
Financial Results Presentation

FY2011

(Fiscal Year Ending March 31, 2012)

May 11, 2012

Otsuka Holdings Co., Ltd.

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1. Restated FY2010 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 “closing exchange rate” to “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 Full-Year Originally reported	FY2010 Full-Year Restated	Effect of changes in accounting policies	(Details)	
				1) Change in method of translation	2) Change in method of presentation
Net Sales	10,902	11,276	374	301	73
Operating income	1,175	1,263	88	15	73
Ordinary income	1,265	1,284	19	19	-
Net income	810	824	14	14	-
R&D expenses	1,645	1,647	2	2	-

	Closing rate	Average rate
USD	81.49	87.79
EURO	107.9	116.27

2. FY2011 Consolidated Financial Results

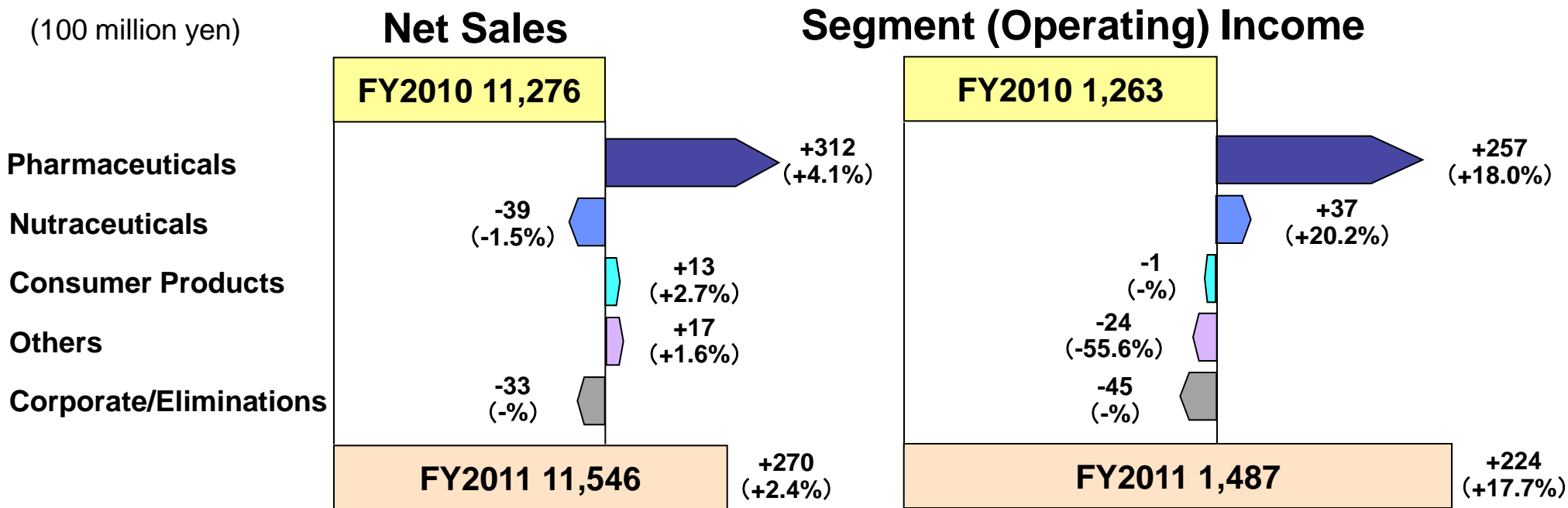
(100 million yen)

	FY2010 Actual	FY2011 Actual	Change	% Change	2011 Estimate	% Achievemnt
Net Sales	11,276	11,546	270	2.4%	11,500	100.4%
Operating Income	1,263	1,487	224	17.7%	1,450	102.5%
Ordinary Income	1,284	1,521	237	18.5%	1,450	104.9%
Net Income	824	922	98	11.9%	940	98.1%
R&D Expenses	1,647	1,592	-54	-3.3%	1,650	96.5%

Impact of exchange rate fluctuations: Net Sales -480, Operating Income -90

3. FY2011 Business Segment Analysis

(100 million yen)



*Parentheses represent % increase

Net Sales	FY2010	FY2011	Change
Pharma	7,511	7,822	312
NC	2,587	2,548	-39
Consumer	479	492	13
Others	1,069	1,086	17
Corp/Elim	-370	-403	-33
Consolidated	11,276	11,546	270

