
Financial Results Presentation

FY2014 Q2

(Six Months Ending September 30, 2014)

November 13, 2014

Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results (FY2014 Q2)
- 2 Business Segment Analysis
- 3 Pharmaceuticals Segment Analysis
- 4 Abilify Sales
- 5 Nutraceuticals Segment Analysis
- 6 FY2014 Estimate

1. Consolidated Financial Results (FY2014 Q2)



(100 million yen)

	FY2013 Q2 Actual	FY2014 Q2 Actual	Change	% Change
Net Sales	7,323	7,883	+560	+7.6%
Operating Income	1,132	1,367	+235	+20.7%
Ordinary Income	1,244	1,481	+237	+19.1%
Net Income	885	995	+110	+12.4%

R&D Expenses	1,030	1,027	▲ 3	▲0.2%
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Foreign Exchange Impact :

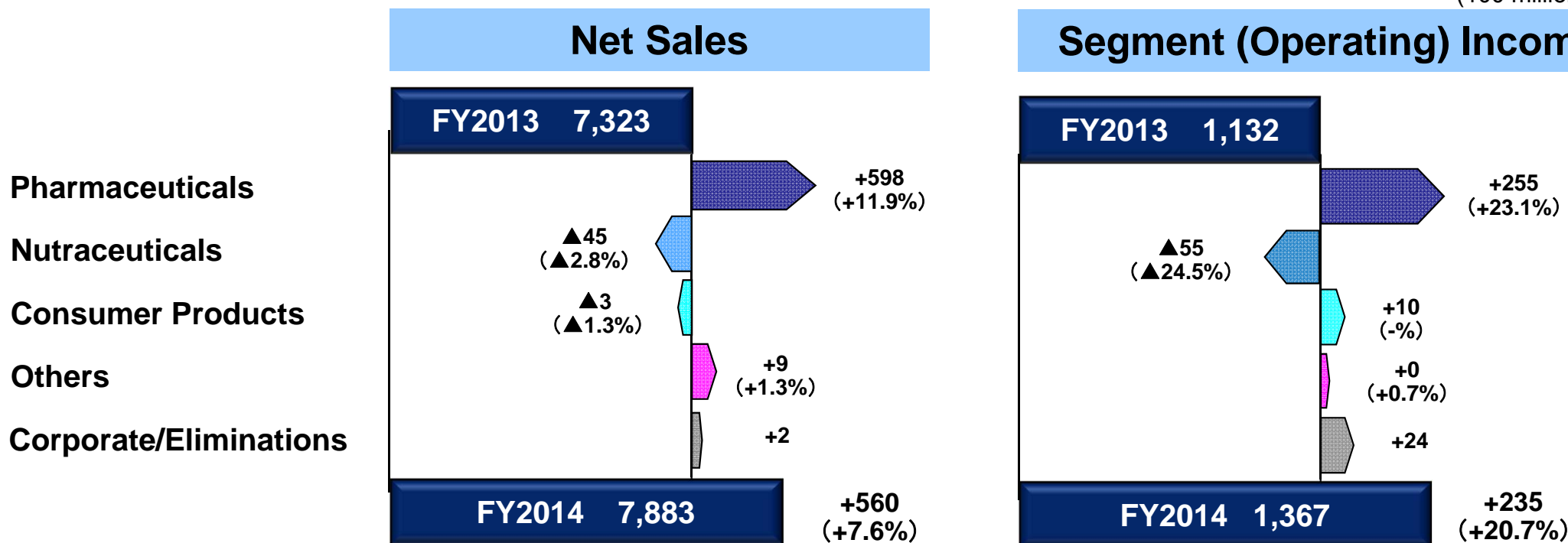
Net Sales approx. +18,000 million yen

Operating Income approx. +4,000 million yen

(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

2. Business Segment Analysis

(100 million yen)



*Parentheses represent % change

Net Sales	FY2013	FY2014	Change
Pharmaceuticals	5,016	5,614	598
Nutraceuticals	1,634	1,589	▲ 45
Consumer Products	245	241	▲ 3
Others	665	673	9
Corp/Elim	▲ 237	▲ 235	2
Consolidated	7,323	7,883	560

