
Financial Results Presentation

FY2013 Q3

(Nine Months Ending December 31, 2013)

February 13, 2014

Otsuka Holdings Co., Ltd.

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- 1 **Consolidated Financial Results**
- 2 **Business Segment Analysis**
- 3 **Pharmaceutical Segment Analysis**
- 4 **Abilify Sales**
 - 【Supplemental】**
 - Purchase Price Allocation of Astex Pharmaceuticals**
- 5 **Nutraceutical Segment Analysis**
- 6 **FY2013 Estimate**

1. Consolidated Financial Results (FY2013 Q3)

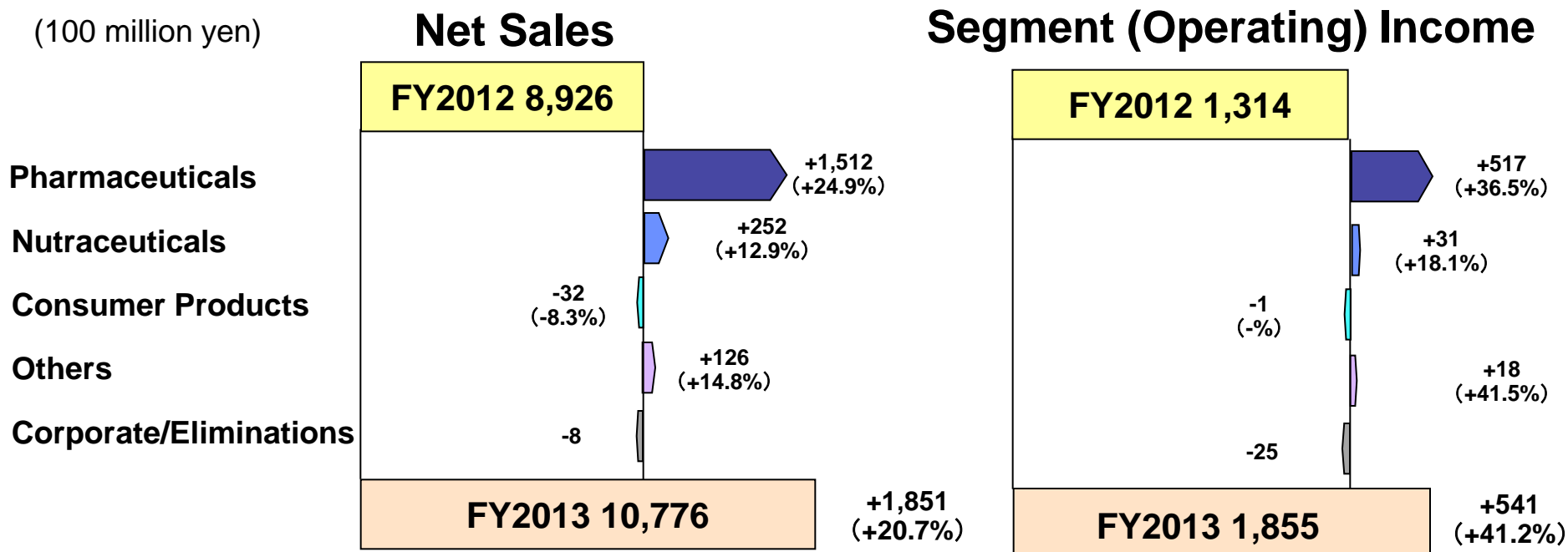
(100 million yen)

	Compared to the previous year's results			
	FY2012 Q3 Actual	FY2013 Q3 Actual	Change	% Change
Net Sales	8,926	10,776	1,851	20.7%
Operating Income	1,314	1,855	541	41.2%
Ordinary Income	1,408	2,030	622	44.2%
Net Income	912	1,428	516	56.6%
R&D Expenses	1,164	1,660	496	42.6%

Impact of exchange rate fluctuations: approx. +970 on net sales
approx. +120 on operating income

2. Business Segment Analysis (FY2013 Q3)

(100 million yen)



*Parentheses represent % increase

Net Sales	FY2012	FY2013	Change
Pharma	6,067	7,578	1,512
NC	1,958	2,210	252
Consumer	379	347	-32
Others	854	980	126
Corp/Elim	-331	-339	-8
Consolidated	8,926	10,776	1,851

