Financial Results Presentation
FY2013 Q2
(Six Months Ending September 30, 2013)

November 13, 2013

Otsuka Holdings Co., Ltd.

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Topics

1. Consolidated Financial Results
2. Business Segment Analysis
3. Pharmaceutical Segment Analysis
4. Abilify Sales

【Supplemental】
- Growing Sales of New Products

5. Nutraceutical Segment Analysis
6. FY2013 Estimate

1. Consolidated Financial Results（FY2013 Q2）

(100 million yen)

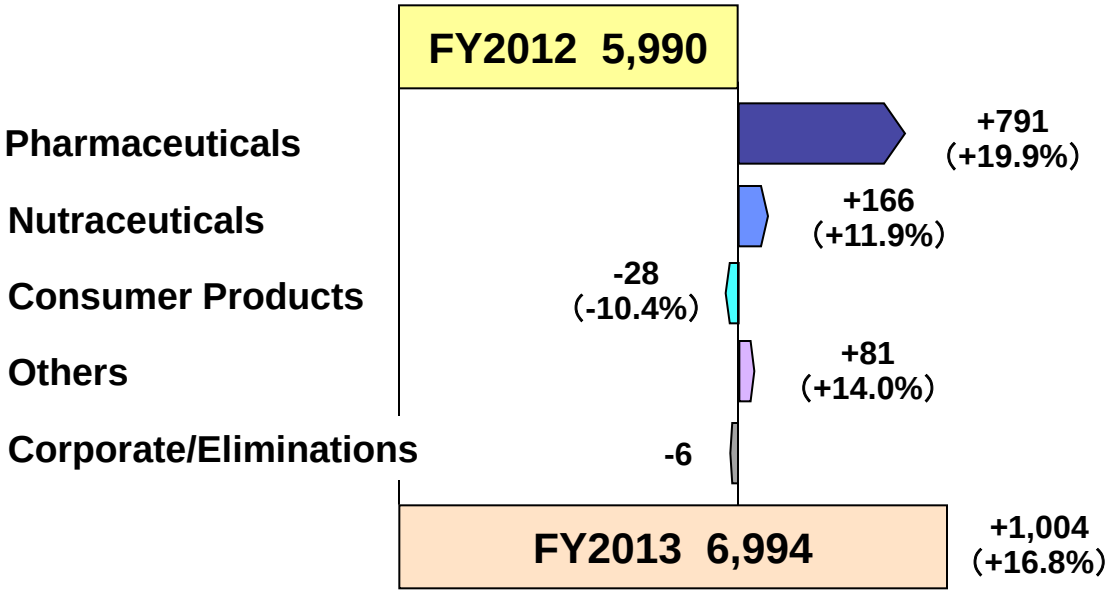
	FY2012 Q2 Actual	FY2013 Q2 Actual	Change	% Change
Net Sales	5,990	6,994	1,004	16.8%
Operating Income	934	1,117	183	19.6%
Ordinary Income	955	1,220	265	27.7%
Net Income	627	870	244	38.9%
R&D Expenses	743	1,053	310	41.7%

Impact of exchange rate fluctuations: approx. +600 on net sales
approx. +80 on operating income

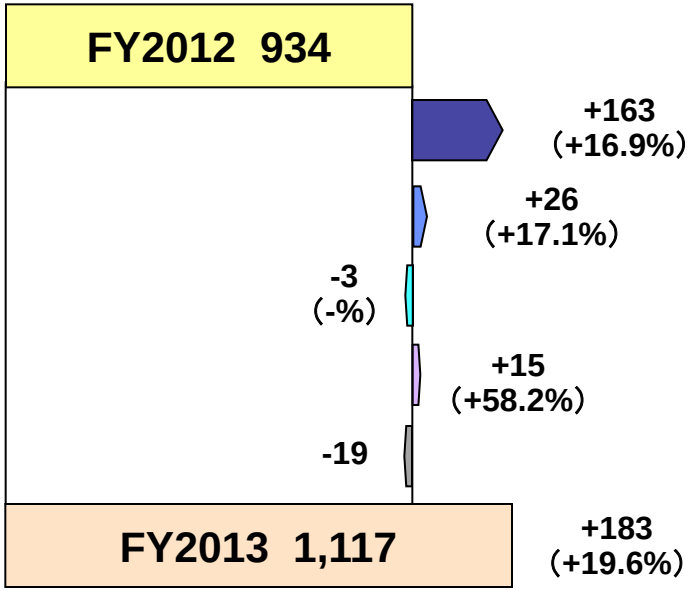
2. Business Segment Analysis（FY2013 Q2）

(100 million yen)

Net Sales



Segment (Operating) Income



*Parentheses represent % increase

Net Sales	FY2012	FY2013	Change
Pharma	3,981	4,771	791
NC	1,392	1,558	166
Consumer	268	240	-28
Others	579	661	81
Corp/Elim	-231	-237	-6
Consolidated	5,990	6,994	1,004

