
Financial Results Presentation

FY2013 Q1

(Three Months Ending June 30, 2013)

August 8, 2013

Otsuka Holdings Co., Ltd.

- This material contains forward-looking statements regarding the financial conditions, results of operations and business activities of Otsuka and its subsidiaries (collectively the “Otsuka Group”). All forward-looking statements, due to their inherent nature, will be influenced by future events and developments for which the occurrence is uncertain, and therefore involve risks and uncertainties. Otsuka cautions you in advance that actual financial conditions, results of operations and business activities could differ materially from those discussed in the forward-looking statements.
- Otsuka disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, further events, or otherwise.
- Further, this material contains statements and information regarding corporate entities other than those belonging to the Otsuka Group, which have been compiled from various publically-available sources. Otsuka has not verified any of such statements or information and does not provide any guarantees with regard to their accuracy and relevance.
- The IMS Health, Euromonitor and other reports described herein (the “Reports”) represent data, research opinions or viewpoints published as part of a syndicated subscription service and are not representations of fact. The Reports speak as of their original publication dates (and not as of the date of this material), and the opinions expressed in the Reports are subject to change without notice.
- This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.

- 1 Consolidated Financial Results**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
- 4 Abilify Sales**
- 5 Nutraceutical Segment Analysis**
- 6 FY2013 Estimate**

1. Consolidated Financial Results (FY2013 Q1)

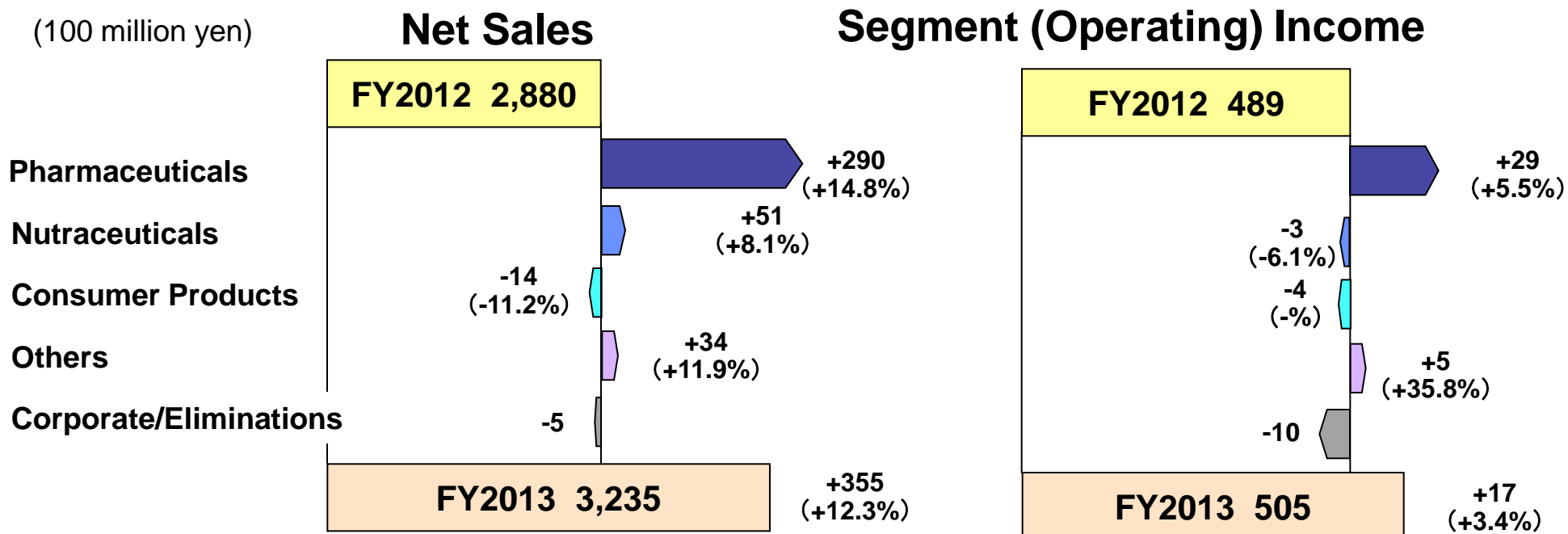
(100 million yen)

