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# Financial Results Presentation

## Q3 FY2012

(Nine Months Ending December 31, 2012)

February 13, 2013

Otsuka Holdings Co., Ltd.

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- 1 FY2012 Q3 Consolidated Financial Results**
- 2 FY2012 Q3 Business Segment Analysis**
- 3 FY2012 Q3 Pharmaceutical Segment Analysis**  
**【Supplemental】**  
**FY2012 Q3 Other Expenses Analysis**
- 4 FY2012 Q3 Abilify Sales**
- 5 FY2012 Q3 Nutraceutical Segment Analysis**
- 6 FY2012 Estimate**

# 1. FY2012 Q3 Consolidated Financial Results

(100 million yen)

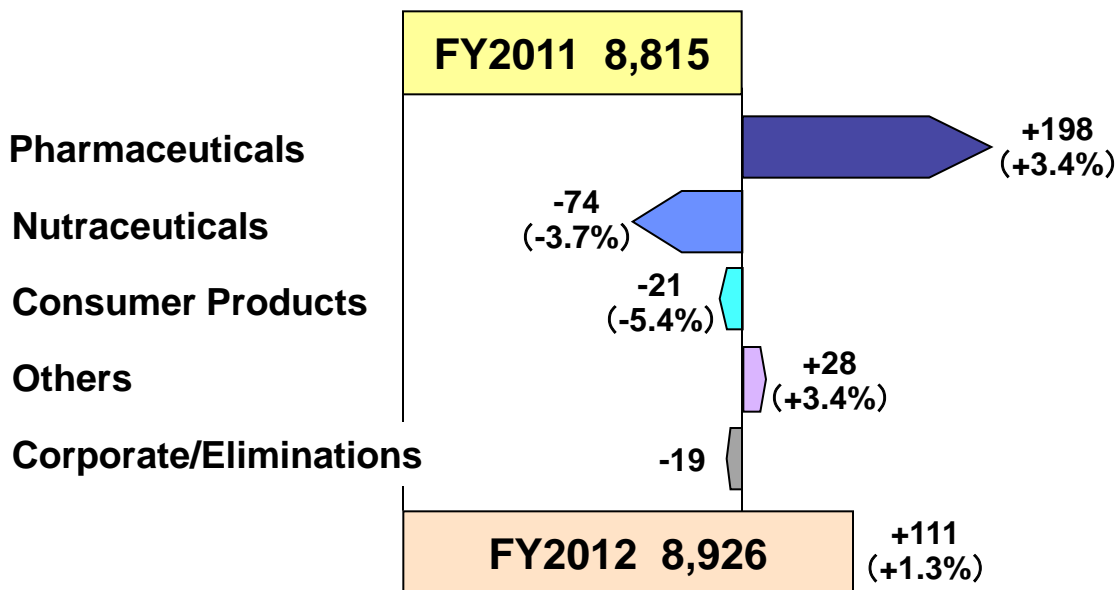
	<b>FY2011 Q3 Actual</b>	<b>FY2012 Q3 Actual</b>	<b>Change</b>	<b>% Change</b>
<b>Net Sales</b>	<b>8,815</b>	<b>8,926</b>	<b>111</b>	<b>1.3%</b>
<b>Operating Income</b>	<b>1,331</b>	<b>1,314</b>	<b>-17</b>	<b>-1.3%</b>
<b>Ordinary Income</b>	<b>1,350</b>	<b>1,408</b>	<b>59</b>	<b>4.4%</b>
<b>Net Income</b>	<b>886</b>	<b>912</b>	<b>26</b>	<b>2.9%</b>
<hr/>				
<b>R&amp;D Expenses</b>	<b>1,150</b>	<b>1,164</b>	<b>14</b>	<b>1.2%</b>

