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# Financial Results Presentation

## Q3 FY2011

(Nine Months Ending December 31, 2011)

February 10, 2012

Otsuka Holdings Co., Ltd.

- 1 Restated FY2010 Q3 Results (Due to Changes in Accounting Policies)**
- 2 FY2011 Q3 Consolidated Financial Results (Compared to Previous Year)**
- 3 FY2011 Q3 Business Segment Analysis**
- 4 FY2011 Q3 Pharmaceutical Segment Analysis**
- 5 FY2011 Q3 Abilify Sales**
- 6 FY2011 Q3 Nutraceutical Segment Analysis**
- 7 FY2011 Forecast**

# 1. Restated FY2010 Q3 Results (Due to Changes in Accounting Policies)

## Changes in Accounting Policies

- 1) Method of translating revenue and expense accounts of foreign subsidiaries was changed from the “closing exchange rate” to the “average exchange rate”
- 2) Classification of upfront licensing payments received (including Abilify upfront payments) was changed from “non-operating income” to “net sales”

(100 million yen)

|                  | FY2010 Q3<br>Originally reported | FY2010 Q3<br>Restated | Effect of changes<br>in accounting<br>policies | (Details)                             |                                        |
|------------------|----------------------------------|-----------------------|------------------------------------------------|---------------------------------------|----------------------------------------|
|                  |                                  |                       |                                                | 1) Change in method<br>of translation | 2) Change in method<br>of presentation |
| Net Sales        | 8,381                            | 8,606                 | 225                                            | 170                                   | 55                                     |
| Operating income | 971                              | 1,029                 | 59                                             | 4                                     | 55                                     |
| Ordinary income  | 1,031                            | 1,038                 | 6                                              | 6                                     | -                                      |
| Net income       | 694                              | 699                   | 5                                              | 5                                     | -                                      |

|              |       |       |   |   |   |
|--------------|-------|-------|---|---|---|
| R&D expenses | 1,220 | 1,219 | 0 | 0 | - |
|--------------|-------|-------|---|---|---|

|      | Closing rate | Average rate |
|------|--------------|--------------|
| USD  | 83.82        | 89.49        |
| EURO | 114.24       | 117.62       |

## 2. FY2011 Q3 Consolidated Financial Results (Compared to Previous Year)



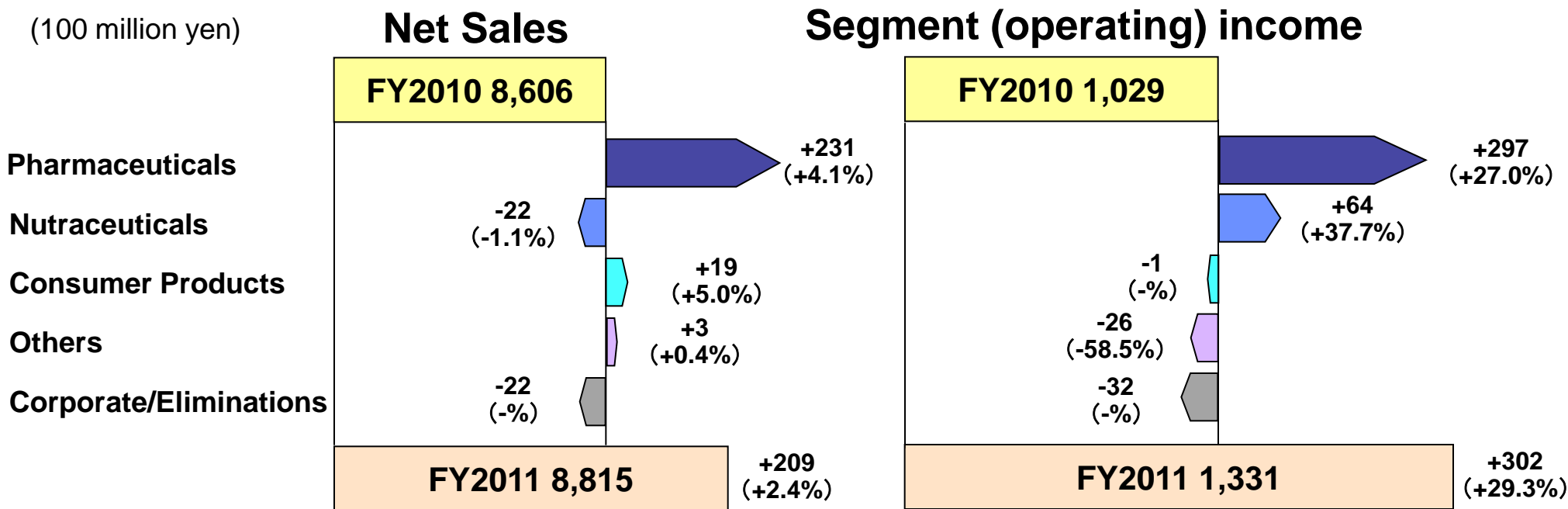
(100 million yen)