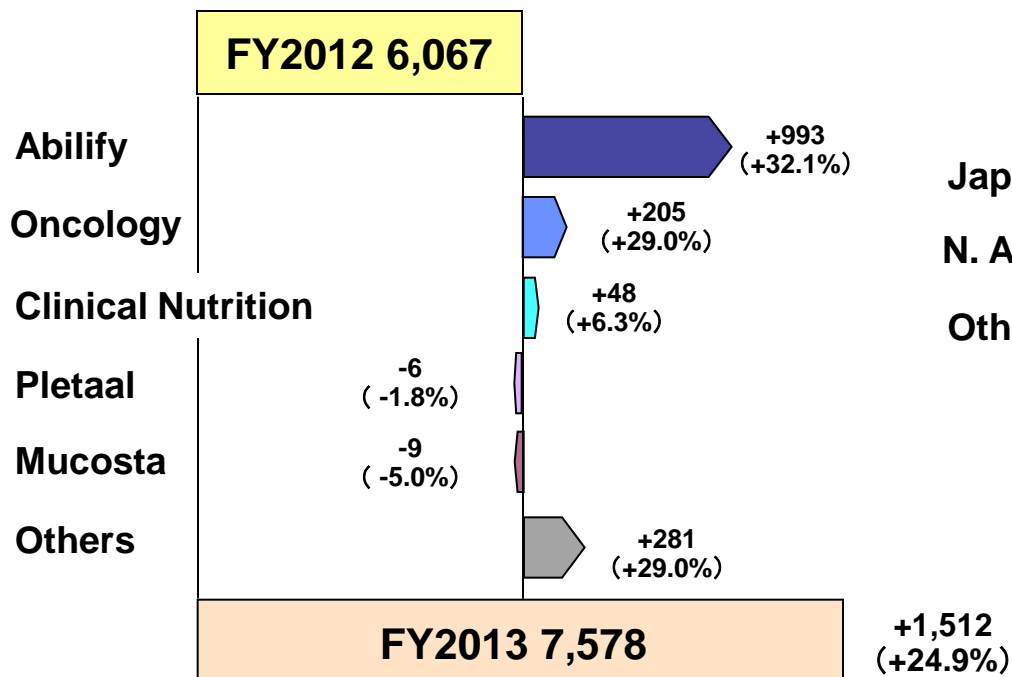
Op income	FY2012	FY2013	Change
Pharma	1,417	1,935	517
NC	173	204	31
Consumer	-14	-15	-1
Others	43	60	18
Corp/Elim	-304	-329	-25
Consolidated	1,314	1,855	541

< Operating margin (%) >

FY2012	FY2013
23.4%	25.5%
8.8%	9.2%
-3.7%	-4.3%
5.0%	6.1%
-	-
14.7%	17.2%

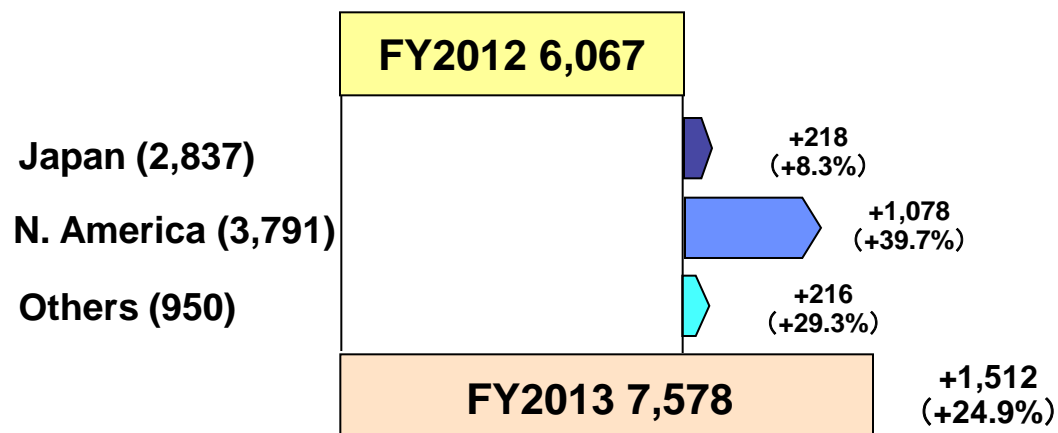
3. Pharmaceutical Segment Analysis (FY2013 Q3)

