

Consolidated Financial Results

FY2015 Q2

(Six Months Ended June 30, 2015)

August 7, 2015
Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results (FY2015 Q2)**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
- 4 Abilify Sales / Actual and Forecasts**
- 5 Sales of New Drugs in Japan**
- 6 Nutraceutical Segment Analysis**
- 7 FY2015 Forecasts**

1. Consolidated Financial Results (FY2015 Q2)

(100 million yen)

| | FY2014 Jan – Jun (unaudited) | FY2015 Jan – Jun | Change | % Change |
|-------------------------|------------------------------------|---------------------|--------|----------|
| Net Sales | 7,339 | 7,458 | +119 | +1.6% |
| Operating Income | 829 | 1,032 | +203 | +24.5% |
| Ordinary Income | 880 | 1,094 | +214 | +24.4% |
| Net Income | 572 | 695 | +122 | +21.4% |
| R&D Expenses | 1,271 | 951 | ▲321 | ▲25.2% |

Foreign Exchange Impact : (100 million yen)

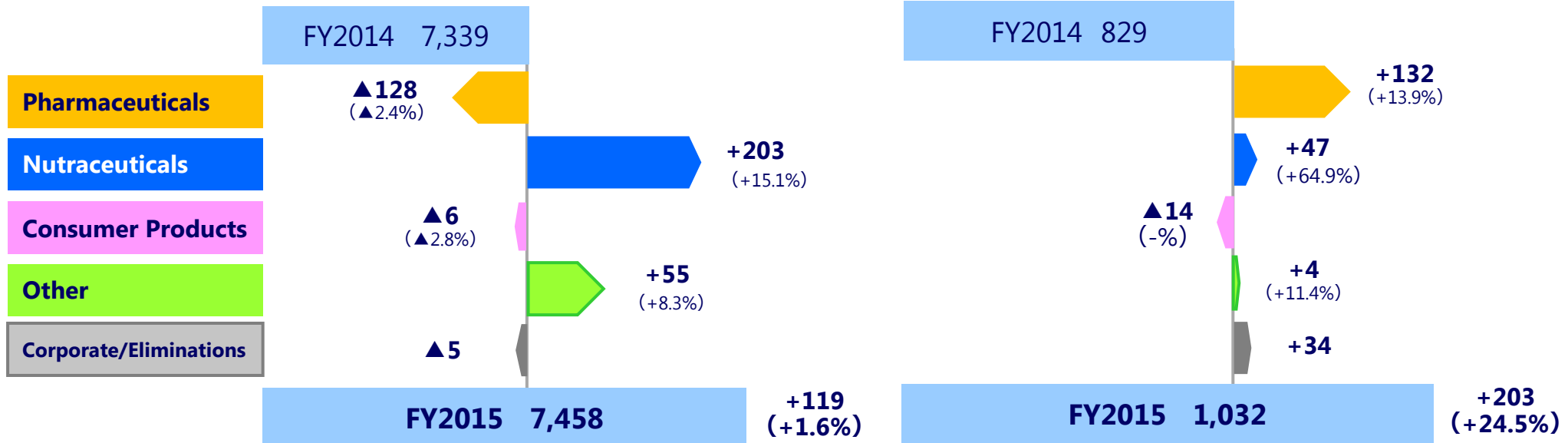
| | | |
|------------------|---------|------|
| Net Sales | approx. | +490 |
| Operating Income | approx. | +10 |

2. Business Segment Analysis

*Parentheses represent % change (100 million yen)

Net Sales

Segment (Operating) Income



| | Net Sales | | Operating Income | | Operating Margin (%) | |
|-------------------------------|-----------|--------------|------------------|--------------|----------------------|--------------|
| | FY2014 | FY2015 | FY2014 | FY2015 | FY2014 | FY2015 |
| Pharmaceuticals | 5,337 | 5,209 | 953 | 1,085 | 17.9% | 20.8% |
| Nutraceuticals | 1,341 | 1,544 | 72 | 119 | 5.4% | 7.7% |
| Consumer Products | 215 | 209 | ▲3 | ▲17 | ▲1.2% | ▲7.9% |
| Other | 664 | 718 | 32 | 36 | 4.9% | 5.0% |
| Corporate/Eliminations | ▲218 | ▲222 | ▲226 | ▲192 | - | - |
| Consolidated | 7,339 | 7,458 | 829 | 1,032 | 11.3% | 13.8% |

