
Financial Results Presentation

FY2014 Q1

(Three Months Ending June 30, 2014)

August 8, 2014

Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
- 4 Abilify Sales**
- 5 Nutraceutical Segment Analysis**
- 6 FY2014 Estimate**

1. Consolidated Financial Results (FY2014 Q1)

(100 million yen)

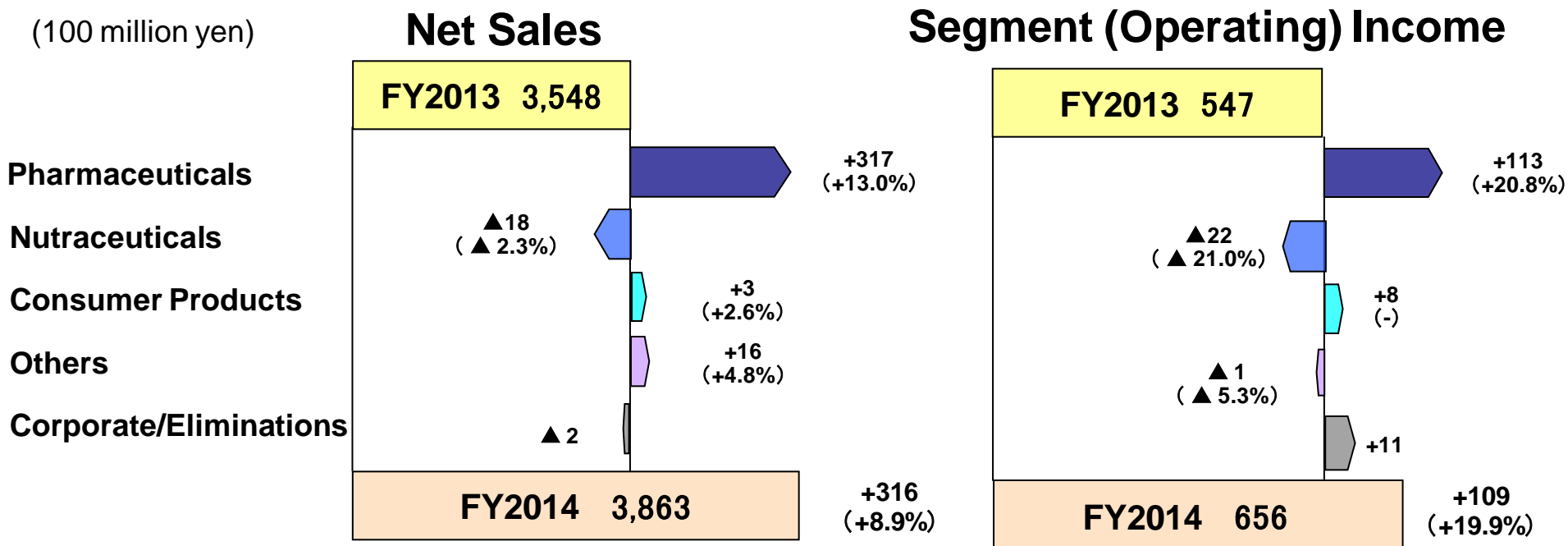
	FY2013 Q1 Actual	FY2014 Q1 Actual	Change	% Change
Net Sales	3,548	3,863	316	8.9%
Operating Income	547	656	109	19.9%
Ordinary Income	628	695	67	10.6%
Net Income	426	452	27	6.3%
R&D Expenses	510	501	▲ 9	▲ 1.7%

Impact of exchange rate fluctuations: approx. +8,000 million yen on net sales
approx. +2,000 million yen on operating income

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

2. Business Segment Analysis

(100 million yen)



*Parentheses represent % change

Net Sales	FY2013	FY2014	Change
Pharma	2,437	2,754	317
NC	789	771	▲18
Consumer	116	119	3
Others	324	340	16
Corp/Elim	▲117	▲120	▲2
Consolidated	3,548	3,863	316

Op income	FY2013	FY2014	Change
Pharma	544	657	113
NC	107	85	▲22
Consumer	▲7	1	8
Others	21	20	▲1
Corp/Elim	▲117	▲106	11
Consolidated	547	656	109

