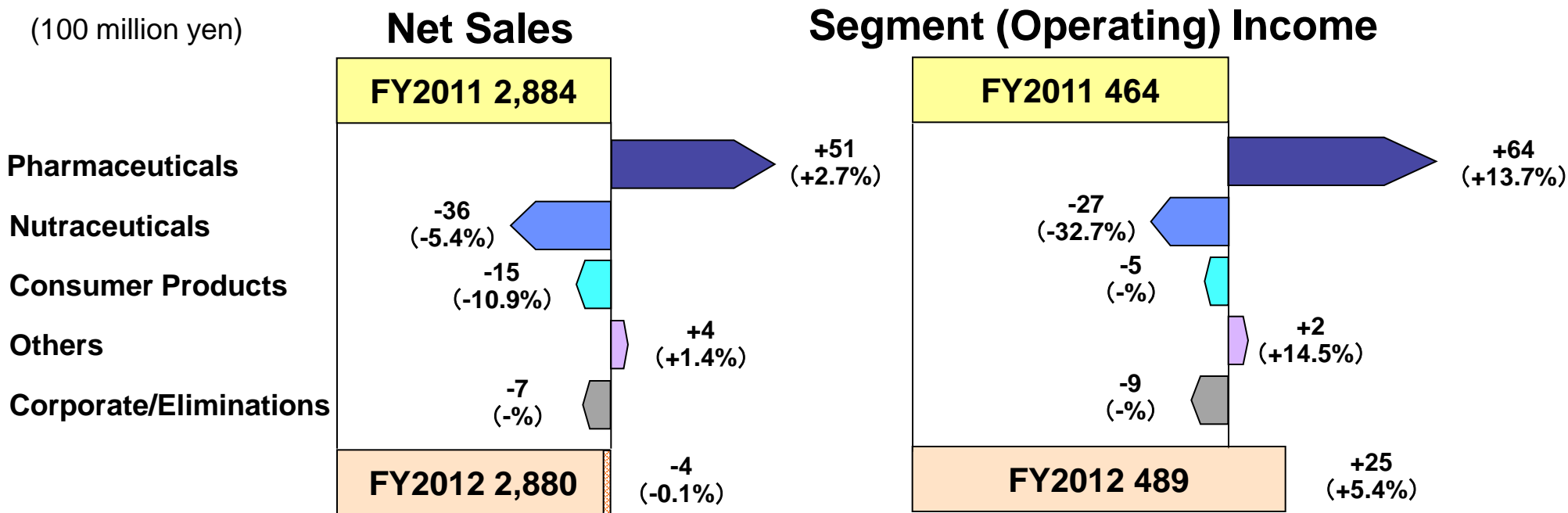
(100 million yen)

	FY2011 Q1 Actual	FY2012 Q1 Actual	Change	% Change
Net Sales	2,884	2,880	-4	-0.1%
Operating Income	464	489	25	5.4%
Ordinary Income	463	487	24	5.3%
Net Income	312	319	8	2.5%
R&D Expenses	385	364	-20	-5.3%

Impact of exchange rate fluctuations: Net Sales -60, Operating Income -10

## 2. FY2012 Q1 Business Segment Analysis

(100 million yen)



\*Parentheses represent % increase

Net Sales	FY2011	FY2012	Change
Pharma	1,901	1,952	51
NC	669	632	-36
Consumer	140	125	-15
Others	279	283	4
Corp/Elim	-105	-112	-7
<b>Consolidated</b>	<b>2,884</b>	<b>2,880</b>	<b>-4</b>