3. Pharmaceutical Segment Analysis

Pharmaceuticals

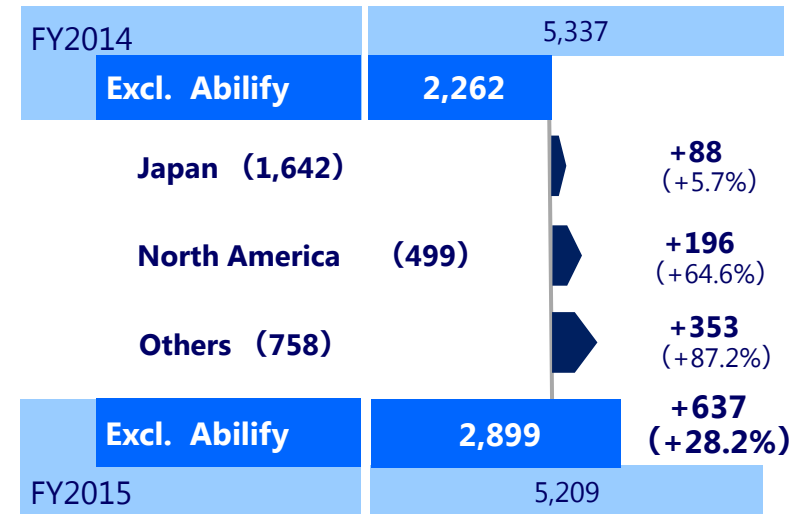
(100 million yen)

Net Sales

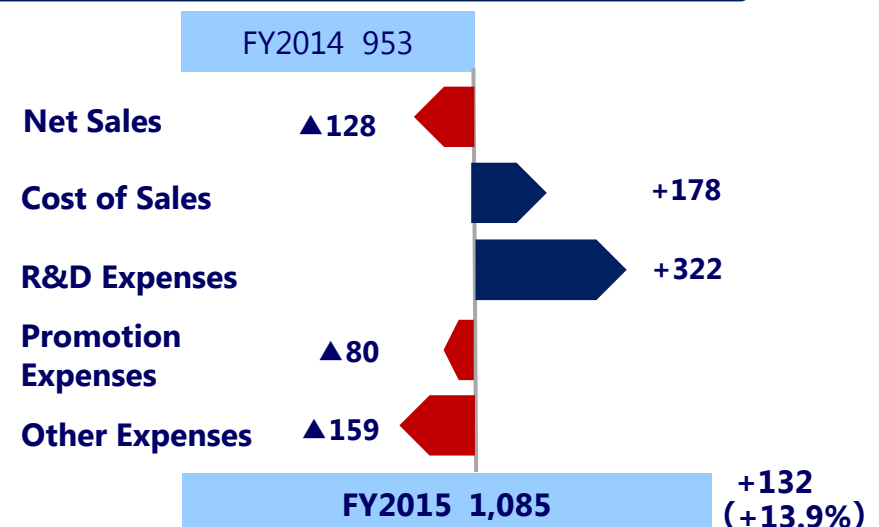


| Products | FY2014 | FY2015 | Change | % Change |
|--------------------------------|--------------|--------------|--------------|---------------|
| Abilify | 3,075 | 2,310 | ▲ 765 | ▲ 24.9% |
| Abilify Maintena | 61 | 172 | 111 | 182.3% |
| Samsca | 118 | 184 | 66 | 55.7% |
| Oncology | 570 | 679 | 110 | 19.2% |
| Pletaal/Mucosta | 274 | 238 | ▲ 36 | ▲ 13.0% |
| Milestone/Upfront revenue | 120 | 322 | 202 | 167.7% |
| Others | 1,119 | 1,303 | 184 | 16.5% |
| Total excluding Abilify | 2,262 | 2,899 | 637 | 28.2% |
| Pharma Total | 5,337 | 5,209 | ▲ 128 | ▲ 2.4% |

