
Financial Results Presentation FY2014

(Fiscal Year Ended December 31, 2014)

February 13, 2015

Otsuka Holdings Co., Ltd.

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- 1 FY2014 Consolidated Financial Results (2014 April - December)
- 2 Business Segment Analysis
- 3 Pharmaceutical Segment Analysis
- 4 Abilify Sales
- 5 Growing Sales of New Products
- 6 Nutraceutical Segment Analysis
- 7 FY2015 Estimate

1. FY2014 Consolidated Financial Results

(100 million yen)

	Actual				Achievement		
	FY2013 Apr - Dec	FY2014 Apr - Dec	Change	% Change	FY2014 Estimate	Difference	% Achievement
Net Sales	11,342	12,243	+901	+7.9%	12,000	+243	102.0%
Operating Income	1,831	1,965	+135	+7.4%	1,900	+65	103.4%
Ordinary Income	1,995	2,172	+177	+8.9%	1,950	+222	111.4%
Net Income	1,394	1,431	+38	+2.7%	1,300	+131	110.1%
R&D Expenses	1,652	1,729	+77	+4.6%	1,800	▲ 71	96.0%

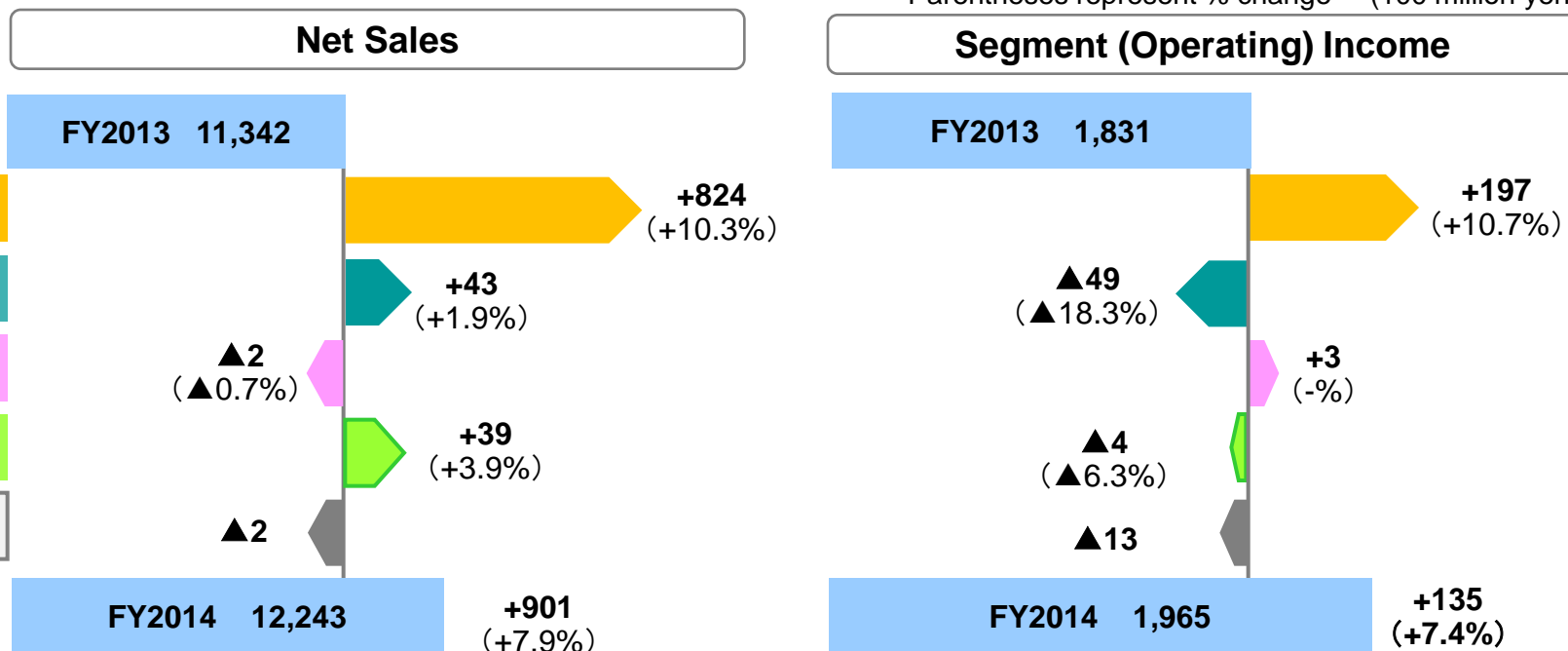
Foreign Exchange Impact :

Net Sales approx. +42,000 million yen
 Operating Income approx. +7,000 million yen

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

2. Business Segment Analysis

*Parentheses represent % change (100 million yen)