**Impact of exchange rate fluctuations: Net Sales -115, Operating Income -20**

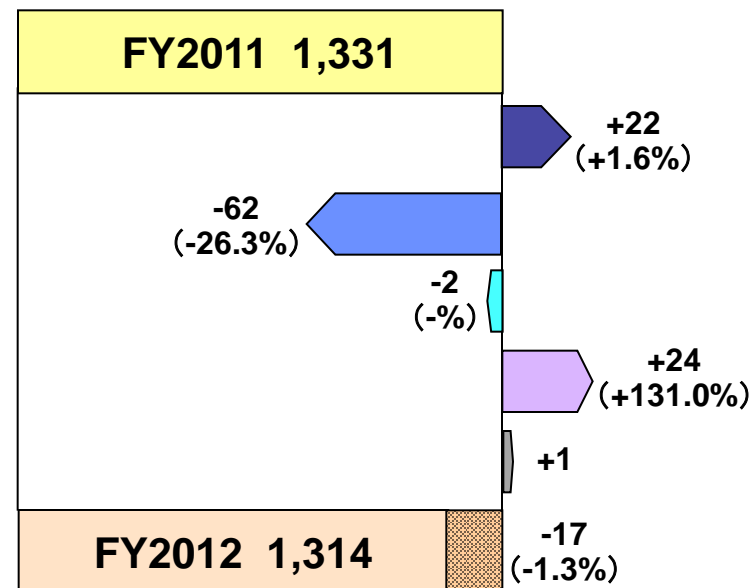
## 2. FY2012 Q3 Business Segment Analysis

(100 million yen)

### Net Sales



### Segment (Operating) Income



\*Parentheses represent % increase

Net Sales	FY2011	FY2012	Change
Pharma	5,869	6,067	198
NC	2,033	1,958	▲ 74
Consumer	400	379	▲ 21
Others	825	854	28
Corp/Elim	▲ 312	▲ 331	▲ 19
<b>Consolidated</b>	<b>8,815</b>	<b>8,926</b>	<b>111</b>

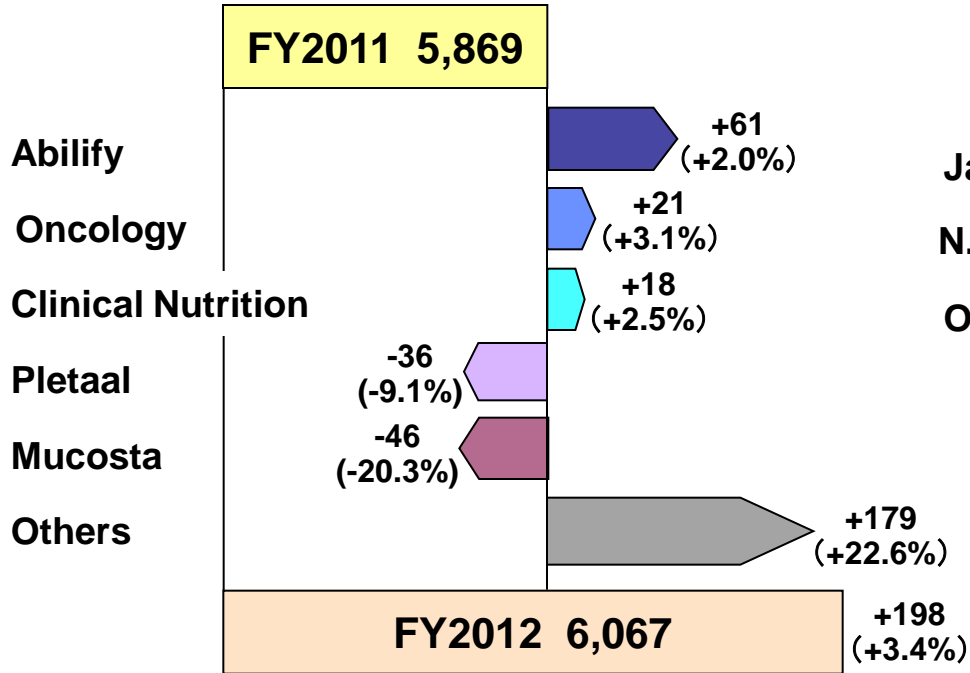
Op income	FY2011	FY2012	Change
Pharma	1,396	1,417	22
NC	234	173	▲ 62
Consumer	▲ 12	▲ 14	▲ 2
Others	18	43	24
Corp/Elim	▲ 305	▲ 304	1
<b>Consolidated</b>	<b>1,331</b>	<b>1,314</b>	<b>▲ 17</b>