Op income	FY2013	FY2014	Change
Pharmaceuticals	1,102	1,357	255
Nutraceuticals	222	168	▲ 55
Consumer Products	▲ 11	▲ 1	10
Others	43	43	0
Corp/Elim	▲ 225	▲ 200	24
Consolidated	1,132	1,367	235

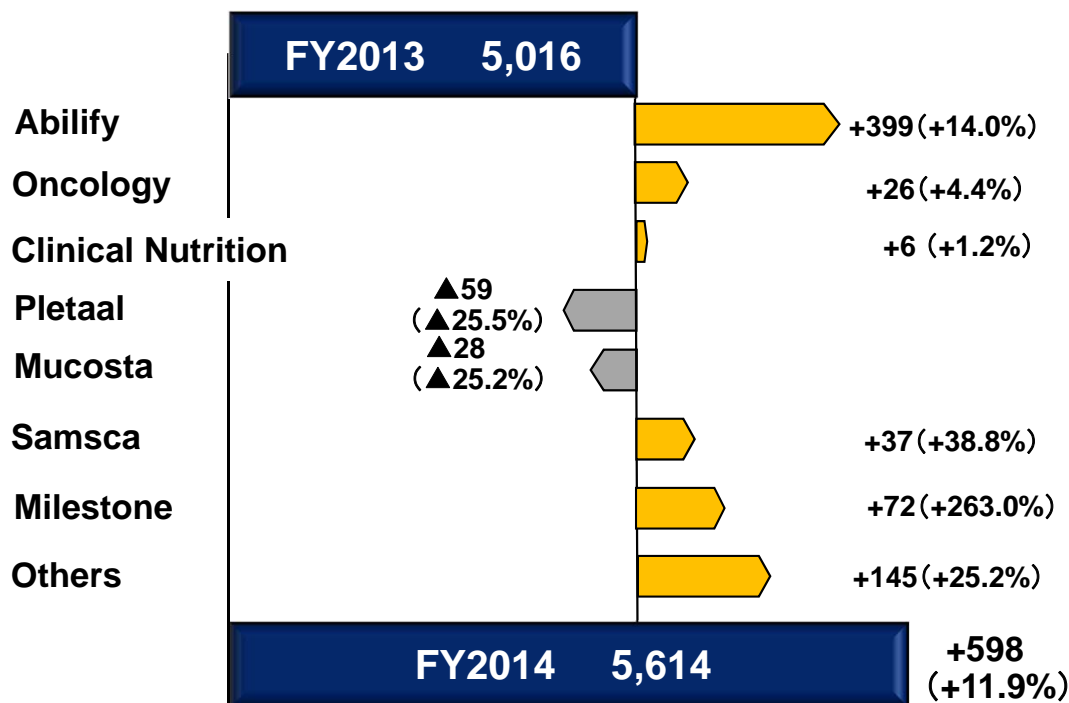
<Operating margin (%)>

	FY2013	FY2014
Pharmaceuticals	22.0%	24.2%
Nutraceuticals	13.6%	10.6%
Consumer Products	▲4.3%	▲0.3%
Others	6.4%	6.4%
Corp/Elim	-	-
Consolidated	15.5%	17.3%