	FY2012 Q1 Actual	FY2013 Q1 Actual	Change	% Change
Net Sales	2,880	3,235	355	12.3%
Operating Income	489	505	17	3.4%
Ordinary Income	487	568	81	16.6%
Net Income	319	397	78	24.4%
R&D Expenses	364	515	150	41.3%

Impact of exchange rate fluctuations: approx. +210 on net sales
approx. +10 on operating income

2. Business Segment Analysis (FY2013 Q1)

(100 million yen)



*Parentheses represent % increase

Net Sales	FY2012	FY2013	Change
Pharma	1,952	2,241	290
NC	632	683	51
Consumer	125	111	-14
Others	283	317	34
Corp/Elim	-112	-117	-5
Consolidated	2,880	3,235	355

Op income	FY2012	FY2013	Change
Pharma	530	559	29
NC	55	51	-3
Consumer	-3	-7	-4
Others	14	19	5
Corp/Elim	-107	-117	-10
Consolidated	489	505	17

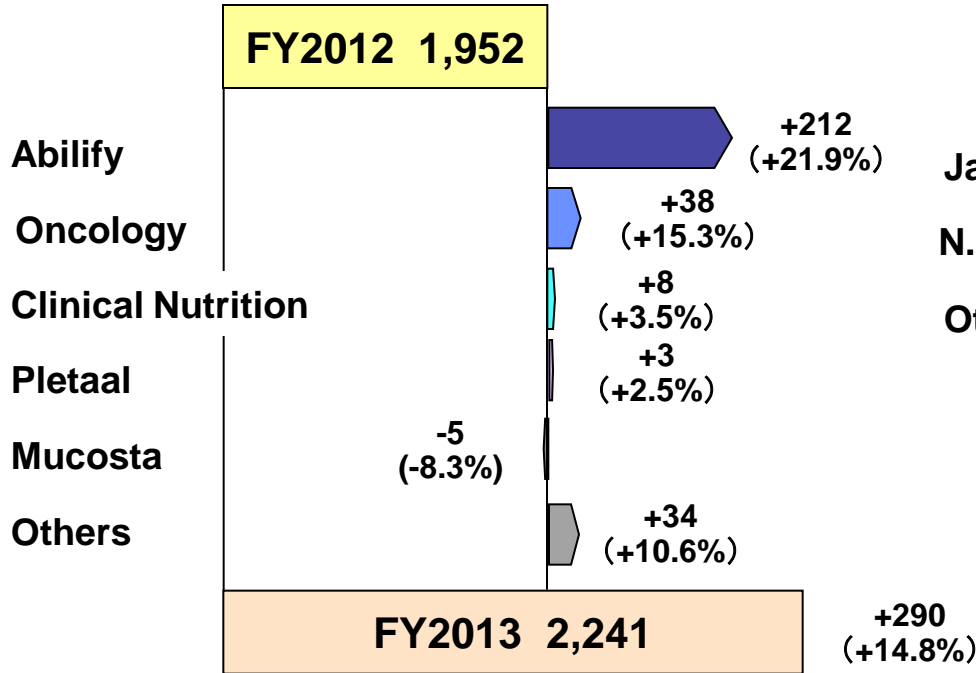
< Operating margin (%) >

FY2012	FY2013
27.2%	25.0%
8.6%	7.5%
-2.4%	-6.2%
4.9%	6.0%
-	-
17.0%	15.6%

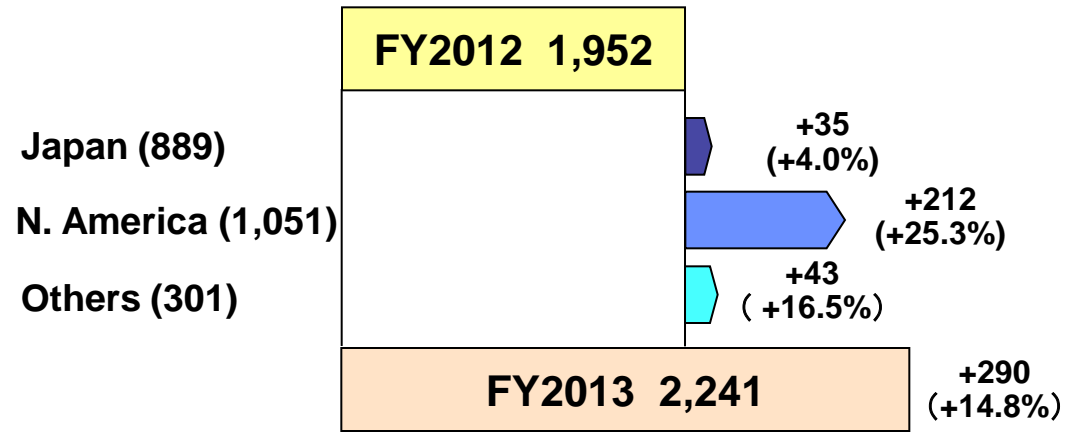
3. Pharmaceutical Segment Analysis (FY2013 Q1)



(100 million yen) **Net Sales**

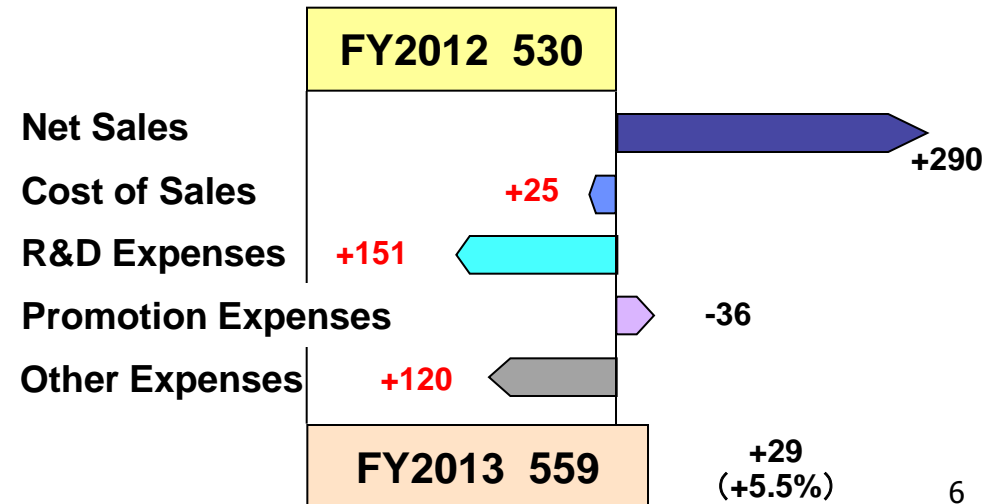


Net Sales by Market



Products	FY2012 Q1	FY2013 Q1	Change	% Change
Abilify	966	1,178	212	21.9%
Oncology	246	284	38	15.3%
Clinical Nutrition	236	245	8	3.5%
Pletaal	117	120	3	2.5%
Mucosta	62	57	-5	-8.3%
Others	324	358	34	10.6%
Pharma Total	1,952	2,241	290	14.8%