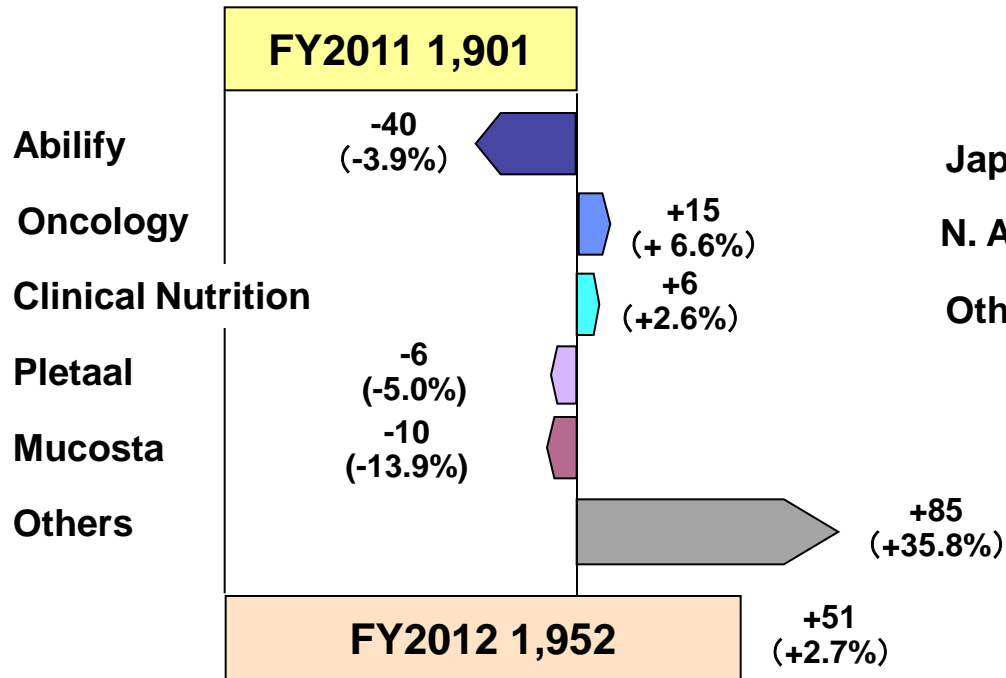
Op income	FY2011	FY2012	Change
Pharma	467	530	64
NC	81	55	-27
Consumer	2	-3	-5
Others	12	14	2
Corp/Elim	-98	-107	-9
<b>Consolidated</b>	<b>464</b>	<b>489</b>	<b>25</b>

< Operating margin (%) >

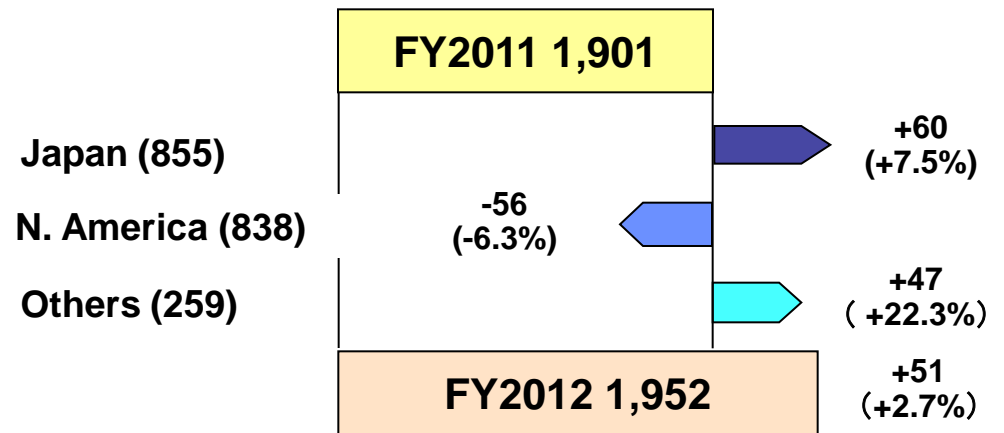
FY2011	FY2012
24.5%	27.2%
12.2%	8.6%
1.2%	-2.4%
4.3%	4.9%
-	-
<b>16.1%</b>	<b>17.0%</b>