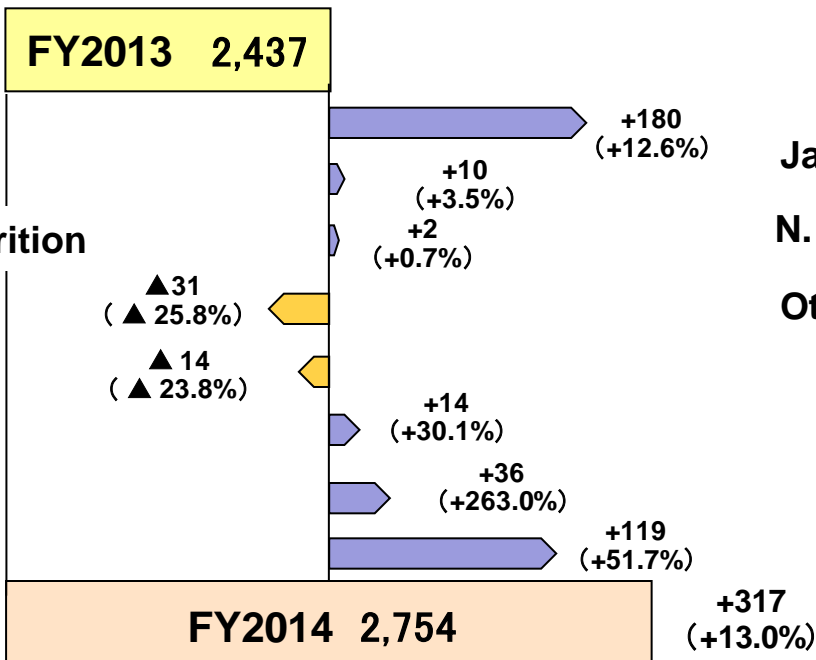
< Operating margin (%) >

FY2013	FY2014
22.3%	23.8%
13.6%	11.0%
▲6.2%	0.9%
6.4%	5.8%
15.4%	17.0%

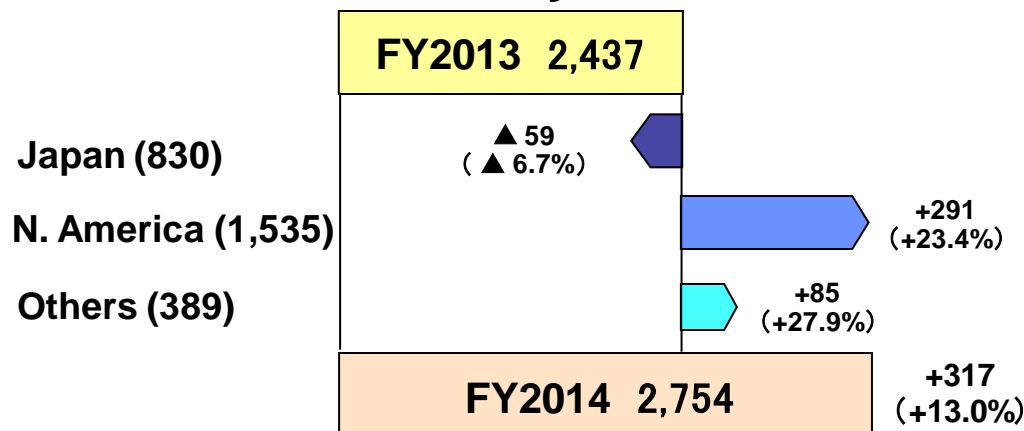
(Note) FY2013 shows the consolidated results from April to June including overseas companies (unaudited)

