**Consolidated Financial Results for Third Quarter of the Fiscal Year Ending March 31, 2014 [Japan GAAP]**

February 13, 2014

| | |
|---|---|
| Company name: | **Otsuka Holdings Company Limited** |
| Stock exchange listing: | Tokyo Stock Exchange |
| Code number: | 4578 |
| URL: | http://www.otsuka.com/en/ |
| Representative: | Tatsuo Higuchi<br>President and Representative Director, CEO |
| Contact: | Takuma Kimura<br>Director, Investor Relations Department<br>Telephone: +81-3-6361-7411 |
| Scheduled date of quarterly securities report submission: | February 14, 2014 |
| Scheduled date of dividend payment commencement: | - |
| Supplementary materials for quarterly financial results: | Yes |
| Earnings announcement for quarterly financial results: | Yes (for institutional investors, analysts and the press) |

(Figures are rounded down to the nearest million yen unless otherwise stated)

## 1. Consolidated Financial Results for the Third Quarter of FY2013 (April 1, 2013 to December 31, 2013)

(1) Consolidated Operating Results (cumulative)

(% change from the same period of the previous fiscal year)

| | Net sales | | Operating income | | Ordinary income | | Net income | |
|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| FY2013 | 1,077,633 | 20.7 | 185,491 | 41.2 | 203,046 | 44.2 | 142,831 | 56.6 |
| FY2012 | 892,563 | 1.3 | 131,414 | (1.3) | 140,848 | 4.4 | 91,196 | 2.9 |

(Note) Comprehensive income: FY2013 ¥174,313 million (90.4%)
FY2012 ¥91,529 million (16.1%)

| | Basic earnings per share | Diluted earnings per share |
|---|---|---|
| | Yen | Yen |
| FY2013 | 262.90 | 262.40 |
| FY2012 | 165.18 | 164.83 |

(2) Consolidated Financial Position

| | Total assets | Net assets | Shareholders' equity ratio | Net assets per share |
|---|---|---|---|---|
| | Million yen | Million yen | % | Yen |
| As of December 31, 2013 | 1,884,096 | 1,451,759 | 75.7% | 2,634.35 |
| As of March 31, 2013 | 1,779,207 | 1,325,071 | 73.7% | 2,381.64 |

(Reference) Shareholders' equity: As of December 31, 2013 ¥1,426,831 million
As of March 31, 2013 ¥1,310,497 million

## 2. Dividends

| | Annual dividend per share | | | | |
|---|---|---|---|---|---|
| | First Quarter | Second Quarter | Third Quarter | Year-end | Total |
| | Yen | Yen | Yen | Yen | Yen |
| FY2012 | - | 28.00 | - | 30.00 | 58.00 |
| FY2013 | - | 30.00 | - | | |
| FY2013 (forecast) | | | | 35.00 | 65.00 |

(Note) Revisions to dividends forecast most recently announced: No

## 3. Forecast of Consolidated Financial Results for FY 2013 (April 1, 2013 to March 31, 2014)

(% change from the previous fiscal year)

| | Net sales | | Operating income | | Ordinary income | | Net income | | Basic earnings per share |
|---|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % | Yen |
| Full Year | 1,435,000 | 17.8 | 215,000 | 26.7 | 225,000 | 22.0 | 155,000 | 26.6 | 285.54 |

(Note) Revisions to financial forecast most recently announced: No

**4. Others**

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): No

(2) Adoption of accounting methods specific only to quarterly consolidated financial statements: No

(3) Changes in accounting policies, accounting estimates and restatements of past financial statements for accounting errors:
1) Changes in accounting policies due to revisions of accounting standards: No
2) Changes in accounting policies due to other reasons: No
3) Changes in accounting estimates: No
4) Restatements of past financial statements for accounting errors: No

(4) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the reporting period (including treasury stock):

| | |
|---|---|
| December 31, 2013 | 557,835,617 shares |
| March 31, 2013 | 557,835,617 shares |

2) Number of shares of treasury stock as of the end of the reporting period:

| | |
|---|---|
| December 31, 2013 | 16,211,015 shares |
| March 31, 2013 | 7,593,160 shares |

3) Average number of shares outstanding during the reporting period:

| | |
|---|---|
| Quarter ended December 31, 2013 | 543,272,445 shares |
| Quarter ended December 31, 2012 | 552,096,852 shares |

*** Information Regarding Quarterly Review Procedures**

While this quarterly financial report is generally exempt from the quarterly review procedures stipulated by the Financial Instruments and Exchange Act of Japan, at the time of disclosure of this report, quarterly financial statement review procedures as set out in the Financial Instruments and Exchange Act of Japan have been completed, and the quarterly review report has been received on February 12, 2014.

*** Disclaimer Regarding Forward-Looking Statements and Other Items of Note**

Forecasts and other forward-looking statements included in this report are based on information currently available and certain assumptions that the Company deems reasonable. Actual performance and other results may differ significantly due to various factors. Please see “Qualitative Information on Forecast of Consolidated Operating Results” on page 11 for additional information.

The company is planning to hold an earnings release conference call for institutional investors, analysts and the press on February 13, 2014. Presentation materials and a webcast of the conference call will be available on the Company’s website promptly after the conference call.

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## 1. Qualitative Information for the Third Quarter of FY2013

### (1) Qualitative Information on Consolidated Operating Results

**<Summary of Operating Results for the Nine Months Ended December 31, 2013>**

For the nine months of Fiscal year 2013 (from April 1 to December 31,2013),, the Otsuka Group recorded consolidated net sales of ¥1,077,633 million (up 20.7% year on year), with operating income of ¥185,491 million (up 41.2%), ordinary income of ¥203,046 million (up 44.2%) and net income of ¥142,831 million (up 56.6%).