### 3. FY2012 Q1 Pharmaceutical Segment Analysis

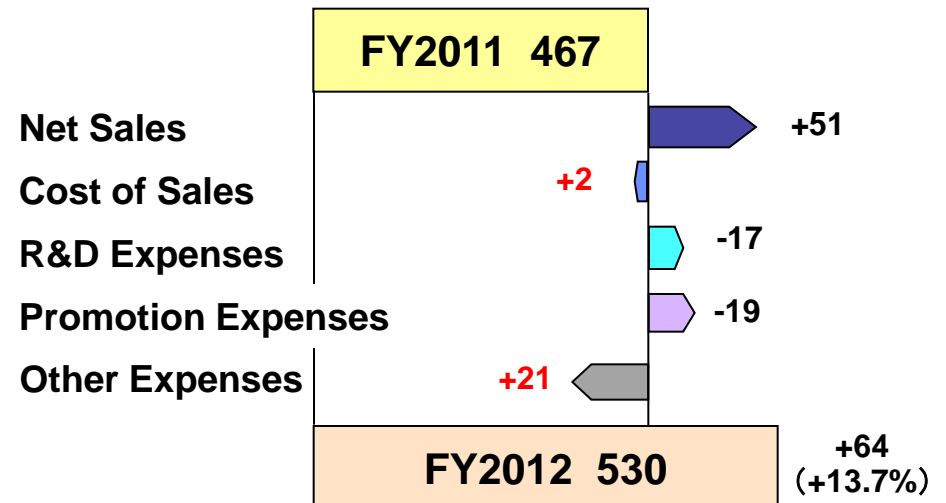
#### (100 million yen) Net Sales



#### Net Sales by Market



#### Segment (Operating) Income



Products	2011 1Q	2012 1Q	Change	% Change
Abilify	1,006	966	-40	-3.9%
Oncology	231	246	15	6.6%
Clinical Nutrition	231	236	6	2.6%
Pletaal	124	117	-6	-5.0%
Mucosta	72	62	-10	-13.9%
Others	238	324	85	35.8%
<b>Pharma Total</b>	<b>1,901</b>	<b>1,952</b>	<b>51</b>	<b>2.7%</b>