< Operating margin (%) >

FY2011	FY2012
23.8%	23.4%
11.5%	8.8%
▲ 3.0%	▲ 3.7%
2.2%	5.0%
-	-
<b>15.1%</b>	<b>14.7%</b>

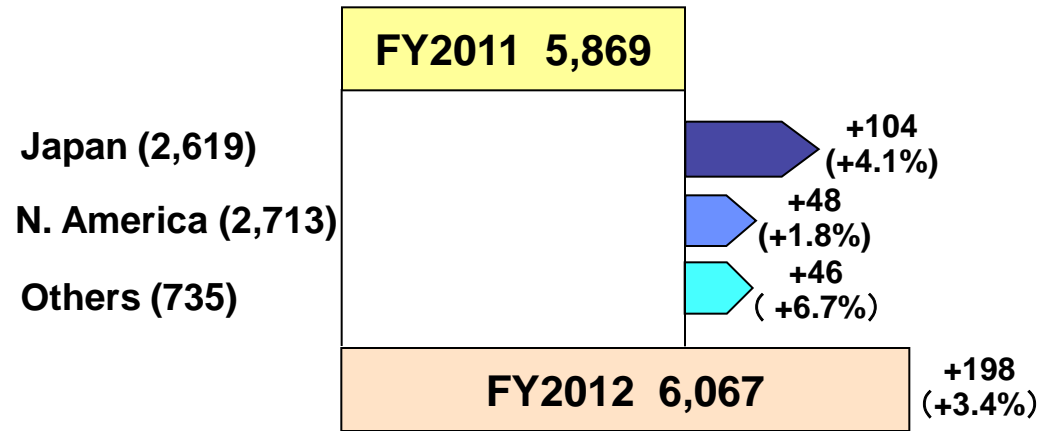
### 3. FY2012 Q3 Pharmaceutical Segment Analysis

(100 million yen) **Net Sales**

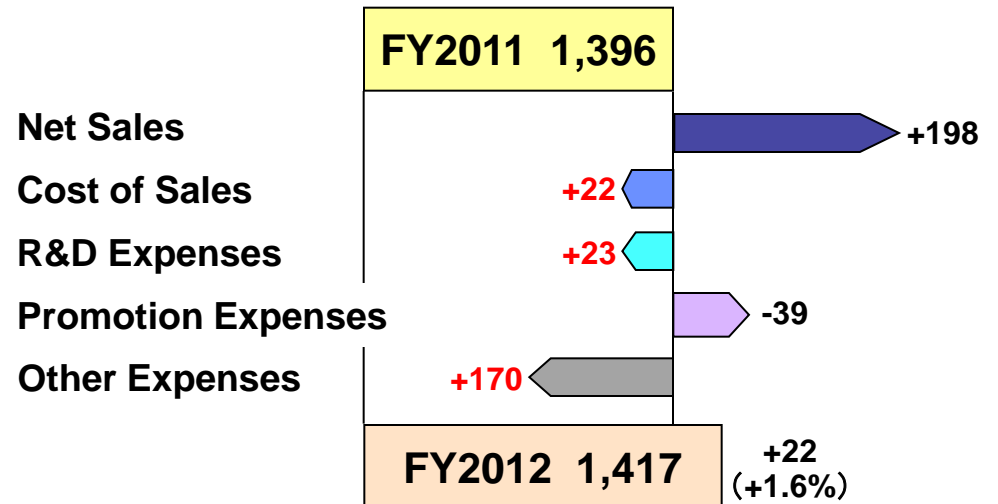


Products	2011 3Q	2012 3Q	Change	% Change
Abilify	3,037	3,098	61	2.0%
Oncology	686	707	21	3.1%
Clinical Nutrition	734	752	18	2.5%
Pletaal	393	357	-36	-9.1%
Mucosta	227	181	-46	-20.3%
Others	791	970	179	22.6%
<b>Pharma Total</b>	<b>5,869</b>	<b>6,067</b>	<b>198</b>	<b>3.4%</b>