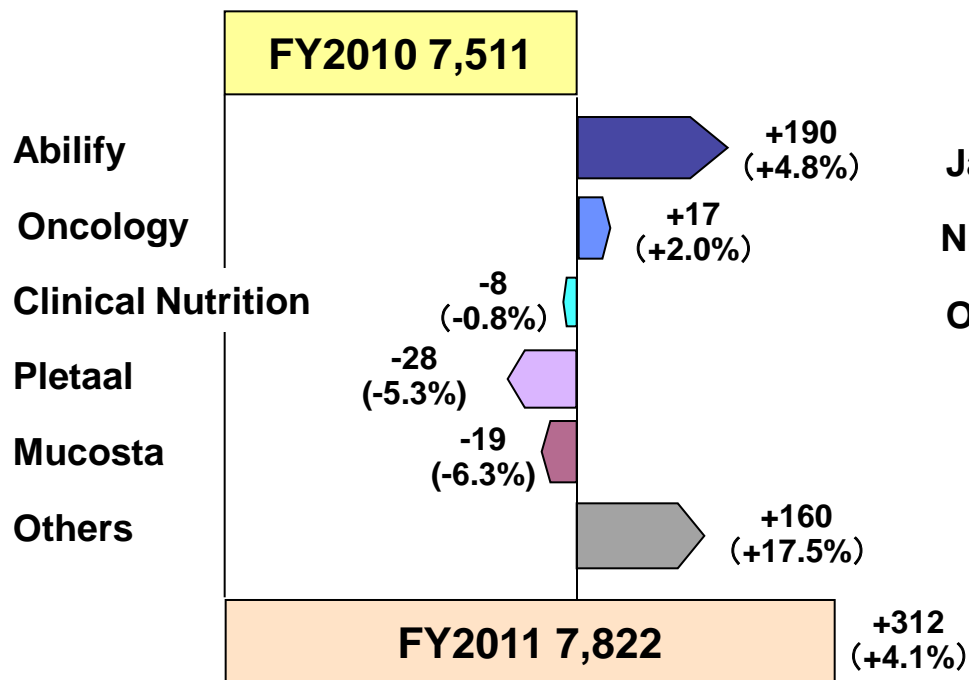
Op income	FY2010	FY2011	Change
Pharma	1,428	1,685	257
NC	184	221	37
Consumer	-22	-23	-1
Others	44	19	-24
Corp/Elim	-371	-416	-45
Consolidated	1,263	1,487	224

< Operating margin (%) >

FY2010	FY2011
19.0%	21.5%
7.1%	8.7%
-4.5%	-4.7%
4.1%	1.8%
-	-
11.2%	12.9%

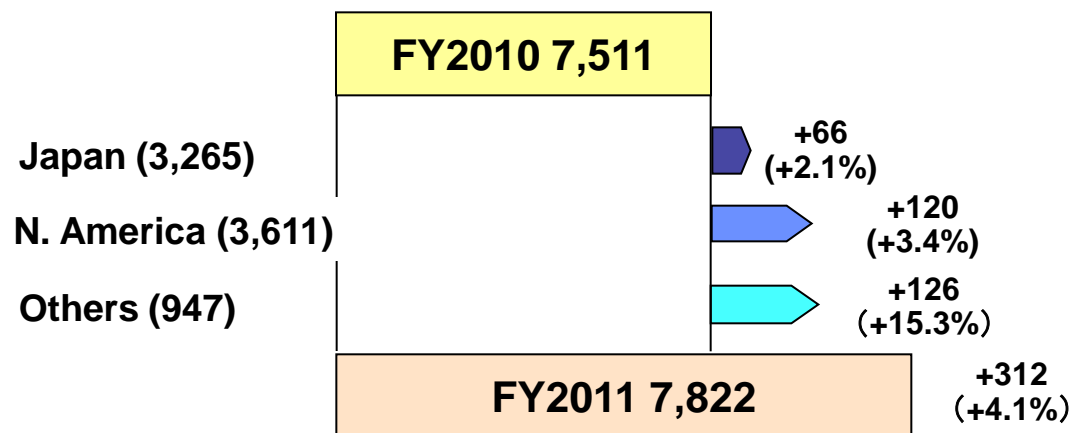
4. FY2011 Pharmaceutical Segment Analysis