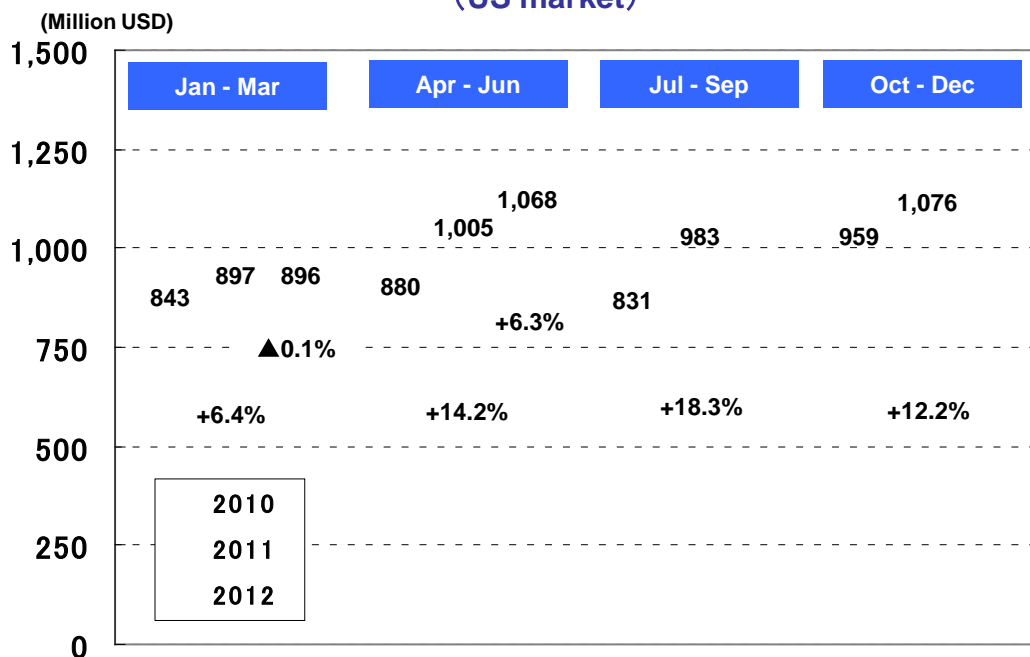
## 4. FY2012 Q1 Abilify Sales

### Abilify Sales by Market

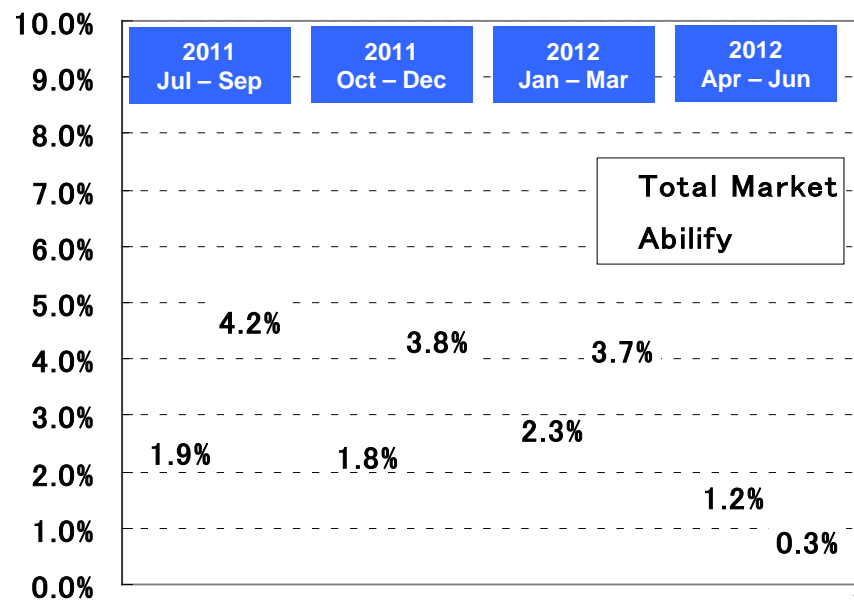
(100 million yen)

	FY2011 Q1	FY2012 Q1	Change	% Change
Abilify	1,006	966	-40	-3.9%
US	738	711	-27	-3.6%
<Million USD>	<897>	<896>	-1	-0.1%
Japan	58	75	17	29.4%
Other	210	180	-30	-14.2%

### Abilify Sales – Quarterly Evolution (US market)



### Atypical antipsychotic prescription market (US market)

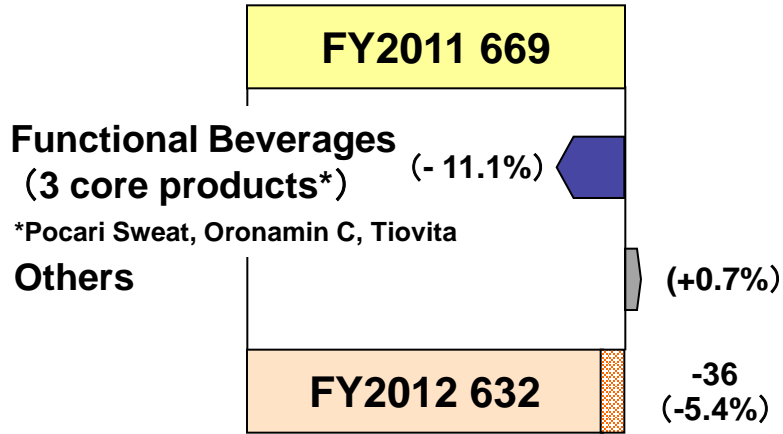


Source: Wolter Kluwer, pharmacy data (June 2012)