(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

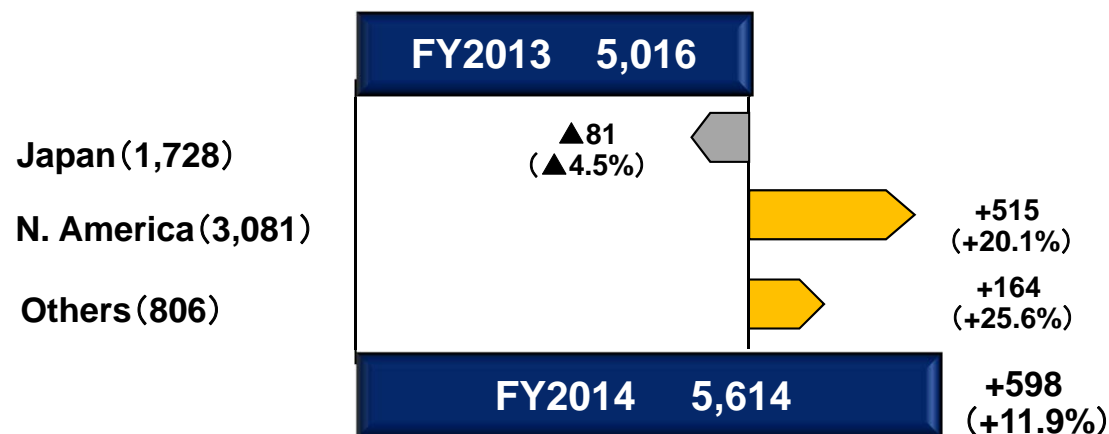
3. Pharmaceuticals Segment Analysis

Net Sales

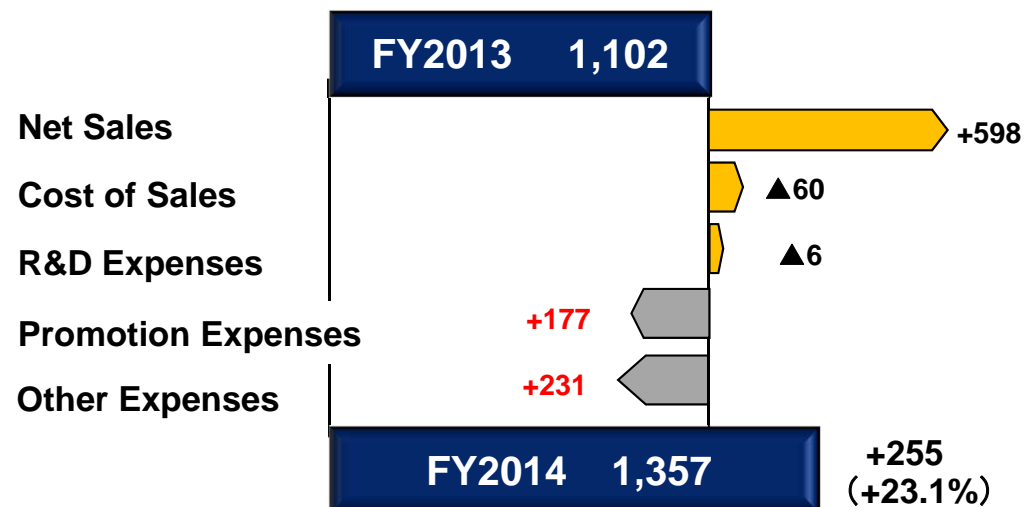


Products	FY2013	FY2014	Change	% Change
Abilify	2,857	3,257	399	14.0%
Oncology	599	625	26	4.4%
Clinical Nutrition	516	522	6	1.2%
Pietaal	233	173	▲ 59	▲25.5%
Mucosta	113	85	▲ 28	▲25.2%
Samsca	96	133	37	38.8%
Milestone	27	99	72	263.0%
Others	576	721	145	25.2%
Pharma Total	5,016	5,614	598	11.9%