Op income	FY2012	FY2013	Change
Pharma	969	1,132	163
NC	152	178	26
Consumer	-6	-10	-3
Others	26	41	15
Corp/Elim	-206	-225	-19
Consolidated	934	1,117	183

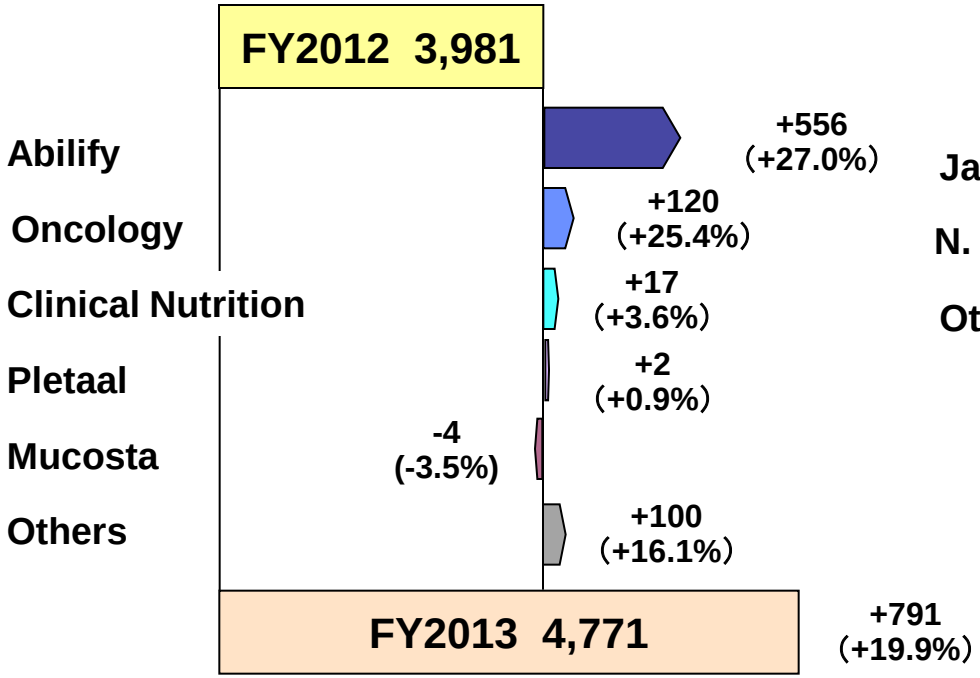
＜Operating margin (%)＞

FY2012	FY2013
24.3%	23.7%
10.9%	11.4%
-2.4%	-4.0%
4.5%	6.3%
-	-
15.6%	16.0%

3. Pharmaceutical Segment Analysis（FY2013 Q2）

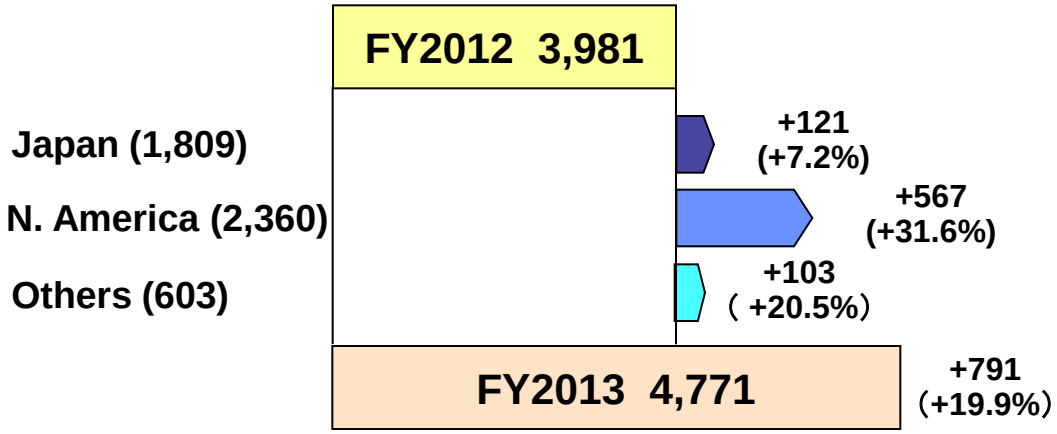
Net Sales

(100 million yen)