|                  | FY2010 Q3<br>Restated | FY2011 Q3 | Change | % Change |
|------------------|-----------------------|-----------|--------|----------|
| Net Sales        | 8,606                 | 8,815     | 209    | 2.4%     |
| Operating Income | 1,029                 | 1,331     | 302    | 29.3%    |
| Ordinary Income  | 1,038                 | 1,350     | 312    | 30.1%    |
| Net Income       | 699                   | 886       | 187    | 26.8%    |
| R&D Expenses     | 1,219                 | 1,150     | -70    | -5.7%    |

Effect of appreciation of the Yen: Net Sales -370, Operating Income -70

### 3. FY2011 Q3 Business Segment Analysis

(100 million yen)



\*Parentheses represent % increase

| Net Sales           | FY2010       | FY2011       | Change     |
|---------------------|--------------|--------------|------------|
| Pharma              | 5,638        | 5,869        | 231        |
| NC                  | 2,055        | 2,033        | -22        |
| Consumer            | 382          | 400          | 19         |
| Others              | 822          | 825          | 3          |
| Corp/Elim           | -290         | -312         | -22        |
| <b>Consolidated</b> | <b>8,606</b> | <b>8,815</b> | <b>209</b> |

| Op income           | FY2010       | FY2011       | Change     |
|---------------------|--------------|--------------|------------|
| Pharma              | 1,099        | 1,396        | 297        |
| NC                  | 170          | 234          | 64         |
| Consumer            | -11          | -12          | -1         |
| Others              | 44           | 18           | -26        |
| Corp/Elim           | -273         | -305         | -32        |
| <b>Consolidated</b> | <b>1,029</b> | <b>1,331</b> | <b>302</b> |