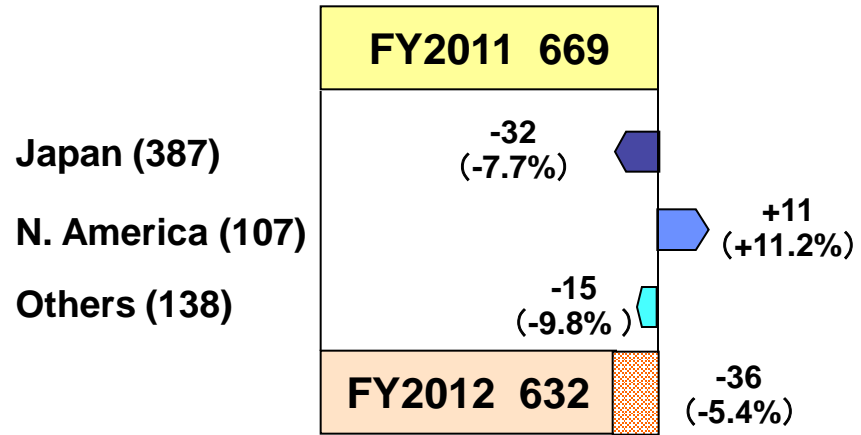
# 5. FY2012 Q1 Nutraceutical Segment Analysis

(100 million yen)

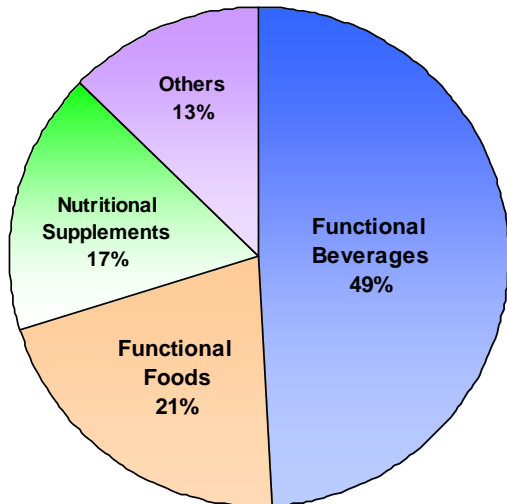
## Net Sales



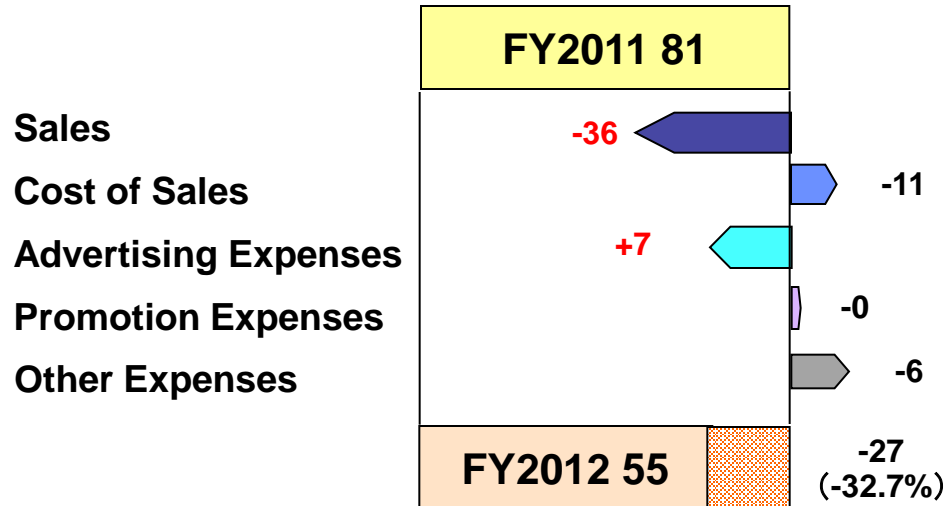
## Net Sales by Market



## Sales by Category



## Segment (Operating) Income





## 6. FY2012 Estimate

(100 million yen)

	FY2011 Q1 Actual	FY2012 Q1 Actual	Change	FY2012 Estimate	% Achievemnt
Net Sales	2,884	2,880	-4	12,000	24.0%
Operating Income	464	489	25	1,650	29.6%
Ordinary Income	463	487	24	1,700	28.7%
Net Income	312	319	8	1,080	29.6%
R&D Expenses	385	364	-20	1,700	21.4%

# Pharmaceutical Development Update

**August 9, 2012**

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 1Q/FY2012**
  - ✓ Approvals
  - ✓ NDA filings
  - ✓ Advance to the next phase
- 3 Topics**
  - ✓ A global P-III clinical study for TAS-102 started
- 4 Progress of projects**  
**Advance to P-III & scheduled NDA submissions**