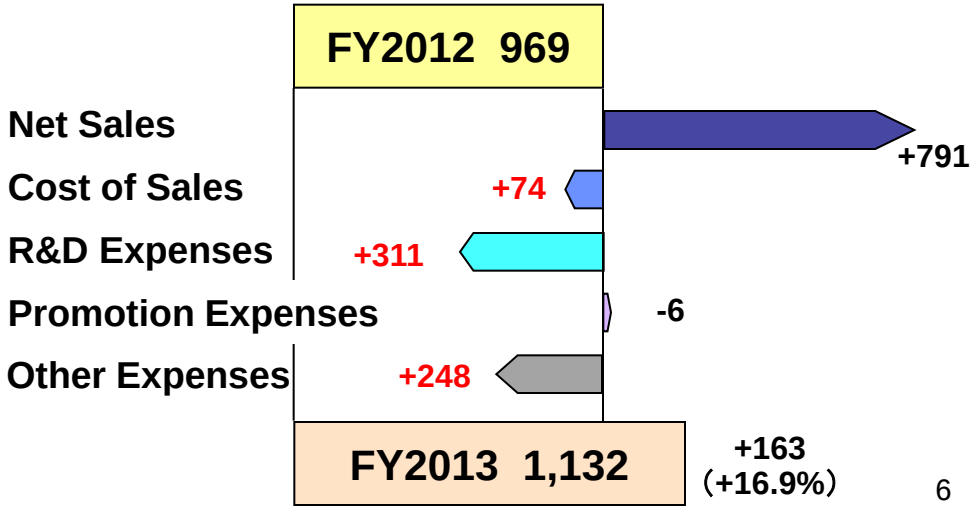


Products	FY2012 Q2	FY2013 Q2	Change	% Change
Abilify	2,054	2,610	556	27.0%
Oncology	472	592	120	25.4%
Clinical Nutrition	487	505	17	3.6%
Pletaal	231	233	2	0.9%
Mucosta	117	113	-4	-3.5%
Others	620	720	100	16.1%
Pharma Total	3,981	4,771	791	19.9%

Net Sales by Market



Segment (Operating) Income



4. Abilify Sales（FY2013 Q2）

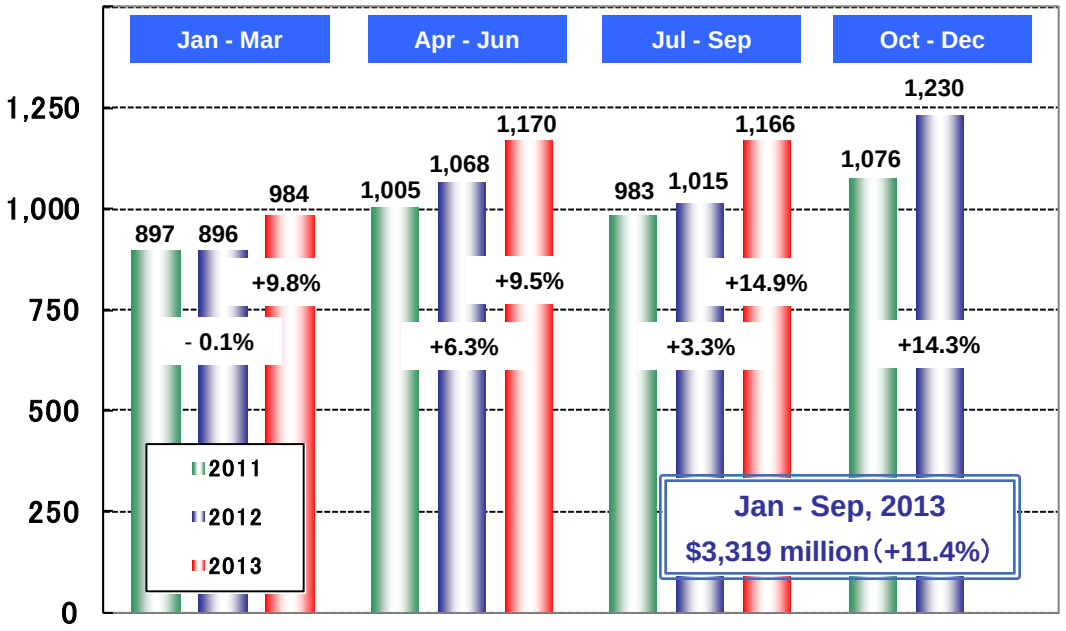
Abilify Sales by Market

(100 million yen)

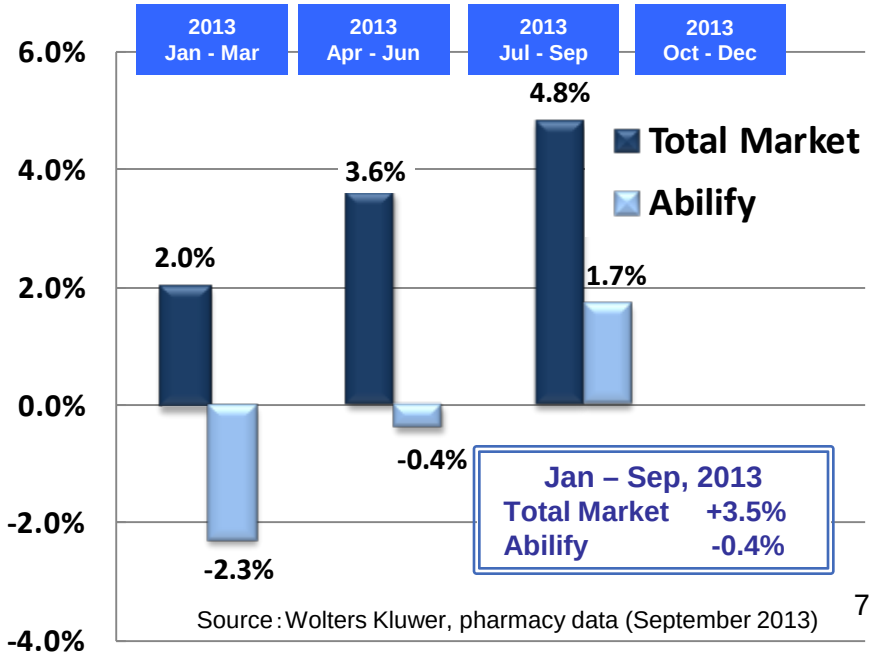
	FY2012 Q2	FY2013 Q2	Change	% Change
Abilify	2,054	2,610	556	27.0%
US*	1,568	2,063	495	31.6%
<Million USD>	<1,964>	<2,154>	<190>	9.7%
Japan	145	156	11	7.8%
Other*	341	390	49	14.4%