3. Pharmaceutical Segment Analysis

(100 million yen) Net Sales

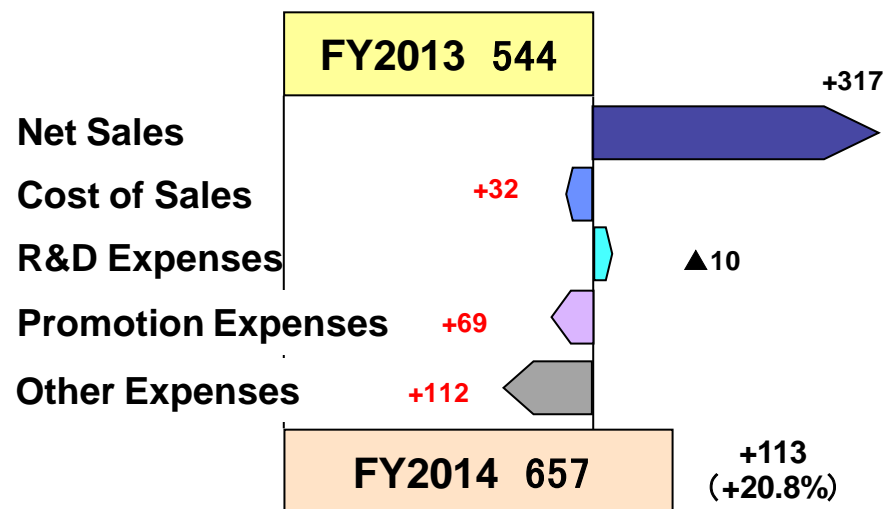


Net Sales by Market



Products	FY2013 Q1	FY2014 Q1	Change	% Change
Abilify	1,426	1,607	180	12.6%
Oncology	291	301	10	3.5%
Clinical Nutrition	251	252	2	0.7%
Pletaal	120	89	▲ 31	▲25.8%
Mucosta	57	43	▲ 14	▲23.8%
Samsca	48	62	14	30.1%
Milestone	14	50	36	263.0%
Others	231	350	119	51.7%
Pharma Total	2,437	2,754	317	13.0%