# 1. Major development projects (as of Jun. 30, 2012)



Phase	P-1	P-2	P-3	NDA
<b>CNS</b>		OPC-34712 ADHD/US	IM Depot Schiz./EU,JP ABILIFY® MDD(Adjunctive)/JP ABILIFY® Tourette's/US E KEPPRA® Epilepsy (Generalized seizures)/JP E KEPPRA® Partial seizures (Injection)/JP E KEPPRA® Partial seizures/Monotherapy(Oral)/JP OPC-34712 MDD(Adjunctive)/US,EU OPC-34712 Schiz./JP,US,EU	IM Depot Schiz./US Rotigotine PD/JP Rotigotine RLS/JP E KEPPRA® Partial seizures in Children/JP
<b>Oncology</b>	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 TAS-115 Solid cancer/JP OCV-501 AML/JP TAS-114 Solid cancer/JP,US,EU	TS-1 Renal/JP TSU-68 Gastric/JP TSU-68 Colorectal/Asia OTS102 Biliary/JP OCV-101 Pancreatic/JP SPRYCEL® Pancreatic/US,EU	TS-1 Gastric/US TS-1 Uterocervical/JP,Asia TS-1 HCC/JP TSU-68 HCC/JP,Asia OVF Cancer pain/JP SATIVEX® Cancer pain/US TAS-102 Colorectal/JP,US,EU	ABRAXANE® Gastric/JP ABRAXANE® NSCLC/JP
		TAS-106 Solid cancer/US		
<b>Cardiovascular</b>	OPC-108459 AF/JP,US		SAMSCA® Hepatic edema/JP,Asia SAMSCA® PKD/JP,US,EU	
<b>Others/ Diagnostics</b>		ACU-4429 AMD/US TAC-201 Cedar pollen allergy/JP OPC-6535 COPD/JP,US,Asia Mucosta® ophthalmic suspension Dry eye/US Mucosta® ophthalmic suspension Keratoconjunctival epithelial disorder/JP	Delamanid Tuberculosis/JP,US,EU Zosyn®(YP-18) Febrile neutropenia/JP	Delamanid Tuberculosis/EU Zosyn®(YP-18) Peritonitis,others/JP ODK-0902 H.influenzae/JP ODK-1003 WT-1 mRNA Assay kit II/JP Saxagliptin Diabetes/JP
	OPA-6566 Glaucoma/US OPB-2045G Anti-infective/JP	OPC-6535 Crohn's/JP,Asia		

Blue column indicates the changes in 1Q

\* Approved

## 2-1. Key Development Progress in 1Q/2012 (as of Jun. 30, 2012)

- One product was launched.

Product name	Country/Area	Details
Abilify®	Japan	Launched on May 11, 2012. New dosage form "ABILIFY® OD Tablets"

☆ PROTECADIN® OD tablets launched on July 24

- Three applications were submitted for approval.

Generic name(Product name)	Country/Area	Indication
Saxagliptin	JP	Type II diabetes mellitus
Levetiracetam (E Keppra®)	JP	Partial onset seizures in children New dry syrup formulation
WT-1 mRNA Assay Kit II 'Otsuka'	JP	AML(Acute myeloid leukemia), MDS (Myelodysplastic syndrome) In-vitro diagnostic kit

☆ Tolvaptan (Samsca®) J-NDA submitted in July for Hepatic edema

## 2-2. Key Development Progress in 1Q/2012 (as of Jun. 30, 2012)

- One project advanced to P-III.

Development code	Country/Area	Indication
TAS-102	JP·US·EU	Colorectal cancer

☆ A Rebamipide ophthalmic suspension P-III study started for dry eye syndrome in July (US)

- One project advanced to P-II.