*Overseas sales are from January to June.

Abilify Sales – Quarterly Evolution （US market）



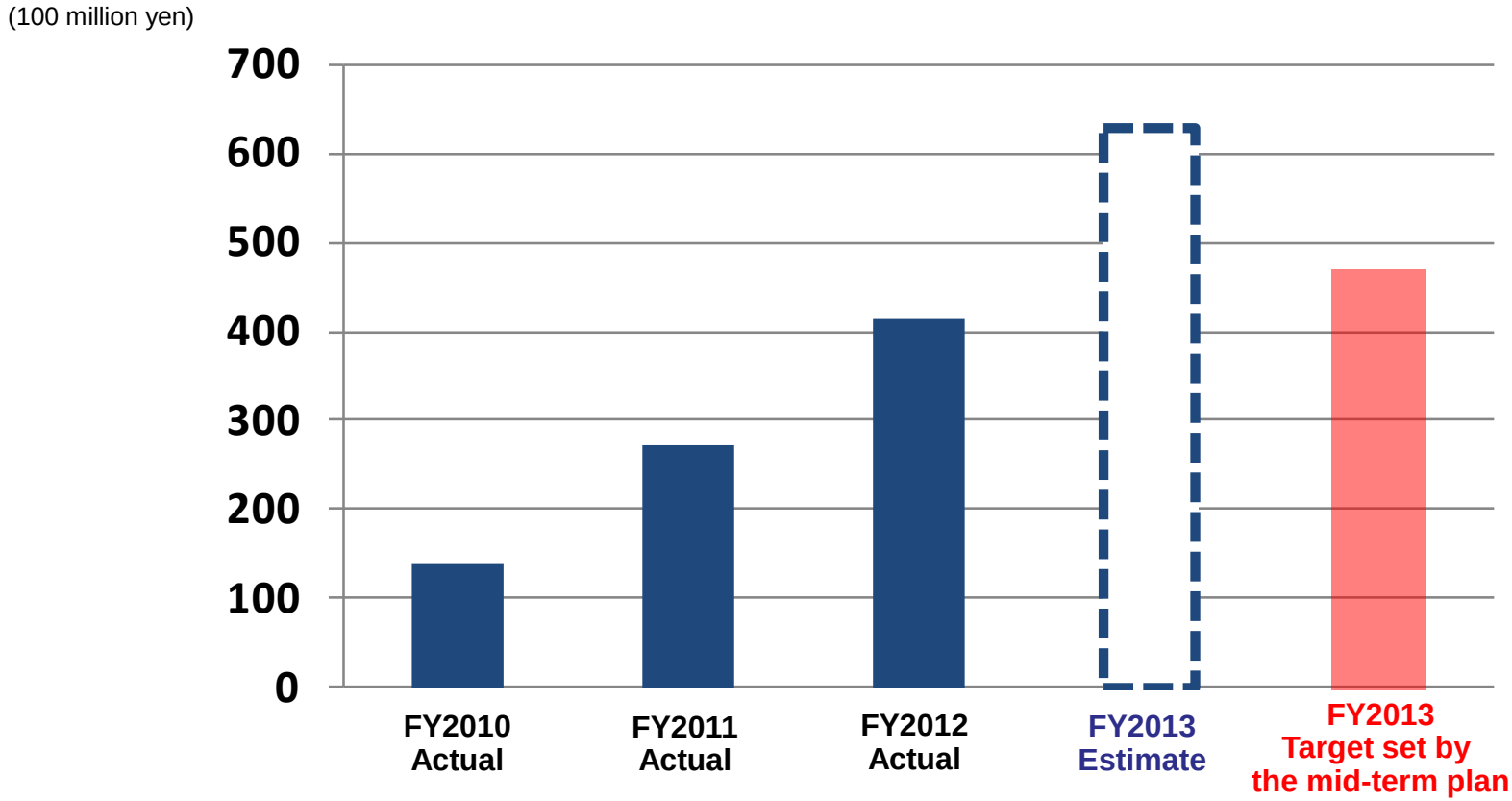
Atypical antipsychotic prescription market （ US market ）



Source：Wolters Kluwer, pharmacy data (September 2013)