Net Sales by Market



Segment (Operating) Income



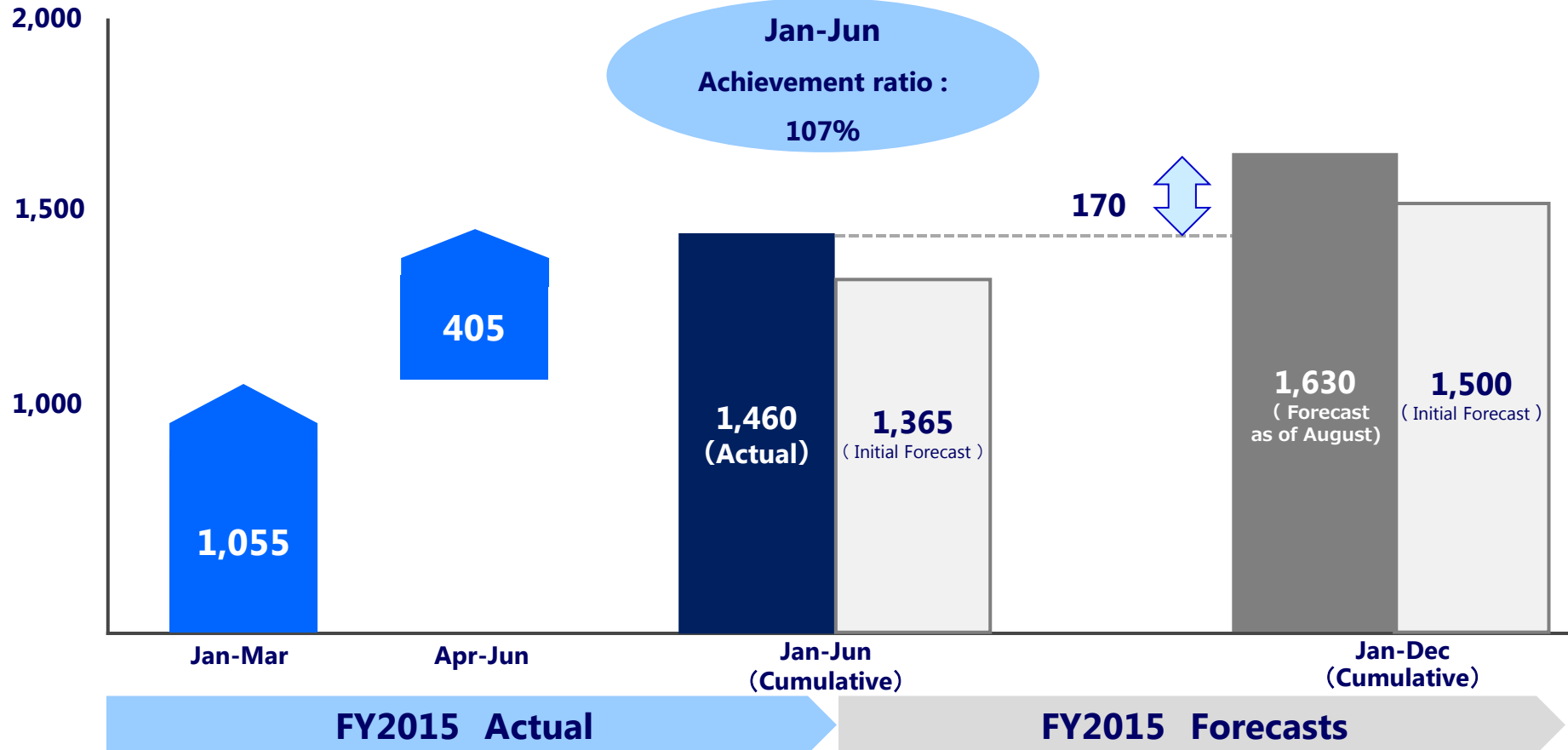
4. Abilify Sales / Actual and Forecasts

Pharmaceuticals



(Million USD)