(100 million yen) Net Sales

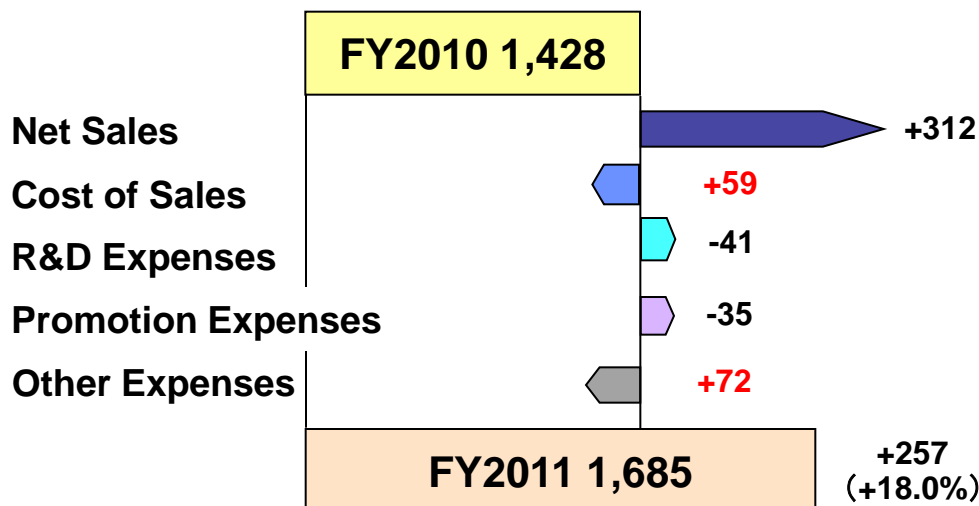


Products	2010 4Q	2011 4Q	Change	% Change
Abilify	3,926	4,116	190	4.8%
Oncology	862	879	17	2.0%
Clinical Nutrition	968	960	-8	-0.8%
Pletaal	532	503	-28	-5.3%
Mucosta	307	287	-19	-6.3%
Others	917	1,077	160	17.5%
Pharma Total	7,511	7,822	312	4.1%