Results by business segment are as follows:

(Millions of yen)

| | Pharmaceuticals | Nutraceuticals | Consumer products | Others | Adjustments | Total |
|---|---|---|---|---|---|---|
| Net sales | 757,828 | 220,988 | 34,739 | 97,979 | (33,901) | 1,077,633 |
| Operating income (loss) | 193,487 | 20,400 | (1,492) | 6,023 | (32,926) | 185,491 |

1) Pharmaceuticals

In the area of the central nervous system, global sales of antipsychotic agent *ABILIFY* continued to expand. Sales rose more than 30% year on year, partly helped by a positive impact from depreciation of the yen. *ABILIFY* is sold in 60 markets worldwide and is ranked seventh in global drug sales[*1]. In the U.S., sales of *ABILIFY* on a local currency basis grew at a double digit pace compared with the same period of the previous fiscal year. This growth mainly reflected price increases and a rise in prescriptions for adjunctive therapy in major depressive disorder and for bipolar disorder. *ABILIFY* also remained the leader[*2] in U.S. drug sales between July and September 2013. In Europe, Otsuka Pharmaceutical Co., Ltd. ("Otsuka Pharmaceutical"), a wholly owned subsidiary of the Company, and H. Lundbeck A/S ("Lundbeck") began to collaborate on sales of *ABILIFY* in April 2013. Amid a slump in the market for atypical antipsychotics due to wider uptake of generics, sales of *ABILIFY* grew significantly, mainly on the back of an increase in prescriptions for the treatment of manic episodes of bipolar disorder. In Asia, sales of *ABILIFY* continued to expand, supported by an increase in prescriptions for adjunctive therapy in major depressive disorder and for pediatric indications, such as Tourette disorder, in South Korea. In Japan, sales of *ABILIFY* grew at a double digit pace compared with the same period of the previous fiscal year. In June 2013, *ABILIFY* became the first atypical antipsychotic agent to be approved for the additional indication of major depressive disorder. Growth in prescriptions for the additional indication and for orally disintegrating tablets was the main factor behind the increase in sales.

Otsuka Pharmaceutical and Lundbeck began sales of *Abilify Maintena*, an aripiprazole intramuscular depot formulation (once-monthly injection), in the U.S. in March 2013. Prescriptions of the drug, the first to be developed under a five compound[*3] global alliance with Lundbeck, have been growing steadily due to recognition of the drug's high profile of safety and tolerability. In Europe, *Abilify Maintena* received marketing approval from the European Commission (EC) for the maintenance treatment of schizophrenia, in November 2013. Separate to the global alliance, Otsuka Pharmaceutical and Lundbeck agreed in October 2013 to collaborate on developing and commercializing nalmefene in Japan. Nalmefene is indicated for the reduction of alcohol consumption. In December 2013, the two companies also signed an agreement to collaborate on the development of Lu AF20513, an investigational vaccine candidate for Alzheimer's disease.

In Japan, antiepileptic drug *E Keppra*, which is co-promoted with UCB Japan, was approved for the treatment of children aged four years and older (additional pediatric indication and dosage) in May 2013. Also, *E Keppra Dry Syrup 50%* was launched in August 2013. These factors led to strong growth in domestic sales compared with the same period of the previous fiscal year. *Neupro Patch*, the world's first transdermal dopamine agonist, which was launched in February 2013, registered steady growth in the number of hospitals prescribing the drug for the treatment of Parkinson's disease and restless legs syndrome.

In the area of the cardiovascular system, global sales of *Samsca*, a first-in-class drug vasopressin $V_2$-receptor antagonist sold in 14 markets worldwide, rose more than 70% year on year. This increase was supported by the drug's growing acceptance among medical specialists due to the new value it brings and its method of use as an oral aquaretic agent. In Japan, *Samsca 7.5mg tablets* were launched in June 2013 and the drug was granted an additional indication for the treatment of fluid retention in patients with hepatic cirrhosis in September 2013. The Group is working to grow the value of *Samsca* in line with considerations of the drug's safety, including providing current information on its proper usage.

Sales of antiplatelet agent *Pletaal/Pletal* have been affected by generics in Japan. However, sales decline was kept to the minimum, as domestic medical practitioners view the drug as a convenient orally disintegrating tablet for patients who have had onset cerebral infarction. Global sales of *Pletaal/Pletal* decreased slightly year on year, supported mainly by sales growth in South Korea.

In the area of anti-cancer and cancer-supportive care, *TS-1 Combination OD Tablets T20, T25* were launched as an additional formulation of anti-cancer agent *TS-1* in Japan in June 2013. Also, the promotion utilizing evidence-based medicine (EBM) approaches helped raise awareness of the drug as a treatment for colorectal cancer and head and neck cancers, supporting steady sales. Overseas, *TS-1* is gradually being rolled out in European markets and is currently sold in 24 markets worldwide, as of December 31, 2013. Sales of anti-cancer agent *UFT* and reduced folic acid formulation *Uzel* both declined year on year as a result of competition. Sales of *Aloxi*, a 5-$HT_3$ receptor antagonist antiemetic agent, increased on the back of steady growth in prescriptions, while sales of anti-cancer agent *Abraxane* significantly grew compared with the same period of the previous fiscal year, mainly supported by its approval for the additional indications of gastric cancer and non-small-cell lung cancer in February 2013. Anti-cancer agent *SPRYCEL*, which is being co-promoted in Japan, the U.S. and Europe with BMS*[4], registered a large rise in distributions compared with the same period of the previous fiscal year. This reflected the drug's growth as a first-line treatment for chronic myeloid leukemia in markets worldwide and a substantial increase from January 2013 in the

ratio used to calculate distributions received by the Group based on sales. *Busulfex*, which is the only allogeneic hematopoietic stem cell pre-transplanting regimen approved by the U.S. Food and Drug Administration (FDA), is now sold by the Group and its partners in more than 50 countries. *Busulfex* has become established as the standard drug for use as a conditioning agent administered prior to bone marrow transplants in place of total-body radiation. Otsuka Pharmaceutical took over sole responsibility for the *Busulfex* promotion in Japan and Asia from April 1, 2013, in addition to the exclusive marketing rights the Group already owns for *Busulfex* in the U.S. and Canada.