Net Sales by Market



Segment (Operating) Income



(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

4. Abilify Sales

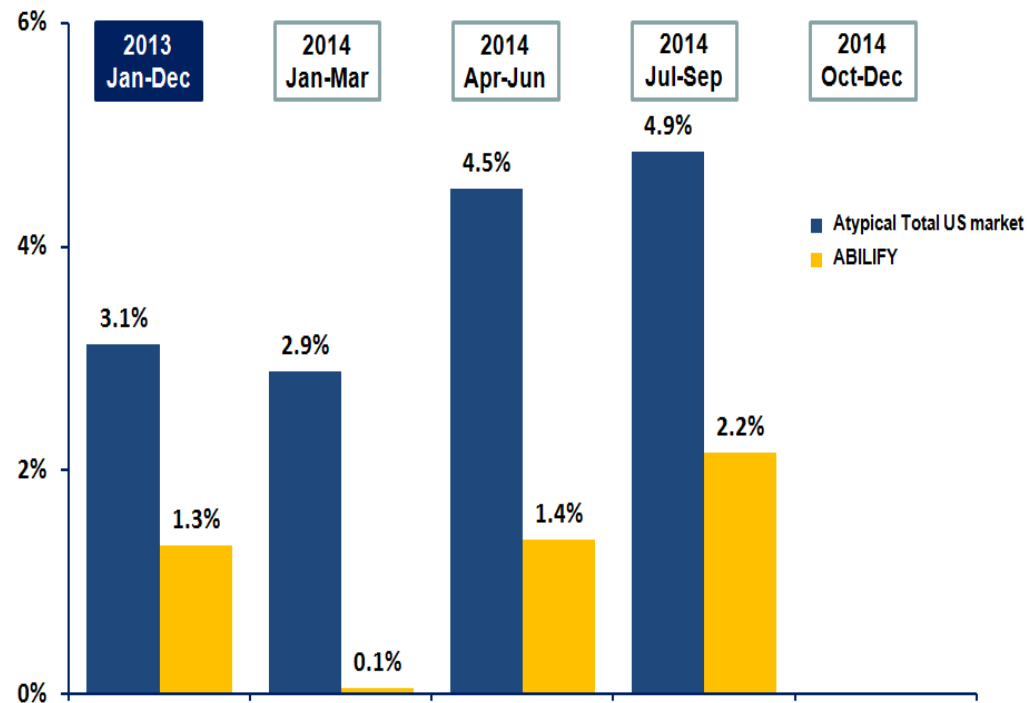
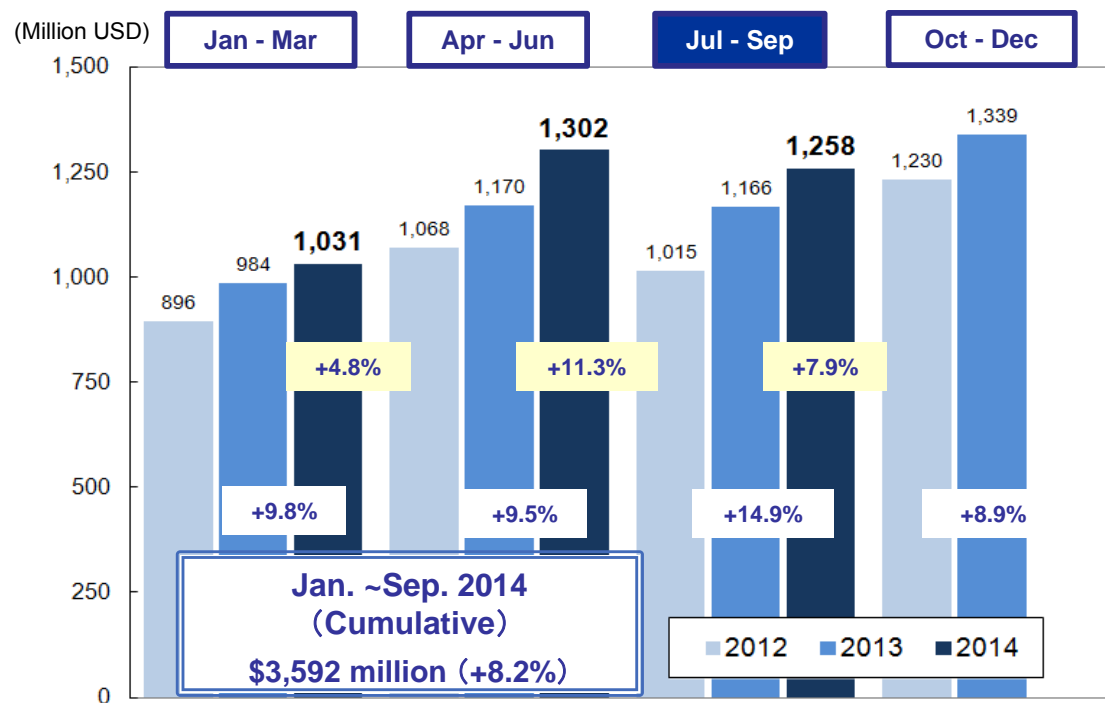
Abilify Sales by Market