Net Sales by Market



Segment (Operating) Income



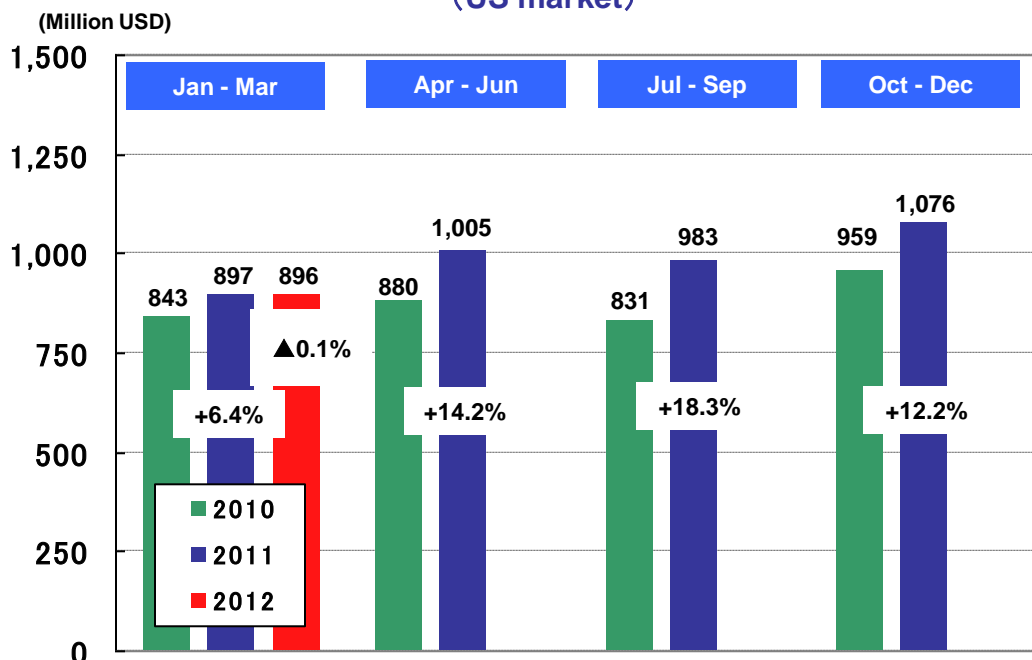
5. FY2011 Abilify Sales

Abilify Sales by Market

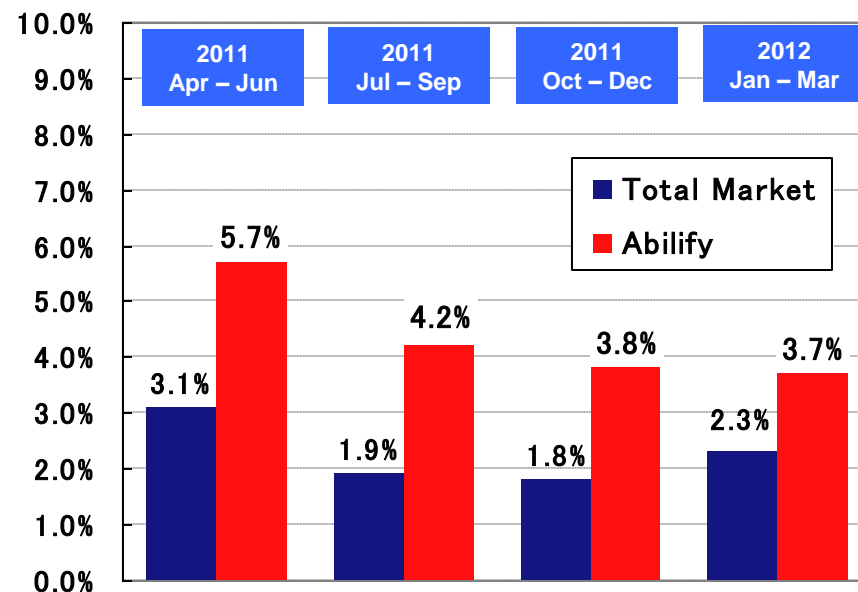
(100 million yen)

	FY2010 Full Year	FY2011 Full year	Change	% Change
Abilify	3,926	4,116	190	4.8%
US	3,083	3,161	78	2.5%
<Million USD>	<3,512>	<3,960>	<447>	12.7%
Japan	230	248	17	7.4%
Other	612	707	94	15.4%

Abilify Sales – Quarterly Evolution (US market)



Atypical antipsychotic prescription market (US market)

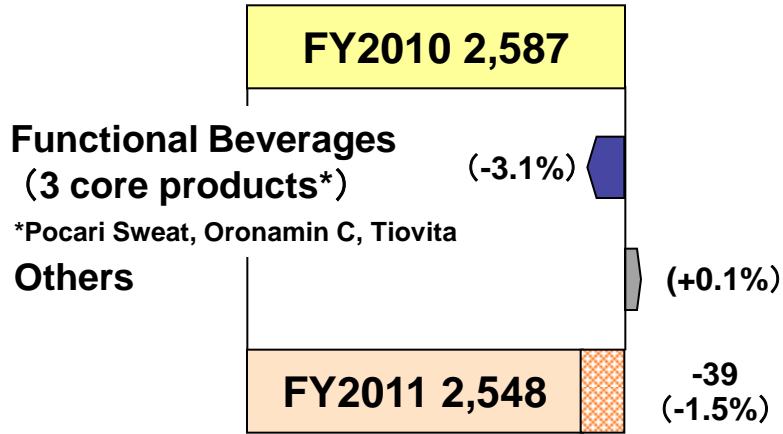


Source: Wolter Kluwer, pharmacy data (March 2012)

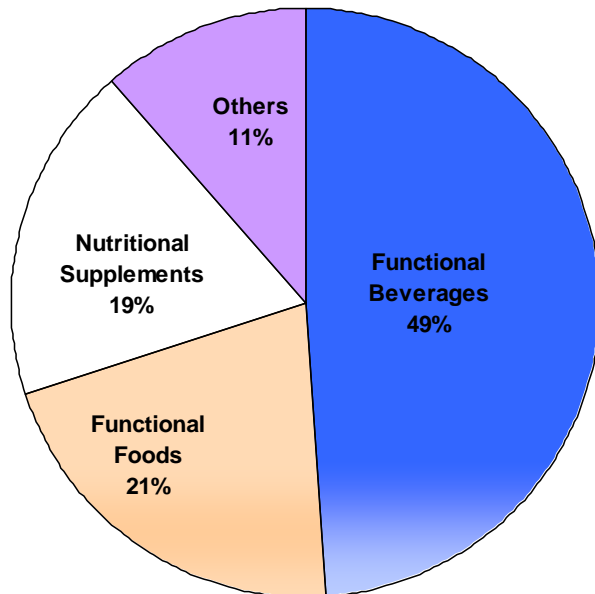
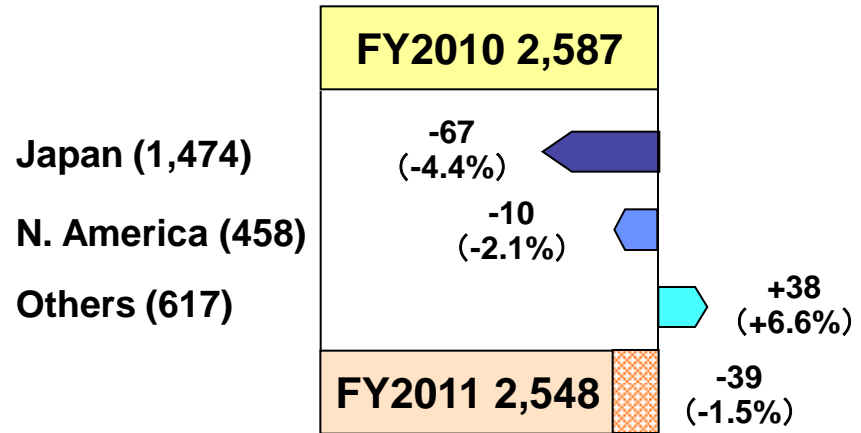
6. FY2011 Nutraceutical Segment Analysis