Segment (Operating) Income



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

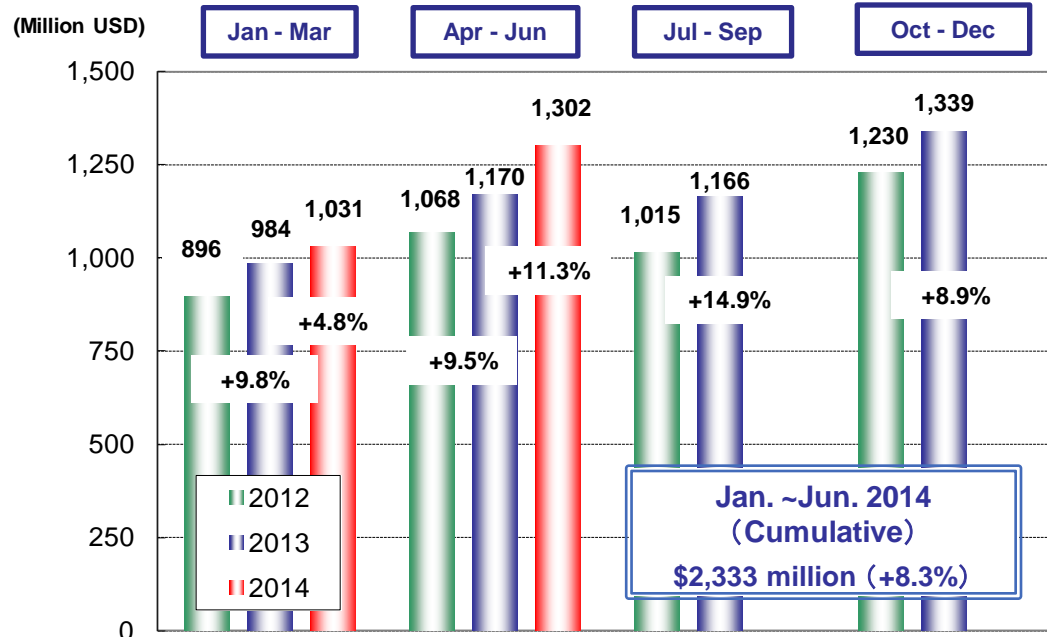
4. Abilify Sales

Abilify Sales by Market

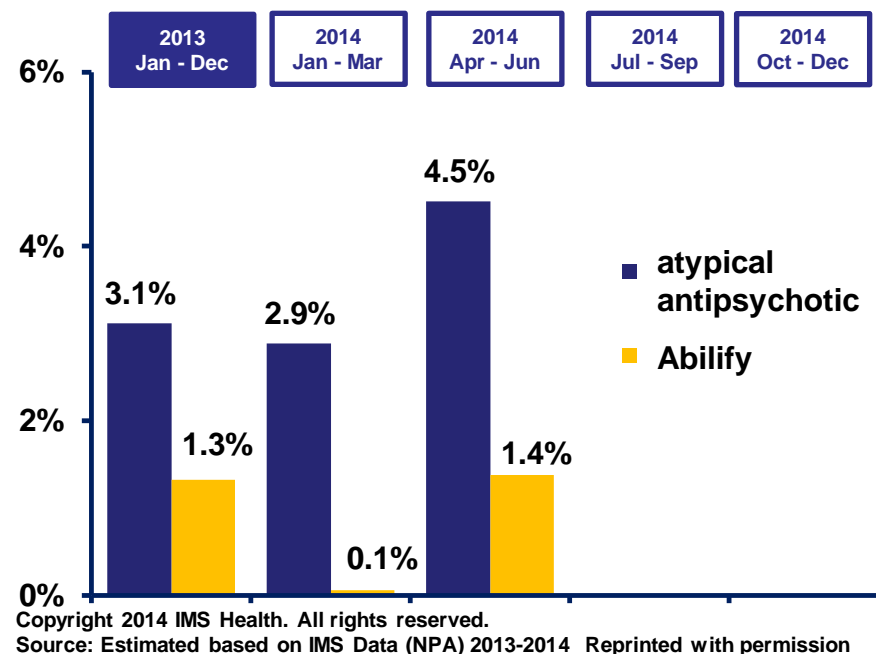
(100 million yen)

	FY2013 Q1	FY2014 Q1	Change	% Change
Abilify	1,426	1,607	180	12.6%
US*	1,157	1,331	175	15.1%
<Million USD>	<1,170>	<1,302>	<132>	11.3%
Japan	78	61	▲17	▲21.8%
Other*	191	214	23	11.8%

Abilify Sales – Quarterly Evolution (US market)



Atypical antipsychotic prescription market (US market)

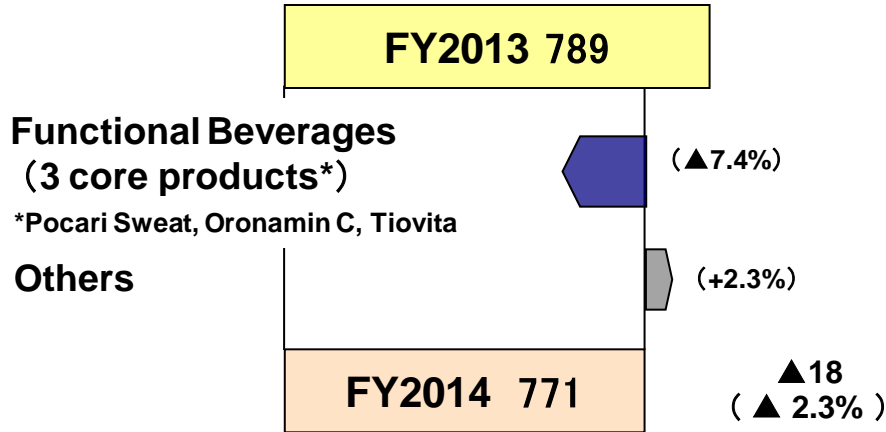


(Note) FY2013 shows the consolidated results from April to June including overseas companies (unaudited)