(100 million yen)

	FY2013 Q2	FY2014 Q2	Change	% Change
Abilify	2,857	3,257	399	14.0%
US	2,311	2,639	329	14.2%
<Million USD>	<2,336>	<2,561>	<225>	9.6%
Japan	156	143	▲ 13	▲ 8.6%
Other	390	474	84	21.5%

Abilify Sales – Quarterly Evolution (US market)

Atypical antipsychotic prescription market (US market)



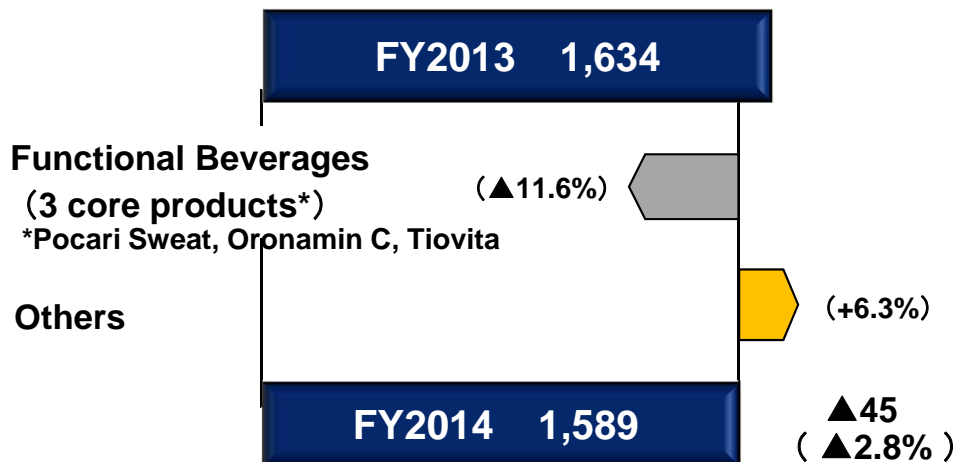
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(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

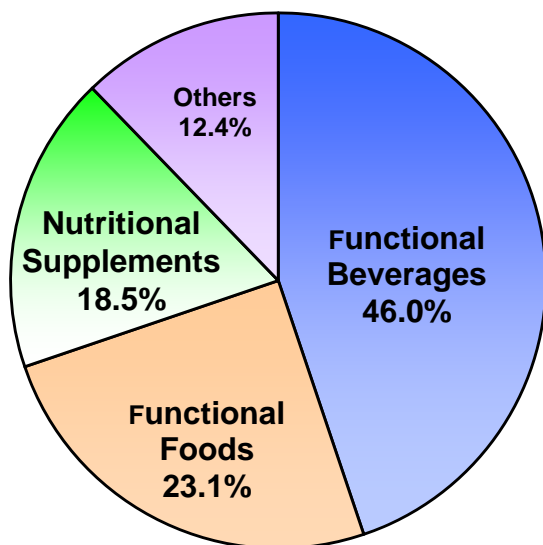
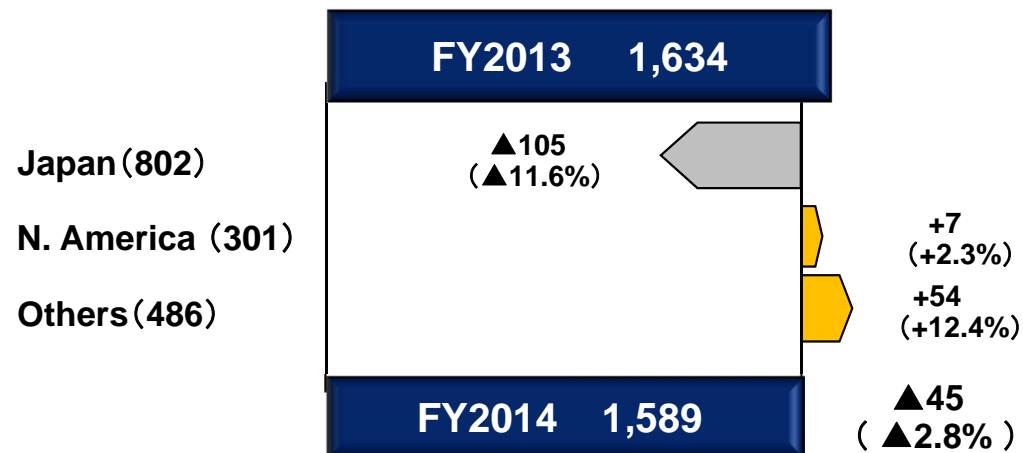
5. Nutraceuticals Segment Analysis