In other areas, sales of anti-gastritis and anti-gastric ulcer agent *Mucosta* declined year on year due to the impact of generics, although steps were taken to strengthen the *Mucosta* brand, including the launch of tablets with the brand name printed on both the front and back. In the area of ophthalmology, prescriptions for dry eye treatment *Mucosta ophthalmic suspension UD 2%* grew steadily, supporting a large increase in sales compared with the same period of the previous fiscal year.

In the area of clinical nutrition, sales of the high-calorie TPN solution *ELNEOPA* increased year on year, as a result of an increase in the number of hospitals adopting *ELNEOPA* and growth in prescriptions. These developments partly reflected greater awareness of the solution among acute care hospitals as a TPN kit product containing trace elements recommended in the 2013 guidelines of the Japanese Society for Parenteral and Enteral Nutrition (JSPEN). They were also the result of its popularity among extended care hospitals for its benefits, such as the reduced risk of infection and shortened labor time at the point when the TPN is mixed and prepared.

With respect to the global development of the Group's pharmaceutical operations, the European pharmaceutical business of Otsuka Pharmaceutical has seen its sales more than double over the last five years. In order to drive the further development of this business, Otsuka Europe Development and Commercialisation Ltd. ("OEDC") was established in London, U.K. in July 2013 as a new center for the clinical development of pharmaceuticals. Also, Otsuka Pharmaceutical acquired U.S. company Astex Pharmaceuticals, Inc. ("Astex") through wholly-owned subsidiary Otsuka America, Inc. in October 2013. Astex's anti-cancer drugs in the clinical development stage and fragment-based drug discovery technology will strengthen not only Otsuka Pharmaceutical's portfolio in the fields of anti-cancer and cancer-supportive care, but also its drug discovery research in the anti-cancer, central-nervous-system, and next-generation fields. In addition, in July 2013 Otsuka Pharmaceutical Factory, Inc. acquired a stake in Claris Otsuka Limited ("Claris Otsuka"), which is based in Ahmedabad, India.

As a result, net sales in the pharmaceutical segment for the nine months ended December 31, 2013 totaled ¥757,828 million (up 24.9% year on year), with operating income of ¥193,487 million (up 36.5%).

*[1]: © 2013 IMS Health. All rights reserved. Estimated based on "World Review Preview 2013 (Year 2012 Sales Data)." Reprinted with permission.
*[2]: © 2013 IMS Health. All rights reserved. Estimated based on "MIDAS Quantum 3Q/2013 Sales data." Reprinted with permission.
*[3]: *Abilify Maintena*, brexpiprazole, Lu AE58054 and two new compounds currently being researched and developed by Lundbeck.
*[4]: Bristol-Myers Squibb Company

2) Nutraceuticals

In the *Pocari Sweat* electrolyte supplement drink brand, the Group launched a new version called *Pocari Sweat Ion Water* in Japan in April 2013 and focused on running sales promotions, including taste testing. As the selection for consumers, which is made according to drinking occasion or taste preference, such as during exercise or while at work indoors in an office etc., has expanded to the two choices of *Pocari Sweat* and *Pocari Sweat Ion Water*, this supported an increase in sales volume compared with the same period of the previous fiscal year. Overseas, where *Pocari Sweat* is sold in 17 markets, consumption expanded in Indonesia amid growth in the number of middle-income earners, and the creation of a more efficient marketing system in China through the use of IT drove an increase in new customers. These and other factors supported ongoing growth in sales volume.

The Otsuka Group continues to develop its soy-related business, based on the concept of "Soylution," which sees soy as a solution to various health and environmental issues faced by people today. In *SoyCarat*, a healthy soy snack, two new flavors – *Nori & Natto* and *Olive Oil & Garlic* – were added to the range in October 2013. Efforts such as promoting the totally new appeal of *SoyCarat* as a healthy snack that can also be eaten before meals and bedtime are helping to raise the brand's visibility. Soy bar *SOYJOY*, which is sold in 11 markets worldwide, registered strong growth in market share, new customers and sales volume compared with the same period of the previous fiscal year. This reflected the launch of new flavor *SOYJOY Peanuts* in Japan in April 2013, which helped attract more users, mainly men, to the *SOYJOY* brand. The Group is also working on dietary education initiatives to encourage wider understanding among consumers of the nutritional benefits of soy through *SoyCarat*, *SOYJOY* and the other product in the soy products range, soy soda beverage *SOYSH*, which is mainly sold online.

The Group implemented sales promotions for carbonated nutritional drink *Oronamin C* using TV commercials and other approaches. The promotions focused on clearly communicating the product's features in order to boost *Oronamin C*'s value as a functional and trusted brand. These efforts raised awareness of the product's features among female consumers, supporting a year-on-year increase in sales volume.