	Net sales		Operating income		Operating margin (%)	
	FY2013	FY2014	FY2013	FY2014	FY2013	FY2014
Pharmaceuticals	8,011	8,835	1,851	2,048	23.1%	23.2%
Nutraceuticals	2,338	2,382	268	219	11.4%	9.2%
Consumer Products	348	345	▲18	▲14	▲5.0%	▲4.1%
Other	984	1,022	59	55	6.0%	5.4%
Corporate/Eliminations	▲339	▲342	▲329	▲343	-	-
Consolidated	11,342	12,243	1,831	1,965	16.1%	16.1%

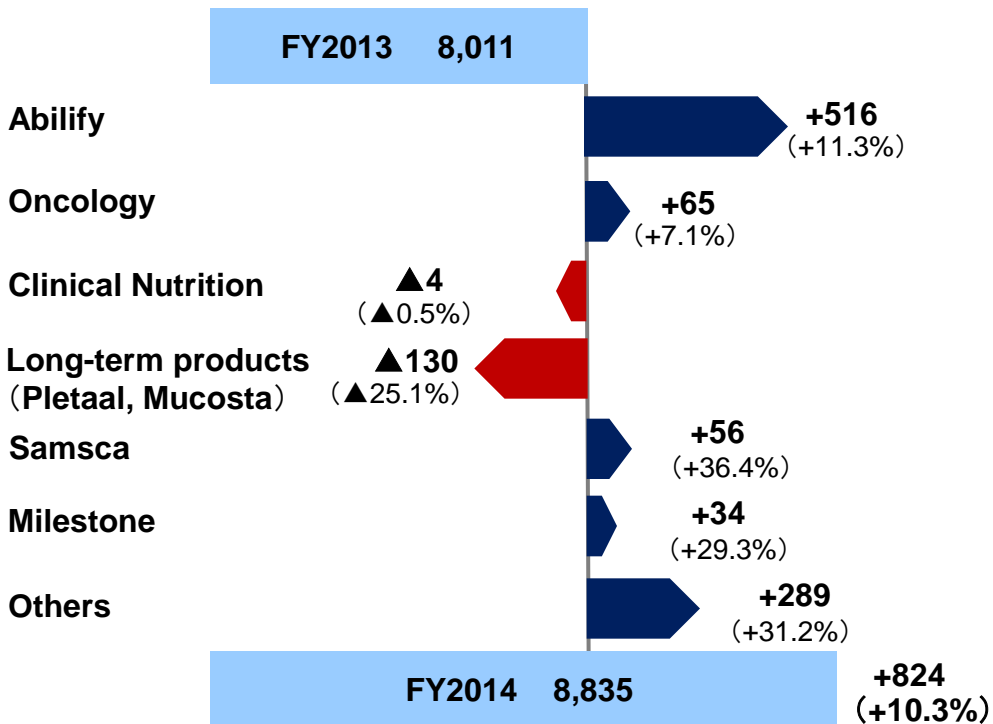
(Note) FY2013 shows the consolidated results from April to December including overseas companies (unaudited)