【Supplemental】Growing Sales of New Products

New Products Launched in the Japanese Market

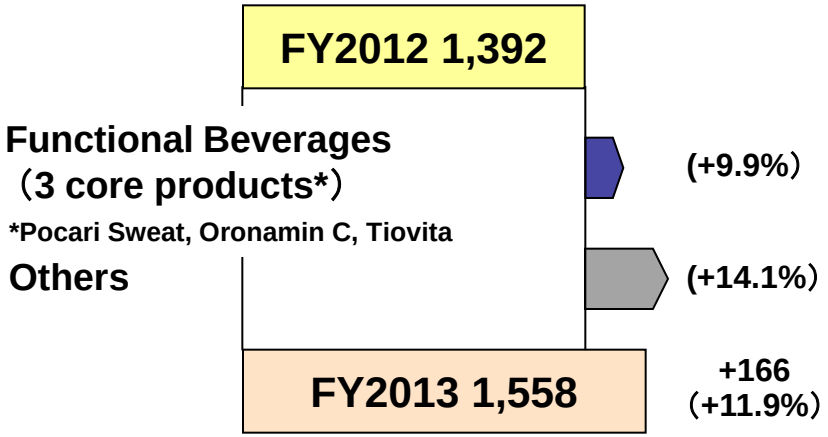


New Products: E Keppra, Aloxi, Abraxane, SAMSCA, ELNEOPA、Mucosta Ophthalmic Suspension, and Neupro Patch

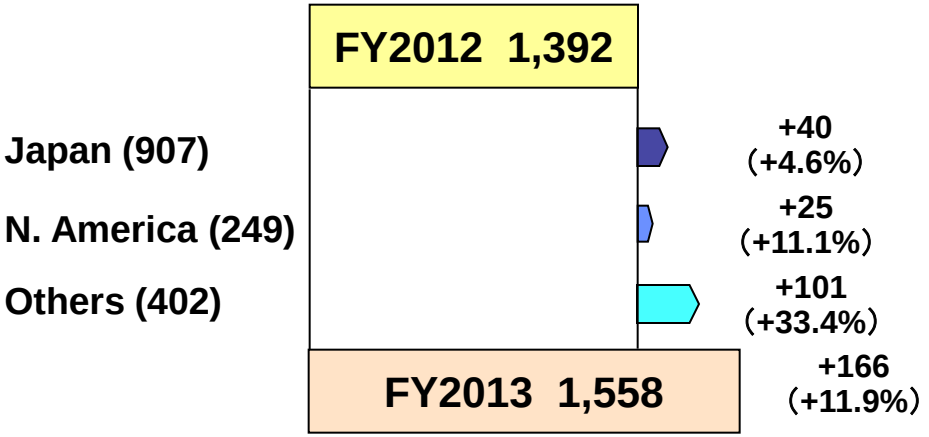
5. Nutraceutical Segment Analysis（FY2013 Q2）

(100 million yen)

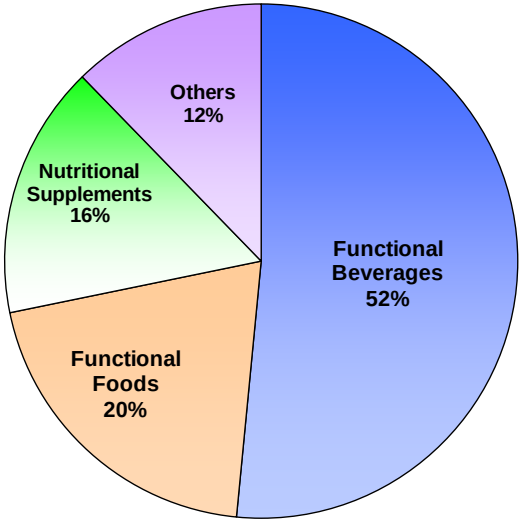
Net Sales



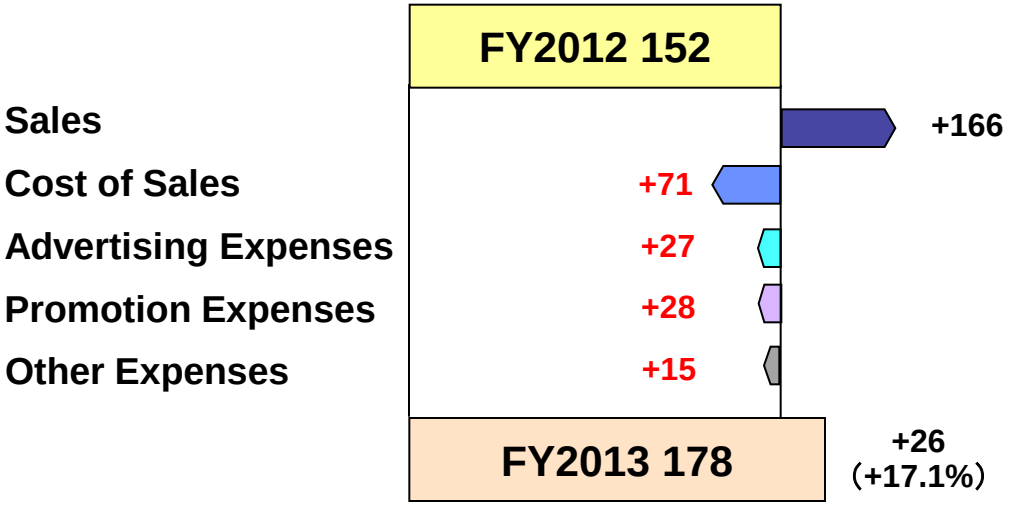
Net Sales by Market



Sales by Category



Segment (Operating) Income



6. FY2013 Estimate

(100 million yen)