(100 million yen) Net Sales

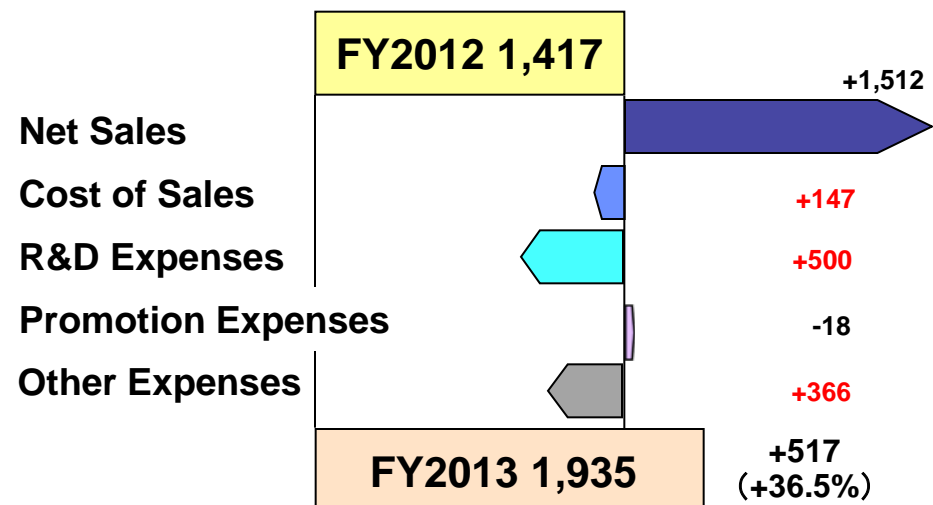


Products	FY2012 Q3	FY2013 Q3	Change	% Change
Abilify	3,098	4,092	993	32.1%
Oncology	707	912	205	29.0%
Clinical Nutrition	752	800	48	6.3%
Pletaal	357	351	-6	-1.8%
Mucosta	181	172	-9	-5.0%
Others	970	1,252	281	29.0%
Pharma Total	6,067	7,578	1,512	24.9%

Net Sales by Market



Segment (Operating) Income



4. Abilify Sales (FY2013 Q3)

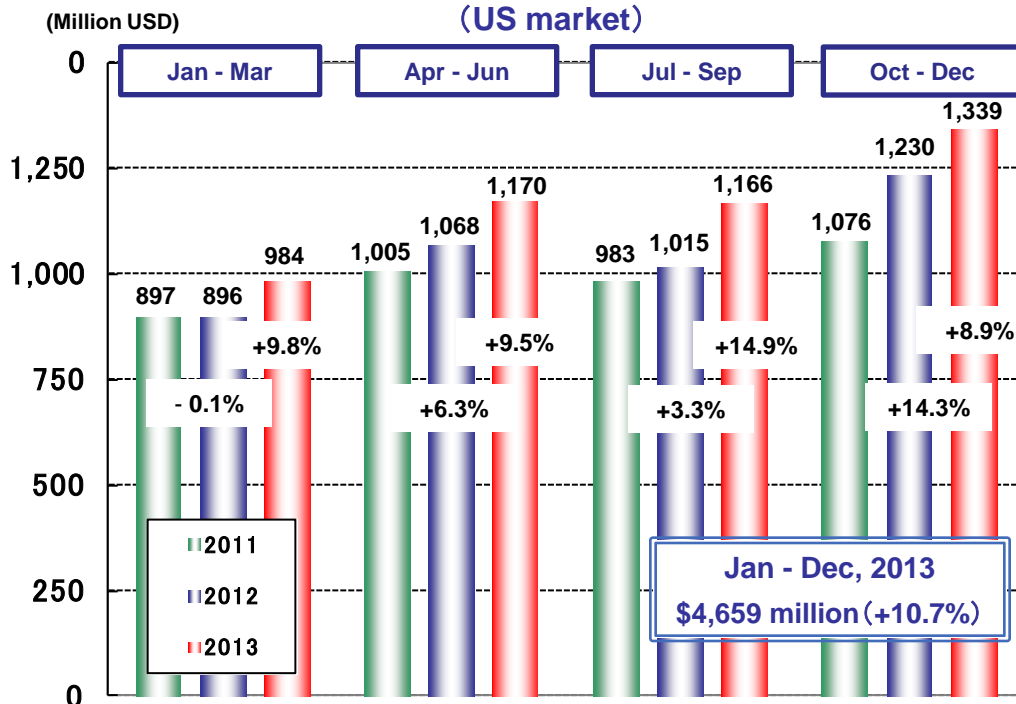
Abilify Sales by Market

(100 million yen)