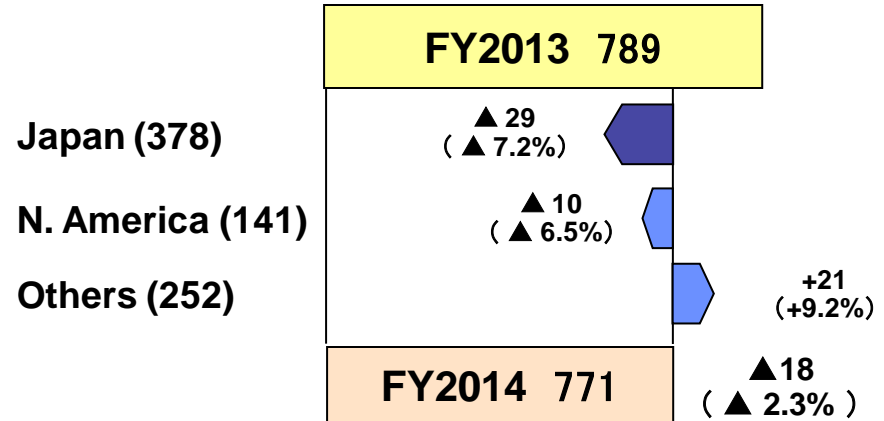
5. Nutraceutical Segment Analysis

(100 million yen)

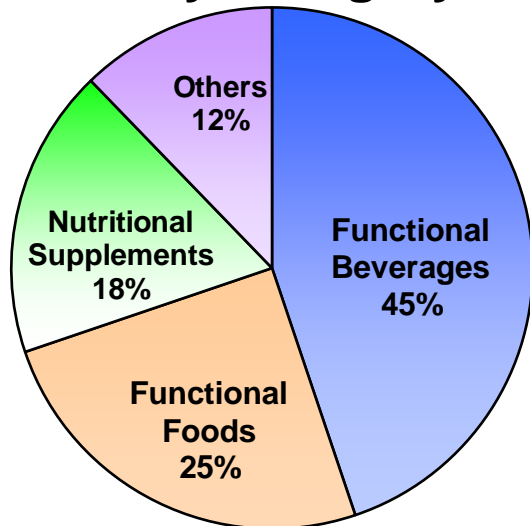
Net Sales



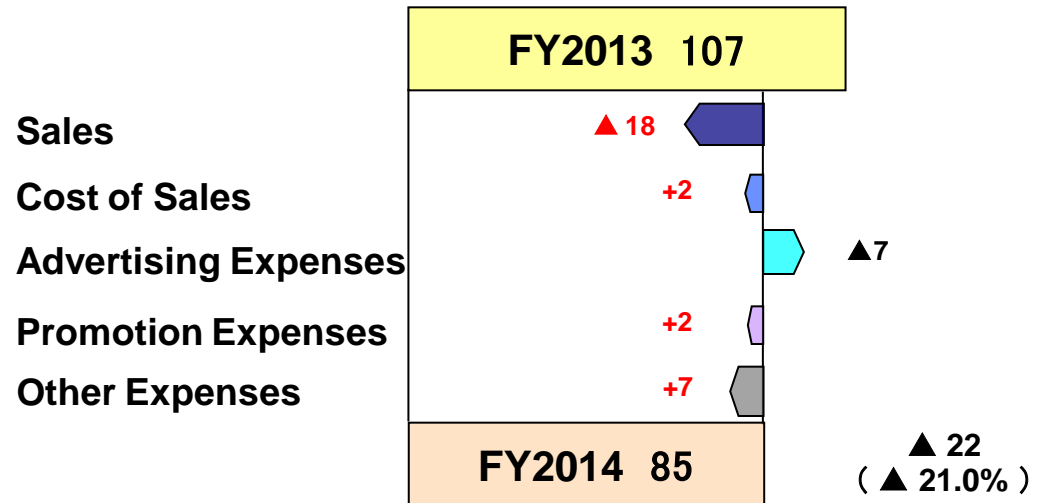
Net Sales by Market



Sales by Category



Segment (Operating) Income



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

6. FY2014 Estimate

(100 million yen)

	FY2013 Q1 Actual	FY2014 Q1 Actual	Change	% Change	2014 Estimate	% Achievement
Net Sales	3,548	3,863	316	8.9%	12,000	32.2%
Operating Income	547	656	109	19.9%	1,900	34.5%
Ordinary Income	628	695	67	10.6%	1,950	35.6%
Net Income	426	452	27	6.3%	1,300	34.8%
R&D Expenses	510	501	▲ 9	▲ 1.7%	1,800	27.9%

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

Pharmaceutical Development Update

August 8, 2014

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 1Q/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 June 30, 2014)