3. Pharmaceutical Segment Analysis

Pharmaceuticals



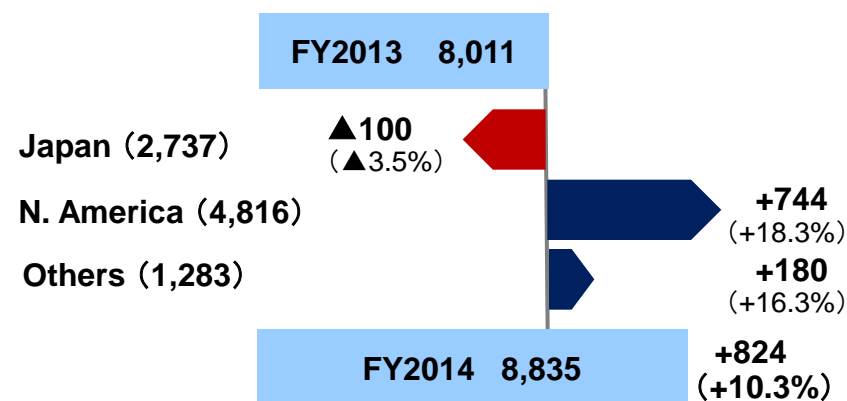
Net Sales



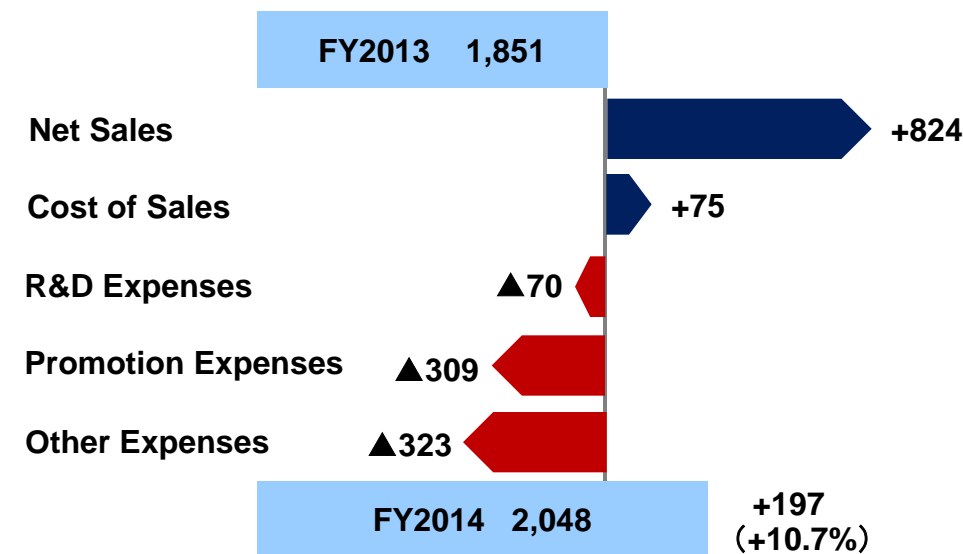
Products	FY2013	FY2014
Abilify	4,558	5,074
Oncology	921	986
Clinical Nutrition	820	815
Long-term products	521	390
Samsca	153	208
Milestone	115	149
Others	924	1,212
Pharma Total	8,011	8,835

Net Sales by Market

(100 million yen)



Segment (Operating) Income



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

4. Abilify Sales

Pharmaceuticals



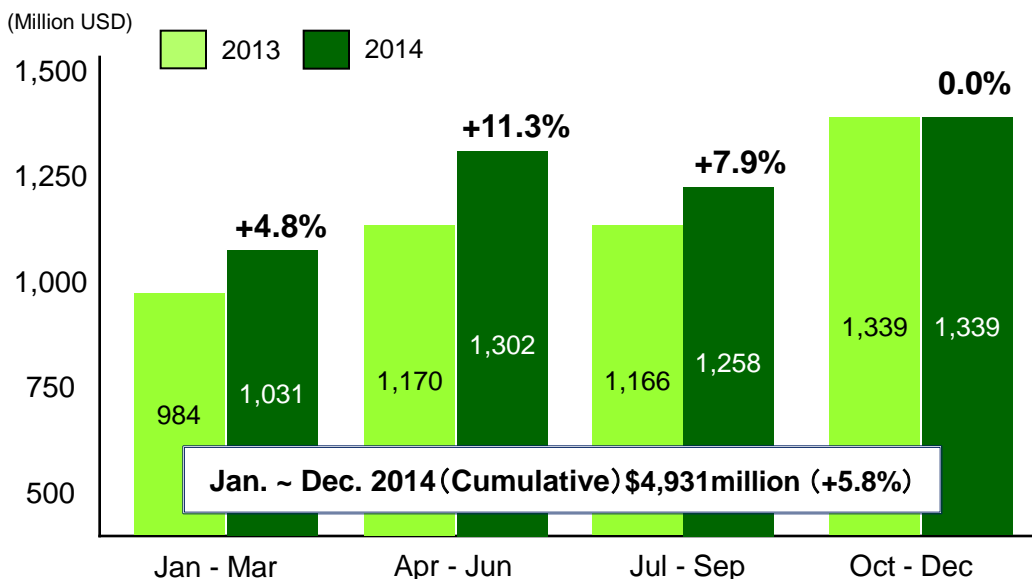
	FY2013 Apr - Dec	FY 2014 Apr - Dec	Change	% Change
Abilify (Total)	4,558	5,074	+516	+11.3%

(100 million yen)