Abilify Sales in US market

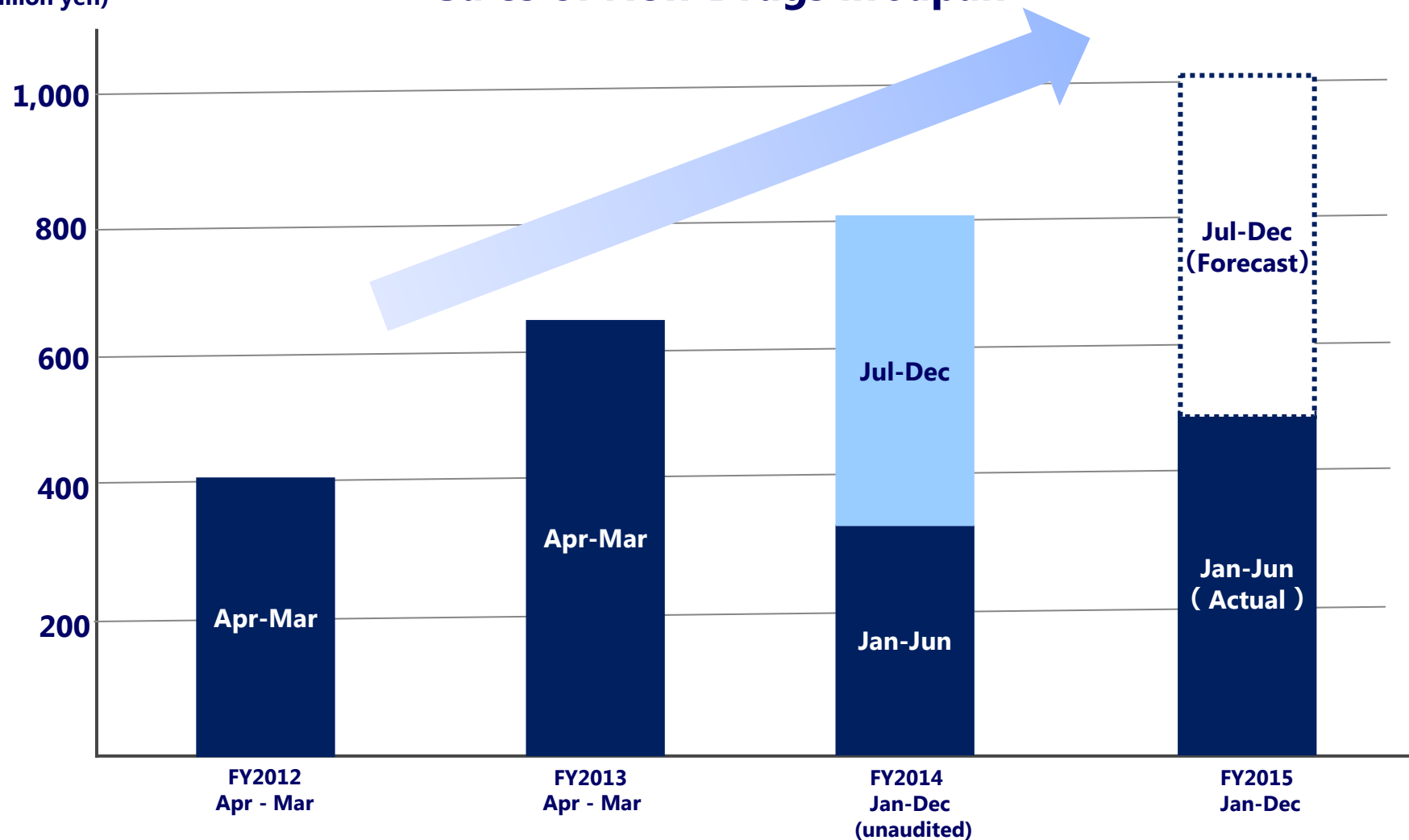


| (100 million yen) | FY2014 | FY2015 | Change | % Change | Jan-Jun Initial Forecast | Jan-Dec Forecast as of August | Jan-Dec Initial Forecast |
|-------------------------------------|--------------|--------------|-------------|---------------|--------------------------|-------------------------------|--------------------------|
| Abilify (Consolidated Total) | 3,075 | 2,310 | ▲765 | ▲24.9% | 2,230 | 2,940 | 2,820 |
| US | 2,391 | 1,756 | ▲635 | ▲26.6% | 1,640 | 1,960 | 1,800 |
| <Million USD> | 2,333 | 1,460 | ▲873 | ▲37.4% | 1,365 | 1,630 | 1,500 |

5. Sales of New Drugs in Japan

(100 million yen)

Sales of New Drugs in Japan



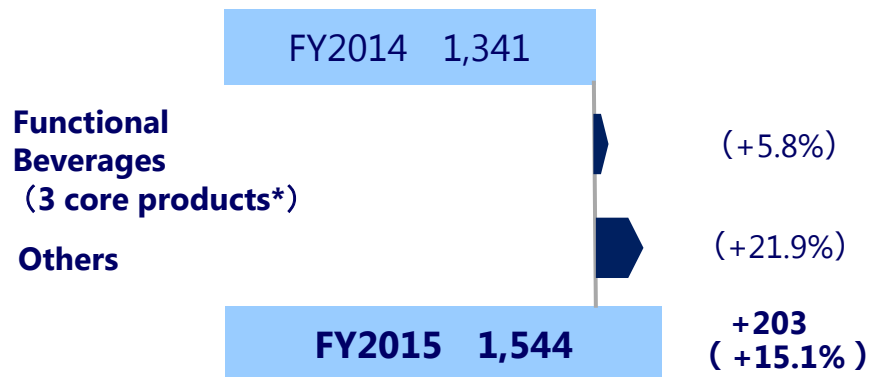
New Drugs in Japan : Products newly launched in Japan after 2009.