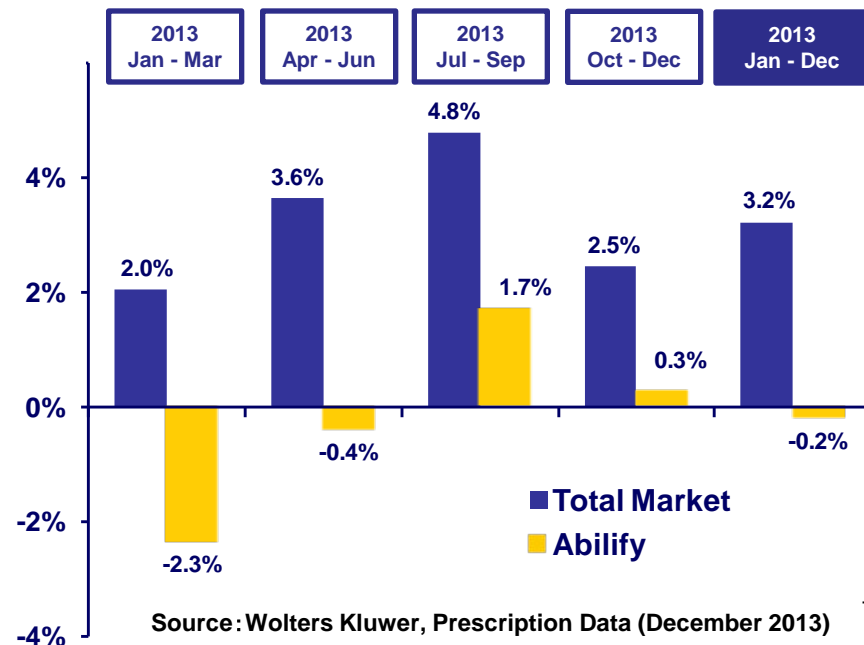
	FY2012 Q3	FY2013 Q3	Change	% Change
Abilify	3,098	4,092	993	32.1%
US*	2,366	3,217	850	35.9%
<Million USD>	<2,979>	<3,319>	<341>	11.4%
Japan	222	250	28	12.4%
Other*	510	625	115	22.6%

*Overseas sales are from January to September.

Abilify Sales – Quarterly Evolution (US market)