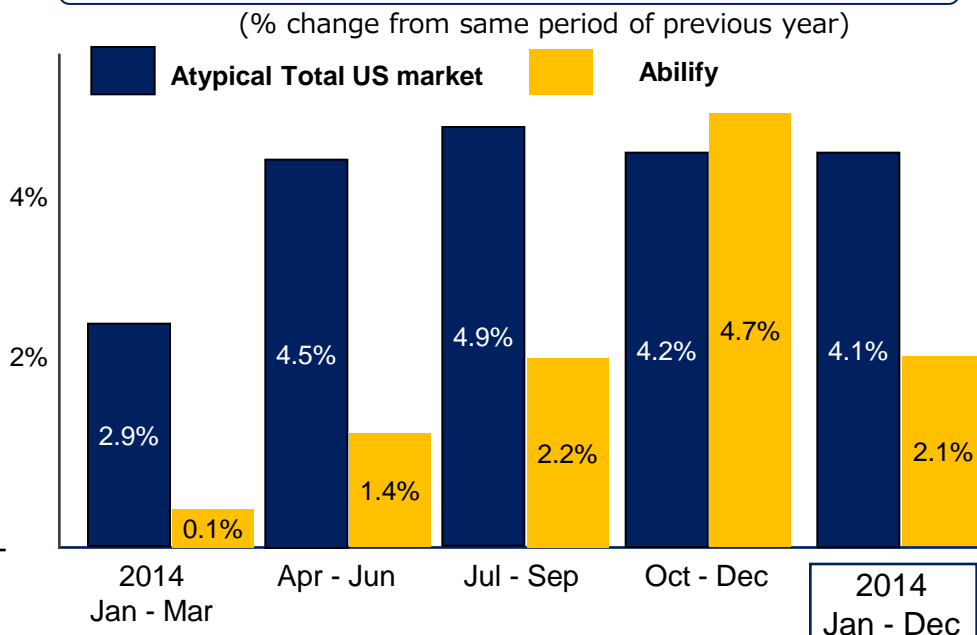
Abilify Sales by Market

Market	FY2013 Apr - Dec	FY 2014 Apr - Dec	Change	% Change
US	3,653	4,165	+511	+14.0%
<Million USD>	3,675	3,900	+225	+6.1%
Japan	250	237	▲13	▲5.3%
Others	655	672	+17	+2.6%

Abilify Sales – Quarterly Evolution (US market)



Atypical antipsychotic prescription market in US)



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

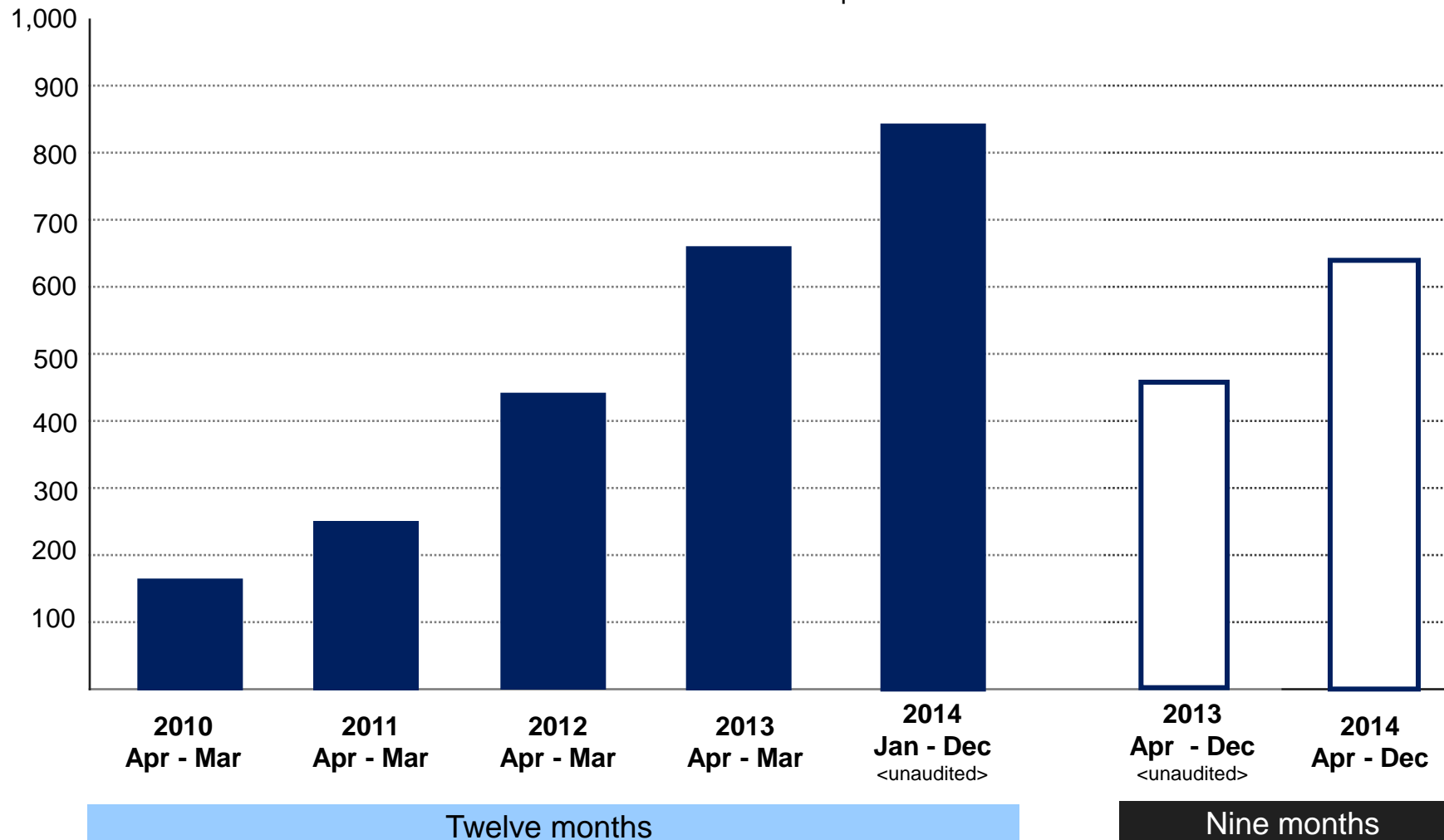
5. Growing Sales of New Products

Pharmaceuticals



(100 million yen)