Sales volume for the balanced nutrition food *Calorie Mate* declined slightly from the same period of the previous fiscal year, despite direct sales promotions using face-to-face marketing aimed at specific consumer groups.

Subsidiary Pharmavite LLC ("Pharmavite") of the U.S. supplies *Nature Made* supplements, which have been selected as the leading pharmacist-recommended brand in eight categories[*5] in the U.S. and have been the number one retail national vitamin and supplement brand in the U.S. for six consecutive years, from 2007 through 2013[*6]. The Group reinforced its manufacturing and supply framework for *Nature Made* supplements with the completion of a new plant in the U.S. state of Alabama in June

2013. In Japan, *Nature Made VitaMelts* supplements (five versions), which dissolve without water, were launched in November 2013. *VitaMelts* were launched as part of efforts to strengthen the *Nature Made* brand, mainly among consumers that are not yet accustomed to supplements.

At Nutrition & Santé SAS, an Otsuka Group subsidiary that operates in more than 40 countries, mainly in Europe, sugar-free and gluten-free food products sold under the *Gerble* nutrition and health food brand continued to drive growth, while sales of organic food products and soy products also remained strong.

In the cosmedics area, where the focus is on the concept of "healthy skin," the Group's two brands – one aimed at men and the other at women – registered very strong growth. In the *UL•OS* men's skincare brand, which is marking its fifth anniversary, *Skin Lotion* and *Skin Milk* now offer the added efficacy of minimizing fine lines and wrinkles caused by dryness. Product tester kits were also launched only through convenience stores nationwide as part of efforts to expand the customer base. In South Korea, where *UL•OS* was launched in March 2012, the brand continued to steadily gain ground. This was illustrated by its selection as the top male cosmetics brand for quality in the country's 2013 consumer choice awards, the second year in a row that the brand has won the award, and growth in the number of stores that stock the *UL•OS* range. In the *InnerSignal* brand aimed at women who seek healthy and beautiful skin, the Group continued to make steady progress in building a loyal base of customers by using the mail-order sales channel to acquire new customers and boost repeat business.

Sales volume for nutrient tonic *Tiovita* declined year on year, mainly reflecting the shrinking market for nutrient tonics and inventory adjustments at retailers.

As a result, net sales in the nutraceutical segment for the nine months ended December 31, 2013 totaled ¥220,988 million (up 12.9% year on year), with operating income of ¥20,400 million (up 18.1%).

*[5]: Based on 2013 US News & World Report - Pharmacy Times Survey, *Nature Made* is the #1 Pharmacist Recommended Brand in Eight Segments - Letter Vitamins, Omega-3/Fish Oil, Coenzyme Q10, Flax Seed Oil, Herbal supplements, Cholesterol Management-Natural, Garlic (tie) and Diabetic Multivitamins (tie).

*[6]: Pharmavite calculation based in part on data reported by Nielsen through its Scantrack® service for the Dietary Supplements category in dollar and unit sales, for the 52-week period ending 12/29/2007 and 12/28/2008 in US Food Drug Mass channels; and for the 52-week period ending 12/26/2009, 12/25/2010, 12/24/2011 and 12/22/2012 in US xAOC channels. ©2013 The Nielsen Company

3) Consumer Products

Sales volume for mineral water products, centered on *Crystal Geyser*, saw a slight increase year on year, reflecting stepped up marketing activities and efforts to boost brand value. To mark the 45th anniversary of *Bon Curry Gold*, a range of instant curry dishes, the Group upgraded its products so they can be heated in a microwave oven without removing the curry pouch from the box while also strengthening its marketing strategy and sales promotion activities to boost brand value. On the other hand, sales volume for *Match*, a carbonated electrolyte drink containing vitamins, declined year on year as a result of competition and other factors, despite the ongoing implementation of an aggressive marketing strategy and sales promotion activities mainly targeting the high school student market.

In the consumer products segment, the Group steps up marketing initiatives and continues to implement a range of initiatives aimed at improving profitability.

As a result, net sales in the consumer products segment for the nine months ended December 31, 2013 totaled ¥34,739 million (down 8.3% year on year), with operating loss of ¥1,492 million (compared with an operating loss of ¥1,407 million in the same period of the previous fiscal year).

4) Others

In the specialty chemical business,

sales of brake friction material modifiers *TISMO* and *Terracess* and new products such as capacitor electrolyte solution increased year on year, with more clients adopting the products amid firm demand in the automotive sector. In the construction field, continued firm demand for foaming agents used in building materials, hardeners used in coating materials, and other chemicals also contributed to sales growth, supporting a large increase in overall sales in the specialty chemical business compared with the same period of the previous fiscal year. In the fine chemical business, sales declined year on year due to a drop in sales volume for pharmaceutical intermediate *DACTA*.

In the transportation and warehousing business, sales rose year on year owing to increases in handling volumes for pharmaceuticals, beverages and other products. Sales in the direct sales support business saw double-digit growth due to an increase in the number of orders.

As a result, net sales in the other businesses for the nine months ended December 31, 2013 totaled ¥97,979 million (up 14.8% year on year), with operating income of ¥6,023 million (up 41.5%).

**< Research and Development Activities>**

Research and development expenses for the nine months ended December 31, 2013 totaled ¥165,954 million.

The primary areas of research and development by business segment were as follows:

(Pharmaceuticals)

1) Therapeutic drugs

The Otsuka Group conducts research and development with a primary focus on addressing unmet medical needs in the areas of the central nervous system and anti-cancer and cancer-supportive care. The Group also conducts research and development in fields such as cardiovascular disease and ophthalmology.