	2013 Initial Estimates	2013 Revised Estimates	Change	2013 Q2 Actual	Progress against revised est.
Net Sales	13,700	14,350	650	6,994	48.7%
Operating Income	2,050	2,150	100	1,117	52.0%
Ordinary Income	2,100	2,250	150	1,220	54.2%
Net Income	1,380	1,550	170	870	56.1%
R&D Expenses	2,000	2,200	200	1,053	47.9%
Earnings Per Share (Yen)	250.79	285.54			
Dividends Per Share (Yen)	65.00	65.00			
Budget exchange rate (USD)	90.00	97.00			
Budget exchange rate (EUR)	120.00	128.00			

Impact of change in budget exchange rate : approx. +440 on net sales
approx. +60 on operating income

Pharmaceutical Development Update

November 13, 2013

Otsuka Holdings Co., Ltd.

Agenda

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

1. Major development projects （as of Sep. 30, 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	Maintena™ — Schiz./EU E Keppra® — Partial seizures (injection)/JP
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 Abraxane® — Pancreatic/JP TAS-106 — Solid cancer/US	TS-1 — Renal/JP TAS-102 — SCLC/JP, EU SPRYCEL® — Pancreatic/ US,EU ET-743 — STS/JP OTS-102 — Biliary/JP OCV-101 — Pancreatic/JP	TS-1 — Gastric/US TS-1 — Uterocervical/ JP,Asia TS-1 — HCC/JP TSU-68 — HCC/JP,Asia TAS-102 — Colorectal/ JP,US,EU TAS-118 — Pancreatic/ JP,Asia SATIVEX® — Cancer pain/US	TAS-102 — Colorectal/ JP
Cardiovascular	OPC-108459 — AF/JP,US	Samsca® — Cancerous edema /JP Samsca® — Edema in hemodialysis /JP Samsca® — Edema in peritoneal dialysis /JP Samsca® — ADPKD/EU	Samsca® — Cardiac edema /Asia	Samsca® — Hepatic edema/ JP,Asia Samsca® — ADPKD/JP,US
Others/ Diagnostics	OPA-15406 — Atopic dermatitis/ US OPA-6566 — Glaucoma/US	Mucosta® ophthaic suspension UD — Keratoconjunctival epithelial disorder/ JP OPC-6535 — COPD/ JP,US,Asia Delamanid — Pediatric MDR-TB / EU TAC-202 — Allergic rhinitis / JP C13-URA — Gastric emptying determination /US	ZOSYN®(YP-18) — Febrile neutropenia / JP Mucosta® ophthalmic suspension MD — Dry eye/ JP Delamanid — Tuberculosis/ JP,US,EU OPB-2045G — Disinfectant/ JP ACU-4429 — AMD/US	Delamanid — Tuberculosis /JP,EU

*Approved(JP)

Blue columns indicate changes from 1Q

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

- **Two products launched**

Product name	Country・Area	Details
E Keppra® dry syrup 50%	Japan	Launched on Aug. 29
E-fen buccal tablets	Japan	Launched on Sep. 26

- **One project approved**

Product name	Country・Area	Indication
Samsca®	Japan	Fluid retention attributed to hepatic cirrhosis

- **Three projects advanced to P-III**

Generic name / Development code	Country・Area	Indication
Aripiprazole IM Depot	JP・EU	Bipolar disorder
Brexpiprazole	US・EU	Agitation associated with dementia of the Alzheimer's type
TAS-118	Japan・Asia	Pancreatic cancer

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

- **Six projects advanced to P-II**

Generic name / Development code	Country・Area	Indication
TAS-102	JP・EU	Small-cell lung cancer
Tolvaptan	Japan	Fluid retention in patients on hemodialysis
Tolvaptan	Japan	Fluid retention in patients on peritoneal dialysis
Delamanid	Europe	Pediatric multidrug-resistant tuberculosis
TAC-202	Japan	Allergic rhinitis
C13-URA (Breath test kit)	USA	Diagnostic tool to identify rapid and/or delayed gastric emptying

- **One P-III project terminated**

Generic name / Development code	Country・Area	Indication
Rebamipide ophthalmic suspension unit dose	USA	Dry eye syndrome

3-1. Topics

<CNS>

- Received positive CHMP* opinion in Europe for Abilify Maintena™, a once-monthly injectable for Schizophrenia (September 20, 2013)
  *CHMP: The Committee for Medicinal Products for Human Use
  http://www.otsuka.co.jp/en/company/release/2013/0920_01.html