(100 million yen)

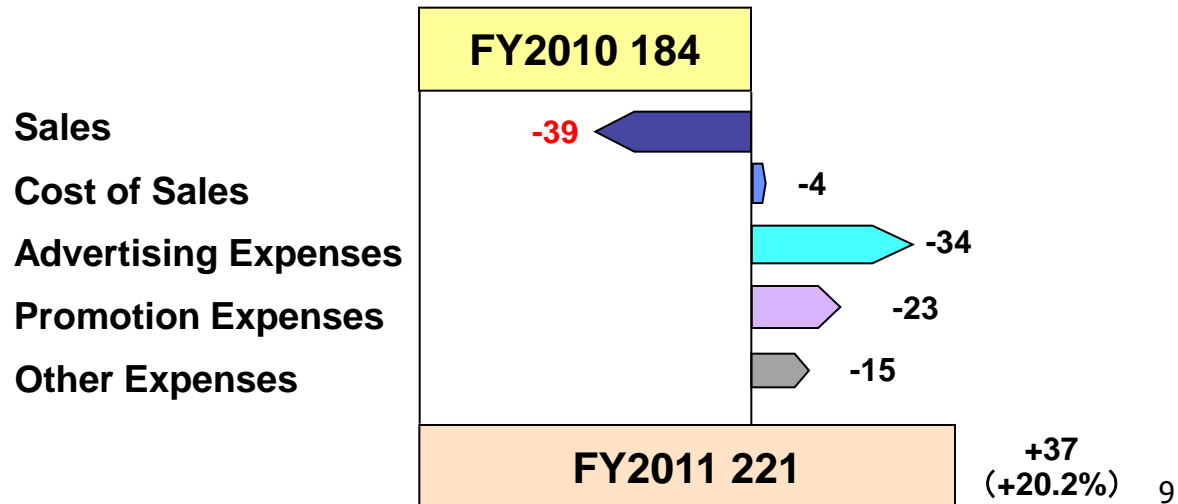
Net Sales



Net Sales by Market

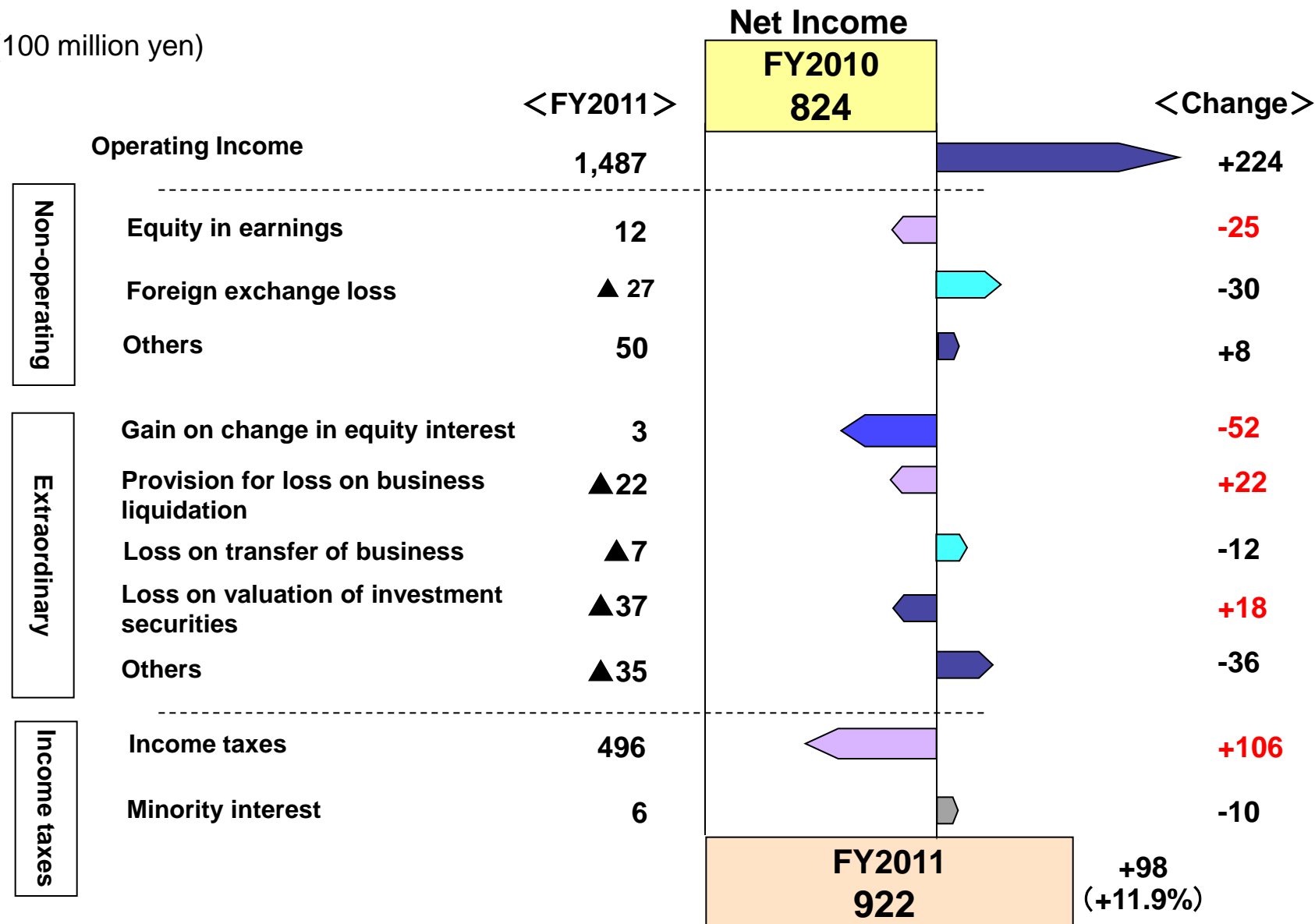


Segment (Operating) Income



7. FY2011 Non-operating and Extraordinary Items

(100 million yen)



8. FY2012 Estimate

(100 million yen)

	FY2011 Actual	FY2012 Estimate	From FY2011 Actual	
			Change	% Change
Net Sales	11,546	12,000	454	3.9%
Operating Income	1,487	1,650	163	11.0%
Ordinary Income	1,521	1,700	179	11.8%
Net Income	922	1,080	158	17.2%
R&D Expenses	1,592	1,700	108	6.8%
Earnings Per Share (Yen)	165.20	193.60		
Dividends Per Share (Yen)	45.00	58.00		
Budget exchange rate (USD)		75		
Budget exchange rate (EUR)		102		

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

	USD	EUR
Net Sales (100 million yen)	52	8
Operating Income (100 million yen)	8	1

Pharmaceutical Development Update

May 11, 2012

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 4Q/FY2011**
 - Key development progress in 4Q/2011
 - Current status of major projects scheduled to start P-III in FY2011
 - Overview of scheduled NDA submissions in FY2011
- 3 Topics**
- 4 Major P-III projects and NDA submissions scheduled in FY2012**

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



Phase	P-1	P-2	P-3	NDA