Segment (Operating) Income



4. Abilify Sales (FY2013 Q1)

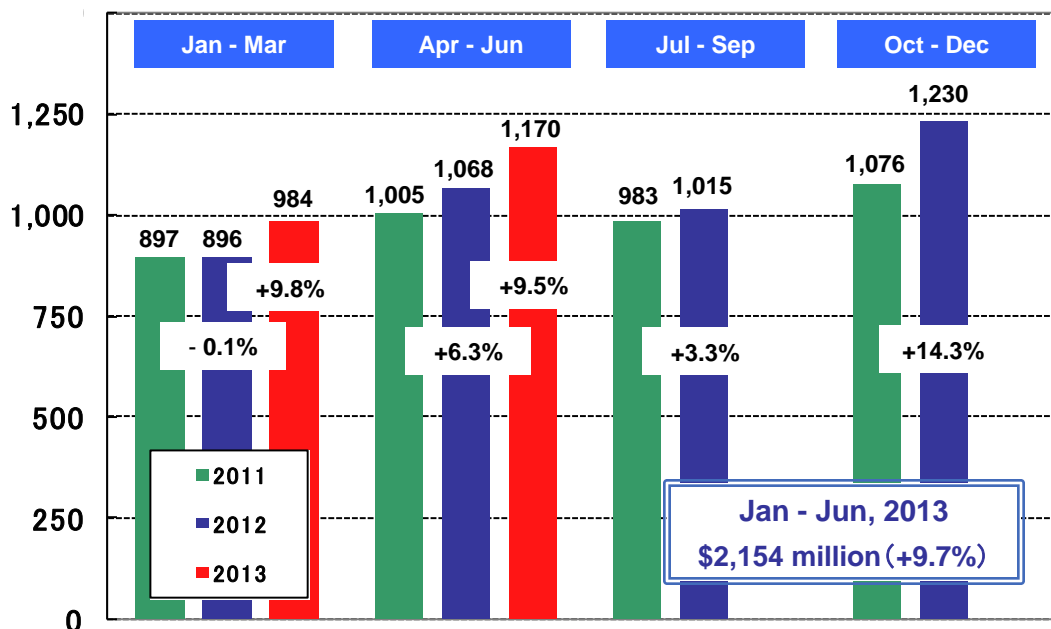
Abilify Sales by Market

(100 million yen)

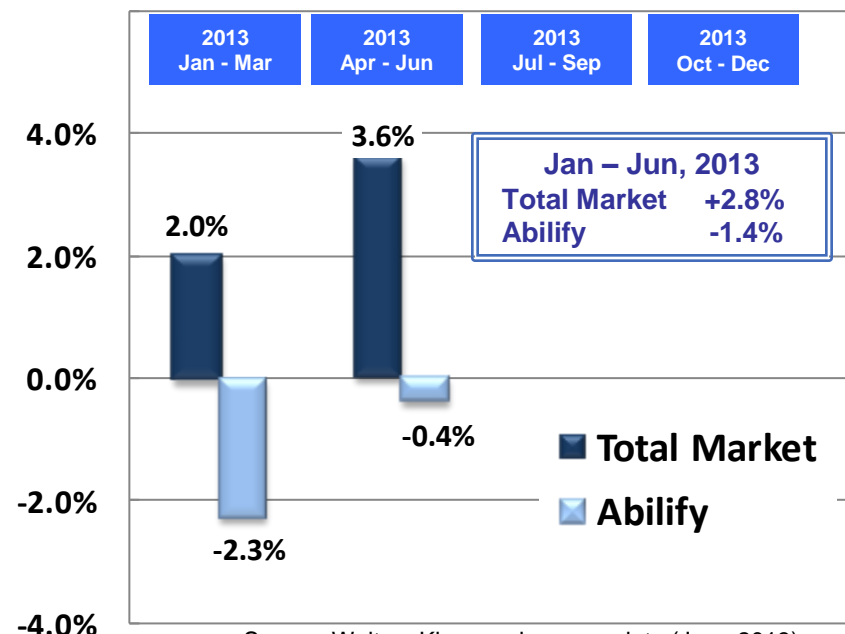
	FY2012 Q1	FY2013 Q1	Change	% Change
Abilify	966	1,178	212	21.9%
US	711	910	199	28.0%
<Million USD>	<896>	<984>	<88>	9.8%
Japan	75	78	3	4.1%
Other	180	189	9	5.2%

Abilify Sales – Quarterly Evolution (US market)

(Million USD)



Atypical antipsychotic prescription market (US market)