- The P-II clinical study demonstrated that treatment with Lu AE58054 as add-on to donepezil improved cognitive performance in patients with moderate Alzheimer's disease
  (Lundbeck and Otsuka presented at AAIC 2013*, held in Boston, Mass., July 16.)
  *AAIC 2013: The Alzheimer's Association International Conference 2013
  http://www.otsuka.co.jp/en/company/release/2013/0717_01.html

- Lundbeck and Otsuka initiated P-III clinical trials on Lu AE58054 as a new add-on treatment for Alzheimer's disease (October 10, 2013)
  http://www.otsuka.co.jp/en/company/release/2013/1010_01.html

- 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

<Cancer>

- Results of the P-III clinical trial (JACCRO* GC-05) of second-line TS-1 therapy on patients with unresectable or recurrent gastric cancer that is refractory to initial therapy with TS-1 (September 11, 2013)
  * JACCRO: The Japan Clinical Cancer Research Organization
  http://www.taiho.co.jp/english/news/20130911.html

<Others>

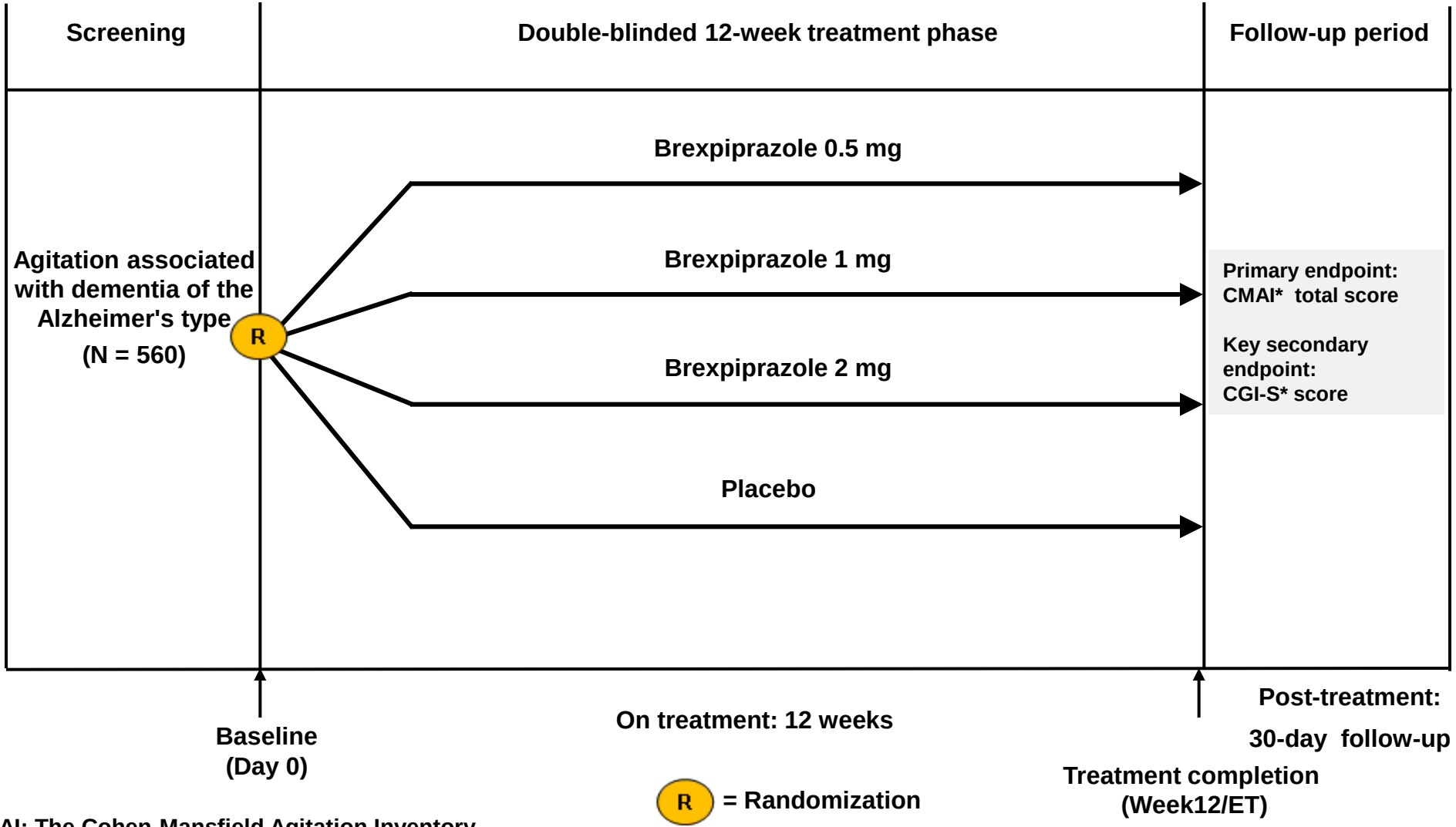
- Received opinion from the CHMP of the EMA on approval of delamanid for the treatment of pulmonary multidrug-resistant tuberculosis (MDR-TB) (July 26, 2013) *EMA: The European Medicines Agency
  http://www.otsuka.co.jp/en/company/release/2013/0726_01.html

