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# Financial Results Presentation

## FY2012

(Fiscal Year Ending March 31, 2013)

May 14, 2013

Otsuka Holdings Co., Ltd.

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- 1 FY2012 Consolidated Financial Results**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**  
【Supplemental】
  - Growing Sales of New Products**
  - Major Expense Items**
- 4 Abilify Sales**
- 5 Nutraceutical Segment Analysis**
- 6 FY2013 Estimate**

# 1. FY2012 Consolidated Financial Results



(100 million yen)

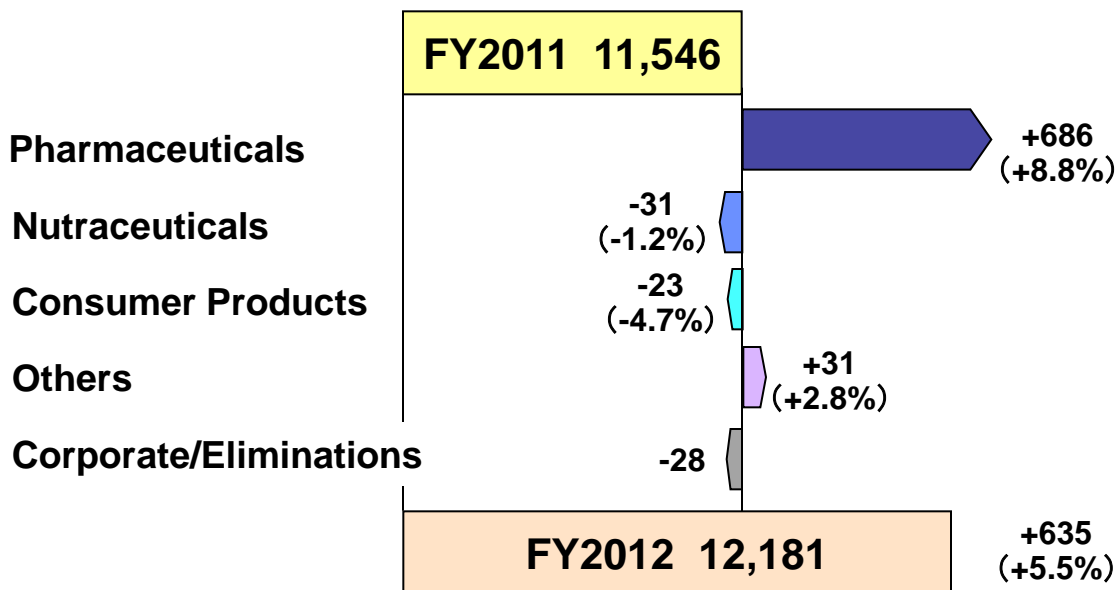
	Compared to the previous year's results				Compared to estimate	
	FY2011 Actual	FY2012 Actual	Change	% Change	2012 Estimate	% Achievement
Net Sales	11,546	12,181	635	5.5%	12,000	101.5%
Operating Income	1,487	1,697	210	14.1%	1,650	102.8%
Ordinary Income	1,521	1,845	323	21.3%	1,700	108.5%
Net Income	922	1,224	303	32.8%	1,080	113.4%
R&D Expenses	1,592	1,924	331	20.8%	1,700	113.2%

Impact of exchange rate fluctuations: approx. -30 on net sales  
 approx. -15 on operating income

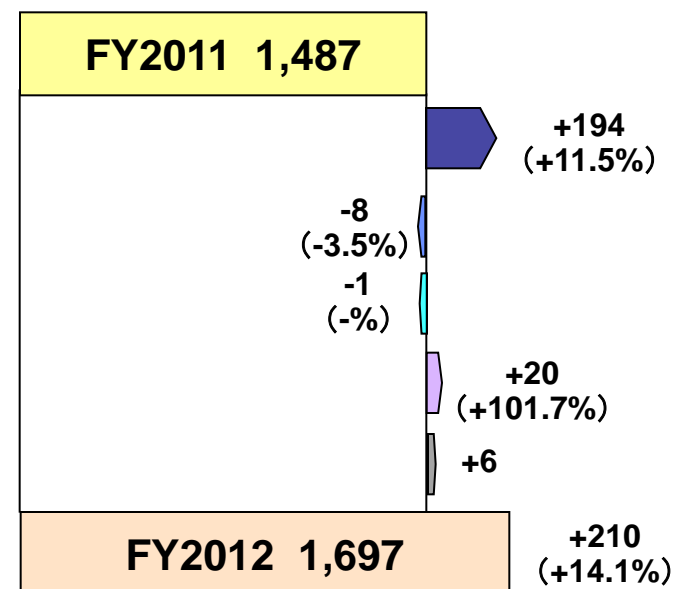
## 2. Business Segment Analysis

(100 million yen)