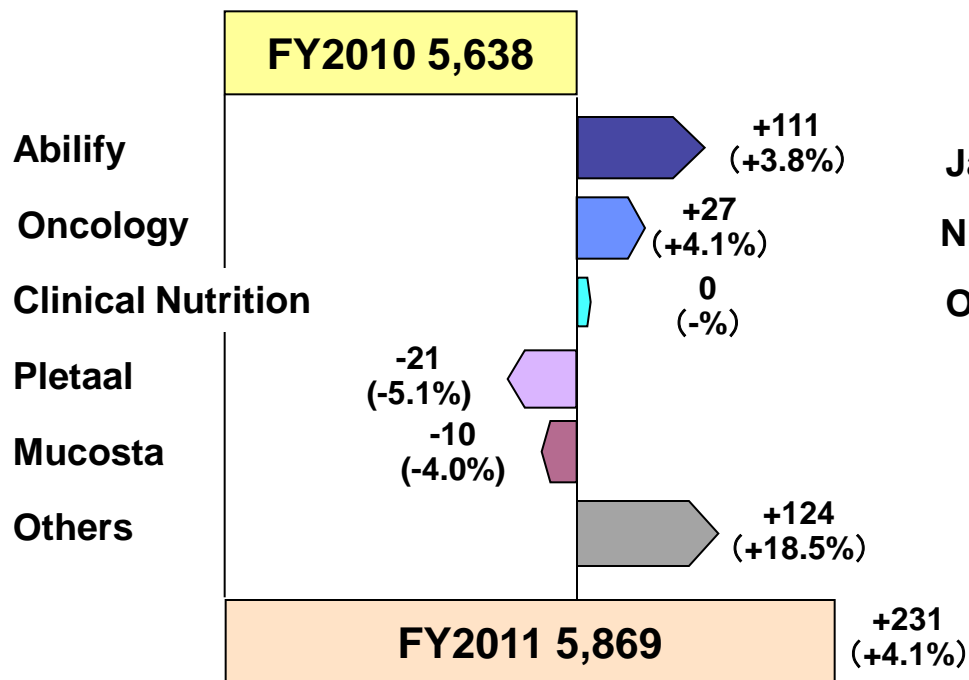
<Operating margin (%)>

|                     | FY2010      | FY2011      |
|---------------------|-------------|-------------|
| Pharma              | 19.5        | 23.8        |
| NC                  | 8.3         | 11.5        |
| Consumer            | -2.9        | -3.0        |
| Others              | 5.4         | 2.2         |
| Corp/Elim           | -           | -           |
| <b>Consolidated</b> | <b>12.0</b> | <b>15.1</b> |