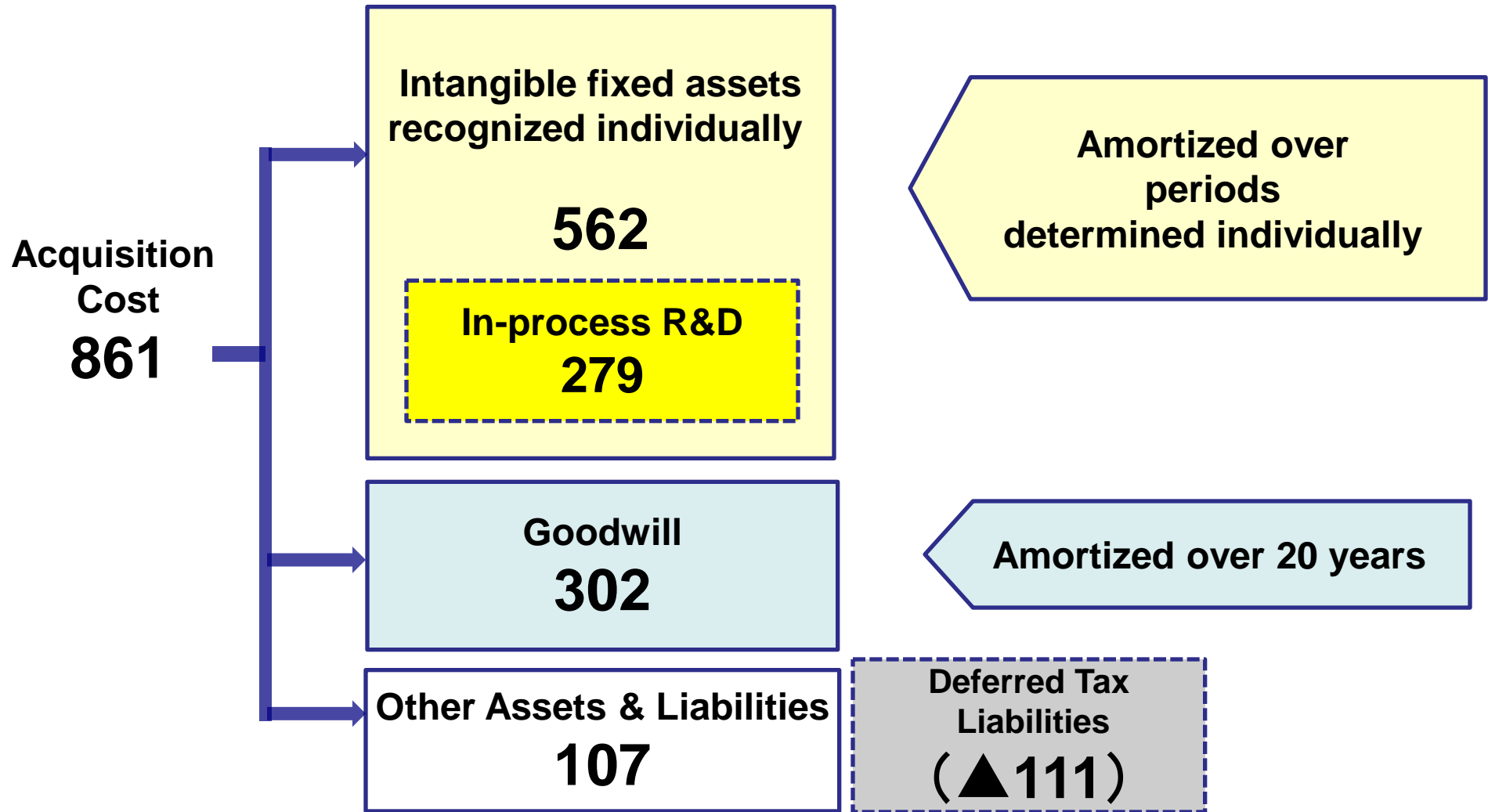


Atypical antipsychotic prescription market (US market)



【Supplemental】 Purchase Price Allocation of Astex Pharmaceuticals Otsuka

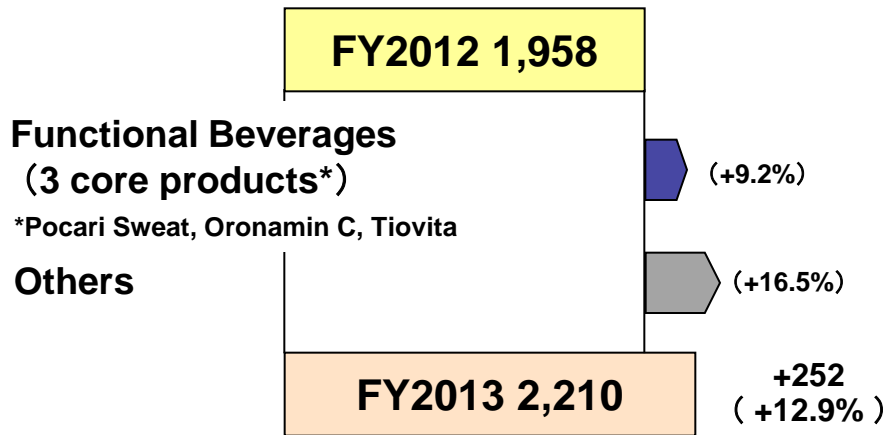
(100 million yen)



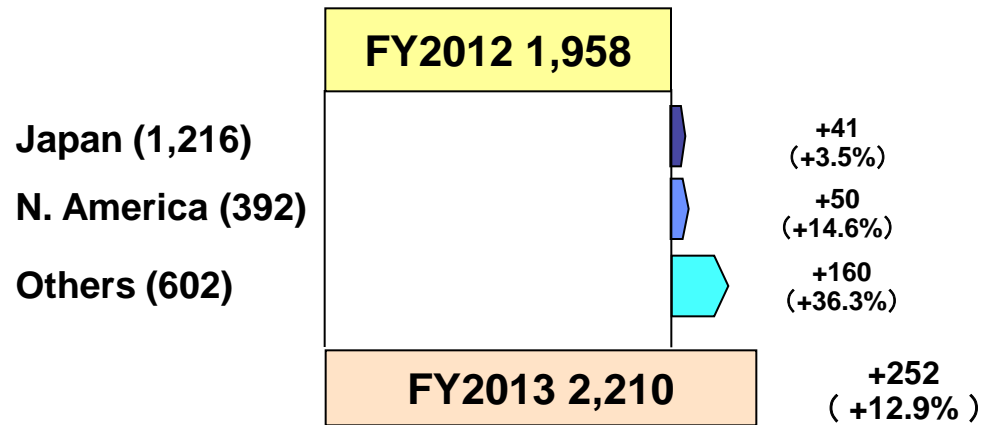
5. Nutraceutical Segment Analysis (FY2013 Q3)