### Net Sales



### Segment (Operating) Income



\*Parentheses represent % increase

Net Sales	FY2011	FY2012	Change
Pharma	7,822	8,509	686
NC	2,548	2,518	-31
Consumer	492	469	-23
Others	1,086	1,117	31
Corp/Elim	-403	-431	-28
<b>Consolidated</b>	<b>11,546</b>	<b>12,181</b>	<b>635</b>

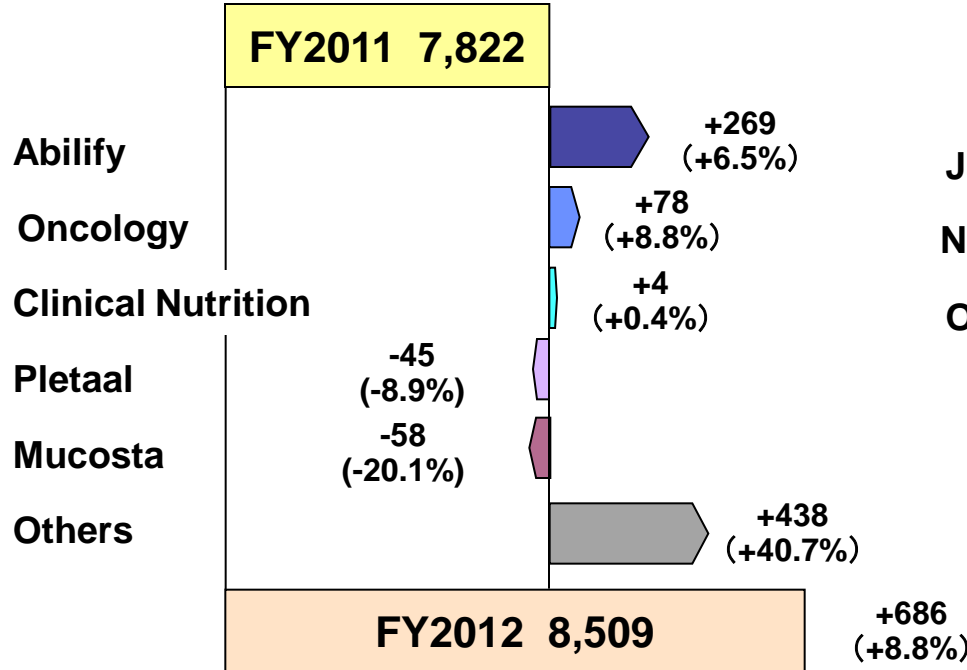
Op income	FY2011	FY2012	Change
Pharma	1,685	1,879	194
NC	221	214	-8
Consumer	-23	-24	-1
Others	19	39	20
Corp/Elim	-416	-410	6
<b>Consolidated</b>	<b>1,487</b>	<b>1,697</b>	<b>210</b>

< Operating margin (%) >

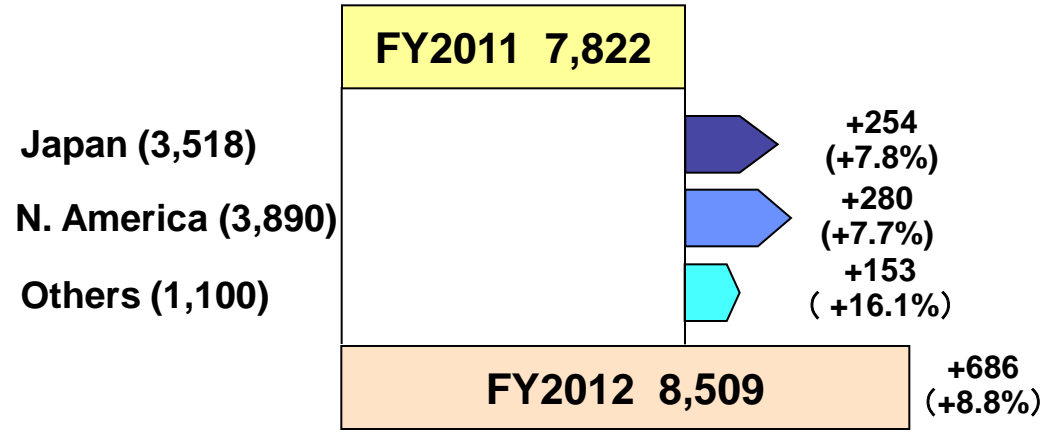
	FY2011	FY2012
Pharma	21.5%	22.1%
NC	8.7%	8.5%
Consumer	-4.7%	-5.2%
Others	1.8%	3.5%
Corp/Elim	-	-
<b>Consolidated</b>	<b>12.9%</b>	<b>13.9%</b>