# 4. FY2011 Q3 Pharmaceutical Segment Analysis

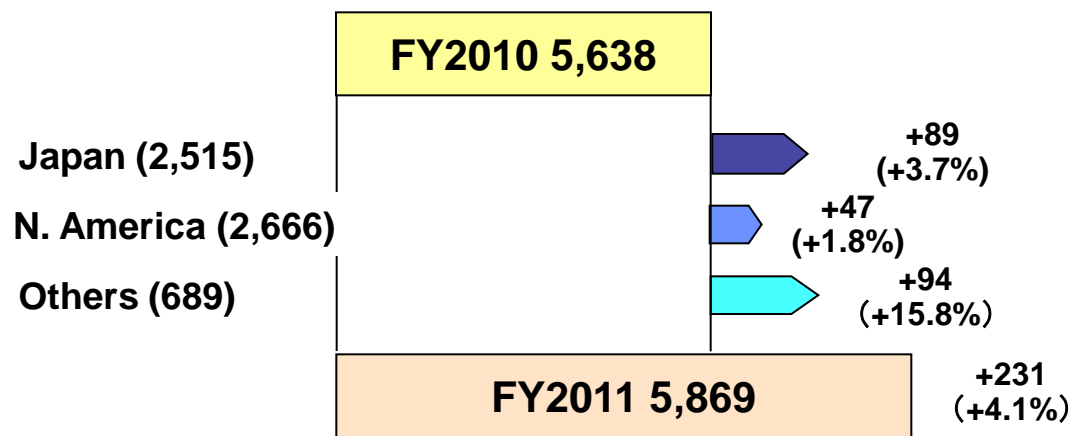


## (100 million yen) Net Sales

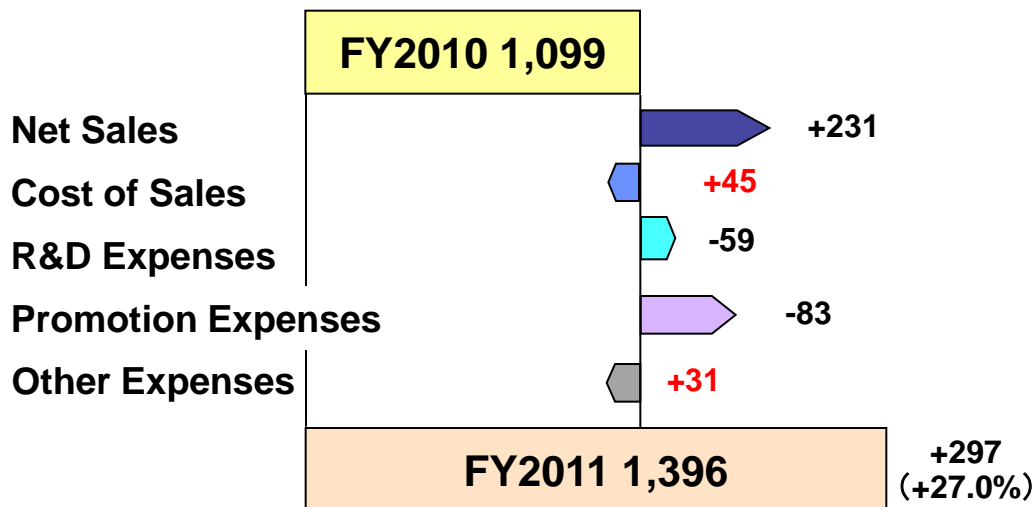


| Products            | 2010 3Q      | 2011 3Q      | Change     | % Change    |
|---------------------|--------------|--------------|------------|-------------|
| Abilify             | 2,927        | 3,037        | 111        | 3.8%        |
| Oncology            | 658          | 685          | 27         | 4.1%        |
| Clinical Nutrition  | 734          | 734          | 0          | 0.0%        |
| Pletaal             | 414          | 393          | -21        | -5.1%       |
| Mucosta             | 237          | 227          | -10        | -4.0%       |
| Others              | 668          | 792          | 124        | 18.5%       |
| <b>Pharma Total</b> | <b>5,638</b> | <b>5,869</b> | <b>231</b> | <b>4.1%</b> |

## Net Sales by Market



## Segment (operating) income

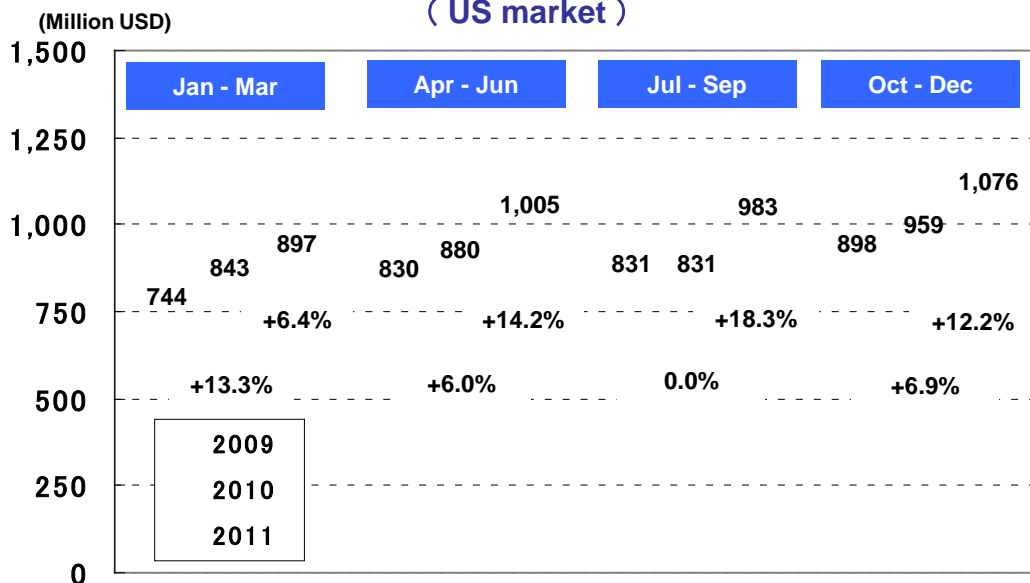


## 5. FY2011 Q3 Abilify Sales

(100 million yen)

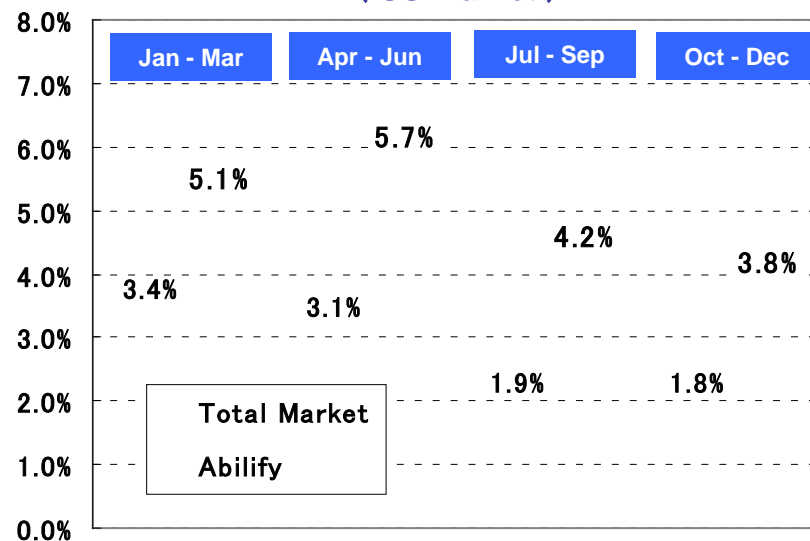
|               | FY2010 Q3 | FY2011 Q3 | Change | % Change |
|---------------|-----------|-----------|--------|----------|
| Abilify       | 2,927     | 3,037     | 111    | 3.8%     |
| US            | 2,285     | 2,327     | 42     | 1.8%     |
| <Million USD> | <2,553>   | <2,884>   | <331>  | 12.9%    |
| Japan         | 173       | 189       | 16     | 9.1%     |
| Other         | 468       | 521       | 53     | 11.3%    |