Research and development activities carried out during the nine months ended December 31, 2013 in the area of therapeutic drugs are summarized below.

| Category | *Brand Name*,<br>(Generic Name),<br>Development Code | Status |
|---|---|---|
| Central nervous system | *ABILIFY*<br>*Abilify Maintena*<br>(aripiprazole) | <Japan><br>Phase III trials of *Abilify Maintena* for the treatment of bipolar disorder were initiated in May 2013.<br>*ABILIFY* was approved in June 2013 for the additional indication of major depressive disorder.<br><Europe><br>*Abilify Maintena* obtained marketing authorization for the maintenance treatment of schizophrenia in November 2013 from the EC. |
| | *E Keppra*<br>(levetiracetam) | <Japan><br>*E Keppra* was approved in May 2013 for the treatment of children aged four years and older (additional pediatric indication and dosage).<br>*E Keppra Dry Syrup 50%* obtained manufacturing and marketing approval in June 2013 and was launched in August 2013.<br>A new drug application was filed in June 2013 for *Levetiracetam Injection* for the treatment of epileptic partial seizures. |
| | (brexpiprazole)<br>OPC-34712 | <Japan><br>The drug was given the generic name brexpiprazole in August 2013.<br><U.S. and Europe><br>Phase III trials for the treatment of agitation associated with dementia of the Alzheimer's type were initiated in August 2013. |
| | Lu AE58054 | At the Alzheimer's Association International Conference (AAIC) in July 2013, Lundbeck announced Phase II clinical data on efficacy for Lu AE58054 as an add-on to donepezil for the treatment of Alzheimer's disease.<br><U.S. and Europe><br>Phase III trials for the treatment of Alzheimer's disease were initiated in October 2013. |

| Category | *Brand Name*,<br>(Generic Name),<br>Development Code | Status |
|---|---|---|
| Anti-cancer and cancer-supportive care | *TS-1* | <Japan><br>*TS-1 Combination OD Tablets T20, T25* were launched in June 2013. |
| | *E-fen Buccal Tablets*<br>(fentanyl citrate)<br>OVF | <Japan><br>The drug was approved in June 2013 as an analgesic for the treatment of acute pain in cancer patients receiving regular doses of powerful opioid analgesics.<br>*E-fen Buccal Tablets 50μg, 100μg, 200μg, 400μg* were launched in September 2013, and *600μg, 800μg* of the same were launched in October. |
| | (trifluridine and tipiracil hydrochloride combination tablets)<br>TAS-102 | <Japan and Europe><br>Phase II trials for the treatment of small cell lung cancer were initiated in July 2013.<br><Asia><br>Phase III trials for the treatment of colorectal cancer were initiated in October 2013. |
| | TAS-118 | <Japan and Asia><br>Phase III trials for the treatment of pancreatic cancer were initiated in July 2013. |
| | OCV-501 | <Japan and Asia><br>Phase II trials for the prevention of relapse of acute myeloid leukemia (AML) in elderly patients were initiated in October 2013. |
| | OPB-111077 | <Asia><br>Phase I trials for the treatment of solid cancer were initiated in June 2013. |
| | SGI-110 | Drug currently under development, acquired through the purchase of Astex in October 2013. The drug's development status is as follows:<br><U.S. and Europe><br>Phase II trials for the treatment of ovarian cancer are currently under way.<br>Phase II trials for the treatment of hepatocellular carcinoma are currently under way.<br><U.S.><br>Phase II trials for the treatment of AML and myelodysplastic syndrome (MDS) are currently under way. |
| | AT13387 | Drug currently under development, acquired through the purchase of Astex in October 2013. The drug's development status is as follows:<br><U.S. and Europe><br>Phase II trials for the treatment of prostate cancer are currently under way.<br>Phase II trials for the treatment of non-small cell lung cancer are currently under way. |

| Category | *Brand Name*,<br>(Generic Name),<br>Development Code | Status |
|---|---|---|
| Anti-cancer and cancer-supportive care | AT7519 | Drug currently under development, acquired through the purchase of Astex in October 2013. The drug's development status is as follows:<br><U.S.><br>Phase II trials for the treatment of multiple myeloma are currently under way. |
| Cardiovascular system | *Samsca*<br>(tolvaptan) | <U.S.><br>The U.S. FDA accepted an application for the additional indication of autosomal dominant polycystic kidney disease (ADPKD) in April 2013. However, Otsuka Pharmaceutical received a complete response letter from the FDA in August 2013 stating that the application could not be approved based on the data in the initial application.<br><Japan><br>An application was filed in May 2013 for the additional indication of ADPKD.<br>*Samsca 7.5mg tablets*, a low-dosage version of *Samsca 15mg tablets*, were launched in June 2013.<br>*Samsca 7.5mg tablets* received approval in September 2013 for the additional indication of the treatment of fluid retention in patients with hepatic cirrhosis.<br>Phase II trials for the treatment of fluid retention associated with hemodialysis were initiated in July 2013.<br>Phase II trials for the treatment of fluid retention associated with peritoneal dialysis were initiated in September 2013.<br><Europe><br>An application for the additional indication of ADPKD was accepted for review by the European Medicines Agency (EMA) in December 2013. |
| Other categories<br>(Ophthalmology and others) | *Mucosta ophthalmic suspension UD 2%*<br>OPC-12759E | <U.S.><br>The decision was taken in September 2013 to terminate the development of the drug in the U.S., as primary outcome measure was not attained in Phase III trials for the treatment of dry eyes.<br><Japan><br>Phase II trials for the treatment of keratoconjunctival epithelial disorder have been terminated. |
| | (delamanid)<br>OPC-67683 | <Europe><br>In November 2013, the drug received a recommendation for approval from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the treatment of multidrug-resistant tuberculosis.<br>Phase II trials for the treatment of multidrug-resistant tuberculosis in children were initiated in August 2013. |
| | TAC-202 | <Japan><br>Phase II trials for the treatment of allergic rhinitis were initiated in September 2013. |

| Category | *Brand Name*,<br>(Generic Name),<br>Development Code | Status |
|---|---|---|
| Other categories<br><br>(Ophthalmology and others) | OPF-105 | <Japan><br><br>Phase III trials for the treatment of post-operative digestive organ patients requiring peripheral parenteral nutrition were initiated in October 2013. |