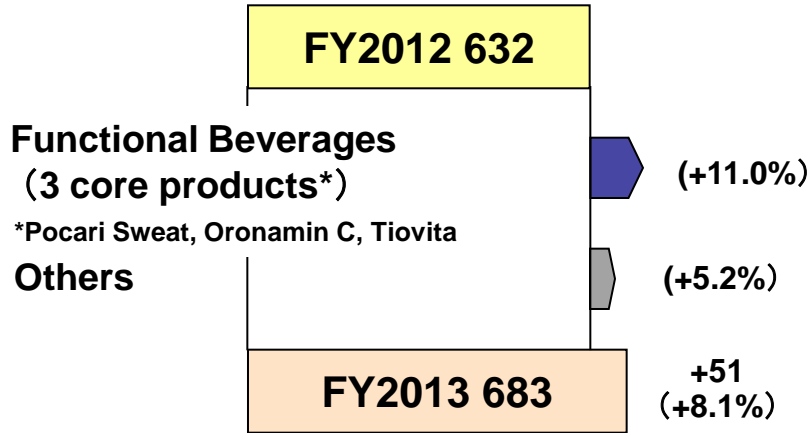


Source: Wolters Kluwer, pharmacy data (June 2013)

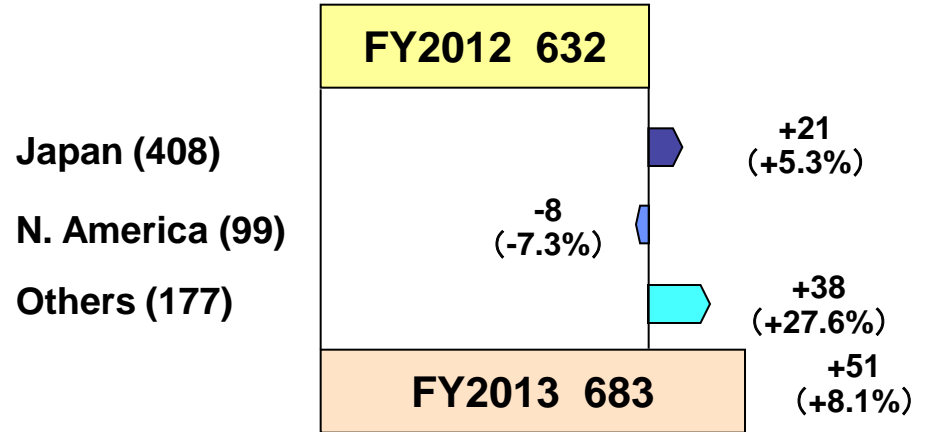
5. Nutraceutical Segment Analysis (FY2013 Q1)

(100 million yen)