# 3. Pharmaceutical Segment Analysis

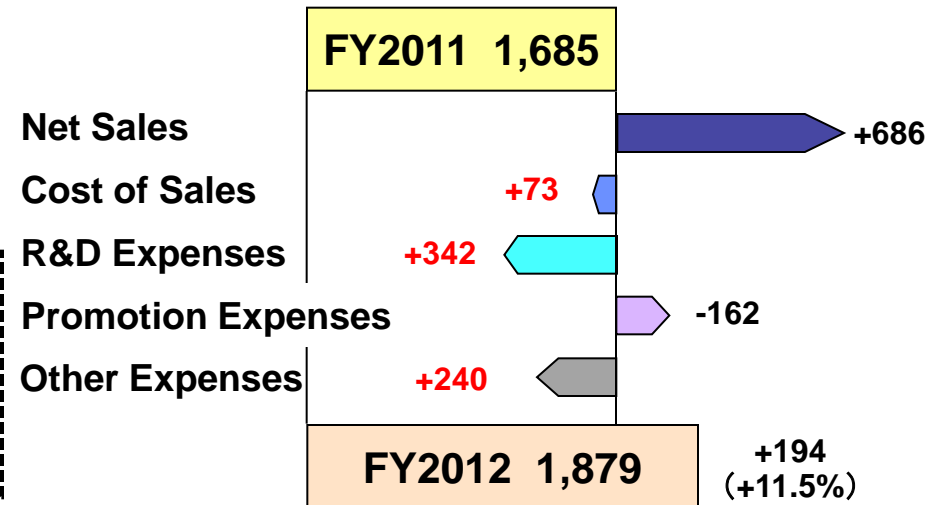
## (100 million yen) Net Sales



## Net Sales by Market



## Segment (Operating) Income



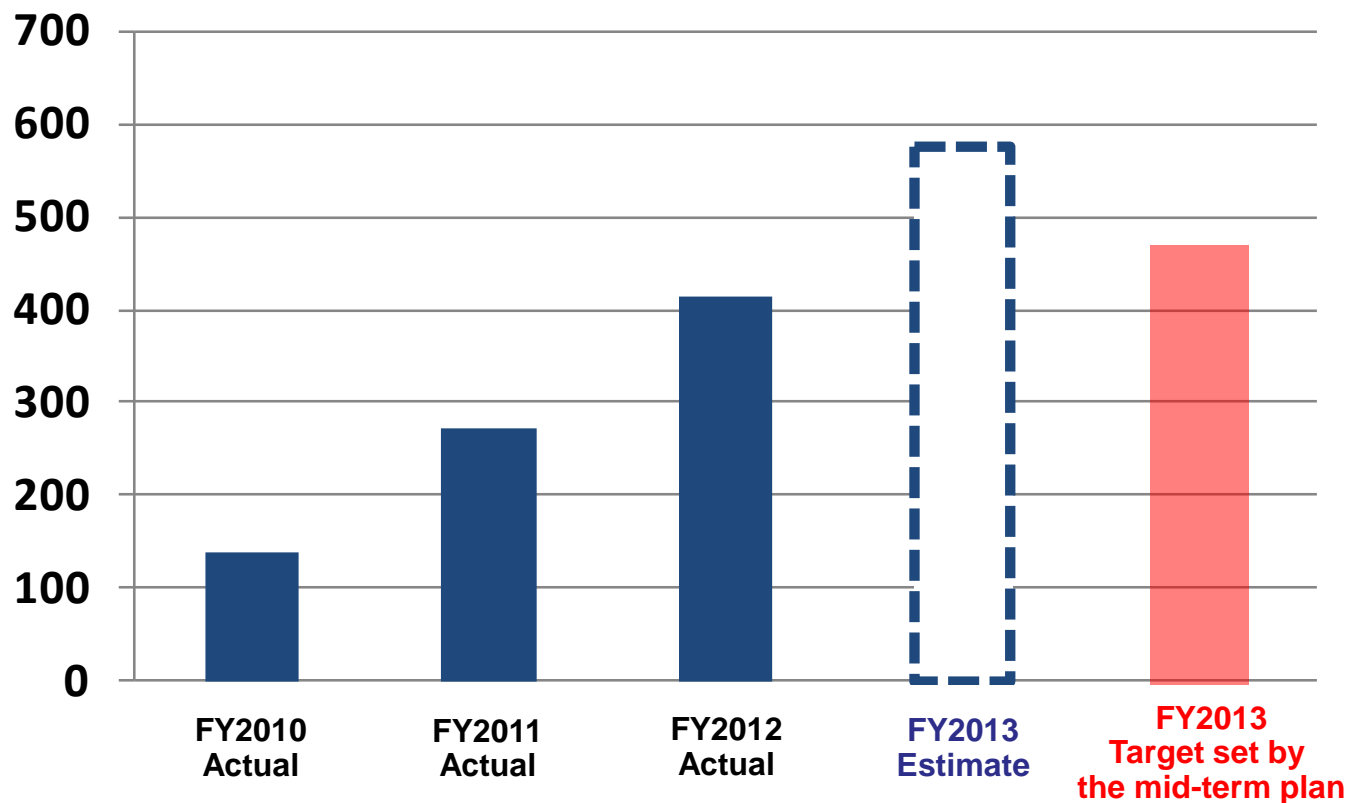
Products	FY2011	FY2012	Change	% Change
Abilify	4,116	4,385	269	6.5%
Oncology	879	957	78	8.8%
Clinical Nutrition	960	964	4	0.4%
Pletaal	503	458	-45	-8.9%
Mucosta	287	230	-58	-20.1%
Others	1,077	1,515	438	40.7%
<b>Pharma Total</b>	<b>7,822</b>	<b>8,509</b>	<b>686</b>	<b>8.8%</b>