Quarterly Evolution  
( US market )



※ For 2011 (Jan-Dec): 3,960 million USD (+12.7%)

Atypical antipsychotic  
prescription market  
( US market )



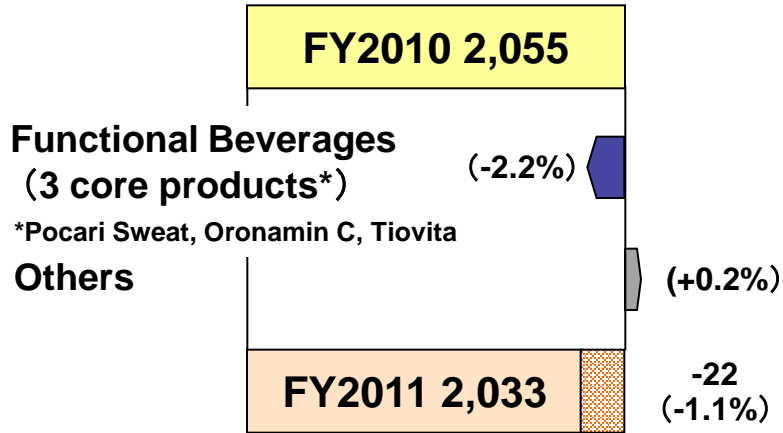
※ For 2011 (Jan-Dec): Total Market +2.5%, Abilify +4.7%

Source: Wolter Kluwer, pharmacy data (December 2011)

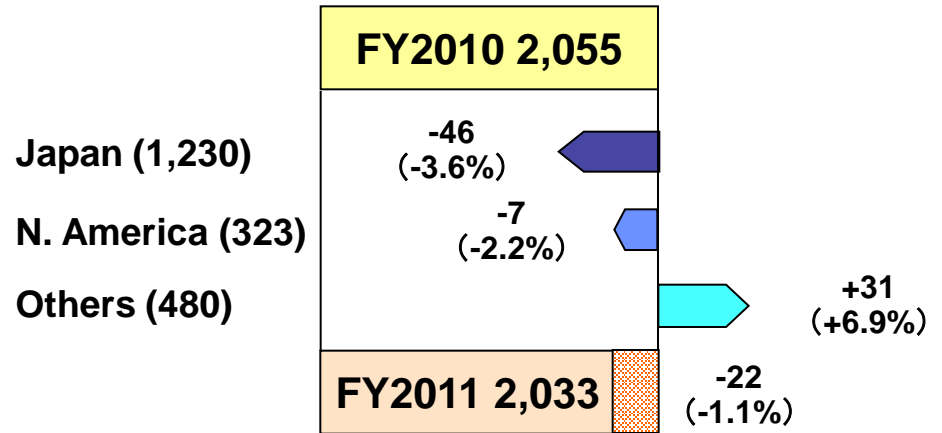
# 6. FY2011 Q3 Nutraceutical Segment Analysis

(100 million yen)