(100 million yen)

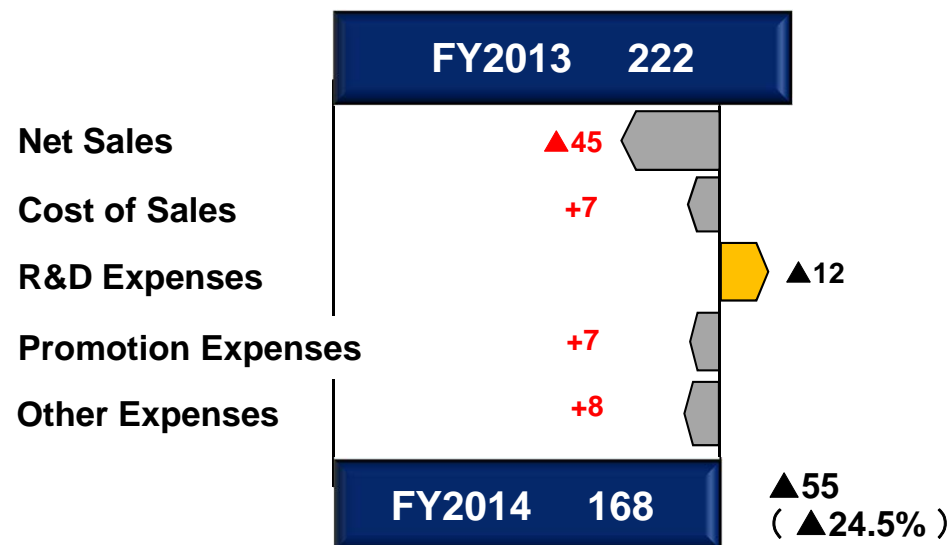
Net Sales



Net Sales by Market



Segment (Operating) Income



(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

6. FY2014 Estimate

(100 million yen)

	FY2013 Q2 Actual	FY2014 Q2 Actual	Change	% Change
Net Sales	7,323	7,883	+560	+7.6%
Operating Income	1,132	1,367	+235	+20.7%
Ordinary Income	1,244	1,481	+237	+19.1%
Net Income	885	995	+110	+12.4%

2014 Estimate	% Achievement
12,000	65.7%
1,900	71.9%
1,950	76.0%
1,300	76.5%

R&D Expenses	1,030	1,027	▲ 3	▲0.2%
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1,800	57.1%
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(Note) FY2013 shows the consolidated results from April to September including overseas companies (unaudited)

Pharmaceutical Development Update

November 13, 2014

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 2Q/FY2014**
 - ✓ Launches
 - ✓ Approvals
 - ✓ NDA filings
 - ✓ Advanced to the next phase
- 3 Topics**
- 4 FY2014 – Progress of key projects advanced to P-III & scheduled NDA submissions**

1-1. Major development projects (as of Sep. 30, 2014)