(100 million yen)

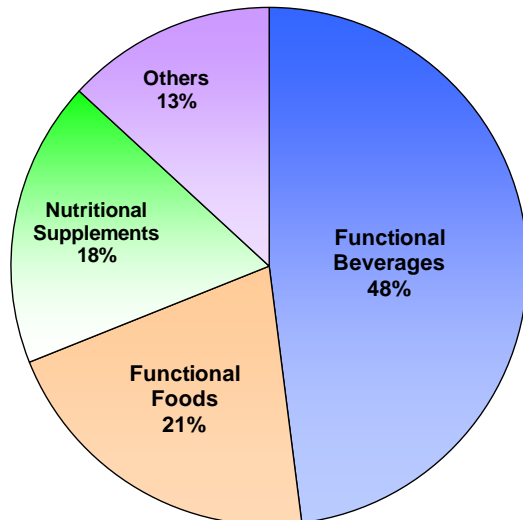
Net Sales



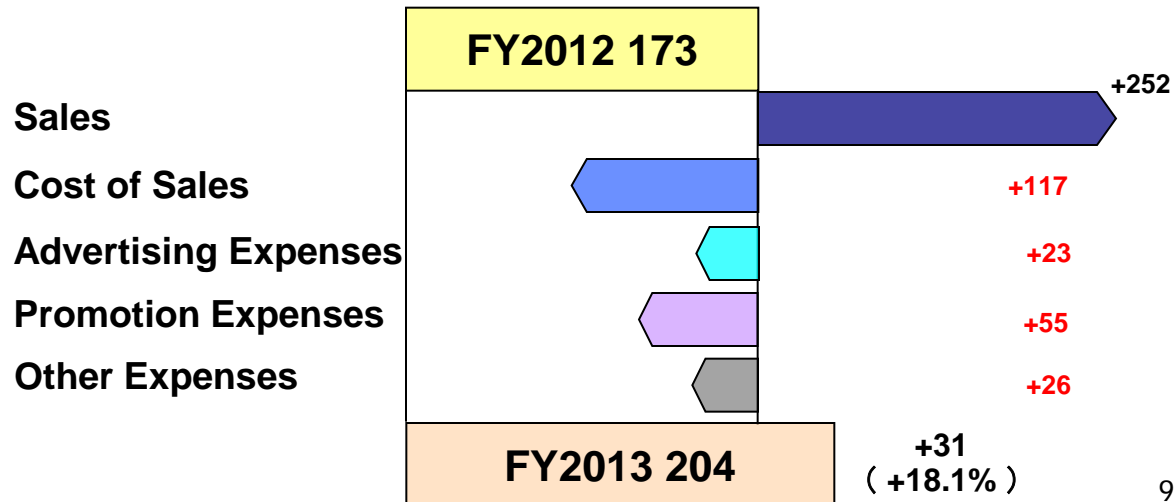
Net Sales by Market



Sales by Category



Segment (Operating) Income



6. FY2013 Estimate

(100 million yen)

	Compared to the previous year's results				Compared to estimate	
	FY2012 Q3 Actual	FY2013 Q3 Actual	Change	% Change	2013 Estimate	% Achievement
Net Sales	8,926	10,776	1,851	20.7%	14,350	75.1%
Operating Income	1,314	1,855	541	41.2%	2,150	86.3%
Ordinary Income	1,408	2,030	622	44.2%	2,250	90.2%
Net Income	912	1,428	516	56.6%	1,550	92.1%
R&D Expenses	1,164	1,660	496	42.6%	2,200	75.4%

Pharmaceutical Development Update

February 13, 2014

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 3Q/FY2013**
 - ✓ Launches
 - ✓ Approvals
 - ✓ Advanced to the next phase
- 3 Topics**
- 4 FY2013 - Progress of key projects advanced to P-III & scheduled NDA submissions**

1-1. Major development projects (as of Dec. 31, 2013)