**Others + 438**

- Saxagliptin +112 (lump sum payment)
- Samsca +61
- E keppra +57
- Others +208 (including lump sum payments from Lundbeck)

## New Products Launched in the Japanese Market

(100 million yen)

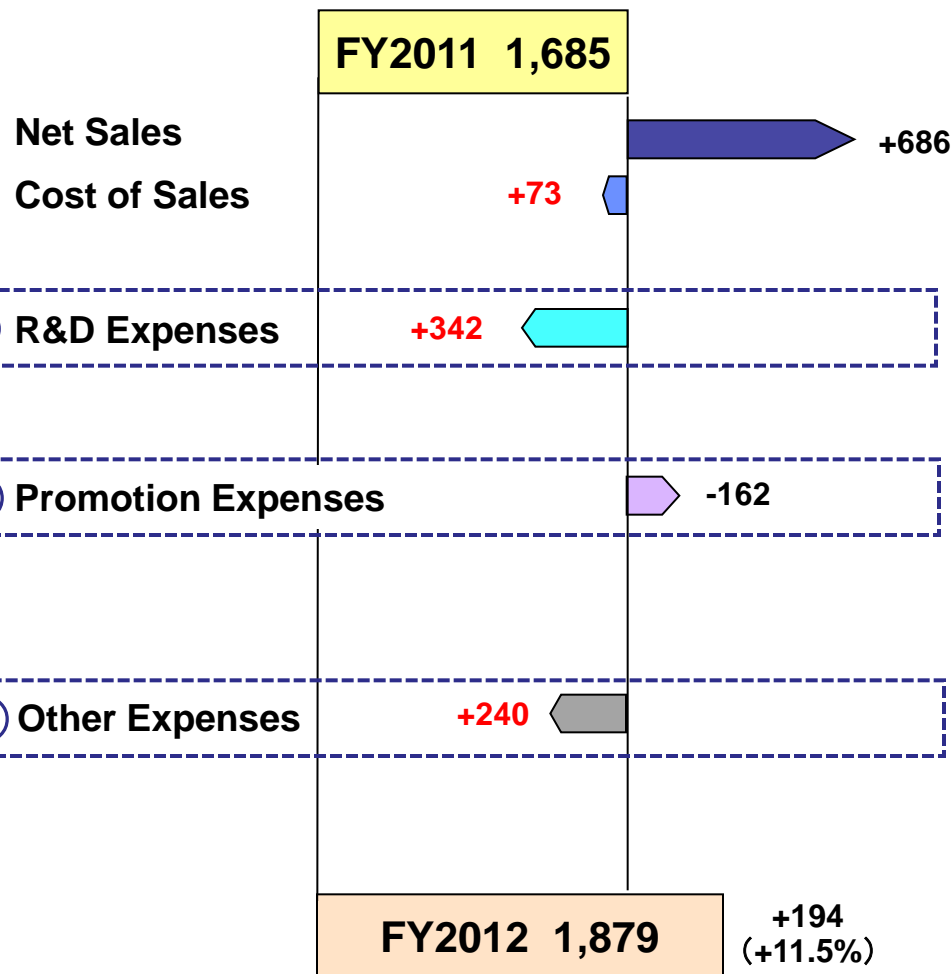


**New Products: E Kepra, Aloxi, Abraxane, SAMSCA, ELNEOPA, Mucosta Ophthalmic Suspension, and Neupro Patch**

# 【Pharmaceutical 2】 Major Expense Items

(100 million yen)

## Segment (Operating) Income



### ① R&D Expenses (+342)

- Progress of clinical trials for Abilify Maintena (IM depot) and OPC34712 and etc.
- An initial payment of JPY14.3 billion to Lundbeck for the co-development of the Alzheimer's drug.

### ② Promotion Expenses (-162)

	For annual net sales of	Otsuka's share of Abilify U.S. net sales*
2012ACT.	\$4.2billion	48.5%
	Up to \$2.7billion	50%
	\$2.7~\$3.2billion	80%
2013/1~	\$3.2~\$3.7billion	93%
2015/4	\$3.7~\$4.0billion	98%
	\$4.0~\$4.2billion	99%
	More than \$4.2billion	80%
2013EST.	Approx. \$4.4billion	Approx.65%

\* Otsuka's share of U.S. net sales after paying co-promotion expenses and etc. to BMS.