New Products Launched in the Japanese Market



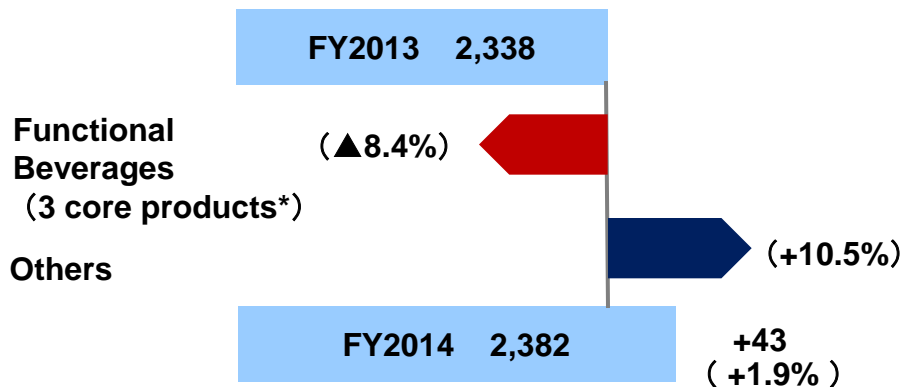
New Products: E Keppra, Aloxi, Abraxane, SAMSCA, ELNEOPA, Mucosta Ophthalmic Suspension, Zolinza, Neupro Patch, Lonsurf, E-fen and Delyba