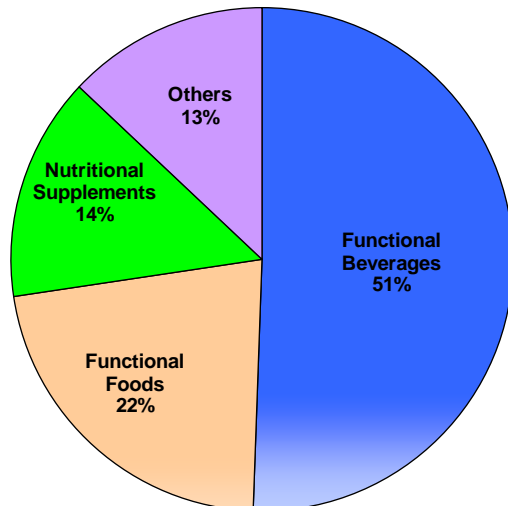
Net Sales



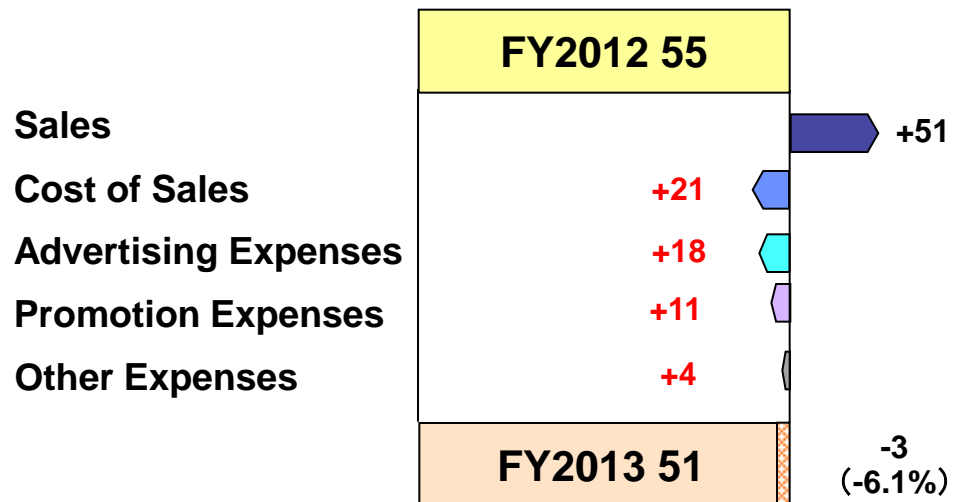
Net Sales by Market



Sales by Category



Segment (Operating) Income



6. FY2013 Estimate

(100 million yen)

	FY2012 Q1 Actual	FY2013 Q1 Actual	Change	% Change	2013 Estimate	% Achievement
Net Sales	2,880	3,235	355	12.3%	13,700	23.6%
Operating Income	489	505	17	3.4%	2,050	24.7%
Ordinary Income	487	568	81	16.6%	2,100	27.1%
Net Income	319	397	78	24.4%	1,380	28.8%
R&D Expenses	364	515	150	41.3%	2,000	25.7%

Pharmaceutical Development Update

August 8, 2013

Otsuka Holdings Co., Ltd.

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

1. Major development projects (as of Jun. 30, 2013)



Phase	P-1	P-2	P-3	NDA	
CNS		Brexpiprazole ADHD/US	Maintena™ Schiz./JP Maintena™ Bipolar/US 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	Maintena™ Schiz./EU ABILIFY® MDD(Adjuvant)/JP E Keppra® Partial seizures in children/JP E Keppra® Partial seizures (injection)/JP	* Approved * Approved
Oncology	TAS-114 Solid cancer /JP,US,EU TAS-115 Solid cancer /JP OPB-31121 Anti-cancer/JP,Asia OPB-51602 Anti-cancer/US,JP,Asia OPB-111077 Solid cancer /US, Asia OCV-501 AML/JP OCV-C02 Colorectal/JP	TS-1 Renal/JP SPRYCEL® Pancreatic/US,EU ET-743 STS/JP OTS-102 Biliary/JP OCV-101 Pancreatic/JP Abraxane® Pancreatic/JP TAS-106 Solid cancer/US	TS-1 Gastric/US TS-1 Uterocervical/JP,Asia TS-1 HCC/JP TSU-68 HCC/JP,Asia TAS-102 Colorectal/JP,US,EU SATIVEX® Cancer pain/US	TAS-102 Colorectal/JP OVF Cancer pain/JP	* Approved
Cardiovascular	OPC-108459 AF/JP,US	Samsca® Cancerous edema /JP Samsca®	Samsca® Cardiac edema /Asia Samsca® ADPKD/EU	Samsca® Hepatic edema/JP,Asia Samsca® ADPKD/JP,US	
Others/ Diagnostics	OPA-15406 Atopic dermatitis/US	Mucosta® Keratoconjunctival epithelial disorder/JP OPC-6535 COPD/JP,US,Asia OPA-6566 Glaucoma/US	ZOSYN®(YP-18) Febrile neutropenia /JP Mucosta® Dry eye/US Mucosta® Dry eye/JP Delamanid Tuberculosis/JP,US,EU OPB-2045G Disinfectant/JP ACU-4429 AMD/US	ODK-1003 WT-1 mRNA assay kit II/JP Delamanid Tuberculosis /JP,EU Saxagliptin Diabetes/JP	* Approved * Approved