(13 products including SAMSCA, Abilify Maintena, Lonsurf, E Keppra, Abraxane, Aloxi, Mucosta eye drop, Neupro patch and TAKECAB)

6. Nutraceutical Segment Analysis

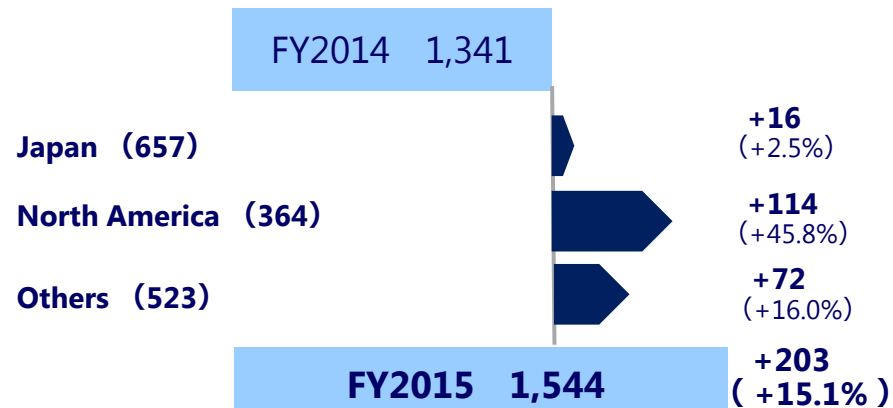
(100 million yen)

Net Sales

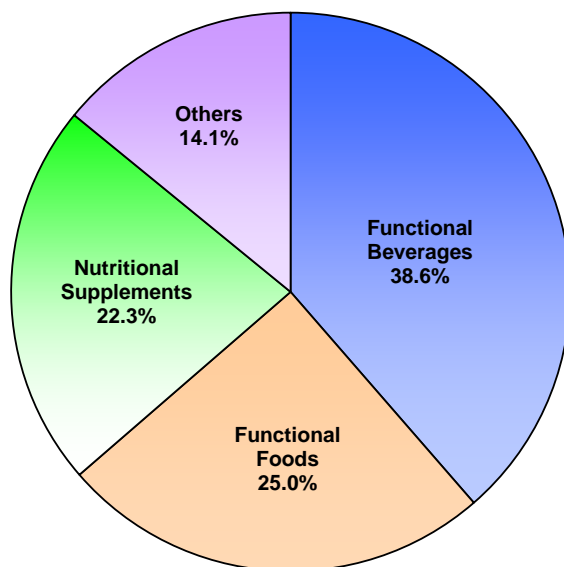
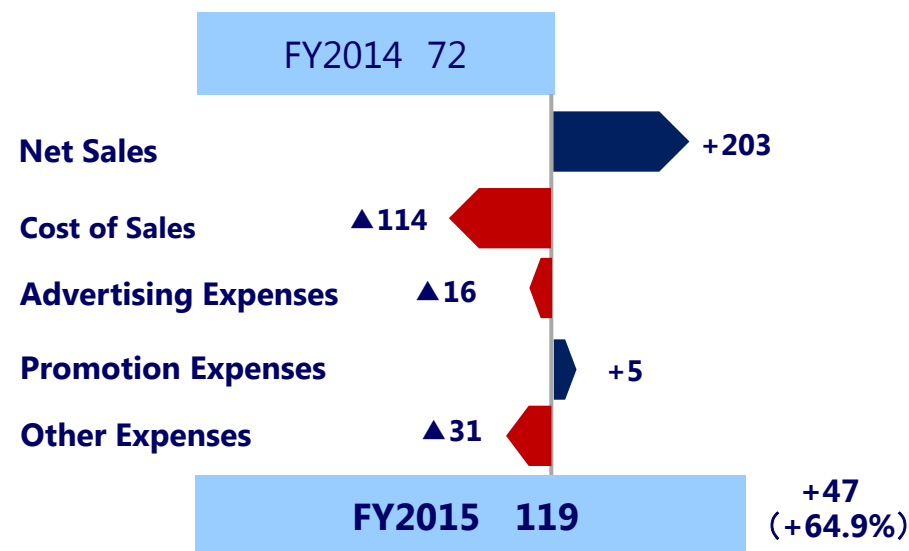


*Pocari Sweat, Oronamin C, Tiovita

Net Sales by Market



Segment (Operating) Income



7. FY2015 Forecasts

(100 million yen)

| | FY2015 Forecasts | | |
|----------------------------|------------------|--------|-----------------------|
| | Initial Forecast | Change | Forecast as of August |
| Net Sales | 13,700 | +100 | 13,800 |
| Operating Income | 1,100 | +100 | 1,200 |
| Ordinary Income | 1,200 | +50 | 1,250 |
| Net Income | 800 | - | 800 |
| R&D Expenses | 2,300 | ▲250 | 2,050 |
| Dividends per share | ¥100.0 | - | ¥100.0 |

Projected foreign currency exchange rate:

| | | | |
|-------|--------|-------|--------|
| 1 USD | ¥120.0 | - | ¥120.0 |
| 1 EUR | ¥130.0 | +¥4.0 | ¥134.0 |

Pharmaceutical Development Update

August 7, 2015

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 2Q/FY2015**
 - ✓ **Launches**
 - ✓ **Approvals**
 - ✓ **NDA filings**
 - ✓ **Advanced to the next phase**
- 3 Topics**
- 4 FY2015 – Progress of key projects advanced to P-III & scheduled NDA submissions (Initial plan)**