### ③ Other Expenses (+240)

- Strengthening of sales structure (labor, operating expense, etc.)
  - (US) Central Nervous System, Cardiovascular System
  - (Europe) Central Nervous System
  - (Japan) Central Nervous System
- Preparation for product launch (labor, research, education expense, etc.)
  - (US) Abilify Maintena



# 4. Abilify Sales

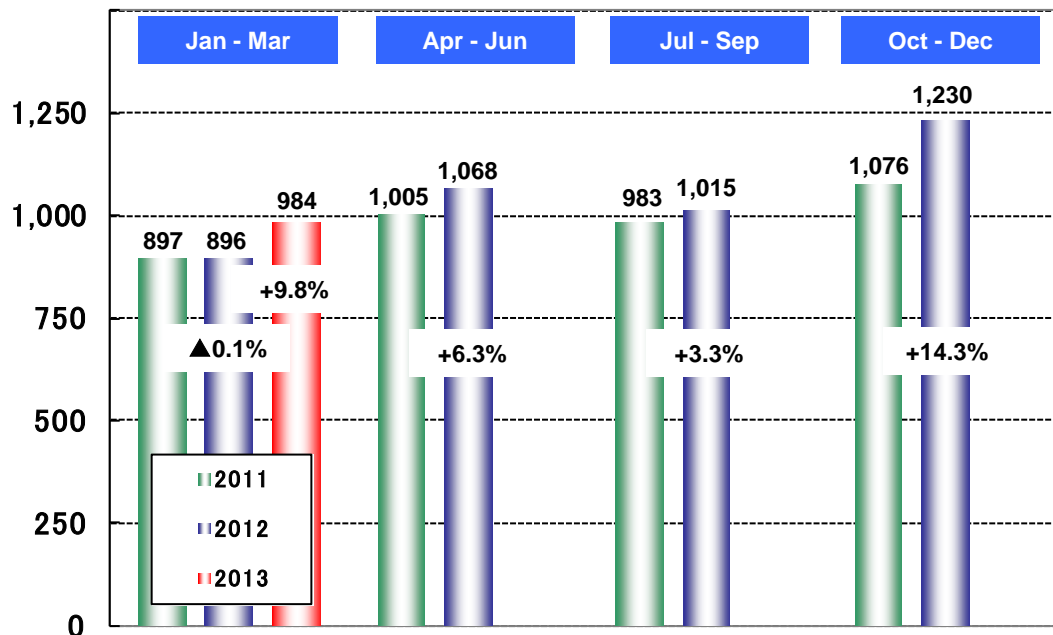
## Abilify Sales by Market

(100 million yen)

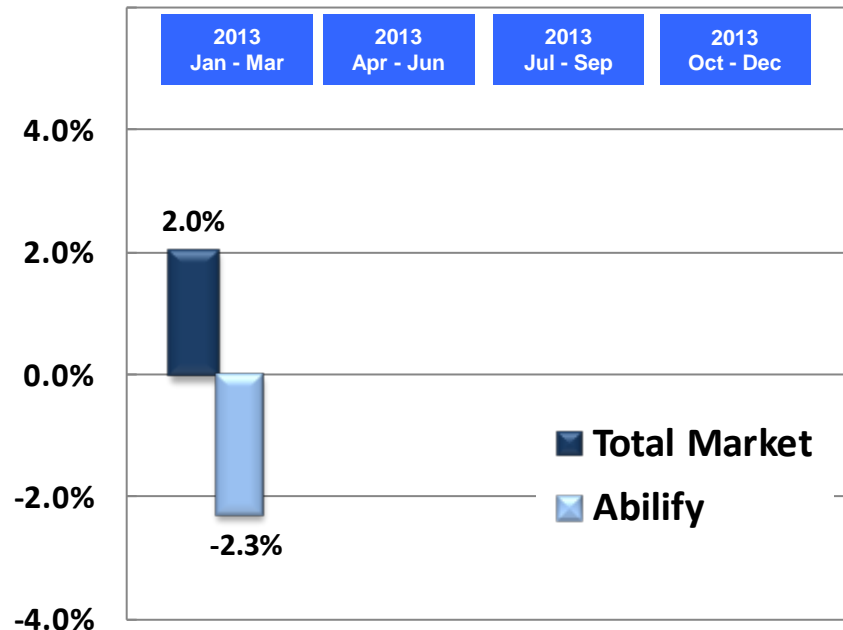
	FY2011	FY2012	Change	% Change
Abilify	4,116	4,385	269	6.5%
US	3,161	3,361	199	6.3%
<Million USD>	<3,960>	<4,208>	<249>	6.3%
Japan	248	286	38	15.5%
Other	707	739	32	4.5%

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

(Million USD)