6. Nutraceutical Segment Analysis

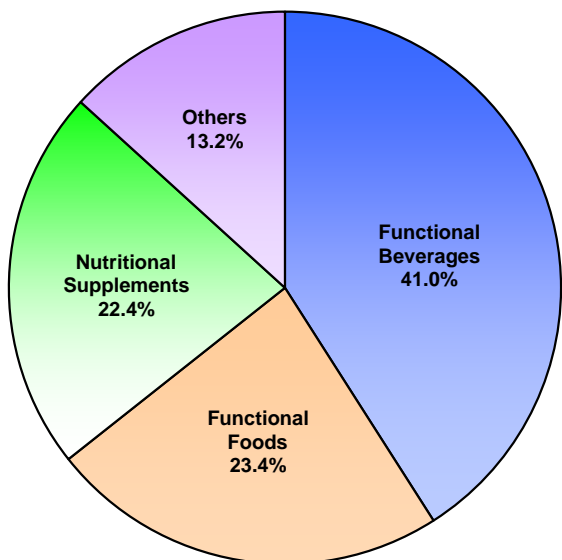
Nutraceuticals



Net Sales

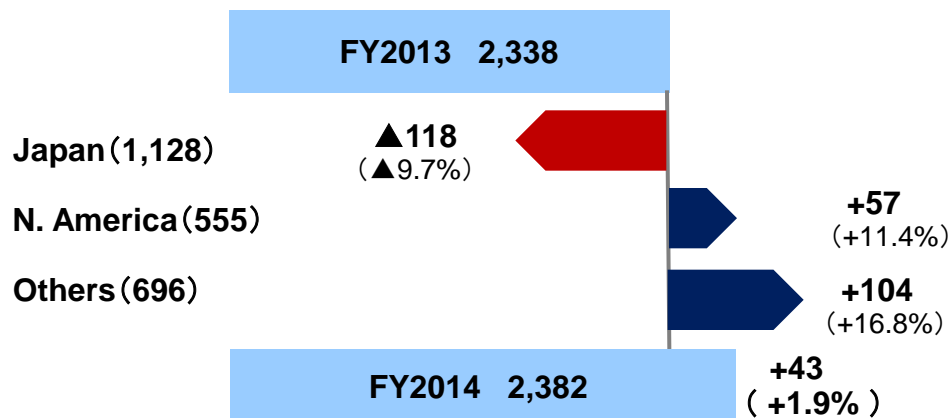


*Pocari Sweat, Oronamin C, Tioivita

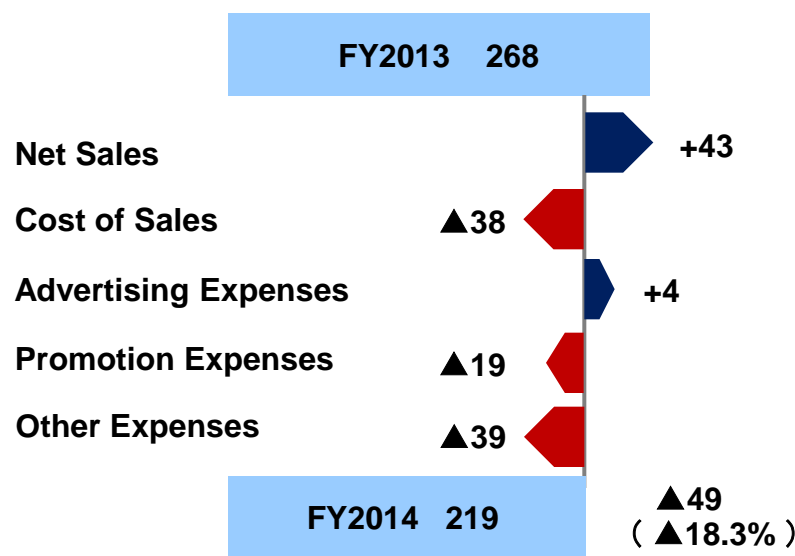


Net Sales by Market

(100 million yen)



Segment (Operating) Income



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

Pharmaceutical Development Update

February 13, 2015

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development updates from Oct. to Dec. in 2014**
 - ✓ **Launches**
 - ✓ **Approvals**
 - ✓ **NDA filings**
 - ✓ **Advanced to the next phase**
- 3 Topics**
- 4 FY2014 - Key development achievements**
FY2015 - Scheduled P-III & NDA submissions (Initial plan)

1-1. Major development projects: CNS (as of Dec. 31, 2014)



		P-1	P-2	P-3	NDA
Mental Disease	Schizophrenia			Brexpiprazole JP-EU	Aripiprazole extended release injectable JP Brexpiprazole US
	MDD		AVP-786* US	Brexpiprazole EU ASC-01 JP-Asia	Brexpiprazole US
	Others		Brexpiprazole ADHD US	Aripiprazole Autism JP Aripiprazole extended release injectable Bipolar JP-US-EU Brexpiprazole PTSD US-EU	Aripiprazole Tourette's syndrome US *Approved
Neurological Disease	Epilepsy			Levetiracetam (oral) Generalized seizures JP	Levetiracetam (oral) Partial seizures (monotherapy) JP Levetiracetam (injection) Partial seizures (monotherapy) JP
	AD		AVP-923* Agitation in AD US	Aripiprazole Agitation in AD JP Brexpiprazole Agitation in AD US-EU AE58054 US-EU	
	Others	TAS-205 DMD JP	AVP-923* PD US		AVP-825 * Acute migraine US

*Avanir's AVP-923, AVP-786 and AVP-825 were included after Jan. 2015.

Blue columns indicate changes since last update.

1-2. Major development projects: Oncology (as of Dec. 31, 2014)



	P-1	P-2	P-3	NDA
Solid cancer	TAS-114 JP·US·EU	Dasatinib US·EU Pancreatic cancer	TAS-118 JP·Asia Pancreatic cancer	ABI-007 JP Pancreatic cancer <small>*Approved</small>
	TAS-115 JP	OCV-101 JP Pancreatic cancer	TAS-102 EU·Asia Colorectal cancer	TAS-102 US Colorectal cancer
	TAS-116 JP	SGI-110 US·EU HCC	S-1 JP·Asia Cervical cancer	
	TAS-119 US·EU	SGI-110 US·EU Ovarian cancer		
	TAS-120 JP·US·EU	AT13387 US·EU Prostate cancer		
	TAS-121 JP	AT13387 US·EU NSCLC		
	OPB-31121 JP·Asia	ET-743 JP STS		
	OPB-51602 JP·US·Asia			
	OPB-111001 EU			
	OPB-111077 US·Asia			
	OCV-C02 JP			
Blood cancer	ASTX727 US	OCV-501 JP·Asia AML		
		SGI-110 US MDS, AML		
		AT7519 US MM		
Palliative & supportive care		Rebamipide(liquid) JP Oral mucositis	Nabiximols US Cancer pain	

Blue columns indicate changes since last update.

1-3. Major development projects: Others (as of Dec. 31, 2014)

	P-1	P-2	P-3	NDA
Cardiovascular	OPC-108459 AF JP-US	Tolvaptan Cancerpus edema JP Tolvaptan Volume overload in hemodialysis JP Tolvaptan Volume overload in peritoneal dialysis JP	Tolvaptan ADPKD US	Tolvaptan Hepatic edema Asia Tolvaptan Cardiac edema Asia Tolvaptan ADPKD EU
		Delamaind Pediatric MDR-TB EU OPC-6535 COPD JP-US -Asia OPA-6566 Glaucoma US	Delamanid MDR-TB US Rebamipide ophthalmic suspension MD Dry eye JP OPC-1085EL Glaucoma JP	YP-18 Febrile neutropenia JP OPB-2045G Disinfectant JP
	Others		ACU-4429 AMD US OPA-15406 Atopic dermatitis US TAC-202 Urticaria JP OPF-105 PPN infusions JP OPF-108 TPN infusions JP	
Diagnosics		C13-URA Gastric emptying determination US C13-CAC Diagnostic kit for gastric acid-related disease JP		

Blue columns indicate changes since last update.