**Net Sales by Market**



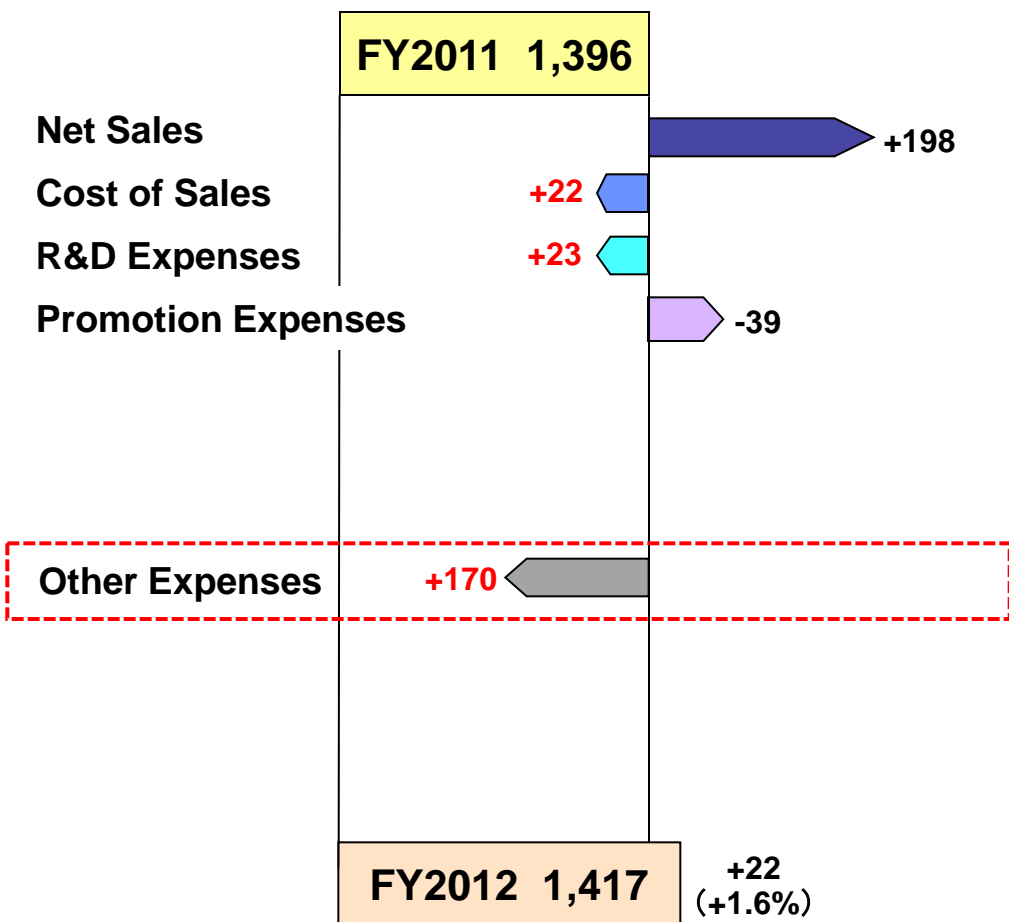
**Segment (Operating) Income**



# 【Supplemental】 Other Expenses Analysis

(100 million yen)