Phase	P-1	P-2	P-3	NDA	
CNS		Brexiprazole ADHD/US	Maintena™ Bipolar/JP,US,EU ABILIFY® Autism/JP ABILIFY® AD agitation/JP Brexiprazole MDD(Adjunctive)/US,EU Brexiprazole Schiz./JP,US,EU Brexiprazole AD agitaion/US,EU Brexiprazole PTSD/US,EU ASC-01 MDD/JP,Asia Lu AE58054 Alzheimer's disease/US,EU E Keppra® Epilepsy (Generalized seizures)/JP	Maintena™ Schiz./JP ABILIFY® Tourette's/US E Keppra® Partial seizures (injection)/JP E Keppra® Partial seizures/Monotherapy(Oral)/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 4Q

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



Phase	P-1	P-2	P-3	NDA
Oncology	TAS-114 Solid cancer/JP,US,EU	TS-1 Renal/JP	TS-1 Gastric/US	Abraxane® Pancreatic/JP
	TAS-115 Solid cancer/JP	TAS-102 SCLC/JP, EU	TS-1 Uterocervical/JP,Asia	
	TAS-116 Solid cancer/JP	SPRYCEL® Pancreatic/US,EU	TS-1 HCC/JP	
	OPB-31121 Anti-cancer/JP,Asia	ET-743 STS/JP	TSU-68 HCC/JP,Asia	
	OPB-51602 Anti-cancer/US,JP,Asia	OCV-101 Pancreatic/JP	TAS-102 Colorectal/JP,US,EU,Asia	
	OPB-111001 Solid cancer/EU	OCV-501 AML/JP,Asia	TAS-118 Pancreatic/JP,Asia	
	OPB-111077 Solid cancer/US,Asia	SGI-110 HCC/US,EU	SATIVEX® Cancer pain/US	
	OCV-C02 Colorectal/JP	SGI-110 Ovarian/US,EU		
		SGI-110 MDS,AML/US		
		AT13387 Prostate/US,EU		
		AT13387 NSCLC/US,EU		
		AT7519 MM/US		
		Rebamipide Oral mucositis/Liquid/JP		
	Others/ Diagnostics		OPC-6535 COPD/JP,US,Asia	ZOSYN®(YP-18) Febrile neutropenia/JP
		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 TB/US	OPB-2045G Disinfectant/JP
		C13-URA Gastric emptying determination /US	OPC-1085EL Glaucoma/JP	
		OPA-15406 Atopic dermatitis/US	OPF-105 Peripheral parenteral nutrition infusions/JP	
		OPA-6566 Glaucoma/US	ACU-4429 AMD/US	
			TAS-202 Urticaria/JP	

Blue columns indicate changes from 4Q

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

- **Three products launched**

Product name	Country·Area	
Lonsurf® combination tablet T15, T20	Japan	Launched on May 26
Samsca 30mg tablet	Japan	Launched on May 29
RACOL-NF semisolid nutrient	Japan	Launched on June 2

☆ Meptin® Swinghaler® 10µg 100Puffs: Launched in Japan on July 2

- **Two projects approved**

Product name / Generic name	Country·Area	Indication
Deltyba™ (Delamanid)	Europe	MDR-TB*
L-Cartin® FF tablet	Japan	Carnitine deficiency

☆ Deltyba®: JP marketing approval on July 4

☆ E Keppra® for IV Drip Infusion 500 mg: JP marketing approval on July 4

*MDR-TB: Multidrug-resistant tuberculosis

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

- **Three applications submitted for approval**

Generic name / Development code	Country·Area	Indication
ABI-007	Japan	Pancreatic cancer
Tolvaptan	Asia	Cardiac edema
OPB-2045G	Japan	Disinfectant

☆ **Brexpiprazole: US filing for the treatment of schizophrenia and MDD* in July**

☆ **ZOSYN® (YP-18): JP filing for the treatment of febrile neutropenia in July**

☆ **Levetiracetam injection: JP filing for the treatment of partial seizures (monotherapy) in July**

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

Generic name / Development code	Country·Area	Indication
Aripiprazole	Japan	Agitation associated with dementia of the Alzheimer's type
OPC-1085EL	Japan	Glaucoma

★ **Tolvaptan: P-III clinical trial in patients with ADPKD* started in the U.S.**