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

Blue columns indicate changes from 2Q

1-2. Major development projects (as of Dec. 31, 2013)



Phase	P-1	P-2	P-3	NDA
Oncology	TAS-114 Solid cancer /JP,US,EU	TS-1 Renal/JP	TS-1 Gastric/US	TAS-102 Colorectal/JP
	TAS-115 Solid cancer /JP	TAS-102 SCLC/JP, EU	TS-1 Uterocervical/JP,Asia	
	OPB-31121 Anti-cancer/JP,Asia	SPRYCEL® Pancreatic/US,EU	TS-1 HCC/JP	
	OPB-51602 Anti-cancer/US,JP,Asia	ET-743 STS/JP	TSU-68 HCC/JP,Asia	
	OPB-111077 Solid cancer /US, Asia	OCV-101 Pancreatic/JP	TAS-102 Colorectal/JP,US,EU,Asia	
	OCV-C02 Colorectal/JP	OCV-501 AML/JP,Asia	TAS-118 Pancreatic/JP,Asia	
		SGI-110 HCC/US,EU	SATIVEX® Cancer pain/US	
		SGI-110 Ovarian/US,EU		
		SGI-110 MDS,AML/US		
		AT13387 Prostate/US,EU		
	AT13387 NSCLC/US,EU			
	AT7519 MM/US			
	Abraxane® Pancreatic/JP			
	TAS-106 Solid cancer/US			
Others/ Diagnostics	OPA-15406 Atopic dermatitis/US	OPC-6535 COPD/JP,US,Asia	ZOSYN®(YP-18) Febrile neutropenia /JP	Delamanid Tuberculosis/JP,EU
		Delamanid Pediatric MDR-TB /EU	Mucosta® ophthalmic suspension MD Dry eye/JP	ODK-1201-01 Diagnostic kit for CML/JP
		TAC-202 Allergic rhinitis /JP	Delamanid Tuberculosis/JP,US,EU	
		C13-URA Gastric emptying determination /US	OPB-2045G Disinfectant/JP	
			OPF-105 Peripheral parenteral nutrition infusions/JP	
		OPA-6566 Glaucoma/US	ACU-4429 AMD/US	

Blue columns indicate changes from 2Q

2-1. Key development progress in 3Q/2013 (as of Dec. 31, 2013)

- **One product launched**

Product name	Country·Area	Details
Plasma substitute Voluven®6%	Japan	Launched on Oct. 25

- **One project approved**

Product name	Country·Area	Indication
Abilify Maintena®	Europe	Schizophrenia

- **Two applications submitted for approval**

Generic name / Development code	Country·Area	Indication
Tolvaptan	Europe	ADPKD*
ODK-1201-01	Japan	Diagnostic reagent kit for CML*

*ADPKD: Autosomal dominant polycystic kidney disease

*CML: Chronic myeloid leukemia

☆ J-NDA submitted for Aripiprazole once-monthly IM depot for the treatment of schizophrenia. (Jan. 2014)

2-2. Key development progress in 3Q/2013 (as of Dec. 31, 2013)

- **Four projects advanced to P-III**

Generic name / Development code	Country·Area	Indication
Brexipiprazole	US·EU	Post-traumatic stress disorder (PTSD)
Lu AE58054	US·EU	Alzheimer's disease
TAS-102	Asia	Colorectal cancer
OPF-105	Japan	Peripheral venous nutrition infusions

- **One project advanced to P-II**

Generic name / Development code	Country·Area	Indication
OCV-501	JP·Asia	Acute myeloid leukemia (AML)

2-3. Key development progress in 3Q/2013 (as of Dec. 31, 2013)

- Six projects added to P-II

Generic name / Development code	Country·Area	Indication
SGI-110	US·EU	Hepatocellular carcinoma (HCC)
SGI-110	US·EU	Ovarian cancer
SGI-110	US	Myelodysplastic syndromes (MDS) Acute myeloid leukemia (AML)
AT13387	US·EU	Prostate cancer
AT13387	US·EU	Non-small cell lung cancer (NSCLC)
AT7519	US	Multiple myeloma (MM)

3-1. Topics (Recent news releases)