2) Diagnostic

ODK-0902 (H. influenzae ELISA kit *Otsuka*) was launched in Japan in April 2013. ODK-1003 (WT1 mRNA assay kit II *Otsuka*) obtained domestic manufacturing and marketing approval in May 2013 and was launched in September 2013. The *Fingraph* fingertip blood sampler, which measures sodium and potassium electrolytes, was launched in Japan in August 2013. A Phase II trial was initiated in the U.S. in July 2013 to evaluate the performance of in vivo diagnostic agent C13-URA (13C-uracil breath test kit) in patients with dyspepsia. An application was filed in October 2013 for the manufacture and marketing of ODK-1201-01 (CML diagnostic aid kit).

Research and development expenses for the pharmaceutical business for the nine months ended December 31, 2013 were ¥159,919 million.

(Nutraceuticals)

In the nutraceutical business, the Group draws on its knowledge in the pharmaceutical business to constantly conduct research and development of world-class products centering on functional food and beverages that support the maintenance and improvement of day-to-day well-being.

In functional beverages, the Group has developed a new product called *Pocari Sweat Ion Water*, a low-calorie beverage with subtle sweetness that retains all the functionality of original *Pocari Sweat*. This product was launched in April 2013. Also, in September 2013, Otsuka Pharmaceutical launched *Omugi Seikatsu*, a product with a high content of barley β-glucans, a type of soluble dietary fiber found in barley. Cooked rice with β-glucan enriched barley has been proven to control postprandial glucose response and achieve a second-meal effect*[1].

The Group's Research Institute of New Functional Products Development in Tokushima continues to focus on the research and development of products that promote the nutrition in soy to consumers around the world in a familiar form. During the period under review, two new flavors were developed to the *SoyCarat* range of healthy soy snacks and were launched in October 2013.

Research and development expenses for the nutraceutical business for the nine months ended December 31, 2013 were ¥3,187 million.

*1: "Effect of Cooked Rice with β-glucan Enriched Barley on Postprandial Glucose Response and Its Second Meal Effect," Fukuhara et al., published in Japanese Pharmacology and Therapeutics, August 20, 2013.

(Consumer products)

In the consumer products business, the Otsuka Group is engaged in the research and development of original and unique products in the food and beverage field.

Research and development expenses for the consumer products business for the nine months ended December 31, 2013 were ¥408 million.

(Others)

In the other businesses, the Otsuka Group is primarily engaged in the research and development of specialty chemical products and fine chemicals.

Research and development expenses for other businesses for the nine months ended December 31, 2013 were ¥2,439 million.

**(2) Qualitative Information on Consolidated Financial Position**

1) Assets

Total assets as of December 31, 2013 were ¥1,884,096 million, an increase of ¥104,888 million compared to ¥1,779,207 million at the end of the previous fiscal year. The increase was due to a ¥13,855 million decrease in current assets, a ¥118,743 million increase in fixed assets.

(Current Assets)

Total current assets as of December 31, 2013 were ¥1,066,787 million, a decrease of ¥13,855 million compared to ¥1,080,642 million at the end of the previous fiscal year. This decrease was due mainly to a decrease in marketable securities by ¥52,897 million, a ¥26,717 million increase in notes and accounts receivable-trade and a ¥13,394 million increase in inventories.

(Fixed Assets)

Total fixed assets as of December 31, 2013 were ¥817,242 million, an increase of ¥118,743 million compared to ¥698,498 million at the end of the previous fiscal year. This increase was due mainly to a ¥29,465 million increase in tangible fixed assets and a ¥98,210 million increase in intangible fixed assets while there was ¥7,146 million decrease in investment securities. The increase in tangible fixed assets reflected the initial investments in a manufacturing facility at the Kitajima Factory of Taiho Pharmaceutical Co., Ltd., and a manufacturing facility at the Alabama Factory of Pharmavite, and the addition of a manufacturing facility at Claris Otsuka, which was newly included in the scope of consolidation. The increase in intangible fixed assets was mainly caused by Claris Otsuka, Astex and one other company, all of which were newly included in the scope of consolidation.

2) Liabilities

(Current Liabilities)

Total current liabilities as of December 31, 2013 were ¥333,731 million, a decrease of ¥12,741 million compared to ¥346,472 million at the end of the previous fiscal year. This decrease was due mainly to reductions in short-term borrowings, income taxes payable, reserves for bonuses and other current liabilities by ¥13,473 million, ¥7,898 million, ¥9,916 million and ¥2,058 million, respectively, while notes and accounts payable-trade increased by ¥20,556 million.

(Fixed Liabilities)

Total fixed liabilities as of December 31, 2013 were ¥98,605 million, a decrease of ¥9,059 million compared to ¥107,664 million at the end of the previous fiscal year, mainly due to a ¥9,388 million decrease in the liability for employees' retirement benefits.