2. Key development updates from Oct. to Dec. in 2014 (as of Dec. 31, 2014)

- **Two products launched**

Product name	Country·Area	
L-Cartin [®] FF tablets	Japan	Launched on Dec. 5
Major BCR-ABL mRNA measurement kit 'Otsuka'	Japan	Launched on Nov. 10

- **Two projects approved**

Product name / Development code	Country·Area	Indication
ABILIFY [®]	USA	Tourette's syndrome
Abraxane [®] (ABI-007)	Japan	Pancreatic cancer

- **One application submitted for approval**

Development code	Country·Area	Indication
TAS-102	USA	Colorectal cancer

☆ET-743 filed for malignant soft tissue sarcoma in Japan (Jan. 2015)

2. Key development updates from Oct. to Dec. in 2014 (as of Dec. 31, 2014) cont'd



- One project advanced to P-I

Development code	Country·Area	Indication
TAS-205	Japan	Duchenne muscular dystrophy

Acquired Avanir's pipeline after Jan. 2015

- NDA filing

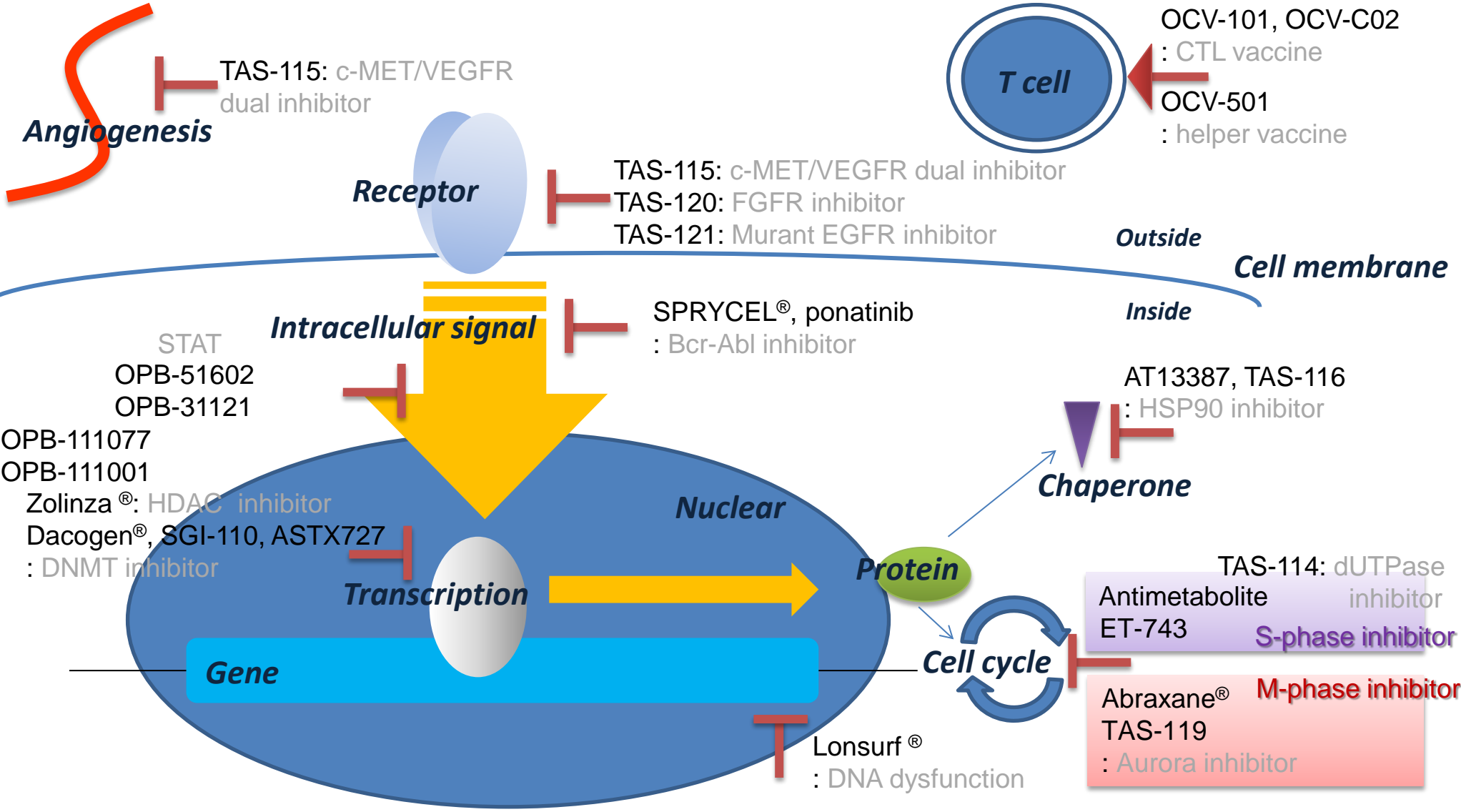
Development code	Country·Area	Indication
AVP-825	USA	Acute migraine