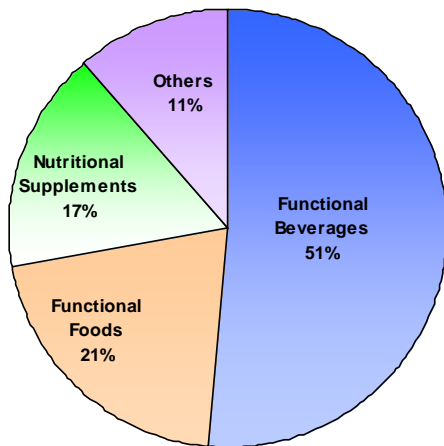
## Net Sales



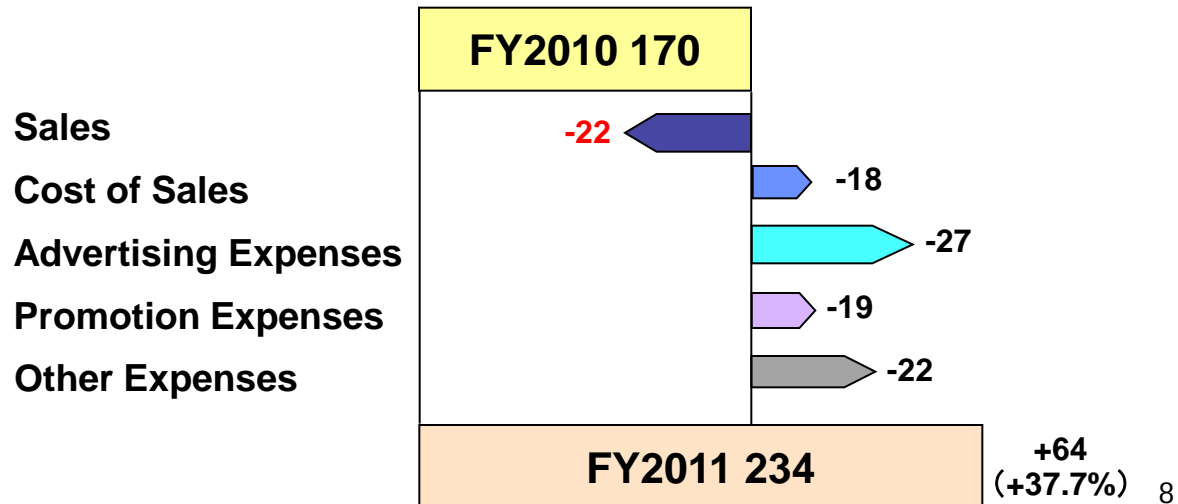
## Net Sales by Market



## Sales by Category



## Segment (operating) income





## 7. FY2011 Forecast

(100 million yen)

|                  | Year-on-year comparison |           |        |          | Forecast                     |                      |
|------------------|-------------------------|-----------|--------|----------|------------------------------|----------------------|
|                  | FY2010 Q3<br>Restated   | FY2011 Q3 | Change | % Change | FY2011 Full-Year<br>Forecast | Progress-to-<br>date |
| Net Sales        | 8,606                   | 8,815     | 209    | 2.4%     | 11,500                       | 76.6%                |
| Operating Income | 1,029                   | 1,331     | 302    | 29.3%    | 1,450                        | 91.8%                |
| Ordinary Income  | 1,038                   | 1,350     | 312    | 30.1%    | 1,450                        | 93.1%                |
| Net Income       | 699                     | 886       | 187    | 26.8%    | 940                          | 94.3%                |
| R&D Expenses     | 1,219                   | 1,150     | -70    | -5.7%    | 1,650                        | 69.7%                |

# Pharmaceutical Development Update

**February 10, 2012**

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development Update in 3Q/FY2011 (as of December 31)**
  - Launches
  - Approvals
  - NDA Filings
  - Advance to Phase III
  - Advance to Phase II
  - Advance to Phase I
- 3 Current status of projects entering into P-III & scheduled NDA submissions**