## 【Pharmaceutical Segment】 Segment (Operating) Income



### Factors of Other Expenses (+170)

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

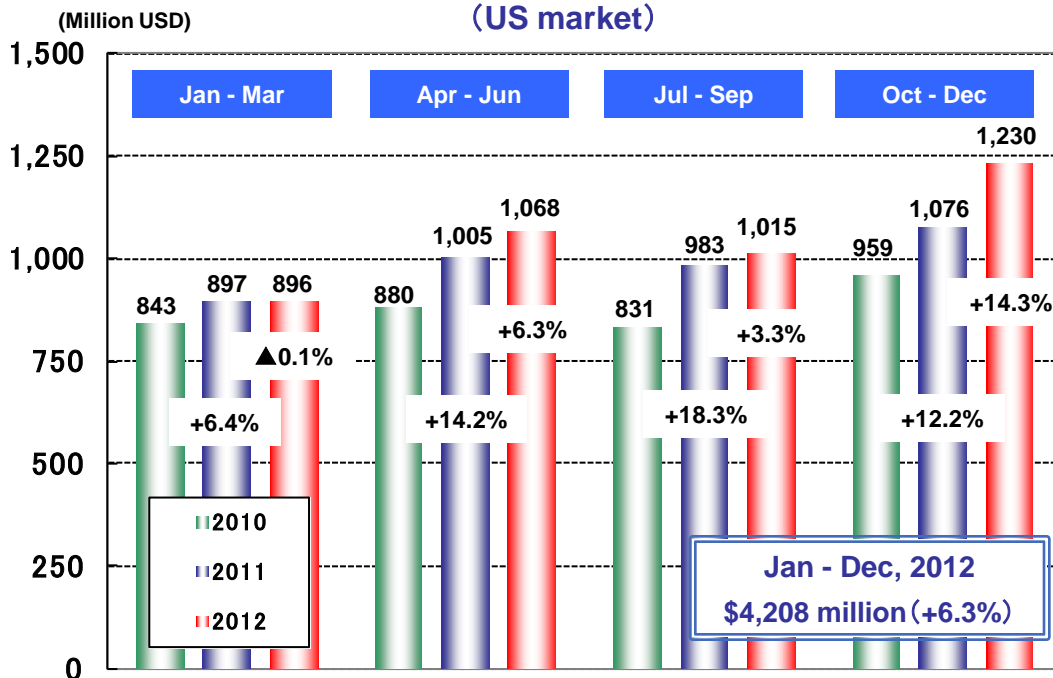
# 4. FY2012 Q3 Abilify Sales

## Abilify Sales by Market

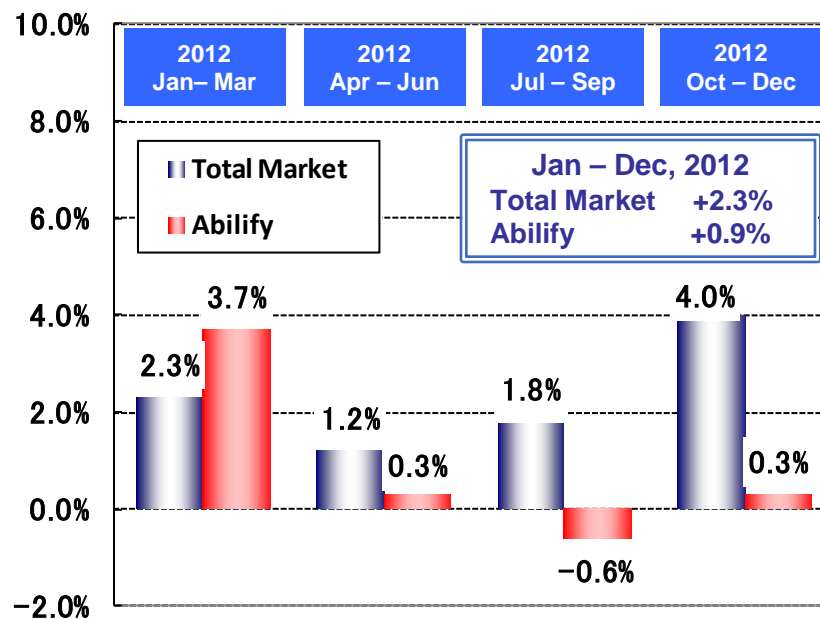
(100 million yen)

	FY2011 Q3	FY2012 Q3	Change	% Change
Abilify	3,037	3,098	61	2.0%
US	2,327	2,366	39	1.7%
<Million USD>	<2,884>	<2,979>	<95>	3.3%
Japan	189	222	33	17.5%
Other	521	510	-12	-2.2%