CNS		OPC-34712 ADHD/US	IM Depot Schiz./EU,JP ABILIFY® MDD(Maintenance)/JP ABILIFY® Tourette's/US E KEPPRA® Epilepsy (Partial seizures in children/ Generalized seizures)/JP E KEPPRA® Partial seizures/ (injection)/JP E KEPPRA® Partial seizures/ Monotherapy(Oral)/JP OPC-34712 MDD(Maintenance)/US,EU OPC-34712 Schiz./JP,US,EU	ABILIFY® Bipolar/JP *Approved IM Depot Schiz./US Rotigotine PD/RLS·JP
Oncology	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 TAS-115 Solid cancer/JP OCV-501 AML/JP TAS-102 Colorectal/US	TS-1 Renal/JP 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 OVF Cancer pain/JP TSU-68 HCC/JP,Asia SATIVEX® Cancer pain/US	ABRAXANE® Gastric/JP ABRAXANE® NSCLC/JP
		TAS-106 Solid cancer/US		
Cardiovascular	OPC-108459 AF/JP,US		SAMSCA® Hepatic edema/JP,Asia SAMSCA® PKD/JP,US,EU	
Others/ Diagnostics		Mucosta® ophthalmic suspension Dry eye/US ACU-4429 AMD/US TAC-201 Cedar pollen allergy/JP OPC-6535 COPD/JP,US,Asia	Saxagliptin Diabetes/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 *Approved
		OPA-6566 Glaucoma/US OPB-2045G Anti-infective/JP	OPC-6535 Crohn's/JP,Asia	

Blue column indicates the changes in 4Q

2-1. Key development progress in 4Q/2011 (as of Mar. 31, 2012)

- **Two products launched.**

Product name	Country/Area	Details
Mucosta [®] ophthalmic suspension UD2%	Japan	Launch: January. 5, 2012. Drug which promotes mucin secretion to treat dry eye syndrome
Teysuno [®] (TS-1)	Northern Europe	Launched in Sweden, Denmark, Norway and Finland.