1-1. Major development projects: CNS and neurological disorders (as of June 30, 2015)

| | | P-1 | P-2 | P-3 | NDA |
|----------------------|---------------|----------------|----------------------------|--|---------------------------------------|
| Mental Disease | Schizophrenia | | | Brexpiprazole JP·EU | 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 Nalmefene Alcoholism JP | |
| Neurological Disease | Epilepsy | | | | Levetiracetam Generalized seizures JP |
| | AD | AF20513 EU | 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 Migraine US |

global project

Blue columns indicate changes since last update.

1-2. Major development projects: Oncology (as of June 30, 2015)

| | P-1 | P-2 | P-3 | NDA |
|------------------------------|--|--|--|---|
| Solid cancer | TAS-114 <small>JP·US ·EU</small> | Dasatinib Pancreatic cancer <small>US·EU</small> | TAS-118 Pancreatic cancer <small>JP· Asia</small> | TAS-102 Colorectal cancer <small>US·EU</small> |
| | TAS-115 <small>JP</small> | OCV-101 Pancreatic cancer <small>JP</small> | TAS-118 Gastric cancer <small>JP· Asia</small> | |
| | TAS-116 <small>JP</small> | SGI-110 HCC <small>US·EU</small> | TAS-102 Colorectal cancer <small>Asia</small> | |
| | TAS-117 <small>JP</small> | SGI-110 Ovarian cancer <small>US·EU</small> | S-1 Cervical cancer <small>JP· Asia</small> | |
| | TAS-119 <small>US·EU</small> | AT13387 Prostate cancer <small>US·EU</small> | | |
| | TAS-120 <small>JP·US ·EU</small> | AT13387 NSCLC <small>US·EU</small> | | |
| | TAS-121 <small>JP</small> | | | |
| | OPB-31121 <small>JP· Asia</small> | | | |
| | OPB-51602 <small>JP·US ·Asia</small> | | | |
| | OPB-111001 <small>EU</small> | | | |
| | OPB-111077 <small>US· Asia</small> | | | |
| OCV-C02 <small>JP</small> | | | ET-743 STS <small>JP</small> | |
| Blood cancer | ASTX727 <small>US</small> | OCV-501 AML <small>JP· Asia</small> | | |
| | SGI-110 <small>JP</small> | SGI-110 MDS, AML <small>US</small> | SGI-110 AML <small>US· EU</small> | |
| | | AT7519 MM <small>US</small> | | |
| Palliative & supportive care | | Rebamipide(liquid) Oral mucositis <small>JP</small> | nabiximols Cancer pain <small>US</small> | |

global project

1-3. Major development projects: Others (as of June 30, 2015)

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

global project

Blue columns indicate changes since last update.

2. Key development progress in 2Q/FY2015 (as of June 30, 2015)

- One product launched

| Product name | Country·Area | |
|--|--------------|--------------------|
| ABILIFY extended-release injectable suspension for intramuscular use | Japan | Launched on May 25 |

- Two projects approved

| Product name (Generic name/Development code) | Country·Area | Indication |
|---|--------------|---------------------|
| JINARC (Tolvaptan) | Europe | ADPKD* |
| Zosyn (YP-18) | Japan | Febrile neutropenia |

☆ Olanedine (OPB-2045G): JP marketing approval on July 3

☆ Brexpiprazole: US marketing approval for the treatment of schizophrenia and MDD* (adjunctive therapy) on July 10

- One application submitted for approval

| Generic name | Country·Area | Indication |
|--------------|--------------|------------|
| Tolvaptan | Asia | ADPKD |

- One project advanced to P-I

| Development code | Country·Area | Indication |
|------------------|--------------|----------------------|
| Lu AF20513 | Europe | Alzheimer's dementia |

*ADPKD: Autosomal dominant polycystic kidney disease
MDD: Major depressive disorder