# 1. Major development projects (as of Dec. 31, 2011)



| Phase                  | P-1                                                                                                                                                                                                      | P-2                                                                                                                                                                                                                                                    | P-3                                                                                                                                                                                                                                            | NDA                                                                                                                                         |             |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| CNS                    |                                                                                                                                                                                                          | OPC-34712 ADHD/US<br>OPC-34712 Schiz./JP                                                                                                                                                                                                               | IM Depot Schiz./EU,JP<br>ABILIFY® MDD/JP<br>ABILIFY® Tourette's/US<br>E KEPPRA® Epilepsy (Partial seizures in children/ Generalized seizures) /JP<br>E KEPPRA® Partial seizures/ (injection)/ JP<br>OPC-34712 MDD/US<br>OPC-34712 Schiz./US,EU | ABILIFY® Bipolar/JP<br>ABILIFY® Tic/Asia<br>IM Depot Schiz./US<br>Rotigotine PD/RLS·JP                                                      | *; Approved |
| Oncology               | TSU-68 NSCLC/JP<br>OPB-31121 Anti-cancer/ JP,Asia<br>OPB-51602 Anti-cancer/ US,JP,Asia<br>OCV-105 Pancreatic/JP<br>ET-743 STS/JP<br>OPB-111001 Prostate/JP<br>TAS-115 Solid cancer /JP<br>OCV-501 AML/JP | TS-1 Prostate,renal/ JP<br>ABI-007 Gastric/JP<br>TSU-68 Breast/JP,Asia<br>TSU-68 Gastric/JP<br>TSU-68 Colorectal/Asia<br>OTS102 Biliary/JP<br>OCV-101 Pancreatic/JP<br>TAS-102 Colorectal/JP<br>SPRYCEL® Pancreatic/ US,EU<br>TAS-106 Solid cancer/ US | TS-1 Gastric/US<br>TS-1 Uterocervical/ JP,Asia<br>TS-1 HCC/JP<br>ABI-007 NSCLC/JP<br>OVF Cancer pain/JP<br>TSU-68 HCC/JP,Asia<br>SATIVEX® Cancer pain/US<br>OTS102 Pancreatic/JP                                                               |                                                                                                                                             |             |
| Cardiovascular         | OPC-108459 AF/JP                                                                                                                                                                                         |                                                                                                                                                                                                                                                        | SAMSCA® PKD/JP,US,EU<br>SAMSCA® Hepatic edema/ JP,Asia                                                                                                                                                                                         | SAMSCA® Hyponatremia/ Asia,Canada                                                                                                           | *; Approved |
| Others/<br>Diagnostics |                                                                                                                                                                                                          | Mucosta® ophthalmic suspension Dry eye/US<br>ACU-4429 AMD/US<br>TAC-201 Cedar pollen allergy/ JP<br>NST-141 Pruritus/JP<br>OPC-6535 COPD/ JP,US,Asia<br>OPA-6566 Glaucoma/US<br>OPB-2045G Anti-infective/ JP                                           | ONGLYZA™ Diabetes/JP<br>Delamanid Tuberculosis/ JP,US<br>OPC-6535 Crohn's/ JP,Asia                                                                                                                                                             | Mucosta® ophthalmic suspension Dry eye/JP<br>Delamanid Tuberculosis /EU<br>Zosyn®(YP-18) Peritonitis,others/ JP<br>ODK-0902 H.influenzae/JP | *; Approved |

Blue column indicates the changes in 3Q

## 2-1. Key Development Progress (as of Dec. 31, 2011)



- Two products launched in Japan.

| Product/Generic name        | Country/Area | Details                                                                                                                     |
|-----------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------|
| RAPIRUN S.<br>pneumoniae HS | Japan        | Launched on Dec. 1, 2011. The <i>Streptococcus Pneumoniae</i> antigen detection reagent by the immunochromatography method. |

★ Mucosta<sup>®</sup> ophthalmic suspension UD2% launched on Jan. 5 (Japan).

- Two new products approved for additional indication.

| Product/Generic name | Country/Area | Details                                            |
|----------------------|--------------|----------------------------------------------------|
| Abilify <sup>®</sup> | Korea        | Approved for Tic Disorder and Tourette's Disorder. |

★ Abilify<sup>®</sup> received additional approval for Bipolar Disorder on Jan. (Japan).