☆ Teysuno[®] has been marketed in the U.K. since April, 2012.

- **Two products approved.**

Product name	Country/Area	Details
TS-ONE [®] (TS-1)	Thailand	Received marketing authorization in Thailand.
Abilify [®]	Japan	Approvals for additional indication "improvement of manic symptoms associated with bipolar disorder" and for New Dosage Form "ABILIFY [®] OD Tablets".

☆ TS-ONE[®] (TS-1) was approved for marketing in Hong Kong in April, 2012.

2-2. Key development progress in 4Q/2011 (as of March 31, 2012)

- Applications submitted for approval of additional indications in Japan

Generic name (Product name)	Country/Area	Indication
Nanoparticle Albumin-bound Paclitaxel - injectable suspension (ABRAXANE®)	Japan	Gastric cancer
	Japan	Non-small cell lung cancer (NSCLC)

☆ In April, 2012, saxagliptin NDA was submitted for the treatment of type II diabetes mellitus in Japan.

- Two project advanced to P-I

Development code	Country/Area	Indication
TAS-102	US	Colorectal cancer
OPC-108459	US	Atrial fibrillation (AF)

2-3. Current status of major P-III projects scheduled to start in FY2011

Four development projects, mainly in CNS, were scheduled to proceed to phase III in FY2011. (Initial plan for FY2011)

⇒ Six projects advanced to Phase III

Advancement to P-III

No.	Areas	Generic name / Development code	Country/ Area	Indication
1	CNS	OPC-34712	US·EU	Major depressive disorder (Adjunctive therapy)
2		OPC-34712	JP·US·EU	Schizophrenia
3		Aripiprazole (Novel Oral Formulation)	US	Tourette's syndrome
4	Others	THN-01	Japan	Tissue adhesion prophylaxis

☆E KEPPRA® (Injection) for partial seizures was advanced to P-III in Japan.

Clinical phase III study for E KEPPRA® (oral agent) monotherapy in patients with partial seizures started in Japan.

Delamanid for MDR tuberculosis* was advanced to P-III in Japan, USA., and Europe.

* MDR tuberculosis: Multidrug-resistant tuberculosis

2-4. Overview of scheduled NDA submissions in FY2011

Ten development projects, mainly in CNS, were scheduled to proceed to filing stage in FY2011. (Initial plan for FY2011)

⇒ Ten projects have completed NDA submissions.

Submitted projects

No.	Areas	Generic name/ Development code	Country/ Area	Indication
1	CNS	Aripiprazole IM Depot	US	Schizophrenia
2		Aripiprazole	Korea	Tics · Tourette's syndrome
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

**NDA submissions: Delamanid for the treatment of MDR tuberculosis in Europe
L-Cartin® injection and oral solution in Japan**

* Otsuka and UCB have agreed to end the co-development and co-promotion agreement for certolizumab pegol in Japan. (News release on Jan. 13)