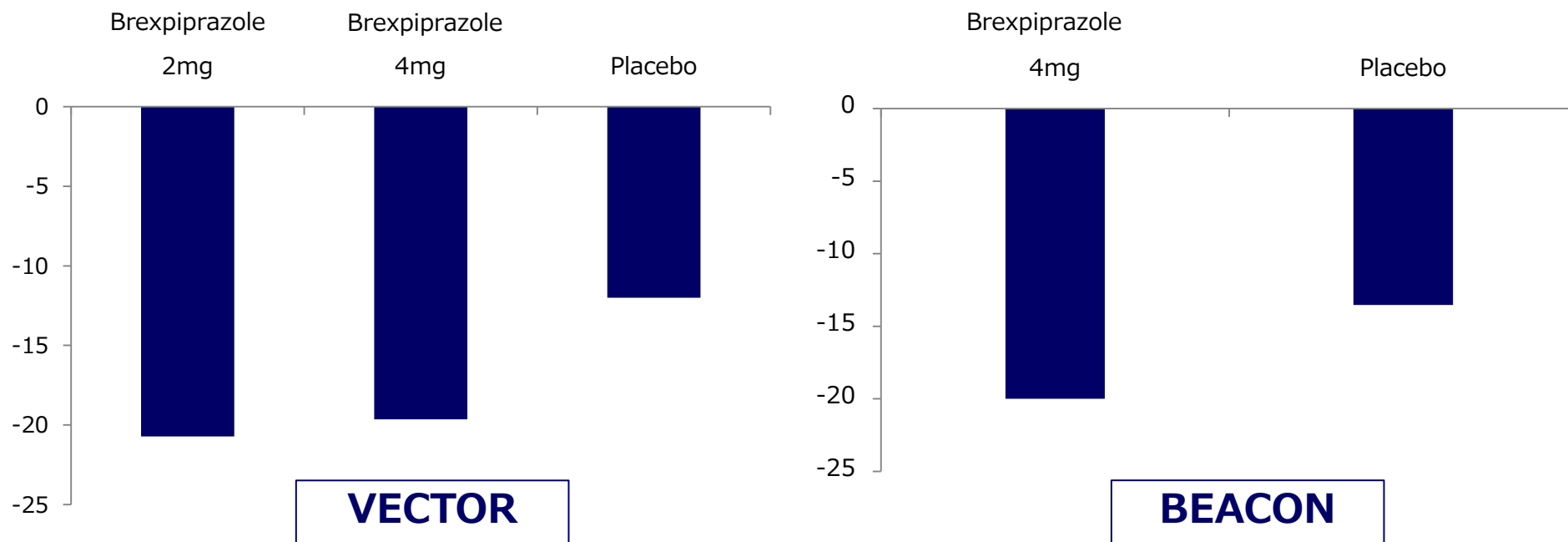
3-1. Progress of key projects (3 global products) in the 2nd mid-term plan

| Generic name / Development code | Country·Area | Development status |
|---|--------------|--|
| Aripiprazole extended-release injectable suspension | Japan | Schizophrenia: Launched in May 2015 Bipolar disorder: Global P-III |
| | US | Schizophrenia: Launched, dual chamber pre-filled syringe in Mar. 2015 Deltoid administration approved in July 2015 Bipolar disorder: Global P-III |
| | Europe | Schizophrenia: Launched; Deltoid administration approved in Jan. 2015 Dual chamber pre-filled syringe approved in Mar. 2015 Bipolar disorder: Global P-III |
| Brexipiprazole | Japan | Schizophrenia: P-III (to be filed by the year-end) |
| | US | Schizophrenia: Approved in July 2015 (launched on Aug. 3, 2015) MDD: Approved in July 2015 (launched on Aug. 3, 2015) AD* agitation: P-III PTSD*: P-III |
| | Europe | Schizophrenia: P-III MDD: P-III AD agitation: P-III PTSD: P-III |
| Tolvaptan | Japan | Cardiac edema·Hepatic edema: Launched ADPKD: Approved in Mar. 2014 as additional indication Fluid retention in patients on dialysis·Cancerous edema: P-II |
| | US | Hyponatremia: Launched ADPKD: P-III |
| | Europe | Hyponatremia due to the syndrome of inappropriate antidiuretic hormone secretion (SIADH): Launched ADPKD: JINARC [®] for approval in May 2015 |

*AD: Alzheimer's disease
PTSD: Post-traumatic stress disorder

3-2. Brexpiprazole P-III Clinical Trials for Schizophrenia (2 trials)

Primary endpoint: Change from baseline in Positive and Negative Syndrome Scale (PANSS) total score (6-week evaluation)*



Most Common Adverse Event

(incidence of 4% or greater in brexpiprazole group, and twice the incidence of placebo)