Phase	P-1	P-2	P-3	NDA	
CNS		Brexpiprazole ADHD/US	Maintena™ Bipolar/JP,US,EU ABILIFY® Autism/JP ABILIFY® AD agitation/JP Brexpiprazole MDD(Adjunctive)/EU Brexpiprazole Schiz./JP,EU Brexpiprazole AD agitaion/US,EU Brexpiprazole PTSD/US,EU ASC-01 MDD/JP,Asia E Keppra® Epilepsy (Generalized seizures)/JP Lu AE58054 Alzheimer's disease/US,EU	Maintena™ Schiz./JP ABILIFY® Tourette's/US Brexpiprazole MDD(Adjunctive)/US Brexpiprazole Schiz./US E Keppra® Partial seizures/Monotherapy(Oral)/JP E Keppra® Partial seizures (injection)/JP *Approved E Keppra® Partial seizures/Monotherapy (injection)/JP	
	Cardiovascular	OPC-108459 AF/JP,US	Samsca® Cancerous edema/JP Samsca® Edema in hemodialysis/JP Samsca® Edema in peritoneal dialysis /JP	Samsca® ADPKD/US	Samsca® Hepatic edema/Asia Samsca® ADPKD/EU Samsca® Cardiac edema /Asia

Blue columns indicate changes from 1Q

1-2. Major development projects (as of Sep. 30, 2014)



Phase	P-1	P-2	P-3	NDA
Oncology	TAS-114 Solid cancer/JP,US,EU	ET-743 STS/JP	TS-1 Uterocervical/JP,Asia	Abraxane® Pancreatic/JP
	TAS-115 Solid cancer/JP	SPRYCEL® Pancreatic/US,EU	TAS-102 Colorectal/JP,US,EU,Asia	
	TAS-116 Solid cancer/JP	OCV-101 Pancreatic/JP	TAS-118 Pancreatic/JP,Asia	
	TAS-119 Solid cancer/US,EU	OCV-501 AML/JP,Asia	SATIVEX® Cancer pain/US	
	TAS-120 Solid cancer/JP,US,EU	SGI-110 HCC/US,EU		
	TAS-121 Solid cancer/JP	SGI-110 Ovarian/US,EU		
	OPB-31121 Anti-cancer/JP,Asia	SGI-110 MDS,AML/US		
	OPB-51602 Anti-cancer/JP,US,Asia	AT13387 Prostate/US,EU		
	OPB-111001 Solid cancer/EU	AT13387 NSCLC/US,EU		
	OPB-111077 Solid cancer/US, Asia	AT7519 MM/US		
	OCV-C02 Colorectal/JP	Rebamipide Oral mucositis/Liquid/JP		
	ASTX727 MDS/US			
	Others/ Diagnostics		Delamanid Pediatric MDR-TB /EU	Delamanid MDR-TB/US
		OPC-6535 COPD/JP,US,Asia	Mucosta® ophthalmic suspension MD Dry eye/JP	ZOSYN®(YP-18) Febrile neutropenia /JP
		OPA-15406 Atopic dermatitis/US	TAC-202 Allergic rhinitis /JP	OPB-2045G Disinfectant/JP
		C13-URA Gastric emptying determination /US	OPC-1085EL Glaucoma/JP	ODK-1201-01 Diagnostic kit for CML/JP *Approved
		C13-CAC Diagnostic kit for gastric acid-related disease/JP	OPF-105 PPN infusions/JP	
			OPF-108 TPN infusions/JP	
		OPA-6566 Glaucoma/US	ACU-4429 AMD/US	
			TAC-202 Urticaria/JP	

Blue columns indicate changes from 1Q

2-1. Key development progress in 2Q/2014 (as of Sep. 30, 2014)



- Two products launched

Product name	Country · Area	
Meptin [®] Swinghaler [®] 10μg 100puffs	Japan	Launched on Jul. 2
Deltyba [™] / Deltyba [®]	EU · JP	Launched in UK (May), Germany (Jun.) and Japan (Sep.)

- Three projects approved

Product name / Generic name	Country · Area	Indication
Deltyba [®] (Delamanid)	Japan	MDR-TB*
E Keppra [®] for IV Drip Infusion 500 mg	Japan	Partial seizures
The Otsuka Major BCR-ABL mRNA Measurement Kit (ODK-1201-01)	Japan	For use as an aid to diagnose and monitor treatment effectiveness for CML*

*MDR-TB: Multidrug-resistant tuberculosis

*CML: Chronic myeloid leukemia

2-2. Key development progress in 2Q/2014 (as of Sep. 30, 2014)

- **Four applications submitted for approval**

Generic name / Development code	Country - Area	Indication
Brexpiprazole	US	Schizophrenia
Brexpiprazole	US	MDD* (Adjunctive therapy)
YP-18 (product name: ZOSYN®)	Japan	Febrile neutropenia
Levetiracetam Injection	Japan	Partial seizures (monotherapy)

☆TAS-102: US filing for the treatment of colorectal cancer in Oct.