- Three projects in P-II

Development code	Country·Area	Indication
AVP-923	USA	Agitation in Alzheimer's disease
AVP-923	USA	Dyskinesia in Parkinson's disease
AVP-786	USA	MDD* (Adjunctive therapy)

*MDD: Major depressive disorder 17

3-1. Topics: Targeted cancer therapies



AT7519: CDK1/2/9 inhibitor

3-2. Comprehensive support for blood cancer

		AML* MDS*	CML*
Diagnostics		WT-1 mRNA assay kit II 'Otsuka'	Major BCR-ABL mRNA measurement kit 'Otsuka'
Treatment	Launched products	Dacogen®	SPRYCEL®
		Busulfex® (Pretreatment drug for allo-HSCT*)	
	Ongoing projects	SGI-110 ASTX727 OCV-501	Ponatinib
Supportive care		Aloxi®	

*AML : Acute myelocytic leukemia

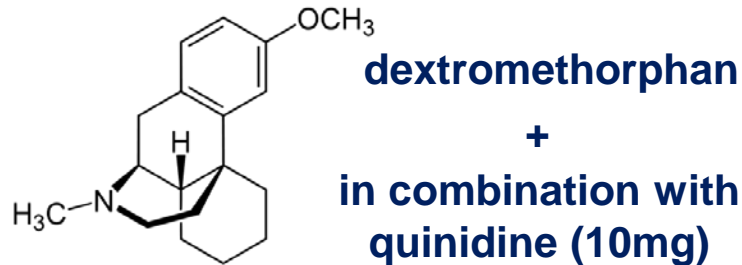
MDS : Myelodysplastic syndromes

CML : Chronic myeloid leukemia

Allo-HSCT: Allogeneic hematopoietic stem cell transplantation

3-3. Topics: Avanir pipeline

AVP-923



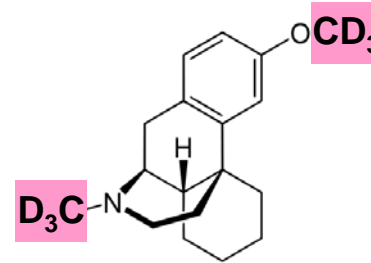
Launched: Pseudobulbar affect (PBA)
P-II: Agitation in Alzheimer's disease
P-II: Dyskinesia in Parkinson's disease

AVP-825

First and only breath-powered powder formulation of sumatriptan

NDA Filing: Acute migraine

AVP-786



deuterium-modified dextromethorphan (d-DM)
+
in combination with ultra-low dose quinidine (< 5mg)

Improved intravital stability by deuteration of dextromethorphan*

*Deuterium modification reduces susceptibility of DM to enzyme cleavage and first pass metabolism without altering its pharmacology

P-II: MDD (Adjunctive therapy)

4-1. R&D update in FY2014 (No. of projects)

	⇒P-I*	⇒P-II	⇒P-III	NDA Filings	Approvals
Total	5	3	5	8	6
CNS	0	0	1	3	2
Oncology	5	1	0	2	1
Cardiovascular	0	0	0	1	0
Others	0	2	4	2	3

***First patient-in
(P-I studies in healthy subjects are not included.)**

• Each development project is counted on the basis of the number of compounds and indications.

4-2. FY2015: Scheduled P-III & NDA submissions (Initial plan)

- Projects scheduled to proceed to P-III

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Nalmefene	Japan	Alcohol dependency
2	Oncology	SIG-110	US·EU	AML
3	Others	13C-CAC	Japan	Diagnostic kit for gastric acid-related diseases

- Projects scheduled to proceed to filing

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Aripiprazole	Japan	Autism
2		Brexipiprazole	Japan	Schizophrenia
3		Levetiracetam	Japan	Epilepsy (generalized seizures)
4	Oncology	TAS-102	EU	Colorectal cancer
5		ET-743	Japan	Malignant soft tissue sarcoma
6		Ponatinib	Japan	CML, ALL*
7	Others	Delamanid	USA	MDR-TB*
8		OPC-1085EL	Japan	Glaucoma
9		TAC-202	Japan	Allergic rhinitis, Urticaria
10		OPF-108	Japan	Total parenteral nutrition

*ALL: Acute lymphatic leukemia MDR-TB: Multidrug-resistant tuberculosis