## Abilify Sales – Quarterly Evolution (US market)



## Atypical antipsychotic prescription market (US market)



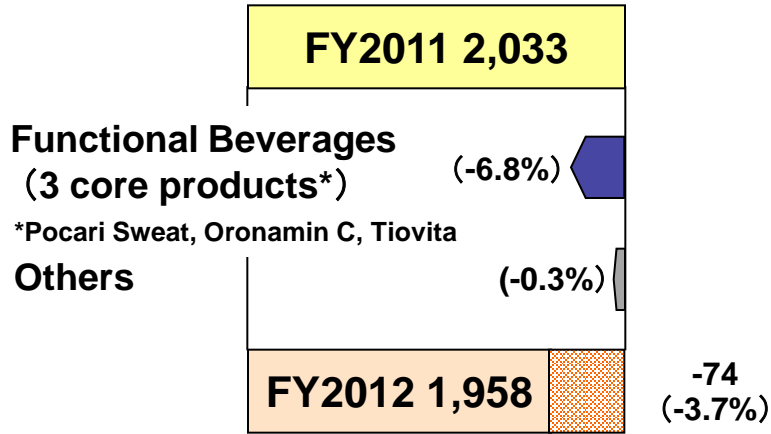
Source: Wolters Kluwer, pharmacy data (December 2012)



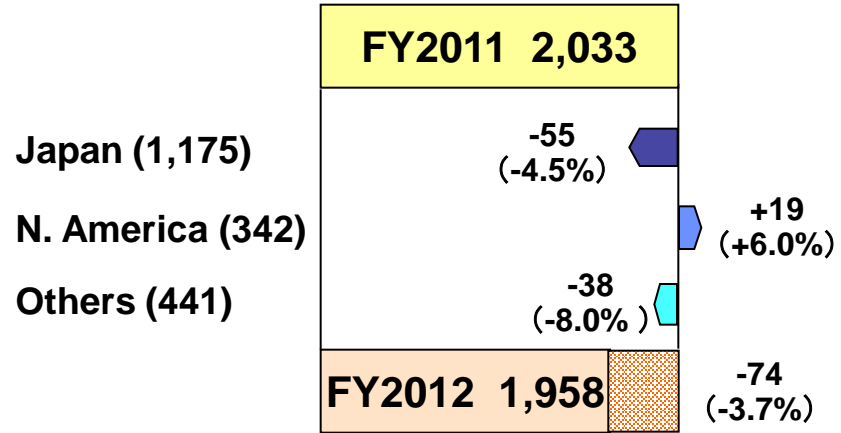
# 5. FY2012 Q3 Nutraceutical Segment Analysis

(100 million yen)