### Atypical antipsychotic prescription market (US market)

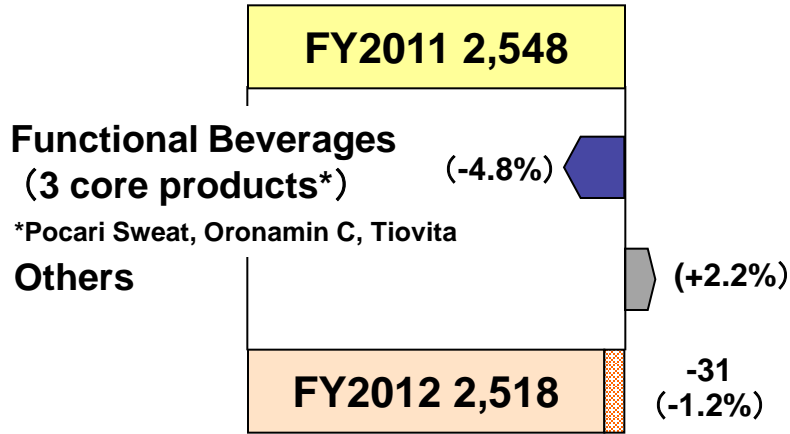


Source: Wolters Kluwer, pharmacy data (March 2013)

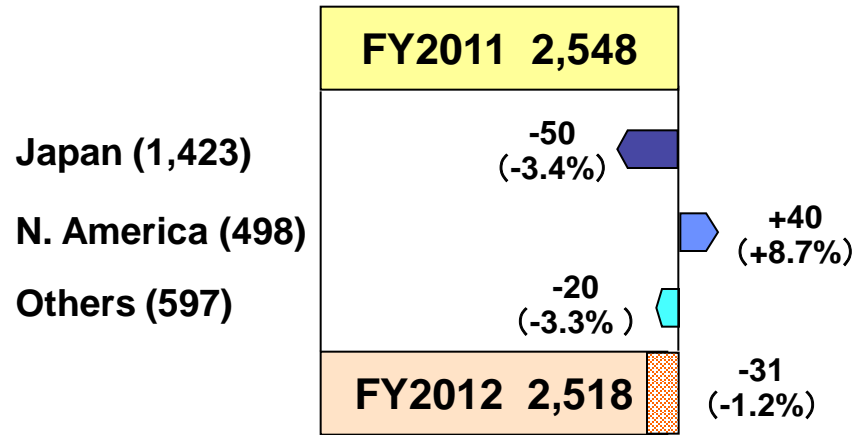
# 5. Nutraceutical Segment Analysis

(100 million yen)

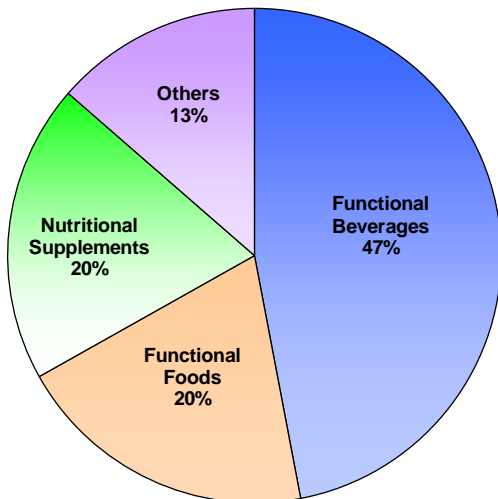
## Net Sales



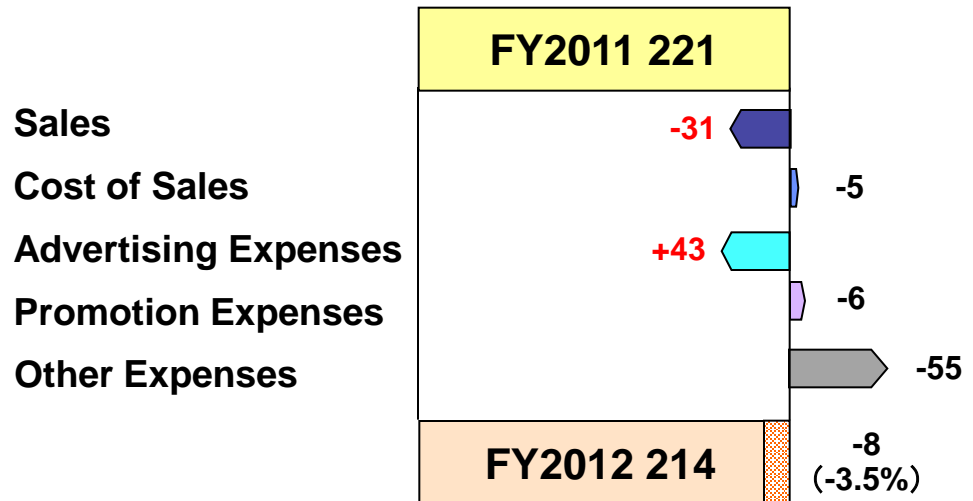
## Net Sales by Market



## Sales by Category



## Segment (Operating) Income



## 6. FY2013 Estimate

(100 million yen)