3) Net Assets

Total net assets as of December 31, 2013 were ¥1,451,759 million, an increase of ¥126,688 million compared to ¥1,325,071 million at the end of the previous fiscal year. This increase was due mainly to a ¥88,079 million increase in total shareholders' equity as a result of ¥142,831 million of quarterly net income, dividend payments amounting to ¥32,752 million and purchases of treasury stock amounting to ¥30,001 million. Other reasons included a ¥28,254 million increase in accumulated other comprehensive income due to currency rate fluctuations and a ¥10,354 million increase in minority interests.

**(3) Qualitative Information on Forecast of Consolidated Operating Results**

There are no changes to the full year consolidated forecast released on November 13, 2013 regarding the FY2013 2Q financial results.

**2. Other Information**

**(1) Changes in significant subsidiaries during the period**

None

**(2) Adoption of accounting methods specific only to quarterly consolidated financial statements**

None

**(3) Changes in accounting policies, accounting estimates and restatements of past financial statements for accounting errors**

None

## 3. Quarterly Consolidated Financial Statements

### (1) Consolidated Balance Sheets

(Millions of yen)

| | As of March 31, 2013 | As of December 31, 2013 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash and deposits | 414,380 | 412,921 |
| Notes and accounts receivable-trade | 318,087 | 344,805 |
| Marketable securities | 137,768 | 84,871 |
| Finished products and merchandise | 71,243 | 78,399 |
| Work in process | 25,842 | 31,522 |
| Raw materials and supplies | 35,266 | 35,823 |
| Other current assets | 78,597 | 79,139 |
| Allowance for doubtful receivables | (543) | (696) |
| Total current assets | 1,080,642 | 1,066,787 |
| Fixed assets | | |
| Tangible fixed assets | 275,967 | 305,433 |
| Intangible fixed assets | | |
| Goodwill | 37,787 | 69,923 |
| Other intangible fixed assets | 36,062 | 102,136 |
| Total intangible fixed assets | 73,850 | 172,060 |
| Investments and other assets | | |
| Investment securities | 276,296 | 269,149 |
| Investments in capital | 31,574 | 34,128 |
| Other assets | 43,164 | 38,236 |
| Allowance for investment loss | (1,569) | (1,021) |
| Allowance for doubtful receivables | (785) | (744) |
| Total investments and other assets | 348,680 | 339,748 |
| Total fixed assets | 698,498 | 817,242 |
| Deferred assets | 66 | 66 |
| Total assets | 1,779,207 | 1,884,096 |
| LIABILITIES | | |
| Current liabilities | | |
| Notes and accounts payable-trade | 97,523 | 118,079 |
| Short-term borrowings | 51,789 | 38,316 |
| Income taxes payable | 33,514 | 25,616 |
| Reserves for bonuses | 15,928 | 6,011 |
| Provisions | 2,399 | 340 |
| Other current liabilities | 145,317 | 145,367 |
| Total current liabilities | 346,472 | 333,731 |
| Long-term liabilities | | |
| Long-term debt | 6,251 | 9,564 |
| Liability for employees' retirement benefits | 40,570 | 31,182 |
| Other allowances | 3,107 | 2,481 |
| Negative goodwill | 24,005 | 22,157 |
| Other long-term liabilities | 33,729 | 33,219 |
| Total long-term liabilities | 107,664 | 98,605 |
| Total liabilities | 454,136 | 432,336 |

| | As of March 31, 2013 | As of December 31, 2013 |
|---|---|---|
| NET ASSETS | | |
| Shareholders' equity | | |
| Common stock | 81,690 | 81,690 |
| Capital surplus | 510,423 | 512,895 |
| Retained earnings | 768,314 | 883,457 |
| Treasury stock | (18,392) | (47,927) |
| Total shareholders' equity | 1,342,036 | 1,430,116 |
| Accumulated other comprehensive income | | |
| Unrealized gain on available-for-sale securities | 8,284 | 12,583 |
| Deferred loss on derivatives under hedge accounting | ― | (12) |
| Foreign currency translation adjustments | (39,823) | (15,856) |
| Total accumulated other comprehensive income | (31,539) | (3,284) |
| Stock acquisition rights | 104 | 104 |
| Minority interests | 14,468 | 24,823 |
| Total net assets | 1,325,071 | 1,451,759 |
| Total liabilities and net assets | 1,779,207 | 1,884,096 |

**(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income**

Consolidated Statements of Income (cumulative)

(Millions of yen)

| | For the nine months ended December 31, 2012 | For the nine months ended December 31, 2013 |
|---|---|---|
| Net sales | 892,563 | 1,077,633 |
| Cost of sales | 295,172 | 329,000 |
| Gross profit | 597,391 | 748,633 |
| Selling, general and administrative expenses | | |
| Promotion expenses | 122,880 | 125,367 |
| Salaries and bonuses | 67,299 | 82,841 |
| Reserve for bonuses | 3,610 | 4,141 |
| Retirement benefit expenses | 5,253 | 3,014 |
| Amortization of goodwill | 3,663 | 2,502 |
| Research and development expenses | 116,396 | 165,954 |
| Other | 146,873 | 179,320 |
| Total selling, general and administrative expenses | 465,976 | 563,141 |
| Operating income | 131,414 | 185,491 |
| Non-operating income | | |
| Interest income | 1,048 | 835 |
| Dividend income | 1,234 | 915 |
| Amortization of negative goodwill | 1,848 | 2,031 |
| Equity in earnings of unconsolidated subsidiaries and affiliated companies | 3,805 | 4,708 |
| Foreign exchange gains, net | 1,268 | 9,307 |
| Other | 1,520 | 1,628 |
| Total non-operating income | 10,725 | 19,426 |
| Non-operating expenses | | |
| Interest expenses | 980 | 932 |
| Other | 311 | 939 |
| Total non-operating expenses | 1,291 | 1,871 |
| Ordinary income | 140,848 | 203,046 |
| Extraordinary income | | |
| Gain on sales of fixed assets | 119 | 516 |
| Gain on sales of subsidiaries' stock | ― | 257 |
| Subsidy income | 7 | 634 |
| Other | 33 | 50 |
| Total extraordinary income | 160 | 1,459 |
| Extraordinary loss | | |
| Loss on retirement of fixed assets | 289 | 416 |
| Impairment loss | 1,867 | 174 |
| Loss on valuation of investment securities | 1,182 | 17 |
| Other | 49 | 151 |
| Total extraordinary loss | 3,388 | 760 |
| Income before income taxes and minority interests | 137,619 | 203,746 |
| Income taxes | | |
| Current | 37,798 | 54,490 |
| Deferred | 7,675 | 4,954 |
| Total income taxes | 45,474 | 59,444 |
| Income before minority interests | 92,145 | 144,301 |
| Minority interests in net income | 949 | 1,469 |
| Net income | 91,196 | 142,831 |