Generic name(Product name)	Country/Area	Indication
Rebamipide ophthalmic suspension (Mucosta <sup>®</sup> ophthalmic suspension )	JP	Keratoconjunctival epithelial disorder

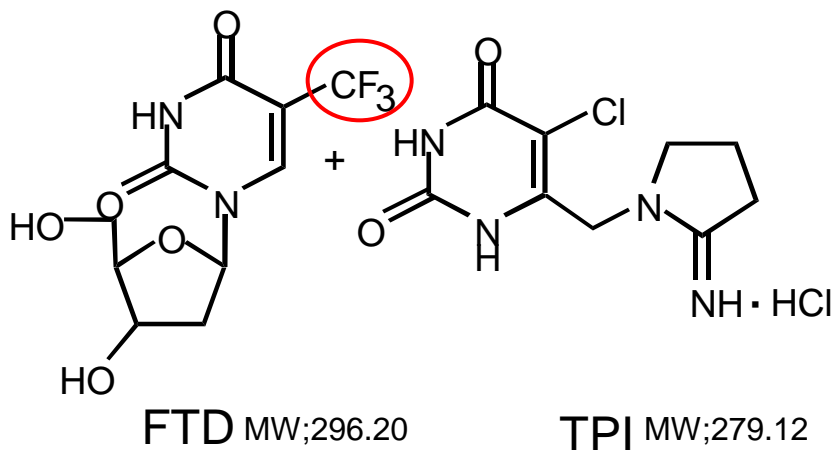
- One project advanced to P-I.

Development code	Country/Area	Indication
TAS-114	JP·US·EU	Solid cancer

## 3-1. TAS-102: Mechanism of action & Features

- Oral nucleoside antitumor agent with a novel mechanism of action.
- Combination drug consisting of FTD and TPI.
- FTD is incorporated into DNA by posing as thymidine, which leads to interfere DNA functions.

FTD:TPI=1:0.5 (molar ratio)



FTD is a thymidine analogue in which hydrogens in the methyl group of base are replaced by fluorines.

**FTD: Trifluorothymidine (Main agent)**  
**TPI: Thymidine Phosphorylase Inhibitor**  
**(Inhibitor of the degradation of FTD)**

## 3-2. A global P-III clinical study for TAS-102 (RECOURSE)

### Study design

Advanced recurrent colorectal cancer that is both unresectable and relapsed/refractory to standard chemotherapies

#### Main institutions

US: Dana-Farber Cancer Institute, Boston, MT

EU: University Hospital Gasthuisberg, Leuven, Belgium

JP: National Cancer Center Hospital East, Kashiwa, Chiba

Primary endpoint: Overall survival (OS)

Secondary endpoint: Progression-free survival (PFS)

Estimated enrollment: 800

Allocation rate (TAS-102 : Placebo=2:1)

Study period: Jun. 2012- Dec. 2014

Randomization



**TAS-102 + BSC\***

35mg/m<sup>2</sup> BID  
Day 1-5, 8-12 q2wks,  
then a 2wk-interval

repeat dosing until the  
discontinuation criteria  
are met

**Placebo + BSC\***

\*BSC: Best supportive care



## 4. Progress of projects

### Advance to P-III & scheduled NDA submissions



#### Two projects advanced to P-III

Advance to P-III - Submitted projects

No.	Areas	Generic name / Development Code	Country/Area	Indication
1	CNS	Aripiprazole IM Depot	US·EU	Bipolar disorder
2	Oncology	TAS-102	JP·US·EU	Colorectal cancer
3	Others	Rebamipide ophthalmic suspension*	US	Dry eye syndrome
4		OPB-2045G	Japan	Anti-infective

\*Rebamipide ophthalmic suspension advanced to P-III in July

#### Two projects proceeded to filing

No.	Areas	Generic Name (Product name)	Country/Area	Indication
1	CNS	Aripiprazole (Abilify)	Japan	MDD (Adjunctive therapy)
2		Levetiracetam (E Keppra®)	Japan	Partial seizures in children
3	Cardiovascular	Tolvaptan (Samsca®)*	JP·Asia	Hepatic edema

J-NDA submitted for ODK-ODK-1003 (WT-1 mRNA assay kit II 'Otsuka')

\*J-NDA filed for Tolvaptan in July