【Release date】

<CNS>

- Otsuka named as Lundbeck's partner in Japan on the development and commercialization of nalmefene for the reduction of alcohol consumption 【October 31, 2013】
http://www.otsuka.co.jp/en/company/release/2013/1031_01.html
- Lundbeck and Otsuka to co-develop Lu AF20513, an investigational vaccine candidate for Alzheimer's disease 【December 11, 2013】
http://www.otsuka.co.jp/en/company/release/2013/1211_01.html
- The first phase III data on brexpiprazole will be presented in an upcoming poster session at the 22nd European Psychiatry Association Congress (EPA) on March 2, 2014 【January 24, 2014】
http://www.otsuka.co.jp/en/company/release/2014/0124_01.html

<Oncology>

- The results of a P-III clinical trial of TS-1 on metastatic colorectal cancer were published in the digital version of The Lancet Oncology 【November 11, 2013】
<http://www.taiho.co.jp/english/news/20131111.html>

<Others>

- The CHMP of the EMA has recommended approval of delamanid for the treatment of multidrug-resistant tuberculosis (MDR-TB). 【November 25, 2013】
*CHMP: The Committee for Medicinal Products for Human Use
*EMA: The European Medicines Agency
http://www.otsuka.co.jp/en/company/release/2013/1125_02.html

3-2. Topics (Details of key development projects)

Development code	Mechanism of action	Ongoing clinical trials	Description
Lu AE58054	Selective serotonin 5-HT6 receptor antagonist	<p>P-III</p> <ul style="list-style-type: none"> ■ Alzheimer's disease (US·EU) -STARSHINE study (adjunctive therapy to donepezil, placebo/30mg/60mg, n=930) -STARBEAM study (adjunctive therapy to donepezil, placebo/10mg/30mg, n=840) -STARBRIGHT study (adjunctive therapy to AChEIs*, placebo/30mg or 60mg, n=720) <p>*AChEIs: Acetylcholinesterase inhibitors</p>	<p>Lu AE58054 is expected to enhance ACh* release by inhibiting GABA** release.</p> <p>*ACh: Acetylcholine **GABA: Gamma-aminobutyric acid</p>
OCV-501	WT1 peptide cancer vaccine	<p>P-II</p> <ul style="list-style-type: none"> ■ Elderly patients with AML (Japan·Asia) 	A peptide cancer vaccine targeting WT1 which is highly expressed in cancer cells. OCV-501 also induces and enhances helper T-cells.
SGI-110	DNMT* inhibitor *DNMT: DNA methyl transferase	<p>P-II</p> <ul style="list-style-type: none"> ■ Hepatocellular carcinoma (US) ■ Ovarian cancer (US·EU) ■ MDS/AML (US) 	SGI-110 is a prodrug of decitabine. It can prolong the plasma half-life and improve the pharmacokinetics.
AT13387	HSP*90 inhibitor *HSP: Heat shock protein	<p>P-II</p> <ul style="list-style-type: none"> ■ Non-small cell lung cancer (US·EU) ■ Prostate cancer (US·EU) 	AT13387 is the second generation Hsp90 inhibitor. Hsp90 is an ATP-dependent molecular chaperone which stabilizes various oncogenic kinases, which are essential for tumor growth.
AT7519	CDK1/2/9 inhibitor	<p>P-II</p> <ul style="list-style-type: none"> ■ Multiple myeloma (US) 	<p>AT7519 inhibits CDKs* which enhance cancer cell growth.</p> <p>*CDKs: Cyclin dependent kinases</p>

4. FY2013 -Progress of key projects advanced to P-III & scheduled NDA submissions



● Three projects advanced to P-III as scheduled

Advanced to P-III as scheduled

No.	Areas	Generic name	Country·Area	Indication
1	CNS	Aripiprazole IM Depot	JP·EU	Bipolar disorder
2		Brexpiprazole	US·EU	Agitation associated with dementia of the Alzheimer's type
3		Brexpiprazole	US·EU	PTSD
4	Others	Rebamipide ophthalmic suspension unit dose	Japan	Keratoconjunctival epithelial disorder

Not included in the initial plan: TAS-118 (JP·Asia), Lu AE58054 (US·EU), TAS-102 (Asia) and OPF-105 (JP)

● Two projects proceeded to filing as scheduled

NDA filing as scheduled

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
5	Cardiovascular	Tolvaptan	JP·EU	ADPKD
6	Others	ODK-1201	Japan	Diagnostic reagent kit for CML

Not included in the initial plan: J-NDA submitted for Levetiracetam injection.

J-NDA submitted for Aripiprazole IM depot for the treatment of schizophrenia.