**Clinical trial results of Aripiprazole Intramuscular Depot
for Long-Term Maintenance Treatment in Schizophrenia**

The 165th Annual Meeting of the American Psychiatric Association

May 5- 9, 2012

in Philadelphia

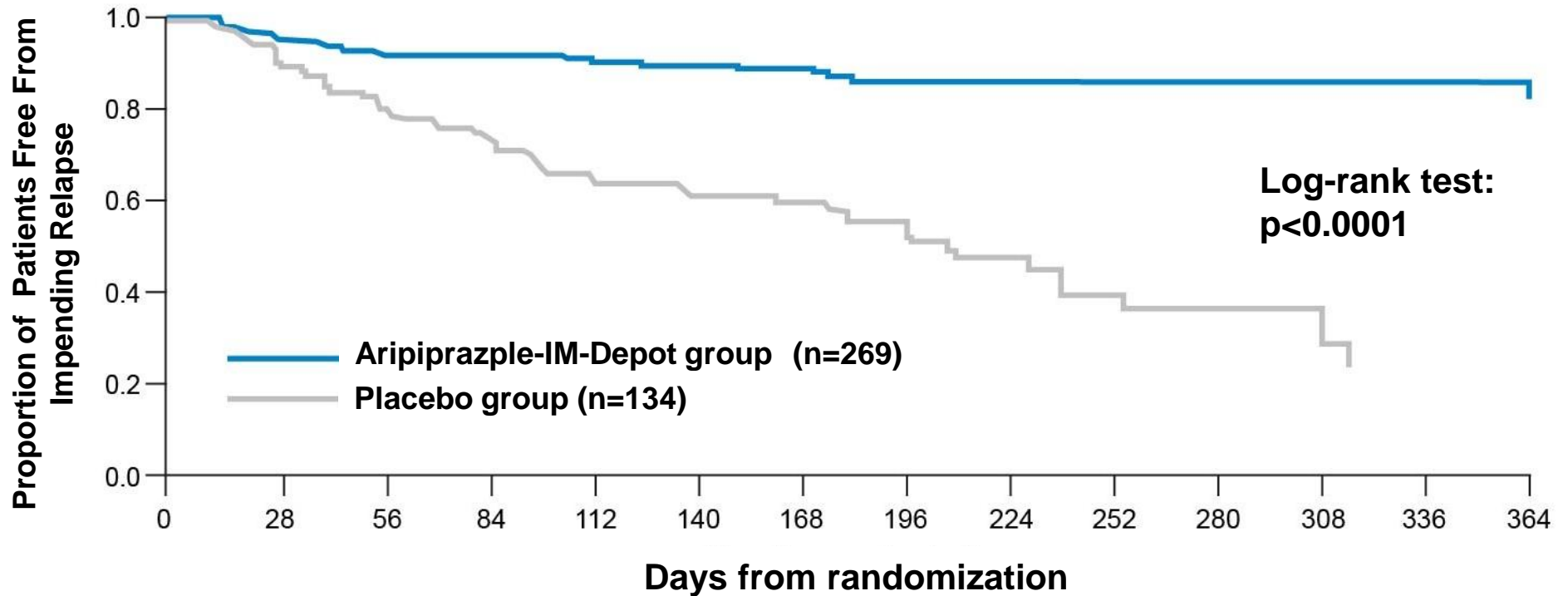
3-2. Study design

Screening	<u>Phase I</u> Conversion	<u>Phase II</u> Oral Stabilization	<u>Phase III</u> IM Depot Stabilization	<u>Phase IV</u> Double-blind Placebo controlled Maintenance
Up to 42 days	Convert from other antipsychotics to Abilify (if needed)	Meet stability criteria on two consecutive 2-week time points	Meet stability criteria for 12 consecutive weeks (6 visits) Single-blind IM Depot 400 mg starting dose (One-time decrease to 300 mg allowed for tolerability with return to 400 mg, if needed)	IM Depot 400 or 300 mg based on final dose of Phase III (Single modification to alternate dose and return to original dose allowed, if needed)
1 or more visits as needed	Weekly visits	Bi-weekly visits	Weekly visits x 4 wks then bi-weekly visits	Bi-weekly visits with weekly calls
Days -42 to -2	4 - 6 Weeks	4 - 12 Weeks	12 - 36 Weeks	52 Weeks

R = Randomization

- Study powered to 125 events
- Interim analyses pre-specified at 63 (50%) and 94 (75%) events
- Primary endpoint: Time to impending relapse

3-3. Time from randomization to impending relapse during double-blind phase



Hazard ratio= 5.03, 95% CI: 3.15-8.02

3-4. Treatment-emergent Adverse Events in Phase IV

AE, n (%)	Aripiprazole-IM-depot maintenance (n=269)	Placebo-IM-depot (n=134)
Insomnia	27 (10.0)	12 (9.0)
Weight gain	26 (9.7)	13 (9.7)
Headache	16 (5.9)	7 (5.2)
Tremor*1	16 (5.9)	2 (1.5)
Anxiety	16 (5.9)	10 (7.5)
Akathisia*2	15 (5.6)	8 (6.0)
Injection-site pain	8 (3.0)	5 (3.7)

*1 Tremor: an involuntary trembling of the body or limbs; it may have either a physical or a psychological cause.

Reference: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. © 2003 by Saunders, an imprint of Elsevier, Inc. All rights reserved.

*2 Akathisia: Agitated or restless movement, usually affecting the legs and accompanied by a sense of discomfort.

It is a common side effect of neuroleptic medications.

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

Four development projects, in CNS, oncology, and others, are scheduled to proceed to phase III in FY2012.

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 [®] eye drops	US	Dry eye syndrome
4		OPB-2045G	Japan	Anti-infective

Three development projects, mainly in CNS, are scheduled to proceed to filing stage. (Initial plan for FY2012)

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 [®])	Asia (Including Japan)	Hepatic edema