- Received a complete response letter from the FDA* for tolvaptan for use in patients with ADPKD* (August 30, 2013)
  *FDA: The U.S. Food and Drug Administration
  *ADPKD: Autosomal dominant polycystic kidney disease
  http://www.otsuka.co.jp/en/company/release/2013/0830_01.html

3-2. Samsca® Tablets
(Additional indication: Fluid retention in hepatic cirrhosis patients)

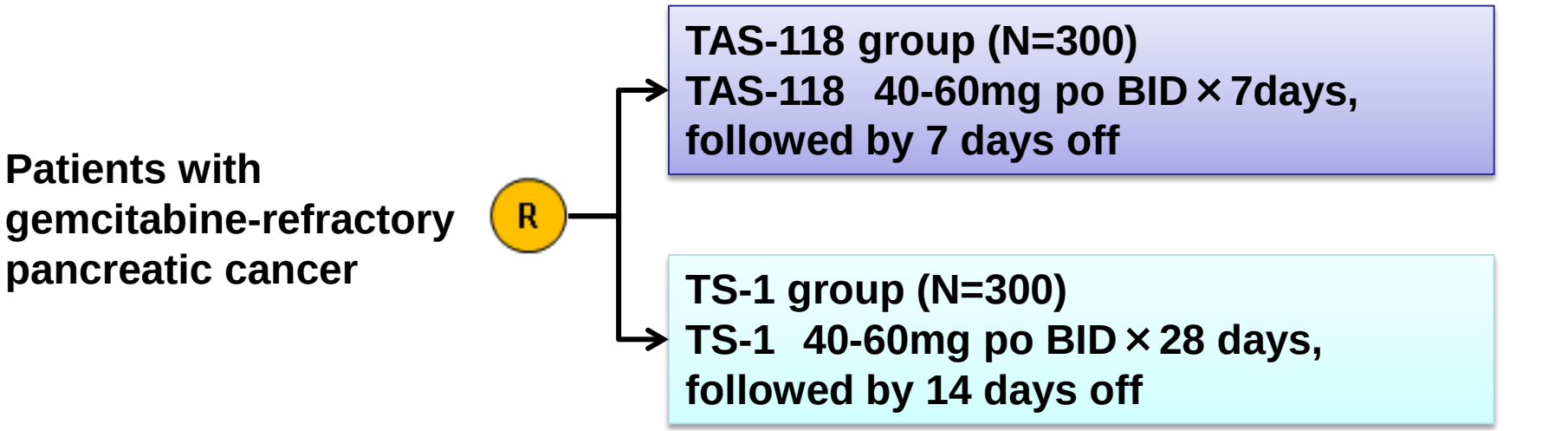
Generic name	Tolvaptan		
Indications	Treatment of fluid retention in heart failure patients who fail to response adequately to treatment with common diuretics. **Treatment of fluid retention in hepatic cirrhosis patients who fail to response adequately to treatment with common diuretics.**		
Name of the medical product	Samsca® Tablets	7.5mg	15mg
Dosage・Administration	【Fluid retention in patients with heart failure】 The usual adult oral dosage of tolvaptan is 15 mg once daily.	○	○
	【Fluid retention in patients with hepatic cirrhosis】 The usual adult oral dosage of tolvaptan is 7.5 mg once daily.	○	
Clinical trials experience	As for primary outcome measures, cases of significant weight loss were observed in a P-III double-blind comparative study in patients with hepatic cirrhosis experiencing difficulties or inadequacy with conventional diuretics. Additionally, medically significant signs and improvement of clinical symptoms attributed to hepatic edema were observed.		
Warnings	Tolvaptan has the potential to worse liver function in patients with hepatic cirrhosis, and it's difficult to distinguish between drug-induced hepatic impairment and worsening primary one. Use of tolvaptan should be judged carefully considering risks and benefits. Severe hepatic impairment can occur at the beginning of administration. Therefore, liver function tests should be performed before the administration and frequently during the first two weeks. Also, tests should be continually performed if patients with impaired liver function wish to continue the tolvaptan treatment.		

3-3. A P-III of Brexpiprazole in patients with agitation associated with dementia of the Alzheimer's type



*CMAI: The Cohen-Mansfield Agitation Inventory
*CGI-S: The Clinical Global Impression-Severity of Illness

3-4. A P-III study of TAS-118 in patients with pancreatic cancer



Repeat above cycle until the discontinuation criteria are met.

Primary endpoint: Overall survival (OS)
Secondary endpoints: Progression-free survival (PFS)
Safety

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

Otsuka

- **Two projects are scheduled to proceed to P-III**

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	Others	Rebamipide ophthalmic suspension unit dose	Japan	Keratoconjunctival epithelial disorder

Not included in the initial plan: TAS-118 advanced to P-III in Japan and Asia.

NDA filing as scheduled

- **Scheduled NDA submission: One project in cardiovascular filed**

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