Blue columns indicate changes from 4Q

2-1. Key development progress in 1Q/2013 (as of Jun. 30, 2013)

- Three products launched

Product name	Country · Area	Details
H. influenzae ELISA kit 'Otsuka'	Japan	Launched on Apr. 24
Samsca® 7.5mg tablets	Japan	Launched on Jun. 4
TS-1® combination OD tablets T20, T25	Japan	Launched on Jun. 27

- Four projects approved

Product name	Country · Area	Indication
ABILIFY®	Japan	MDD* (Adjunctive therapy)
E Keppra®	Japan	Partial seizures in children
E-fen	Japan	Cancer pain
WT-1 mRNA assay kit II 'Otsuka'	Japan	Diagnostic kit for AML* · MDS*

E-fen: Development code 'OVF'

*MDD: Major depressive disorder

AML: Acute myeloid leukemia

MDS: Myelodysplastic syndromes ¹³

2-2. Key development progress in 1Q/2013 (as of June 30, 2013)

- **Two projects submitted for approval**

Generic name	Country·Area	Indication
Levetiracetam injection	Japan	Partial seizures
Tolvaptan	Japan	ADPKD*

*ADPKD: Autosomal dominant polycystic kidney disease

- **One project advanced to Phase I**

Development code	Country·Area	Indication
OPB-111077	Asia	Solid cancer

3. Topics

<CNS>

- “ABILIFY MAINTENA™” Effects of treatment on psychiatric hospitalization rates for patients with schizophrenia presented at the American Psychiatric Association Annual Meeting, held in San Francisco, California (May 18-22)
http://www.otsuka.co.jp/en/company/release/2013/0522_01.html

<Cancer>

- Results of the P-III clinical study (GEST) of TS-1 in patients with advanced pancreatic cancer published in the online version of the Journal of Clinical Oncology (April 3)
<http://www.taiho.co.jp/english/news/20130403.html> *GEST: Gemcitabine and TS-1 Trial
- Results of P-III trials of TS-1 in patients with colorectal cancer and head and neck cancers announced at ASCO®, held in Chicago, Illinois (May 31-June 4)
<http://www.taiho.co.jp/english/news/20130606.html> *ASCO®: The American Society of Clinical Oncology®

<Others>

- Phase-IIa clinical results of emixustat hydrochloride (ACU-4429) in patients with geographic atrophy (GA) associated with dry age-related macular degeneration (AMD) presented at ARVO 2013 Annual Meeting, held in Seattle, Washington (May 5-9)
http://www.otsuka.co.jp/en/company/release/2013/0509_01.html
*ARVO: The Association for Research in Vision and Ophthalmology

News release on July 26

- Received opinion from the CHMP of the EMA on approval of delamanid for the treatment of pulmonary multidrug-resistant tuberculosis (MDR-TB)
http://www.otsuka.co.jp/en/company/release/2013/0726_01.html
*CHMP: The Committee for Medicinal Products for Human Use
*EMA: The European Medicines Agency

New release on August 6

- The U.S. FDA's cardiovascular and renal drugs advisory committee voted against approval of tolvaptan for the treatment of ADPKD.
http://www.otsuka.co.jp/en/company/release/2013/0806_02.html
*FDA: Food and Drug Administration

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

- Three projects are scheduled to proceed to Phase III

NDA filing as scheduled

No.	Areas	Generic name	Country·Area	Indication
1	CNS	Aripiprazole IM Depot	Japan	Bipolar disorder
2		Brexpiprazole	USA	New indication
3	Others	Rebamipide ophthalmic suspension unit dose	Japan	Keratoconjunctival epithelial disorder

- Scheduled NDA submissions: One project in cardiovascular proceeded to filing

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

*CML: Chronic myeloid leukemia