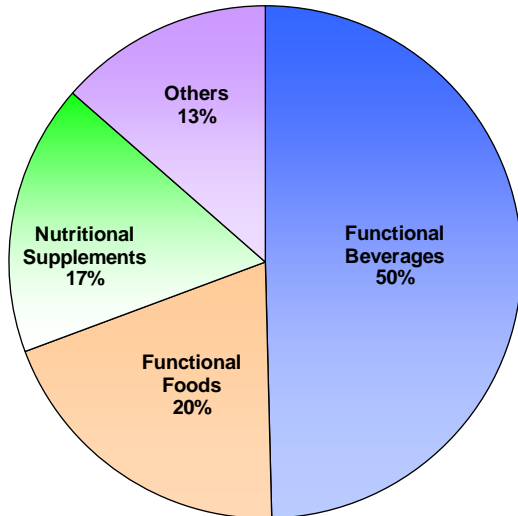
## Net Sales



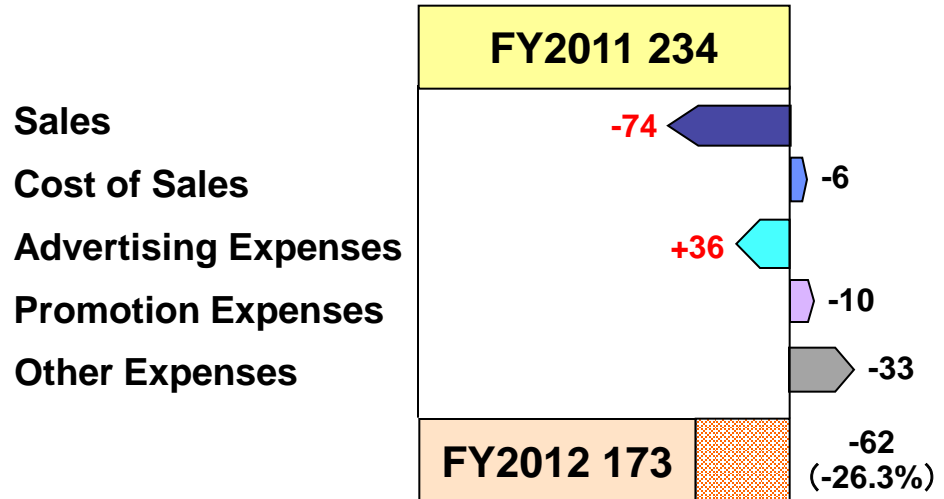
## Net Sales by Market



## Sales by Category



## Segment (Operating) Income



## 6. FY2012 Estimate

(100 million yen)

	FY2011 Q3 Actual	FY2012 Q3 Actual	Change	FY2012 Estimate	% Progress
Net Sales	8,815	8,926	111	12,000	74.4%
Operating Income	1,331	1,314	-17	1,650	79.6%
Ordinary Income	1,350	1,408	59	1,700	82.9%
Net Income	886	912	26	1,080	84.4%
R&D Expenses	1,150	1,164	14	1,700	68.5%

# Pharmaceutical Development Update

**February 13, 2013**

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 3Q/FY2012**
  - ✓ **Launches**
  - ✓ **Approvals**
  - ✓ **NDA filings**
  - ✓ **Advanced to the next phase**
- 3 Topics**
- 4 Progress of projects**  
**Advanced to P-III & scheduled NDA submissions**

# 1. Major development projects (as of Dec. 31, 2012)



Phase	P-1	P-2	P-3	NDA			
CNS		OPC-34712 ADHD/US	IM Depot Schiz./JP IM Depot 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 OPC-34712 MDD(Adjunctive) /US,EU OPC-34712 Schiz./JP,US,EU	IM Depot Schiz./US,EU ABILIFY® MDD(Adjuvant)/JP E Keppra® Partial seizures in children/JP Rotigotine PD/JP Rotigotine RLS/JP	*; Approved *; Approved		
	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	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 OVF Cancer pain/JP		
			Abraxane® Pancreatic/JP TAS-106 Solid cancer/US				
		Cardiovascular	OPC-108459 AF/JP,US	Samsca® Cancerous edema /JP	Samsca® Cardiac edema /Asia Samsca® PKD/JP,US,EU	Samsca® Hepatic edema/JP,Asia	
		Others/ Diagnostics		Mucosta® Keratoconjunctival epithelial disorder/JP OPC-6535 COPD/JP,US,Asia ACU-4429 AMD/US TAC-201 Cedar pollen allergy/JP	ZOSYN®(YP-18) Febrile neutropenia /JP Mucosta® Dry eye/US Mucosta® Dry eye/JP Delamanid Tuberculosis/JP,US OPB-2045G Disinfectant/JP	ODK-0902 H. influenzae/JP ODK-1003 WT-1 mRNA assay kit II/JP Delamanid Tuberculosis /EU Saxagliptin Diabetes/JP	*; Approved
				OPA-6566 Glaucoma/US			

Blue columns indicate changes from 2Q

## 2-1. Key development progress in 3Q/2012 (as of Dec. 31, 2012)

- One product launched

Product name	Country · Area	Details
Aloxi® I.V. infusion bag 0.75mg	Japan	Launched on Dec. 5, 2012 5-HT <sub>3</sub> Receptor Antagonist New formulation

- Four projects approved

Generic name (Product name)	Country · Area	Indication
Rotigotine (Neupro® Patch)	Japan	Parkinson's disease
Rotigotine (Neupro® Patch)	Japan	Restless Legs Syndrome
Levocarnitine (L-Cartin® FF oral solution 10%)	Japan	Carnitine deficiency
Levocarnitine (L-Cartin® FF injection 1000mg)	Japan	Carnitine deficiency