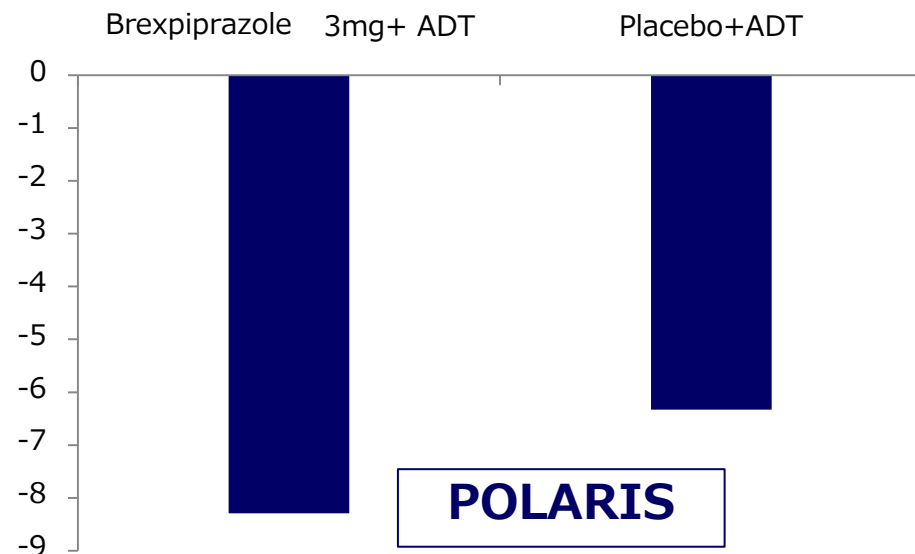
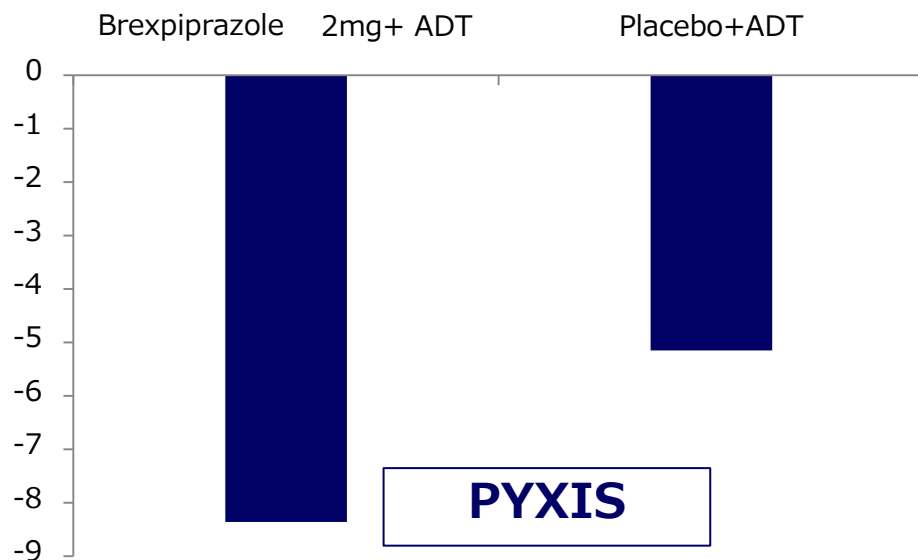
| Adverse Event | Brexpiprazole | Placebo |
|---------------|---------------|---------|
| Weight gain | 4% | 2% |

*Both trials are 6-week, randomized, placebo-controlled clinical trials with fixed dose of brexpiprazole and placebo.

3-3. Brexpiprazole P-III Clinical Trials as Adjunctive Therapy for MDD (2 trials)

Primary endpoint: Change in MADRS total score (6-week evaluation)

MADRS: Montgomery-Åsberg Depression Rating Scale



Most Common Adverse Event

(incidence of 5% or greater in brexpiprazole group, and twice the incidence of placebo)

| Adverse Event | Brexpiprazole+ ADT | Placebo+ADT |
|---------------|--------------------|-------------|
| Akathisia | 9% | 2% |
| Weight gain | 7% | 2% |

Clinical trial subjects : Adult patients who met DSM-IV-TR criteria for MDD, with or without symptoms of anxiety, and previously failed to reach an adequate response during one to three treatment attempts with antidepressant therapy (ADT), and further failed to reach adequate response in a single-blind ADT phase for 8 weeks.

4. Major P-III projects and NDA submissions scheduled in FY2015

● Projects scheduled to proceed to P-III

Advanced to P-III·NDA filing as scheduled

| No. | Areas | Generic name / Development code | Country·Area | Indication |
|-----|----------|---------------------------------|--------------|--|
| 1 | CNS | Nalmefene | Japan | Alcohol dependency |
| 2 | Oncology | SGI-110 | US·EU | AML* |
| 3 | Others | C13-CAC | Japan | Diagnostic kit for gastric acid-related diseases |

Not included in the initial plan: TAS-118, Gastric cancer (JP·Asia)

● Projects scheduled to proceed to filing

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

Not included in the initial plan: Tolvaptan, ADPKD (Asia)