Consolidated Statements of Comprehensive Income (cumulative)

(Millions of yen)

| | For the nine months ended December 31, 2012 | For the nine months ended December 31, 2013 |
|---|---|---|
| Income before minority interests | 92,145 | 144,301 |
| Other comprehensive income | | |
| Unrealized gain on available-for-sale securities | 235 | 4,354 |
| Deferred loss on derivatives under hedge accounting | (11) | (12) |
| Foreign currency translation adjustments | (921) | 14,391 |
| Share of other comprehensive income of equity method affiliates | 81 | 11,277 |
| Total other comprehensive income | (616) | 30,011 |
| Total comprehensive income | 91,529 | 174,313 |
| Total comprehensive income attributable to: | | |
| Owners of the parent | 90,523 | 172,254 |
| Minority interests | 1,006 | 2,058 |

**(3) Notes regarding Quarterly Consolidated Financial Statements**

**(Note regarding Assumption of Going Concern)**

Not applicable

**(Note regarding Significant Changes in the Amount of Shareholders' Equity)**

**For the nine months of Fiscal year 2013 (from April 1, 2013 to December 31, 2013)**

The Company repurchased 8,784,800 shares of common stock at a cost of ¥29,999 million in accordance with the resolution of the board of directors held on May 14, 2013.

As a result of the disposal of 167,470 treasury stocks at a cost of ¥465 million due to the exercise of stock options, the Company held 16,211,015 shares of treasury stock at a cost of ¥47,927 million as of December 31, 2013.

**(Segment Information)**

**For the nine months of Fiscal year 2012 (from April 1, 2012 to December 31, 2012)**

1) Net sales and segment income (loss) by reporting segment

(Millions of yen)

| | Pharma-ceuticals | Nutra-ceuticals | Consumer products | Others | Total | Adjustments | Consolidated |
|---|---|---|---|---|---|---|---|
| Net sales | | | | | | | |
| Sales to customers | 606,653 | 192,259 | 36,794 | 56,856 | 892,563 | — | 892,563 |
| Intersegment sales | — | 3,550 | 1,104 | 28,494 | 33,149 | (33,149) | — |
| Total | 606,653 | 195,809 | 37,899 | 85,351 | 925,713 | (33,149) | 892,563 |
| Segment income (loss) | 141,748 | 17,267 | (1,407) | 4,255 | 161,863 | (30,448) | 131,414 |

Notes:

1) Adjustments to segment income (loss) of ¥(30,448) million include intersegment eliminations of ¥423 million and unallocated corporate expenses of ¥(30,871) million, including head office costs.
2) Segment income (loss) has been adjusted to operating income as shown in the quarterly consolidated statement of income.

**For the nine months of Fiscal year 2013 (from April 1, 2013 to December 31, 2013)**

1) Net sales and segment income (loss) by reporting segment

(Millions of yen)

| | Pharma-ceuticals | Nutra-ceuticals | Consumer products | Others | Total | Adjustments | Consolidated |
|---|---|---|---|---|---|---|---|
| Net sales | | | | | | | |
| Sales to customers | 757,828 | 216,460 | 34,632 | 68,712 | 1,077,633 | — | 1,077,633 |
| Intersegment sales | — | 4,527 | 106 | 29,267 | 33,901 | (33,901) | — |
| Total | 757,828 | 220,988 | 34,739 | 97,979 | 1,111,535 | (33,901) | 1,077,633 |
| Segment income (loss) | 193,487 | 20,400 | (1,492) | 6,023 | 218,417 | (32,926) | 185,491 |

Notes:

1) Adjustments to segment income (loss) of ¥(32,926) million include intersegment eliminations of ¥527 million and unallocated corporate expenses of ¥(33,453) million, including head office costs.
2) Segment income (loss) has been adjusted to operating income as shown in the quarterly consolidated statement of income.

2) Impairment losses and goodwill by reporting segment

(Significant changes in goodwill)

In the Pharmaceuticals segment, the acquisitions of shares in Claris Otsuka and Astex have resulted in a significant change in goodwill. The increase in goodwill that occurred in the nine months ended December 31, 2013 was ¥33,626 million.

**(Subsequent Events)**

Loan to an affiliated company

On June 18, 2013, the board of directors of Otsuka Medical Devices Co., Ltd. ("OMD"), a consolidated subsidiary, decided to provide a loan of US$200 million to MicroPort Scientific Corporation, an affiliated company of OMD. The loan agreement was signed by OMD on December 15, 2013, and executed on January 9, 2014.