	FY2012 Actual	FY2013 Estimate	From FY2012 Actual	
			Change	% Change
Net Sales	12,181	13,700	1,519	12.5%
Operating Income	1,697	2,050	353	20.8%
Ordinary Income	1,845	2,100	255	13.8%
Net Income	1,224	1,380	156	12.7%
R&D Expenses	1,924	2,000	76	4.0%
Earnings Per Share (Yen)	221.90	250.79		
Dividends Per Share (Yen)	58.00	65.00		
Budget exchange rate (USD)		90		
Budget exchange rate (EUR)		120		

【 Estimated impact of exchange rate fluctuations (one yen movement for full year)】

	USD	EUR
Net Sales (100 million yen)	approx. 55	approx. 7
Operating Income (100 million yen)	approx. 9	-

# Pharmaceutical Development Update

**May 14, 2013**

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 4Q/FY2012**
  - ✓ Launches
  - ✓ Approvals
  - ✓ NDA filings
  - ✓ Advanced to the next phase
- 3 Key development achievements in FY2012**
- 4 Major P-III projects and NDA submissions scheduled in FY2013 (Initial plan)**

# 1. Major development projects (as of Mar. 31, 2013)



Phase	P-1	P-2	P-3	NDA			
CNS		Brexpirazole ADHD/US	Maintena™ Schiz./JP Maintena™ Bipolar/US ABILIFY® Tourette's/US ABILIFY® Autism/JP E Keppra® Epilepsy (Generalized seizures) /JP E Keppra® Partial seizures/ (injection)/JP E Keppra® Partial seizures/ Monotherapy(Oral) /JP Brexpirazole MDD(Adjunctive) /US,EU Brexpirazole Schiz./JP,US,EU	Maintena™ Schiz./EU ABILIFY® MDD(Adjuvant)/JP E Keppra® Partial seizures in children/JP	* Approved (US)		
	Oncology	TAS-114 Solid cancer /JP,US,EU TAS-115 Solid cancer /JP OPB-31121 Anti-cancer/ JP,Asia OPB-51602 Anti-cancer/ US,JP,Asia OPB-111077 Solid cancer /US OCV-501 AML/JP OCV-C02 Colorectal/JP	TS-1 Renal/JP SPRYCEL® Pancreatic/ US,EU ET-743 STS/JP OTS-102 Biliary/JP OCV-101 Pancreatic/JP	TS-1 Gastric/US TS-1 Uterocervical/ JP,Asia TS-1 HCC/JP TSU-68 HCC/JP,Asia TAS-102 Colorectal/ JP,US,EU SATIVEX® Cancer pain/US	Abraxane® Gastric/JP Abraxane® NSCLC/JP TAS-102 Colorectal/ JP OVF Cancer pain/JP	* Approved * Approved	
			Abraxane® Pancreatic/JP TAS-106 Solid cancer/US				
		Cardiovascular	OPC-108459 AF/JP,US	Samsca® Cancerous edema /JP	Samsca® Cardiac edema /Asia Samsca® ADPKD/JP,EU	Samsca® Hepatic edema/ JP,Asia Samsca® ADPKD/US	
			Others/ Diagnostics	OPA-15406 Atopic dermatitis/ US	Mucosta® Keratoconjunctival epithelial disorder/ JP OPC-6535 COPD/ JP,US,Asia	ZOSYN®(YP-18) Febrile neutropenia / JP Mucosta® Dry eye/ US Mucosta® Dry eye/ JP Delamanid Tuberculosis/ US OPB-2045G Disinfectant/ JP	ODK-0902 H. influenzae/JP ODK-1003 WT-1 mRNA assay kit II /JP Delamanid Tuberculosis /JP,EU Saxagliptin Diabetes/JP
				OPA-6566 Glaucoma/US	ACU-4429 AMD/US		

Blue columns indicate changes from 3Q

## 2-1. Key development progress in 4Q/2012 (as of Mar. 31, 2013)

- Four products launched

Product name	Country-Area	Details
Abilify Maintena™	USA	Approved for the treatment of schizophrenia on Feb. 28. Launched on Mar. 18.
Neupro® Patch	Japan	Japan's first transdermal dopamine agonist patch. For the treatments of Parkinson's disease and restless legs syndrome. Launched on Feb. 26.
L-Cartin® FF oral solution 10% L-Cartin® FF injection 1000mg	Japan	Launched two new drug formulations for carnitine deficiency on Feb. 26.

☆ H. influenzae ELISA kit 'Otsuka' : Launched on Apr. 24.