*MDD: Major depressive disorder

*ADPKD: Autosomal dominant polycystic kidney disease

2-3. Key development progress in 1Q/2014 (as of June 30, 2014)

- One project advanced to P-II/III

Generic name / Development code	Country·Area	Indication
Bilastine (TAC-202)	Japan	Chronic idiopathic urticaria, eczema/dermatitis, prurigo and cutaneous pruritus

- Two projects advanced to P-II

Generic name / Development code	Country·Area	Indication
Rebamipide liquid	Japan	Chemoradiotherapy-induced oral mucositis
OPA-15406	USA	Atopic dermatitis

- One project advanced to P-I

Generic name / Development code	Country·Area	Indication
TAS-116	Japan	Solid cancer

3-1. Topics

<Cancer>

- **Results of P-III clinical trial (SELECT BC) of TS-1 in patients with metastatic breast cancer announced at ASCO[®] in Chicago, US [5/30-6/3]** *ASCO: American Society of Clinical Oncology
<http://www.taiho.co.jp/english/news/20140603.html>
- **Results of P-II clinical trial of ET-743 (trabectedin) in patients with malignant soft tissue sarcoma presented at ASCO[®] [5/30-6/3]- ET-743 achieved statistically significant improvements in progression-free survival**
<http://www.taiho.co.jp/english/news/20140604.html>
- **Results of TAS-102 global P-III RECURSE trial for refractory metastatic colorectal cancer presented at ESMO 16th world congress on gastrointestinal cancer in Barcelona, Spain [6/25-6/28] - TAS-102 demonstrated statistically significant improvement in overall survival** *ESMO: the European Society for Medical Oncology
<http://www.taiho.co.jp/english/news/20140630.html>
- **P-III clinical trial of S-1 in patients with advanced HCC* did not meet its primary endpoint [7/25]**
<http://www.taiho.co.jp/english/news/20140725.html>
- **Termination of P-III clinical trial of angiogenesis inhibitor TSU-68 (orantinib) in patients with HCC* [7/31]**
<http://www.taiho.co.jp/english/news/20140731.html>

*HCC: Hepatocellular carcinoma

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

Generic name/ Development code	Mechanism of action	Ongoing clinical trials	Description
OPB-2045G	Disinfectant	Filed (JP)	Broad-spectrum disinfectant. OPB-2045G demonstrates bactericidal activities against species (ex. MRSA and VRE, etc.) which are resistant to existing disinfectants.
OPC-1085EL	Inhibition of aqueous humor production(β blocker) and enhancement of aqueous humor drainage(PGF 2α)	P-III ■Glaucoma (JP)	Combination drug composed of β blocker, carteolol and prostaglandin F 2α derivative, latanoprost.
OPA-15406	PDE4* inhibitor	P-II ■Atopic dermatitis (US)	OPA-15406 has anti-inflammatory effects. As a PDE4 inhibitor, it blocks hydrolysis of cAMP, thereby increasing levels of intracellular cAMP and inhibiting the production of cytokine and chemical mediators.
Rebamipide liquid	Mucosal protection Free radical scavenger	P-II ■Chemoradiotherapy-induced oral mucositis (JP)	Rebamipide liquid is expected to shorten duration and decrease incidence of severe chemoradiotherapy-induced oral mucositis in patients with head and neck cancer.
TAS-116	HSP90* inhibitor	P-I ■Solid cancer (JP)	A new class of orally available HSP90 selective inhibitor. TAS 116 inhibits HSP90 which stabilizes various oncogenic kinases, which are essential for tumor growth and survival. Its distinctive biodistribution reduces risk of visual disorder.

*PDE: Phosphodiesterase HSP: Heat shock protein cAMP: Cyclic adenosine monophosphate

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, P-III), TAC-202 Chronic urticaria (JP, P-II/III)

● Projects scheduled to proceed to filing

NDA filing as scheduled

No.	Areas	Generic name / Development code	Country - Area	Indication
1	CNS	Brexipiprazole	USA	Schizophrenia
2		Brexipiprazole	USA	MDD (Adjunctive therapy)
3	Oncology	TS-1	Japan	HCC
4		ABI-007	Japan	Pancreatic cancer
5		TAS-102	USA	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)