## 2-2. Key Development Progress

- **NDA application for five projects.**

| <b>Generic name/<br/>Development code</b> | <b>Country/Area</b> | <b>Indication</b>                                |
|-------------------------------------------|---------------------|--------------------------------------------------|
| <b>Aripiprazole IM Depot</b>              | <b>USA</b>          | <b>Schizophrenia</b>                             |
| <b>Rotigotine</b>                         | <b>Japan</b>        | <b>Parkinson's Disease</b>                       |
| <b>Rotigotine</b>                         | <b>Japan</b>        | <b>Idiopathic Restless Legs Syndrome</b>         |
| <b>Delamanid</b>                          | <b>EU</b>           | <b>Multiple Drug Resistance<br/>Tuberculosis</b> |
| <b>YP-18</b>                              | <b>Japan</b>        | <b>Intra-abdominal Abscess</b>                   |

## 2-3. Key Development Progress

- One project advanced to P III.

| Generic name/<br>Development code | Country/Area | Indication                               |
|-----------------------------------|--------------|------------------------------------------|
| Delamanid<br>(OPC-67683)          | JP, US, EU   | Multiple Drug Resistance<br>Tuberculosis |

- One project advanced to P II.

| Generic name/<br>Development code | Country/Area | Indication    |
|-----------------------------------|--------------|---------------|
| OPC-34712                         | Japan        | Schizophrenia |

- Three projects advanced to P I.

| Generic name/<br>Development code | Country/Area | Indication                |
|-----------------------------------|--------------|---------------------------|
| TAS-115                           | Japan        | Solid Cancer              |
| OCV-501                           | Japan        | Prevention of relapse AML |
| OPC-108459                        | Japan        | Atrial Fibrillation       |

## 3-1. Major P<sup>III</sup> projects expected to start in FY2011

Four development projects, mainly in CNS, are scheduled to proceed to phase<sup>III</sup> in FY2011. (Initial plan) ⇒ Five projects advanced to Phase<sup>III</sup>.

Advancement to P<sup>III</sup>

| No. | Areas  | Generic name / Development code       | Country/Area | Indication                  |
|-----|--------|---------------------------------------|--------------|-----------------------------|
| 1   | CNS    | OPC-34712                             | US           | Major Depressive Disorder   |
| 2   |        | OPC-34712                             | US           | Schizophrenia               |
| 3   |        | Aripiprazole (Novel Oral Formulation) | US           | Tourette's Syndrome         |
| 4   | Others | THN-01                                | Japan        | Tissue Adhesion Prophylaxis |

☆E KEPPRA<sup>®</sup> (Injection) in patients with partial seizures advanced to Phase<sup>III</sup> in Japan.  
Delamanid in patients with MDRTB\* advanced to Phase<sup>III</sup> in JP, US, EU

\*; MDRTB  
Multiple drug resistance tuberculosis



## 3-2. NDA submissions scheduled in FY2011

Ten development projects, mainly in CNS, are scheduled to proceed to filing stage in FY2011 (plan at beginning of year). ⇒Five projects have completed NDA submission.

Submitted projects

| No. | Areas    | Generic name/ Development code                                | Country/<br>Area | Indication                  |
|-----|----------|---------------------------------------------------------------|------------------|-----------------------------|
| 1   | CNS      | Aripiprazole IM Depot                                         | US               | Schizophrenia               |
| 2   |          | Aripiprazole                                                  | Korea            | Tic and Tourette's Disorder |
| 3   |          | Rotigotine                                                    | Japan            | Parkinson's Disease         |
| 4   |          |                                                               | Japan            | Restless Legs Syndrome      |
| 5   | Oncology | Nanoparticle Albumin-bound Paclitaxel (injectable suspension) | Japan            | Gastric Cancer              |
| 6   |          |                                                               | Japan            | NSCLC                       |
| 7   | Others   | Saxagliptin                                                   | Japan            | Type II Diabetes Mellitus   |
| 8   |          | Certolizumab Pegol*                                           | Japan            | Rheumatoid Arthritis        |
| 9   |          | YP-18                                                         | Japan            | Intra-abdominal Abscess     |
| 10  |          | P0201 (Semisolid nutrient)                                    | Japan            | Nutritional Support         |

\*; Otsuka and UCB will end their co-development and co-promotion agreement for certolizumab pegol in Japan (13 Jan 2012 released).

☆NDA for delamanid was filed in EU for MDRTB.