- **Two projects advanced to P-III**

Generic name / Development code	Country - Area	Indication
TAC-202	Japan	Allergic rhinitis
OPF-108	Japan	High-calorie infusion

*MDD: Major depressive disorder

2-3. Key development progress in 2Q/2014 (as of Sep. 30, 2014)

- One project advanced to P-II

Generic name / Development code	Country·Area	
C13-CAC	Japan	Calcium carbonate-13C breath test (Diagnostic kit for gastric acid-related diseases)

- Four projects advanced to P-I

Generic name / Development code	Country·Area	Indication
TAS-119	US·EU	Solid cancer
TAS-120	JP·US·EU	Solid cancer
TAS-121	JP	Solid cancer
ASTX727	US	Myelodysplastic syndrome

3. Topics (Details of our new molecular entities)

Development code	Mechanism of action	Clinical development	Description
TAS-119	Selective Aurora A kinase inhibitor	P-I <ul style="list-style-type: none"> ■Solid cancer ■US and Europe 	TAS-119 inhibits Aurora kinase which is associated with cancer-cell-cycle and tumorigenesis. It selectively inhibits Aurora A which reportedly develops resistance to taxane anticancer agents. TAS-119 is expected to enhance taxane's efficacy when used in combination.
TAS-120	Selective FGFR* inhibitor	P-I <ul style="list-style-type: none"> ■Solid cancer ■Japan, US and Europe 	TAS-120 inhibits FGFRs, one of the growth factors for cancer proliferation. It is highly selective for FGFRs compared with other kinases including VEGFRs.
TAS-121	Mutant selective EGFR* inhibitor	P-I <ul style="list-style-type: none"> ■Solid cancer ■Japan 	TAS-121 selectively inhibits activated mutations associated with cancer and mutations that have a resistance to existing EGFR inhibitors. TAS-121 is expected to decrease the risk of adverse events caused by EGFR wild-type inhibition.
ASTX727	DNMT* inhibitor	P-I <ul style="list-style-type: none"> ■Myelodysplastic syndrome ■US 	Orally available DNMT inhibitor. Combination of decitabine (as main agent) and an inhibitor of its degrading enzyme, cytidine deaminase, improves pharmacokinetic profile, enabling the oral agent to have the same effects as an injection form. Due to its ease of use, patients may find it more convenient to receive treatment.

* FGFR: Fibroblast growth factor receptor
 EGFR: Epidermal growth factor receptor
 DNMT: DNA methyl transferase

4. FY2014 - Progress of key projects advanced to P-III & scheduled NDA submissions



● Projects scheduled to proceed to P-III

Advanced to P-III as scheduled

No.	Areas	Generic name	Country · Area	Indication
1	Oncology	TAS-118	Japan	Stomach cancer
2	Others	Bilastine (TAC-202)	Japan	Allergic rhinitis
3		OPC-1085EL	Japan	Glaucoma

Not included in the initial plan: Aripiprazole Agitation in AD* (JP), TAC-202 Chronic urticaria (JP), OPF-108 High-calorie infusion (JP)

● Projects scheduled to proceed to filing

NDA filing as scheduled

No.	Areas	Generic name / Development code	Country · Area	Indication
1	CNS	Brexipiprazole	US	Schizophrenia
2		Brexipiprazole	US	MDD (Adjunctive therapy)
3	Oncology	TS-1	Japan	Hepatocellular carcinoma
4		ABI-007	Japan	Pancreatic cancer
5		TAS-102	US	Colorectal cancer
6	Others	YP-18	Japan	Febrile neutropenia
7		OPB-2045G	Japan	Disinfectant

Not included in the initial plan: Tolvaptan Cardiac edema (Asia), Levetiracetam injection Partial seizures, monotherapy (JP)