- Three projects approved

Product name	Country-Area	Indication
Abraxane®	Japan	Gastric cancer
Abraxane®	Japan	Non-small cell lung cancer
Onglyza®	Japan	Type 2 diabetes

## 2-2. Key development progress in 4Q/2012 (as of Mar. 31, 2013)

- Three applications submitted for approval

Generic name / Development code	Country- Area	Indication
TAS-102	Japan	Colorectal cancer
Delamanid	Japan	Multidrug-resistant tuberculosis (MDR-TB)
Tolvaptan	USA	Autosomal dominant polycystic kidney disease (ADPKD)

- One project advanced to P-II/III

Generic name / Development code	Country- Area	Indication
ACU-4429	USA	Age-related macular degeneration (AMD)

- Two projects advanced to P-I

Generic name / Development code	Country- Area	Indication
OCV-C02	Japan	Colorectal cancer
OPA-15406	USA	Atopic dermatitis



## 3-1. Key development achievements in FY2012

- Ten projects approved

No.	Areas	Product name	Country·Area	Indication
1	CNS	Abilify Maintena™	USA	Schizophrenia
2		ABILIFY®	Europe	Moderate to severe manic episodes in bipolar I disorder in adolescents
3		Neupro® Patch	Japan	Parkinson's disease
4		Neupro® Patch	Japan	Restless legs syndrome
5	Oncology	Abraxane®	Japan	Gastric cancer
6		Abraxane®	Japan	Non-small cell lung cancer
7	Others	Onglyza®	Japan	Type 2 diabetes
8		ZOSYN®	Japan	Peritonitis, intra-abdominal abscess, cholecystitis, and cholangitis
9		L-Cartin® FF oral solution 10%	Japan	Carnitine deficiency
10		L-Cartin® FF injection 1000mg	Japan	Carnitine deficiency

## 3-2. Key development achievements in FY2012

### ● Ten projects submitted for approval

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Aripiprazole IM Depot	Europe	Schizophrenia
2		Aripiprazole	Japan	MDD (Adjunctive therapy)
3		Levetiracetam	Japan	Partial seizures in children
4	Oncology	TAS-102	Japan	Colorectal cancer
5		OVF	Japan	Cancer pain
6	Cardiovascular	Tolvaptan	JP·Asia	Hepatic edema
7		Tolvaptan	USA	ADPKD*
8	Others	Saxagliptin	Japan	Type 2 diabetes
9		Delamanid	Japan	MDR-TB*
10		WT1 mRNA Kit	Japan	Diagnostic kit for AML*·MDS*

\*ADPKD: Autosomal dominant polycystic kidney disease MDR-TB: Multidrug-resistant tuberculosis  
 AML: Acute myeloid leukemia MDS: Myelodysplastic syndromes

## 3-3. Key development achievements in FY2012

- Seven projects advanced to P-III

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Aripiprazole IM Depot	USA	Bipolar disorder
2		Aripiprazole	Japan	Autism
3	Oncology	TAS-102	JP·US·EU	Colorectal cancer
4	Cardiovascular	Tolvaptan	Asia	Cardiac edema
5	Others	Rebamipide ophthalmic suspension unit dose	USA	Dry eye syndrome
6		Rebamipide ophthalmic suspension multiple dose	Japan	Dry eye syndrome
7		OPB-2045G	Japan	Disinfectant

- One project advanced to P-II/III

No.	Areas	Development code	Country·Area	Indication
1	Others	ACU-4429	USA	AMD

\*AMD: Age-related macular degeneration 19

## 3-4. Key development achievements in FY2012

- Three projects advanced to P-II

No.	Areas	Generic name / Development code	Country·Area	Indication
1	Oncology	ET-743	Japan	Soft-tissue sarcoma
2	Cardiovascular	Tolvaptan	Japan	Cancerous edema
3	Others	Rebamipide ophthalmic suspension unit dose	Japan	Keratoconjunctival epithelial disorder

- One project advanced to P-I/II

No.	Areas	Development code	Country·Area	Indication
1	Oncology	ABI-007	Japan	Pancreatic cancer

- Four projects advanced to P-I

No.	Areas	Development code	Country·Area	Indication
1	Oncology	TAS-114	JP·US·EU	Solid cancer
2		OPB-111077	USA	Solid cancer
3		OCV-C02	Japan	Colorectal cancer
4	Others	OPA-15406	USA	Atopic dermatitis

## 4. Major P-III projects and NDA submissions scheduled in FY2013 (Initial plan)

- Three projects in CNS and others are scheduled to proceed to phase III

No.	Areas	Generic name	Country·Area	Indication
1	CNS	Aripiprazole IM Depot	Japan	Bipolar disorder
2		Brexpiprazole	USA	New indication
3	Others	Rebamipide ophthalmic suspension unit dose	Japan	Keratoconjunctival epithelial disorder

- Six projects in CNS, oncology, cardiovascular and others are scheduled to proceed to filing stage.

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Aripiprazole	USA	Tourette's syndrome
2		Brexpiprazole	USA	Schizophrenia
3		Brexpiprazole	USA	MDD* (Adjunctive therapy)
4	Oncology	S-1	Japan	Hepatocellular carcinoma (HCC)
5	Cardiovascular	Tolvaptan	JP·EU	ADPKD
6	Others	ODK-1201	Japan	Diagnostic reagent kit for CML*

\*MDD: Major depressive disorder CML: Chronic myeloid leukemia