★ABILIFY®: Additional EU approval for the treatment of moderate to severe manic episodes in bipolar I disorder in adolescents in January

## 2-2. Key development progress in 3Q/2012 (as of Dec. 31, 2012)

- One application submitted for approval

Generic name	Country · Area	Indication
Aripiprazole IM Depot	EU	Schizophrenia

- Two projects advanced to P-III

Generic name (Product name)	Country · Area	Indication
Aripiprazole (ABILIFY®)	Japan	Autism
Tolvaptan (Samsca®)	Asia	Cardiac edema

- One project advanced to P-II

Generic name (Product name)	Country · Area	Indication
Tolvaptan (Samsca®)	Japan	Cancerous edema

## 2-3. Key development progress in 3Q/2012 (as of Dec. 31, 2012)

- One project advanced to P-I/II

Development code (Product name)	Country · Area	Indication
ABI-007(Abraxane®)	Japan	Pancreatic cancer

- One project advanced to P-I

Development code	Country · Area	Indication
OPB-111077	USA	Solid cancer



## 3-1. Neupro® Patch:

### Approved for manufacturing and marketing



- **Neupro® Patch (Generic name: rotigotine)**
- **Otsuka Pharmaceutical Co., Ltd. acquired the exclusive rights for development and marketing in Japan from UCB (Former Schwarz Pharma AG) in 2002**
- **Mechanism of action: Dopamine agonist**
- **Indications: Parkinson's disease, Restless Legs Syndrome (RLS)**
- **Approved in over 50 countries for Parkinson's disease, and over 30 countries for Restless Legs Syndrome**
- **Features:**
  - ☆ **The world's first transdermal dopamine agonist patch**
  - ☆ **Once-a-day application provides a stable blood concentration of the drug for 24 hours.**



## 3-2. Parkinson's disease & Restless Legs Syndrome

### Parkinson's disease

- **No. of patients in Japan:**  
Approximately 140,000<sup>1)</sup>
- **Primary symptoms:**  
Resting tremor, rigidity, bradykinesia/  
akinesia, and postural reflex  
impairment
- **Peak ages of onset:**  
In late 50's and 60's<sup>2)</sup>
- **Gender differences in incidence:**  
Almost none<sup>2)</sup>
- **Pathogenesis:**  
Loss of dopamine-producing neurons  
in the substantia nigra (by unknown  
cause)  
Decrease in nigrostriatal dopamine in  
the midbrain

### Restless Legs Syndrome (RLS)

- **No. of patients in Japan:**  
Over 2 million (estimate)
- **Primary symptoms:**  
A uncomfortable leg sensations at  
rest which lead to sleep disruption
- **Peak ages of onset:**  
Aged 40 or over
- **Gender differences in incidence:**  
Higher in women
- **Pathogenesis:**  
No known cause of RLS  
  
Hypotheses are dopamine deficiency  
or impairment of dopamine function.

Cited references

1) Ministry of Health, Labour and Welfare, FY2008 patients survey

2) Web page, Japan Intractable Diseases Information Center

(<http://www.nanbyou.or.jp/>) The last access: Jan. 2013

# 4. Major P-III projects and NDA submissions scheduled in FY2012



## Four projects advanced to P-III

Advanced to P-III as scheduled

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 unit dose	USA	Dry eye syndrome
4		OPB-2045G	Japan	Disinfectant

Other projects not included in the initial plan:

- 1) Rebamipide ophthalmic suspension multiple dose for dry eye syndrome advanced to P-III in Japan
- 2) ABILIFY® for autism advanced to P-III in Japan\*
- 3) Samsca® for cardiac edema advanced to P-III in Asia\*

## Three projects proceeded to filing

NDA filings as scheduled

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

Other projects not included in the initial plan:

- 1) J-NDA submitted for WT-1 mRNA assay kit II 'Otsuka'
- 2) NDA submitted for IM Depot for the treatment of schizophrenia in EU\*

\*updated